UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 001-36740

FIBROGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0357827**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
409 Illinois Street San Francisco, CA	**94158**
(Address of Principal Executive Offices)	**(Zip Code)**

(415) 978-1200
Registrant's telephone number, including area code:

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.01 par value	FGEN	The Nasdaq Global Select Market

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2). Yes ☐ No ☑

The number of shares of common stock outstanding as of October 31, 2020 was 91,010,718.

FIBROGEN, INC.

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FIBROGEN, INC.

PART I—FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share amounts)
(Unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 532,468	$ 126,266
Short-term investments	155,398	407,491
Accounts receivable, net ($4,715 and $4,845 from a related party)	26,252	28,455
Inventories	11,803	6,887
Prepaid expenses and other current assets ($165 and $125,210 from related parties)	11,563	133,391
Total current assets	737,484	702,490
Restricted time deposits	2,072	2,072
Long-term investments	247	61,118
Property and equipment, net	36,153	42,743
Finance lease right-of-use assets	32,028	39,602
Other assets ($1,483 and $0 from a related party)	4,031	9,372
Total assets	$ 812,015	$ 857,397
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 7,553	$ 6,088
Accrued and other current liabilities ($4,135 and $36,883 to a related party)	90,572	83,816
Deferred revenue	7,912	490
Finance lease liabilities, current	12,311	12,351
Total current liabilities	118,348	102,745
Long-term portion of lease obligations	839	1,141
Product development obligations	17,790	16,780
Deferred revenue, net of current	137,954	99,449
Finance lease liabilities, non-current	28,514	37,610
Other long-term liabilities	37,639	64,266
Total liabilities	341,084	321,991
Commitments and Contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 125,000 shares authorized; no shares issued and outstanding at September 30, 2020 and December 31, 2019	—	—
Common stock, $0.01 par value; 225,000 shares authorized at September 30, 2020 and December 31, 2019; 90,885 and 87,657 shares issued and outstanding at September 30, 2020 and December 31, 2019	909	877
Additional paid-in capital	1,370,384	1,300,725
Accumulated other comprehensive loss	(4,256)	(747)
Accumulated deficit	(915,377)	(784,720)
Total stockholders' equity	451,660	516,135
Non-controlling interests	19,271	19,271
Total equity	470,931	535,406
Total liabilities, stockholders' equity and non-controlling interests	$ 812,015	$ 857,397

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

FIBROGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue:				
License revenue (includes $0, $11,935, $0 and $129,405 from a related party)	$ —	$ 11,935	$ —	$ 162,517
Development and other revenue (includes $4,736, $3,533, $14,239 and $25,615 from a related party)	20,663	20,660	59,065	85,507
Product revenue, net	22,683	579	43,331	579
Drug product revenue (includes $(3,957), $0, $4,281 and $0 from a related party)	686	—	8,924	—
Total revenue	44,032	33,174	111,320	248,603
Operating costs and expenses:				
Cost of goods sold	2,207	242	6,253	242
Research and development	58,476	49,963	174,792	152,467
Selling, general and administrative	(48,981)	35,823	64,157	84,772
Total operating costs and expenses	11,702	86,028	245,202	237,481
Income (loss) from operations	32,330	(52,854)	(133,882)	11,122
Interest and other, net				
Interest expense	(580)	(702)	(1,864)	(2,209)
Interest income and other, net (includes $(13), $0, $(13) and $0 from a related party)	1,469	4,193	5,279	12,496
Total interest and other, net	889	3,491	3,415	10,287
Income (loss) before income taxes	33,219	(49,363)	(130,467)	21,409
Provision for income taxes	215	76	190	256
Net income (loss)	$ 33,004	$ (49,439)	$ (130,657)	$ 21,153
Net income (loss) per share:				
Basic	$ 0.36	$ (0.57)	$ (1.46)	$ 0.24
Diluted	$ 0.35	$ (0.57)	$ (1.46)	$ 0.23
Weighted average number of common shares used to calculate net income (loss) per share:				
Basic	90,558	87,007	89,414	86,390
Diluted	93,678	87,007	89,414	91,995

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

FIBROGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net income (loss)	$ 33,004	$ (49,439)	$ (130,657)	$ 21,153
Other comprehensive income (loss):				
Foreign currency translation adjustments **(Note 1)**	(2,038)	623	(3,372)	734
Available-for-sale investments:				
Unrealized gain (loss) on investments, net of tax effect	(657)	(385)	(137)	712
Other comprehensive income (loss), net of taxes	(2,695)	238	(3,509)	1,446
Comprehensive income (loss)	$ 30,309	$ (49,201)	$ (134,166)	$ 22,599

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

FIBROGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
(In thousands, except share data)
(Unaudited)

	For The Three Month Period						
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Non Controlling	
	Shares	Amount	Capital	Income (Loss)	Deficit	Interests	Total
Balance at June 30, 2020	90,228,293	$ 902	$ 1,344,912	$ (1,561)	$ (948,381)	$ 19,271	$ 415,143
Net loss	—	—	—	—	33,004	—	33,004
Change in unrealized gain or loss on investments	—	—	—	(657)	—	—	(657)
Foreign currency translation adjustments	—	—	—	(2,038)	—	—	(2,038)
Shares issued from stock plans, net of payroll taxes paid	656,463	7	7,581	—	—	—	7,588
Stock-based compensation	—	—	17,891	—	—	—	17,891
Balance at September 30, 2020	90,884,756	$ 909	$ 1,370,384	$ (4,256)	$ (915,377)	$ 19,271	$ 470,931
Balance at June 30, 2019	86,847,072	$ 868	$ 1,265,783	$ (462)	$ (637,158)	$ 19,271	$ 648,302
Net loss	—	—	—	—	(49,439)	—	(49,439)
Change in unrealized gain or loss on investments	—	—	—	(385)	—	—	(385)
Foreign currency translation adjustments	—	—	—	623	—	—	623
Shares issued from stock plans, net of payroll taxes paid	363,597	4	(180)	—	—	—	(176)
Stock-based compensation	—	—	14,793	—	—	—	14,793
Balance at September 30, 2019	87,210,669	$ 872	$ 1,280,396	$ (224)	$ (686,597)	$ 19,271	$ 613,718

FIBROGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (CONTINUED)
(In thousands, except share data)
(Unaudited)

	For The Nine Month Period						
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Non Controlling	
	Shares	Amount	Capital	Loss	Deficit	Interests	Total
Balance at December 31, 2019	87,657,489	$ 877	$ 1,300,725	$ (747)	$ (784,720)	$ 19,271	$ 535,406
Net income	—	—	—	—	(130,657)	—	(130,657)
Change in unrealized gain or loss on investments	—	—	—	(137)	—	—	(137)
Foreign currency translation adjustments **(Note 1)**	—	—	—	(3,372)	—	—	(3,372)
Shares issued from stock plans, net of payroll taxes paid	3,227,267	32	17,208	—	—	—	17,240
Stock-based compensation	—	—	52,451	—	—	—	52,451
Balance at September 30, 2020	90,884,756	$ 909	$ 1,370,384	$ (4,256)	$ (915,377)	$ 19,271	$ 470,931
Balance at December 31, 2018	85,432,102	$ 854	$ 1,226,453	$ (2,281)	$ (715,827)	$ 19,271	$ 528,470
Impact of adoption of ASC 842	—	—	—	—	8,688	—	8,688
Impact of change in accounting principle upon adoption of ASU 2018-02	—	—	—	611	(611)	—	—
Net loss	—	—	—	—	21,153	—	21,153
Change in unrealized gain or loss on investments	—	—	—	712	—	—	712
Foreign currency translation adjustments	—	—	—	734	—	—	734
Shares issued from stock plans, net of payroll taxes paid	1,778,567	18	5,078	—	—	—	5,096
Stock-based compensation	—	—	48,865	—	—	—	48,865
Balance at September 30, 2019	87,210,669	$ 872	$ 1,280,396	$ (224)	$ (686,597)	$ 19,271	$ 613,718

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

FIBROGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2020	2019
Operating activities		
Net income (loss)	$ (130,657)	$ 21,153
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	8,671	8,715
Amortization of finance lease right-of-use assets	7,886	7,720
Net accretion of discount on investments	103	(3,354)
Unrealized loss on equity investments	(3)	(78)
Investment loss in unconsolidated variable interest entity	13	—
Gain on disposal of property and equipment	(3)	(10)
Stock-based compensation	52,451	48,865
Realized loss on sales of available-for-sale securities	258	—
Changes in operating assets and liabilities:		
Accounts receivable, net	2,520	44,459
Inventories	(5,206)	(4,908)
Prepaid expenses and other current assets	121,923	(128,922)
Other assets	7,586	(953)
Accounts payable	1,440	(5,084)
Accrued and other liabilities	3,249	5,484
Deferred revenue	45,925	(50,915)
Accrued interest for finance lease liabilities	(196)	104
Other long-term liabilities	(27,130)	24,069
Net cash provided by (used in) operating activities	88,830	(33,655)
Investing activities		
Purchases of property and equipment	(1,604)	(4,017)
Payment made for acquisition	(2,145)	—
Purchases of available-for-sale securities and term deposit	(38)	(155,932)
Proceeds from sales of available-for-sale securities	10,606	—
Proceeds from maturities of investments	301,900	305,000
Net cash provided by (used in) investing activities	308,719	145,051
Financing activities		
Repayments of finance lease liabilities	(9,254)	(8,810)
Repayments of lease obligations	(302)	(302)
Cash paid for payroll taxes on restricted stock unit releases	(9,007)	(10,614)
Proceeds from issuance of common stock	26,247	15,710
Net cash provided by (used in) financing activities	7,684	(4,016)
Effect of exchange rate change on cash and cash equivalents	969	(46)
Net increase (decrease) in cash and cash equivalents	406,202	107,334
Total cash and cash equivalents at beginning of period	126,266	89,258
Total cash and cash equivalents at end of period	$ 532,468	$ 196,592

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

FIBROGEN, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Significant Accounting Policies

Description of Operations

FibroGen, Inc. (“FibroGen” or the “Company”) was incorporated in 1993 in Delaware and are headquartered in San Francisco, California, with subsidiary offices in Beijing and Shanghai, People’s Republic of China (“China”). FibroGen is a leading biopharmaceutical company developing and commercializing a pipeline of first-in-class therapeutics. The Company applies its pioneering expertise in hypoxia-inducible factor (“HIF”), connective tissue growth factor (“CTGF”) biology, and clinical development to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer.

Roxadustat, FibroGen’s most advanced product, is an oral small molecule inhibitor of HIF prolyl hydroxylase (“HIF-PH”) activity that has received marketing authorization in China (tradename: □□□®) for the treatment of anemia caused by chronic kidney disease (“CKD”) in dialysis and non-dialysis patients. Evrenzo® (roxadustat) is also approved in Japan for the treatment of anemia associated with CKD in dialysis patients. In January 2020, Astellas Pharma Inc. (“Astellas”) submitted a supplemental New Drug Application (“NDA”) in Japan for the treatment of anemia in non-dialysis CKD patients.

The Company’s NDA filing in the United States (“U.S.”) for roxadustat for the treatment of anemia in dialysis and non-dialysis CKD patients was accepted by the U.S. Food and Drug Administration (“FDA”) in February 2020. In Europe, the Marketing Authorization Application (“MAA”) filing for roxadustat for the treatment of anemia in dialysis and non-dialysis CKD patients was accepted for regulatory review by the European Medicines Agency (“EMA”) in May 2020.

Roxadustat is in Phase 3 clinical development in the U.S. and Europe and in Phase 2/3 development in China for anemia associated with myelodysplastic syndromes. Roxadustat is in Phase 2 clinical development for chemotherapy-induced anemia.

Pamrevlumab, an anti-CTGF human monoclonal antibody, is in Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis, pancreatic cancer and Duchenne muscular dystrophy, and is also in Phase 2 development in Severe Acute Respiratory Syndrome Coronavirus 2019 Disease (“COVID-19”).

Basis of Presentation and Principles of Consolidation

The condensed consolidated financial statements include the accounts of FibroGen, its wholly owned subsidiaries and its majority-owned subsidiaries, FibroGen Europe Oy and FibroGen China Anemia Holdings, Ltd. (“FibroGen Cayman”). All inter-company transactions and balances have been eliminated in consolidation. For any variable interest entity for which FibroGen is not the primary beneficiary, the Company uses the equity method of accounting. The Company operates as one segment — the discovery, development and commercialization of novel therapeutics to treat serious unmet medical needs.

The unaudited condensed consolidated financial statements and related disclosures have been prepared in accordance with accounting principles generally accepted in the U.S. (“U.S. GAAP”) applicable to interim financial reporting and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the U.S. Securities and Exchange Commission (“SEC”) and, therefore, do not include all information and footnote disclosures normally included in the annual consolidated financial statements. The financial information included herein should be read in conjunction with the consolidated financial statements and related notes in the Company’s Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2019 (“2019 Form 10-K”).

Out-of-Period Adjustments

During the third quarter of 2020, the Company recorded out-of-period adjustments that resulted in a net decrease in revenue of $2.1 million. The Company does not believe the correction of these errors is individually or in aggregate material to the consolidated financial statements for the three and nine months ended September 30, 2020 or to any prior period consolidated financial statements.

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. The more significant areas requiring the use of management estimates and assumptions include valuation and recognition of revenue. On an ongoing basis, management reviews these estimates and assumptions. Changes in facts and circumstances may alter such estimates and actual results could differ from those estimates. In the Company's opinion, the accompanying unaudited condensed consolidated financial statements include all normal recurring adjustments necessary for a fair statement of its financial position, results of operations and cash flows for the interim periods presented.

Net Income (Loss) per Share

The following is a reconciliation of the basic and diluted net income (loss) per share calculation for the periods presented (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net income (loss)	$ 33,004	$ (49,439)	$ (130,657)	$ 21,153
Weighted average shares used to compute net income (loss) per share:				
Basic	90,558	87,007	89,414	86,390
Dilutive effect of potential common shares	3,120	—	—	5,605
Diluted	93,678	87,007	89,414	91,995
Net income (loss) per share:				
Basic	$ 0.36	$ (0.57)	$ (1.46)	$ 0.24
Diluted	$ 0.35	$ (0.57)	$ (1.46)	$ 0.23

Potential common shares that would have the effect of increasing diluted earnings per share are considered to be anti-dilutive and as such, these shares are not included in the calculation of diluted earnings per share. During the nine months ended September 30, 2020, and the three months ended September 30, 2019, the Company reported a net loss. Therefore, dilutive common shares are not assumed to have been issued since their effect is anti-dilutive.

Diluted weighted average shares excluded potential common shares related to stock options, restricted stock units and shares to be purchased under the employee stock purchase plan totaling 4.2 million and 9.2 million, respectively, for the three months ended September 30, 2020 and 2019, and totaling 8.9 million and 3.6 million, respectively, for the nine months ended September 30, 2020 and 2019, as they were anti-dilutive.

Risks and Uncertainties

The Company's business is subject to risks and uncertainties, including those related to COVID-19 and the related shelter-in-place, stay-at-home and other similar governmental orders issued in response to the COVID-19 pandemic.

Starting in the first quarter of 2020, the Company experienced slower enrollment in its clinical trials due to the interruption caused by COVID-19 in the worldwide healthcare system. The future impact of the COVID-19 pandemic on the Company's business is highly uncertain and difficult to predict. The COVID-19 pandemic may continue to affect enrollment in and initiation of the Company's clinical trials, and could affect the Company's supply chain if further social distancing and other business restrictions are put in place by various government entities, particularly in China and the U.S. COVID-19 may affect the health of the Company's employees limiting the Company's productivity. The COVID-19 pandemic may also impact the market for the Company's products and product candidates in the future, affecting sales of the Company's products. Such possible risks and uncertain impacts from the COVID-19 pandemic could have a material adverse effect on the Company's drug development, commercialization revenues, and other portions of its business, and in particular, could impact the Company's assumptions of accounts receivable collectability, fair value measurements of investments, liquidity, and development costs. The extent of the pandemic's effect on the Company's operational and financial performance will depend in large part on future developments, particularly with respect to the scope and severity of the pandemic, governmental restrictions put in place to fight the pandemic, and the development of vaccines and treatments for COVID-19. Due to the inherent uncertainty of the unprecedented and rapidly evolving situation, the Company is unable to estimate the likely impact of the COVID-19 pandemic on its future operations.

Recently Issued and Adopted Accounting Guidance

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. This guidance requires capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). This guidance was effective for annual reporting periods beginning after December 15, 2019, including interim periods. The Company adopted this guidance on January 1, 2020 using the prospective method, and the adoption of this guidance did not have material impact to the Company's condensed consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). This guidance is intended to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. This guidance requires the measurement of financial assets with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. This guidance requires an impairment model, known as the current expected credit loss model, which is based on expected losses rather than incurred losses. Entities are required to carry an allowance for expected credit losses for financial assets, including most debt instruments (except those carried at fair value) and trade receivables. In November 2019, the FASB issued ASU No. 2019-11, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses* ("ASU 2019-11"), which has the same effective dates and transition requirements as ASU 2016-13. ASU 2016-13 and ASU 2019-11 were effective for annual reporting periods beginning after December 15, 2019 including interim periods. The Company's investment portfolio primarily consists of U.S. Treasury bills and notes carried at fair value, which is required to follow the impairment model under Topic 326. The Company adopted this guidance on January 1, 2020. Based on the composition of the Company's trade receivables and investment portfolio, economic conditions and historical credit loss activity, the adoption of this guidance did not have material impact to the Company's condensed consolidated financial statements.

Recently Issued Accounting Guidance Not Yet Adopted

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. This guidance simplifies the accounting for income taxes by clarifying and amending existing guidance related to the recognition of franchise tax, the evaluation of a step up in the tax basis of goodwill, and the effects of enacted changes in tax laws or rates in the effective tax rate computation, among other clarifications. This guidance is effective for annual reporting periods beginning after December 15, 2020 including interim periods, with early adoption permitted. The Company does not plan to early adopt this guidance and does not anticipate a material impact to its consolidated financial statements upon adoption of this guidance.

Significant Accounting Policies

The accounting policies used by the Company in its presentation of interim financial results are consistent with those presented in Note 2 to the consolidated financial statements included in the 2019 Form 10-K, except for the following:

Variable Interest Entity

Under the Accounting Standards Codification ("ASC") 810, *Consolidation* ("ASC 810"), when the Company obtains an economic interest in an entity, it evaluates the entity to determine if it should be deemed a variable interest entity ("VIE"), and, if so, whether the Company is the primary beneficiary and is therefore required to consolidate the VIE, based on significant judgment whether the Company (i) has the power to direct the activities that most significantly impact the economic performance of the VIE and (ii) has the obligation to absorb losses or the right to receive benefits of the VIE that could potentially be significant to the VIE.

Foreign currency translation

Prior to April 1, 2020, the functional currency of the Company's subsidiary, FibroGen (China) Medical Technology Development Co., Ltd. ("FibroGen Beijing"), was the U.S. dollar. Accordingly, monetary assets and liabilities of FibroGen Beijing in the currencies other than USD were remeasured using exchange rates in effect at the end of the period. Revenues and costs in its local currency, Renminbi Yuan ("CNY"), were remeasured using average exchange rates for the period, except for costs related to those balance sheet items that were remeasured using historical exchange rates. The resulting remeasurement gains and losses were included within interest income and other, net in the consolidated statements of operations as incurred.

On April 1, 2020, FibroGen Beijing adopted CNY as its functional currency based on reassessment of the primary economic operational environment of FibroGen Beijing that is mainly associated with its growing manufacturing and product sales activities conducted in CNY. As such, monetary assets and liabilities of FibroGen Beijing in currencies other than CNY are remeasured using exchange rates in effect at the end of the period. The assets and liabilities are translated to U.S. dollars at exchange rates in effect at the balance sheet date. All income statement accounts are translated at monthly average exchange rates. Resulting foreign currency translation adjustments are recorded directly in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. This change in FibroGen Beijing's functional currency was accounted for prospectively from April 1, 2020, and the prior condensed consolidated financial statements were not restated. The related currency translation adjustment was $1.3 million at April 1, 2020, upon adoption.

Trade accounts receivable

The allowance for doubtful accounts is based on the Company's assessment of the collectability of customer accounts. The Company makes estimates of expected credit losses for the allowance for doubtful accounts by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, current economic and regulatory conditions that may affect a customer's ability to pay, and estimates of expected future losses. The Company's bad debt expense for the three and nine months ended September 30, 2020 and the allowance for doubtful accounts as of September 30, 2020 were immaterial.

Credit losses – Available-for-sale debt securities

The Company periodically assesses its available-for-sale investments for other-than-temporary impairment. For debt securities in an unrealized loss position, the Company first considers its intent to sell, or whether it is more likely than not that the Company will be required to sell the debt securities before recovery of their amortized cost basis. If either of these criteria are met, the amortized cost basis of such debt securities is written down to fair value through interest and other, net.

For debt securities in an unrealized loss position that do not meet the aforementioned criteria, the Company assesses whether the decline in the fair value of such debt securities has resulted from credit losses or other factors. The Company considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and any adverse conditions specifically related to the securities, among other factors. If this assessment indicates that a credit loss may exist, the Company then compares the present value of cash flows expected to be collected from such securities to their amortized cost basis. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded through interest and other, net, limited by the amount that the fair value is less than the amortized cost basis. Any additional impairment not recorded through an allowance for credit losses is recognized in other comprehensive income.

Changes in the allowance for credit losses are recorded as provision for, or reversal of, credit loss expense. Losses are charged against the allowance when the Company believes that an available-for-sale security is confirmed uncollectable or when either of the criteria regarding intent or requirement to sell is met.

Product revenue, net

The Company sells roxadustat in China through a number of pharmaceutical distributors located in China. These pharmaceutical distributors are the Company's customers. Hospitals order roxadustat through a distributor and the Company ships the product directly to the distributors. The delivery of roxadustat to a distributor represents a single performance obligation. Distributors are responsible for delivering product to end users, primarily hospitals. Distributors bear inventory risk once they receive and accept the product. Product revenue is recognized when control of the promised good is transferred to the customer in an amount that reflects the consideration to which the Company expects to be entitled to in exchange for the product.

The period between the transfer of control of the promised goods and when the Company receives payment is based on a general 60-day payment term. As such, product revenue is not adjusted for the effects of a significant financing component.

Product revenue is recorded at the net sales prices (transaction price) which includes the following estimates of variable consideration:

- Price adjustment: In December 2019, China's National Healthcare Security Administration released price guidance for roxadustat under the National Reimbursement Drug List ("NRDL"), effective January 1, 2020. Any channel inventories as of January 1, 2020 that had not been sold to hospitals by distributors, or to patients by hospitals, were eligible for a price adjustment under the price protection. The price adjustment is calculated based on estimated channel inventory levels at January 1, 2020. If price guidance changes in the future, the price adjustment will be calculated in the same manner;
- Contractual sales rebate: The contractual sales rebate is calculated based on the stated percentage of gross sales by each distributor in the distribution agreement entered between FibroGen and each distributor. The contractual sales rebate is recorded as a reduction to revenue at the point of sale to the distributor;
- Key account hospital sales rebate: An additional sales rebate is provided to a distributor for product sold to key account hospitals as a percentage of gross sales made by the distributor to eligible hospitals. This additional rebate is recorded as a reduction to revenue at the point of sale to the distributor;
- Transfer fee discount: The transfer fee discount is offered to a distributor who has its downstream distributors supply to eligible hospitals. This discount is calculated based on a percentage of gross sales made to the downstream distributors, and recorded as a reduction to revenue as incurred;
- Sales return: Distributors can request to return product to the Company only due to quality issues or for product purchased within one year prior to the product's expiration date. The Company, at its sole discretion, decides whether to accept such return request; and
- Non-key account hospital listing award: A one-time fixed-amount award is offered to a distributor who successfully lists the product with an eligible hospital, and who meets certain requirements. The Company considers this particular award to be an upfront payment to a customer within the definitions of ASC 606. The non-key account hospital listing award is capitalized when the distributor meets eligibility requirements, and amortized as reduction to product revenue over future sales orders made by the distributor until exhausted.

The calculation of the above variable consideration is based on gross sales to the distributor, or estimated utilizing best available information from the distributor, maximum known exposures and other available information including estimated channel inventory levels and estimated sales made by the distributor to hospitals, which involve a substantial degree of judgment.

The above rebates and discounts all together are eligible to be applied against the distributor's future sales order, limited to certain maximums until such rebates and discounts are exhausted. These rebates and discounts are recorded as contract liabilities at the time they become eligible and in the same period that the related revenue is recorded. Due to the distributor's legal right to offset, at each balance sheet date, the liability for rebates and discounts are presented as reductions of gross accounts receivable from the distributor, or as a current liability to the distributor to the extent that the total amount exceeds the gross accounts receivable. The distributor's legal right of offset is calculated at the individual distributor level.

2. Acquisition and Variable Interest Entity

On July 8, 2020, FibroGen Cayman, FibroGen Beijing, and FibroGen International (Hong Kong) Limited (collectively, "FibroGen China") and AstraZeneca AB ("AstraZeneca") entered into an amendment, effective July 1, 2020, to the collaboration agreement for the development and commercialization (but not manufacture) of roxadustat for the treatment of anemia in China ("China Agreement"), relating to the development and commercialization of roxadustat in China (the "China Amendment").

The China Amendment provides for the establishment of a jointly owned entity that will perform roxadustat distribution, as well as conduct sales and marketing through AstraZeneca. To prepare for the establishment of this jointly owned entity, in July 2020, FibroGen Beijing acquired 100% of the outstanding shares of Beijing Kangda Yongfu Pharmaceutical Co., LTD ("Kangda") in exchange for cash consideration of CNY15.0 million (approximately $2.1 million). The purpose of the acquisition was to acquire a distribution license owned by Kangda for commercializing and distributing roxadustat in China. FibroGen Beijing will continue to hold all of the regulatory licenses issued by China regulatory authorities and will continue to be primarily responsible for regulatory, clinical, manufacturing, medical affairs and pharmacovigilance. The transaction costs related to the execution of the acquisition, primarily legal expenses, totaled CNY5.0 million and were shared equally with AstraZeneca. Therefore, the acquisition costs for FibroGen Beijing were CNY2.5 million (approximately $0.4 million).

Under the ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, the Company determined that the all of the value of Kangda was attributable to the acquired license, and therefore the transaction was accounted for as an asset acquisition. The Company allocated the entire purchase price of $2.5 million to the acquired license that was recorded as an intangible asset, to be amortized over the duration of expected sales of roxadustat. There was no excess consideration over the estimated fair value. Through September 15, 2020, Kangda was consolidated as a wholly owned subsidiary of the Company. The amortization of the license was immaterial during the short period of time before Kangda was deconsolidated upon the establishment of the jointly owned entity described below.

On September 15, 2020, FibroGen Beijing and AstraZeneca entered into an equity transfer agreement and shareholders agreement, under which FibroGen Beijing sold 48.9% of the outstanding shares of Kangda to AstraZeneca in exchange for cash consideration of CNY7.3 million (approximately $1.0 million). Concurrently with the equity transfer, the two parties renamed Kangda to Beijing Falikang Pharmaceutical Co. Ltd. (“Falikang”). Following the sale, FibroGen Beijing owns 51.1% of the outstanding shares of Falikang. The gain (loss) resulting from the equity transfer was immaterial.

Pursuant to the guidance under ASC 810, the Company concluded that Falikang qualifies as a VIE. As Falikang is a distribution entity for roxadustat and AstraZeneca is the final decision maker for all the roxadustat commercialization activities, the Company lacks the power criterion while AstraZeneca meets both the power and economic criteria under ASC 810, to direct the activities of Falikang that most significantly impact its performance. Therefore, the Company is not the primary beneficiary of this VIE. As a result, the Company accounted for its investment in Falikang under the equity method, and Falikang is not consolidated into the Company’s condensed consolidated financial statements. Accordingly, The Company recorded its investment in Falikang of CNY10.2 million (approximately $1.5 million), which is the total of the 51.1% of Falikang’s equity and the acquisition costs, as an investment in unconsolidated subsidiary in other assets in the condensed consolidated balance sheet. In addition, the Company recognized its proportionate share of the reported profits or losses of Falikang, beginning September 15, 2020, as other income (loss) in the condensed consolidated statement of operations, and as an adjustment to its investment in unconsolidated subsidiary in the condensed consolidated balance sheet. Falikang has not incurred material profit or loss to date. The Company will assess the impairment of its equity method investment whenever events or changes in circumstances indicate that a decrease in value of the investment has occurred that is other than temporary.

The Company may be required to provide shareholder loans to Falikang to meet necessary financial obligations as part of its operations. To date, these loans have been immaterial.

On an ongoing basis, the Company will re-evaluate the VIE assessment based on potential changes in facts and circumstances, including but not limited to, the shareholder loans received by Falikang and the execution of any future significant agreements between Falikang and its shareholders and/or other third parties.

As of September 30, 2020, the Company’s equity method investment in Falikang was $1.5 million. Falikang is considered as a related party to the Company. See Note 9, *Related Party Transactions*, for related disclosures.

As of September 30, 2020, the cash consideration of CNY7.3 million for the above equity transfer, together with AstraZeneca’s share of the acquisition costs of CNY2.5 million, totaling CNY9.8 million (approximately $1.4 million), was recorded as a receivable from AstraZeneca in prepaid expenses and other current assets in the condensed consolidated balance sheet. In October 2020, CNY7.3 million cash consideration was received.

3. Collaboration Agreements and Revenues

Astellas Agreements

Japan Agreement

In June 2005, the Company entered into a collaboration agreement with Astellas for the development and commercialization (but not manufacture) of roxadustat for the treatment of anemia in Japan (“Japan Agreement”). Under this agreement, Astellas paid license fees and other consideration totaling $40.1 million (such amounts were fully received as of February 2009). Under the Japan Agreement, the Company is also eligible to receive from Astellas an aggregate of approximately $132.5 million in potential milestone payments, comprised of (i) up to $22.5 million in milestone payments upon achievement of specified clinical and development milestone events (such amounts were fully received as of July 2016), (ii) up to $95.0 million in milestone payments upon achievement of specified regulatory milestone events, and (iii) up to approximately $15.0 million in milestone payments upon the achievement of specified commercial sales milestone. The aggregate amount of consideration received through September 30, 2020 totals $90.1 million. The Japan Agreement also provides for tiered payments based on net sales of roxadustat in the low 20% range after commercial launch.

Europe Agreement

In April 2006, the Company entered into a separate collaboration agreement with Astellas for the development and commercialization of roxadustat for the treatment of anemia in Europe, the Middle East, the Commonwealth of Independent States and South Africa ("Europe Agreement"). Under the terms of the Europe Agreement, Astellas paid license fees and other upfront consideration totaling $320.0 million (such amounts were fully received as of February 2009). The Europe Agreement also provides for additional development and regulatory approval milestone payments up to $425.0 million, comprised of (i) up to $90.0 million in milestone payments upon achievement of specified clinical and development milestone events (such amounts were fully received as of 2012), (ii) up to $335.0 million in milestone payments upon achievement of specified regulatory milestone events. Under the Europe Agreement, Astellas committed to fund 50% of joint development costs for Europe and North America, and all territory-specific costs. The Europe Agreement also provides for tiered payments based on net sales of roxadustat in the low 20% range. The aggregate amount of consideration received through September 30, 2020 totals $540.0 million.

During the second quarter of 2019, the Company received positive topline results from analyses of pooled major adverse cardiac event ("MACE") and MACE plus hospitalized unstable angina and hospitalized congestive heart failure ("MACE+") data from its Phase 3 trials evaluating roxadustat as a treatment for dialysis and non-dialysis CKD patients, enabling Astellas to prepare for an MAA submission to the EMA, following the Company's NDA submission to the FDA. These milestones became probable of being achieved in the second quarter of 2019, and the total consideration of $130.0 million associated with these milestones was included in the transaction price and allocated to performance obligations under the Europe Agreement in the second quarter of 2019, of which $128.8 million was recognized as revenue during 2019, and $0.6 million was recognized as revenue during the nine months ended September 30, 2020, from performance obligations satisfied or partially satisfied. According to the Europe Agreement, these milestone payments were billed to Astellas upon the submission of an MAA in the second quarter of 2020 and the total $130.0 million was received during the same quarter.

AstraZeneca Agreements

U.S./Rest of World ("RoW") Agreement

Effective July 30, 2013, the Company entered into a collaboration agreement with AstraZeneca for the development and commercialization of roxadustat for the treatment of anemia in the U.S. and all other countries in the world, other than China, not previously licensed under the Astellas Europe and Astellas Japan Agreements ("U.S./RoW Agreement"). It also excludes China, which is covered by a separate agreement with AstraZeneca described below. Under the terms of the U.S./RoW Agreement, AstraZeneca paid upfront, non-contingent, non-refundable and time-based payments totaling $374.0 million (such amounts were fully received as of June 2016). Under the U.S./RoW Agreement, the Company is also eligible to receive from AstraZeneca an aggregate of approximately $875.0 million in potential milestone payments, comprised of (i) up to $65.0 million in milestone payments upon achievement of specified clinical and development milestone events, $15.0 million of which was received in 2015 as a result of the finalization of its two audited pre-clinical carcinogenicity study reports, and the remaining $50.0 million was received in April 2020 as a result of the NDA submission milestone, (ii) up to $325.0 million in milestone payments upon achievement of specified regulatory milestone events, (iii) up to $160.0 million in milestone payments related to activity by potential competitors and (iv) up to approximately $325.0 million in milestone payments upon the achievement of specified commercial sales events. The aggregate amount of consideration received through September 30, 2020 totals $439.0 million.

As mentioned above, during the second quarter of 2019, the Company received positive topline results from analyses of pooled MACE and MACE+ data from its Phase 3 trials for roxadustat, enabling the Company's NDA submission to the FDA. The regulatory milestone payment associated with this NDA submission became probable of being achieved in the second quarter of 2019. Accordingly, the consideration of $50.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the U.S./ RoW Agreement in the second quarter of 2019, of which $42.4 million was recognized as revenue during 2019, and $0.6 million was recognized as revenue during the nine months ended September 30, 2020, from performance obligations satisfied or partially satisfied. The Company submitted such NDA in December 2019, which was accepted by the FDA for review in February 2020. According to the U.S/RoW Agreement, this milestone payment is billable to AstraZeneca when the NDA is accepted by the FDA. Therefore, this $50.0 million was billed during the first quarter of 2020, the payment of which was fully received in April 2020.

AstraZeneca and Astellas approved the development of roxadustat for the treatment of chemotherapy-induced anemia in December 2018 and January 2019, respectively. Costs associated with the development of this indication are expected to be shared 50/50 between AstraZeneca and Astellas. In addition, in December 2018, anemia of chronic inflammation and multiple myeloma was approved for development by AstraZeneca and is expected to be fully funded by them. For revenue recognition purposes, the Company concluded that the addition of these new indications represents a modification to the collaboration agreements and will be accounted for separately, meaning the development costs associated with the new indications are distinct from the original development costs. The development service period for roxadustat for the treatment of chemotherapy-induced anemia, anemia of chronic inflammation and multiple myeloma under the AstraZeneca agreements is estimated to continue through the end of 2024, to allow for development of these additional indications.

China Agreement

Effective July 30, 2013, the Company (through its subsidiaries affiliated with China) entered into the China Agreement. Under the terms of the China Agreement, AstraZeneca agreed to pay upfront consideration totaling $28.2 million (such amounts were fully received in 2014). Under the China Agreement, the Company is also eligible to receive from AstraZeneca an aggregate of approximately $348.5 million in potential milestone payments, comprised of (i) up to $15.0 million in milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $146.0 million in milestone payments upon achievement of specified regulatory milestone events, and (iii) up to approximately $187.5 million in milestone payments upon the achievement of specified commercial sales and other events. The China Agreement was structured as a 50/50 profit or loss share (as defined), which was amended under the China Amendment discussed below in the third quarter of 2020, and provides for joint development costs (including capital and equipment costs for construction of the manufacturing plant in China), to be shared equally during the development. The aggregate amount of such consideration received for milestone and upfront payments through September 30, 2020 totals $77.2 million.

In December 2019, roxadustat was included on the updated NRDL released by China's National Healthcare Security Administration for the treatment of anemia in CKD, covering patients who are non-dialysis dependent as well as those who are dialysis-dependent. The inclusion on the NRDL triggered a total of $22.0 million of milestones payable to the Company by AstraZeneca. Accordingly, the total consideration of $22.0 million associated with these milestones was included in the transaction price and allocated to performance obligations under the China Agreement during the fourth quarter of 2019. This milestone payment was received during the first quarter of 2020.

China Amendment

On July 8, 2020, FibroGen China and AstraZeneca (together with FibroGen China, the "Parties") entered into the China Amendment, effective July 1, 2020, relating to the development and commercialization of roxadustat in China. While the responsibilities of the Parties under the China Agreement remain largely the same, certain changes were made.

Under the China Amendment, in September 2020, FibroGen Beijing and AstraZeneca completed the establishment of a jointly owned entity, Falikang, which will perform roxadustat distribution, as well as conduct sales and marketing through AstraZeneca. See Note 2, *Acquisition and Variable Interest Entity*, for details.

In accordance with the China Amendment, the Company is currently in the interim period. Under the China Amendment, the interim period is defined as the period from April 1, 2020 to the time when Falikang is fully operational, expected in early 2021. During the interim period, FibroGen will continue to sell product directly to the distributors, who remain as the Company's customers. Under the China Amendment, the calculation for profit or loss share has changed related to sales of roxadustat in China for the period from April 1, 2020 onwards. With effect from April 1, 2020, the Parties have changed the method under which commercial expenses incurred by AstraZeneca are calculated and billed. AstraZeneca's co-promotion expenses for their sales and marketing efforts are now subject to a cap of a percentage of net sales. Once AstraZeneca has been fully reimbursed for their sales and marketing costs under the cap, AstraZeneca will bill the co-promotion expenses based on actual costs on a prospective basis. In addition, the China Amendment has allowed for a higher cost of manufacturing incurred by FibroGen Beijing to be included in the profit or loss share calculation, subject to an annual cap, among other changes.

Once Falikang is fully operational, AstraZeneca will bill the co-promotion expenses to Falikang, rather than FibroGen Beijing. In addition, FibroGen Beijing will manufacture and supply commercial product to Falikang based on an agreed upon transfer price. Development costs will continue to be shared 50/50 between the Parties.

As a result, the interim period primarily includes the following activities:

- Co-promotion expenses: The China Amendment revised the payment arrangements and calculation of the historical unpaid co-promotion expenses to AstraZeneca for its sales and marketing efforts associated with the commercial sales for roxadustat in China since the product launch. Under the previous China Agreement, payment of these historical co-promotion expenses was subject to certain profitability and cash flow thresholds. No amount of the historical co-promotion costs had been paid prior to the China Amendment as these thresholds had not yet been met. Under the China Amendment, a portion of the historical unpaid co-promotion expenses was adjusted to reduce the amount owed by FibroGen Beijing and the current period co-promotion expenses are capped at a percentage of net roxadustat sales in China. As a result, in the third quarter of 2020, the Company reversed approximately $84.4 million of previously accrued co-promotion expenses payable, which was recorded as a reduction to selling, general and administrative expenses, where these expenses were initially recorded during the periods from the initiation of commercial activities in the first quarter of 2019 to the second quarter of 2020. The co-promotion expenses for the three and nine months ended September 30, 2020, capped at a percentage of net roxadustat sales in China, were $8.8 million and $14.8 million, respectively, included in the selling, general and administrative expenses. After this adjustment, as of September 30, 2020, $14.8 million of the recalculated accrued co-promotion expenses was recorded as a current liability, as it is anticipated to be paid within the next 12 months; and $26.3 million of the recalculated accrued co-promotion expenses remained in the long-term liabilities, as it is not anticipated to be paid within the next 12 months.
- Profit share: Profit/loss share between FibroGen China and AstraZeneca is based on a calculation of the current period net roxadustat sales in China and deductible expenses pursuant to the China Agreement. Based on the calculation, a profit was achieved during the third quarter of 2020. As a result, the Company recorded a profit share liability of $2.0 million to AstraZeneca in the three months ended September 30, 2020 in the condensed consolidated statement of operations.

Summary of Revenue Recognized Under the Collaboration Agreements

The table below summarizes the accounting treatment for the various performance obligations pursuant to each of the Astellas and AstraZeneca agreements. License amounts identified below are included in the “License revenue” line item in the condensed consolidated statements of operations. All other elements identified below are included in the “Development and other revenue” line item in the condensed consolidated statements of operations.

Amounts recognized as revenue under the Japan Agreement were as follows (in thousands):

		Three Months Ended September 30,		Nine Months Ended September 30,	
Agreement	Performance Obligation	2020	2019	2020	2019
Japan	License revenue	$ —	$ 11,935	$ —	$ 11,935
	Development revenue	$ 86	$ 537	$ 413	$ 1,151

The transaction price related to consideration received and accounts receivable has been allocated to each of the following performance obligations under the Japan Agreement, along with any associated deferred revenue as follows (in thousands):

Japan Agreement	Cumulative Revenue Through September 30, 2020	Deferred Revenue at September 30, 2020	Total Consideration Through September 30, 2020
License	$ 86,024	$ —	$ 86,024
Development revenue	15,543	164	15,707
Total license and development revenue	$ 101,567	$ 164	$ 101,731

The revenue recognized under the Japan Agreement for the three months ended September 30, 2020 included an increase in revenue of $0.1 million resulting from changes to estimated variable consideration in the current period relating to performance obligations satisfied or partially satisfied in previous periods. The remainder of the transaction price related to the Japan Agreement includes no further variable consideration from estimated future co-development billing.

Amounts recognized as revenue under the Europe Agreement were as follows (in thousands):

		Three Months Ended September 30,		Nine Months Ended September 30,	
Agreement	Performance Obligation	2020	2019	2020	2019
Europe	License revenue	$ —	$ —	$ —	$ 117,470
	Development revenue	$ 4,651	$ 2,996	$ 13,827	$ 24,463

The transaction price related to consideration received and accounts receivable has been allocated to each of the following performance obligations under the Europe Agreement, along with any associated deferred revenue as follows (in thousands):

Europe Agreement	Cumulative Revenue Through September 30, 2020	Deferred Revenue at September 30, 2020	Total Consideration Through September 30, 2020
License	$ 487,951	$ —	$ 487,951
Development revenue	244,834	2,096	246,930
Total license and development revenue	$ 732,785	$ 2,096	$ 734,881

The revenue recognized under the Europe Agreement for the three months ended September 30, 2020 included an increase in revenue of $1.3 million resulting from changes to estimated variable consideration in the current period relating to performance obligations satisfied or partially satisfied in previous periods. The remainder of the transaction price related to the Europe Agreement includes $31.5 million of variable consideration from estimated future co-development billing and is expected to be recognized over the remaining development service period.

Amounts recognized as revenue under the U.S./RoW and China Agreement were as follows (in thousands):

Agreement	Performance Obligation	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
U.S. / RoW and China	License revenue	$ —	$ —	$ —	$ 33,112
	Development revenue	15,220	17,106	43,525	59,872
	China performance obligation	$ 706	$ 19	$ 1,300	$ 19

The transaction price related to consideration received and accounts receivable has been allocated to each of the following performance obligations under the U.S./RoW Agreement and China Agreement, along with any associated deferred revenue as follows (in thousands):

U.S. / RoW and China Agreements	Cumulative Revenue Through September 30, 2020	Deferred Revenue at September 30, 2020	Total Consideration Through September 30, 2020
License	$ 341,844	$ —	$ 341,844
Co-development, information sharing & committee services	536,792	2,435	539,227
China performance obligation	1,390	141,171	142,561
Total license and development revenue	$ 880,026	$ 143,606	$ 1,023,632

The revenue recognized under the U.S./RoW Agreement for the three months ended September 30, 2020 included a decrease of $0.6 million in revenue resulting from changes to estimated variable consideration in the current period relating to performance obligations satisfied or partially satisfied in previous periods. The remainder of the transaction price related to the U.S./RoW Agreement and China Agreement includes $52.3 million of variable consideration from estimated future co-development billing and is expected to be recognized over the remaining development service period, except for amounts allocated to the China performance obligation, which are expected to be recognized in a pattern consistent with estimated deliveries of the commercial drug product. As mentioned above, a profit share with AstraZeneca of $2.0 million was recorded in the condensed consolidated statement of operations for the three months ended September 30, 2020.

Product Revenue, Net

Product revenue from roxadustat commercial sales in China is recognized in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those products, net of various sales rebates and discounts. Product revenue, net was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Gross revenue	$ 27,900	$ 622	$ 53,105	$ 622
Non-key account hospital listing award	(2,930)	—	(5,495)	—
Contractual sales rebate	(1,966)	(43)	(3,714)	(43)
Other discounts and rebates	(313)	—	(512)	—
Sales return	(8)	—	(53)	—
Product revenue, net	$ 22,683	$ 579	$ 43,331	$ 579

In the second quarter of 2020, the Company amended the agreement with its pharmaceutical distributors, which triggered accounting modifications particularly related to non-key account hospital listing award. For the three and nine months ended September 30, 2020, the non-key account hospital listing award was $2.9 million and $5.5 million, respectively, which was recorded as a reduction to the revenue and calculated based on eligible non-key account hospital listing to date achieved by each distributor with certain requirements met during the period.

For the three and nine months ended September 30, 2020, the contractual sales rebate was $2.0 million and $3.7 million, respectively, which were calculated based on the stated percentage of gross sales by each distributor in the distribution agreement entered between FibroGen and each distributor. All other rebates and discounts, including sales return allowance were immaterial for the periods presented.

The rebates and discounts that the Company's pharmaceutical distributors have earned are eligible to be applied against future sales orders, limited to certain maximums until such rebates and discounts are exhausted. These rebates and discounts are recorded as contract liabilities at the time they become eligible in the same period that the related revenue is recorded. Due to the distributor's legal right to offset, at each balance sheet date, the rebates and discounts are presented as reductions to gross accounts receivable from the distributor, or as a current liability to the distributor to the extent that the total amount exceeds the gross accounts receivable. The distributor's legal right of offset is calculated at the individual distributor level. The following table includes a roll-forward of the contract liabilities (in thousands):

	Balance at December 31, 2019	Additions	Deduction	Currency Translation and Other	Gross Contract Liabilities Balance	Balance Presented Net Against Accounts Receivable	Balance at September 30, 2020
Contract liabilities	$ (1,102)	$ (10,623)	$ 450	$ (117)	$ (11,392)	$ 9,759	$ (1,633)

As of September 30, 2020, the total rebates and discounts as reductions to gross accounts receivable was $9.8 million, and the total contract liabilities was $1.6 million, which was included in accrued and other current liabilities in the condensed consolidated balance sheet.

The reductions to gross accounts receivable, including the above-mentioned contra-accounts receivable items related to product revenue, consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Price adjustment	$ 529	$ 936
Contractual sales rebate	3,479	148
Non-key account hospital listing award	5,238	—
Other discounts and rebates	513	18
Sales return	53	—
Provision for credit loss	102	—
Total reductions to gross accounts receivable	$ 9,914	$ 1,102

Drug Product Revenue

Drug product revenue was as follows (in thousands):

	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2020
Astellas	$ (3,957)	$ 4,281
AstraZeneca	4,643	4,643
Drug product revenue	$ 686	$ 8,924

In 2018, FibroGen and Astellas entered into an amendment to the Japan Agreement that allows Astellas to manufacture roxadustat drug product for commercialization in Japan (the "Japan Amendment"). Under this amendment, FibroGen would continue to manufacture and deliver to Astellas roxadustat active pharmaceutical ingredient ("API") for the roxadustat commercial launch in Japan. Related to the API shipments in 2018 under the Japan Amendment, during the three months ended September 30, 2020, the Company recorded a $4.0 million reduction to drug product revenue, related to a change in estimated variable consideration. Specifically, the change in estimated variable consideration was based on the API held by Astellas at March 31, 2020 adjusted to reflect the updated listed price for roxadustat issued by the Japanese Ministry of Health, Labour and Welfare and changes in the estimated bulk product strength mix intended to be manufactured by Astellas, estimated cost to convert the API to bulk product tablets, and estimated yield from the manufacture of bulk product tablets, among others.

During the three months ended June 30, 2020, the Company fulfilled delivery obligations under the term of the Japan Amendment, and recognized the related drug product revenue of $8.2 million in the same period. The amount represents variable consideration and was estimated based on the quantity of product shipped, actual listed price for roxadustat issued by the Japanese Ministry of Health, Labour and Welfare and possible future changes to the listed price, adjusted for estimated bulk product strength mix intended to be manufactured by Astellas, estimated cost to convert the API to bulk product tablets, and estimated yield from the manufacture of bulk product tablets, among others.

Under the U.S./RoW Agreement, FibroGen would manufacture and deliver to AstraZeneca roxadustat bulk drug product in support of commercial supplies. The Company delivered bulk drug product to AstraZeneca as pre-commercial supply for process validation purposes in the three months ended March 31, 2020, June 30, 2020 and September 30, 2020, respectively. The related drug product revenue of $4.6 million was recognized in the three months ended September 30, 2020. The drug product revenue amount represents variable consideration and was estimated based on the quantity of product shipped and an estimated price.

The amount of variable consideration that is included in the transaction price may be constrained, and is included in the drug product revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received in the future may differ from the Company's estimates, for which the Company will adjust these estimates and affect the drug product revenue in the period such variances become known.

Other Revenues

Other revenues consist primarily of collagen material sold for research purposes. Other revenues were immaterial for all periods presented.

Deferred Revenue

Deferred revenue represents amounts billed, or in certain cases, yet to be billed to the Company's collaboration partners for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met. The current portion of deferred revenue represents the amount to be recognized within one year from the balance sheet date based on the estimated performance period of the underlying performance obligations. The long-term portion of deferred revenue represents amounts to be recognized after one year through the end of the non-contingent performance period of the underlying performance obligations.

Deferred revenue includes amounts allocated to the China unit of accounting under the AstraZeneca arrangement as revenue recognition associated with this unit of accounting is tied to the commercial sales of the products within China. As of September 30, 2020, approximately $3.2 million of the deferred revenue related to the China unit of accounting was included in short-term deferred revenue, which represents the amount of deferred revenue associated with the China unit of accounting that is expected to be recognized within the next 12 months, associated with the commercial sales in China.

4. Fair Value Measurements

The fair values of the Company's financial assets that are measured on a recurring basis are as follows (in thousands):

	September 30, 2020			
	Level 1	Level 2	Level 3	Total
U.S. treasury notes and bills	$ 125,388	$ —	$ —	$ 125,388
Equity investments	247	—	—	247
Money market funds	451,917	—	—	451,917
Certificate of deposit	—	30,010	—	30,010
Total	$ 577,552	$ 30,010	$ —	$ 607,562

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
U.S. treasury notes and bills	$ 347,383	$ 80,123	$ —	$ 427,506
Bond and mutual funds	10,816	—	—	10,816
Equity investments	255	—	—	255
Money market funds	85,551	—	—	85,551
Certificate of deposit	—	30,032	—	30,032
Total	$ 444,005	$ 110,155	$ —	$ 554,160

The Company's Level 2 investments are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar investments, issuer credit spreads, benchmark investments, prepayment/default projections based on historical data and other observable inputs.

The fair values of the Company's financial liabilities that are carried at historical cost are as follows (in thousands):

	September 30, 2020			
	Level 1	Level 2	Level 3	Total
Lease obligations	$ —	$ —	$ 1,242	$ 1,242

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Lease obligations	$ —	$ —	$ 1,544	$ 1,544

The fair values of the Company's financial liabilities were derived by using an income approach, which required Level 3 inputs such as discounted estimated future cash flows.

There were no transfers of assets or liabilities between levels for any of the periods presented.

5. Leases

The Company's lease assets and related lease liabilities were as follows (in thousands):

	Balance Sheet Line Item	September 30, 2020	December 31, 2019
Assets			
Finance:			
Right-of-use assets - cost		$ 50,220	$ 49,909
Accumulated amortization		(18,192)	(10,307)
Finance lease right-of-use assets, net	Finance lease right-of-use assets	32,028	39,602
Operating:			
Right-of-use assets - cost		2,796	2,736
Accumulated amortization		(1,554)	(805)
Operating lease right-of-use assets, net	Other assets	1,242	1,931
Total lease assets		$ 33,270	$ 41,533
Liabilities			
Current:			
Finance lease liabilities	Finance lease liabilities, current	$ 12,311	$ 12,351
Operating lease liabilities	Accrued and other current liabilities	770	983
Non-current:			
Finance lease liabilities	Finance lease liabilities, non-current	28,514	37,610
Operating lease liabilities	Other long-term liabilities	472	942
Total lease liabilities		$ 42,067	$ 51,886

The components of lease expense were as follows (in thousands):

		Three Months Ended September 30,		Nine Months Ended September 30,	
	Statement of Operations Line Item	2020	2019	2020	2019
Finance lease cost:					
Amortization of right-of-use assets	Cost of goods sold; Research and development; Selling, general and administrative expenses	$ 2,639	$ 2,580	$ 7,886	$ 7,720
Interest on lease liabilities	Interest expense	462	578	1,511	1,826
Operating lease cost	Cost of goods sold; Research and development; Selling, general and administrative expenses	304	290	868	579
Sublease income	Selling, general and administrative expenses	(301)	(310)	(899)	(1,135)
Total lease cost		$ 3,104	$ 3,138	$ 9,366	$ 8,990

Supplemental cash flow information related to leases were as follows (in thousands):

	Nine Months Ended September 30,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 812	$ 540
Operating cash flows from finance leases	1,468	1,640
Financing cash flows from finance leases	9,254	8,810
Right-of-use assets obtained in exchange for new lease liabilities:		
Finance leases	434	49,784
Operating leases	$ 55	$ 2,723

Lease term and discount rate were as follows:

	September 30, 2020	December 31, 2019
Weighted-average remaining lease term (years):		
Finance leases	3.1	3.6
Operating leases	1.6	2.1
Weighted-average discount rate:		
Finance leases	4.39%	4.42%
Operating leases	4.73%	4.75%

Maturities of lease liabilities as of September 30, 2020 are as follows (in thousands):

Year Ending	Finance Leases	Operating Leases
2020 (Remaining three month period)	$ 3,542	$ 245
2021	13,683	714
2022	13,883	329
2023	12,524	—
Total future lease payments	43,632	1,288
Less: Interest	(2,807)	(46)
Present value of lease liabilities	$ 40,825	$ 1,242

6. Balance Sheet Components

Cash and Cash Equivalents

Cash and cash equivalents consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Cash	$ 80,551	$ 40,715
Money market funds	451,917	85,551
Total cash and cash equivalents	$ 532,468	$ 126,266

The underlying investments in the money market funds as of September 30, 2020 are all US government obligations. At September 30, 2020 and December 31, 2019, a total of $51.2 million and $11.9 million, respectively, of the Company’s cash and cash equivalents were held outside of the U.S. in its foreign subsidiaries to be used primarily for its China operations.

Investments

The Company's investments consist of available-for-sale debt investments, marketable equity investments, term deposit and certificate of deposit. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's investments by major investments type are summarized in the tables below (in thousands):

	September 30, 2020			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
U.S. treasury notes and bills	$ 124,993	$ 395	$ —	$ 125,388
Certificates of deposit	30,000	10	—	30,010
Equity investments	125	122	—	247
Total investments	$ 155,118	$ 527	$ —	$ 155,645

	December 31, 2019			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
U.S. treasury notes and bills	$ 426,995	$ 536	$ (25)	$ 427,506
Certificates of deposit	30,000	32	—	30,032
Bond and mutual funds	10,730	86	—	10,816
Equity investments	125	130	—	255
Total investments	$ 467,850	$ 784	$ (25)	$ 468,609

At September 30, 2020, all of the available-for-sale investments had contractual maturities within one year. During the three and nine months ended September 30, 2020 and 2019, the Company did not recognize any other-than-temporary impairment loss.

Inventories

Inventories consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Raw materials	$ 1,152	$ 325
Work-in-progress	5,616	2,264
Finished goods	5,034	4,298
Total inventories	$ 11,803	$ 6,887

The provision to write-down excess and obsolete inventory was immaterial for the three and nine months ended September 30, 2020. There was no provision to write-down excess and obsolete inventory for the three and nine months ended September 30, 2019.

Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Unbilled contract assets	$ —	$ 180,000
Deferred revenues from associated contracts	—	(54,790)
Net unbilled contract assets	—	125,210
Prepaid assets	5,549	6,464
Other current assets	6,014	1,717
Total prepaid expenses and other current assets	$ 11,563	$ 133,391

The unbilled contract assets as of December 31, 2019 included two regulatory milestones totaling $130.0 million under the Europe Agreement with Astellas associated with the planned MAA submission in Europe. The MAA was submitted in the second quarter of 2020. Therefore, the $130 million milestones were billed in the same quarter. The unbilled contract assets as of December 31, 2019 also included a $50.0 million regulatory milestone under the U.S./RoW Agreement with AstraZeneca associated with the NDA submission in the U.S, which was submitted in December 2019 and accepted for review in February 2020. Therefore, the $50.0 million milestone was billed during the first quarter of 2020. See Note 3, *Collaboration Agreements and Revenues*, for details.

Property and Equipment

Property and equipment consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Leasehold improvements	$ 101,162	$ 101,548
Laboratory equipment	17,890	17,329
Machinery	8,012	8,217
Computer equipment	9,124	8,399
Furniture and fixtures	6,110	5,822
Construction in progress	1,506	1,792
Total property and equipment	$ 143,804	$ 143,107
Less: accumulated depreciation	(107,651)	(100,364)
Property and equipment, net	$ 36,153	$ 42,743

Accrued and Other Current Liabilities

Accrued and other current liabilities consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Preclinical and clinical trial accruals	$ 29,396	$ 16,279
API product price adjustment	3,957	36,324
Payroll and related accruals	19,606	19,784
Accrued co-promotion expenses - current	14,836	—
Property taxes and other	6,057	2,044
Professional services	7,384	4,842
Other	9,336	4,543
Total accrued and other current liabilities	$ 90,572	$ 83,816

The API product price adjustment of $36.3 million accrued as of December 31, 2019 was related to the change in estimated variable consideration of API product at the time the roxadustat listed price was issued by the Japanese Ministry of Health, Labour and Welfare in the fourth quarter of 2019. This amount was fully paid during the first quarter of 2020. The API product price adjustment of $4.0 million accrued as of September 30, 2020 related to the change in estimated variable consideration of API product at the time an updated roxadustat listed price was issued by the same Japanese authority in the first quarter of 2020. See Note 3, *Collaboration Agreements and Revenues*, for details.

On July 8, 2020, the Parties entered into an amendment to the China Agreement, relating to the development and commercialization of roxadustat in China, which revised, among other things, the arrangements and calculation of the estimated co-promotion expenses payable to AstraZeneca for its sales and marketing efforts associated with the commercial sales for roxadustat in China. As a result, the previously accrued long-term co-promotion expenses were significantly reduced during the third quarter of 2020. $14.8 million of the recalculated accrued co-promotion expenses is anticipated to be paid within the next 12 months, therefore was recorded as a current liability as of September 30, 2020.

Other Long-term Liabilities

Other long-term liabilities consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Accrued long-term co-promotion expenses	$ 26,344	$ 53,071
Other long-term tax liabilities	8,637	8,913
Operating lease liabilities, non-current	472	942
Other	2,186	1,340
Total other long-term liabilities	$ 37,639	$ 64,266

As mentioned above, the China Amendment revised the arrangements and calculation of the estimated co-promotion expenses payable to AstraZeneca. As a result, we reversed approximately $84.4 million of previously accrued long-term co-promotion expenses during the third quarter of 2020. $26.3 million of the recalculated accrued co-promotion expenses remained in the long-term liabilities as of September 30, 2020, as it is not anticipated to be paid within the next 12 months.

7. Stock-Based Compensation

Stock-based compensation expense was recorded directly to research and development and selling, general and administrative expense as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 11,236	$ 10,185	$ 32,653	$ 30,214
Selling, general and administrative	6,655	4,608	19,798	18,651
Total stock-based compensation expense	$ 17,891	$ 14,793	$ 52,451	$ 48,865

The assumptions used to estimate the fair value of stock options granted and purchases under the Company's 2014 Employee Share Purchase Plan ("ESPP") using the Black-Scholes option valuation model were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Stock Options				
Expected term (in years)	5.6	5.3	5.7	5.3
Expected volatility	59.0 %	67.8 %	67.7 %	67.9 %
Risk-free interest rate	0.3 %	1.7 %	0.8 %	2.4 %
Expected dividend yield	—	—	—	—
Weighted average estimated fair value	$ 22.48	$ 25.17	$ 18.11	$ 32.44
ESPPs				
Expected term (in years)	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0
Expected volatility	50.4 - 77.1 %	48.1 - 62.1 %	49.5 - 77.1 %	48.1 - 62.1 %
Risk-free interest rate	0.2 - 2.9 %	1.6 - 2.9 %	0.2 - 2.9 %	1.3 - 2.9 %
Expected dividend yield	—	—	—	—
Weighted average estimated fair value	$ 17.00	$ 19.27	$ 17.74	$ 19.53

8. Income Taxes

Provision for income tax for the three and nine months ended September 30, 2020 and 2019 were primarily due to foreign taxes.

Based upon the weight of available evidence, which includes its historical operating performance, reported cumulative net losses since inception, the Company has established and continues to maintain a full valuation allowance against its deferred tax assets as it does not currently believe that realization of those assets is more likely than not.

9. Related Party Transactions

Astellas is an equity investor in the Company and considered a related party. The Company recorded revenue related to collaboration agreements with Astellas of $4.7 million and $15.5 million for the three months ended September 30, 2020 and 2019, respectively, and $14.2 million and $155.0 million for the nine months ended September 30, 2020 and 2019, respectively.

The drug product revenue from Astellas for the three months ended September 30, 2020 represented a change in estimated variable consideration at the time an updated listed price for roxadustat was issued by the Japanese Ministry of Health, Labour and Welfare, which resulted in a $4.0 million reduction to revenue, related to roxadustat API sales in 2018. See Note 3, *Collaboration Agreements and Revenues*, for details. The drug product revenue from Astellas for the nine months ended September 30, 2020 was $4.3 million, as the Company recorded $8.2 million drug product revenue from Astellas in the second quarter of 2020.

The Company recorded expense related to collaboration agreements with Astellas of $0.2 million and $0.9 million during the three months ended September 30, 2020 and 2019, respectively, and $0.5 million and $2.2 million during the nine months ended September 30, 2020 and 2019, respectively.

As of September 30, 2020 and December 31, 2019, accounts receivable from Astellas were $4.7 million and $4.8 million, respectively, and amounts due to Astellas were $4.1 million and $36.9 million, respectively, which included $4.0 million and $36.3 million of changes in estimated variable consideration related to the API product revenue recognized in 2018, at the time the roxadustat listed price was issued or updated by the Japanese Ministry of Health, Labour and Welfare in the first quarter of 2020 and the fourth quarter of 2019. The $36.3 million was fully paid during the first quarter of 2020.

Prepaid expenses and other current assets as of December 31, 2019 included $125.2 million of net unbilled contract assets from Astellas, representing a $130.0 million unbilled contract asset related to two regulatory milestones under the Europe Agreement with Astellas associated with the planned MAA submission to the EMA, net of $4.8 million of associated deferred revenue. According to the Europe Agreement, this $130.0 million was billed to Astellas upon the submission of an MAA in the second quarter of 2020. See Note 3, *Collaboration Agreements and Revenues*, for details.

In September 2020, FibroGen Beijing and AstraZeneca completed the establishment of a jointly owned entity, Falikang, which was determined to be an unconsolidated VIE. As such, Falikang is accounted for as an equity method investment, and considered as a related party to the Company. The Company's investment in Falikang was approximately $1.5 million, which is the total of the 51.1% of Falikang's equity and the acquisition costs. In addition, the Company recognized its proportionate share of the reported profits or losses of Falikang, beginning September 15, 2020, as other income (loss) in the condensed consolidated statement of operations, and as an adjustment to its investment in unconsolidated subsidiary in the condensed consolidated balance sheet. Falikang has not incurred material profit or loss to date. As of September 30, 2020, the Company's other assets included $1.5 million of its equity investment in Falikang, and prepaid expenses and other current assets included its miscellaneous receivables of $0.2 million from Falikang. See Note 2, *Acquisition and Variable Interest Entity*, for details.

10. Commitments and Contingencies

Contract Obligations

As of September 30, 2020, the Company had outstanding total non-cancelable contract obligations of $33.1 million, including $16.7 million for manufacture and supply of roxadustat, $10.9 million for future milestone payments for research and pre-clinical stage development programs, and $5.5 million for other purchases. The Company expects to fulfill our commitments under these agreements in the normal course of business, and as such, no liability has been recorded.

Legal Proceedings

From time to time, the Company is a party to various legal actions, both inside and outside the U.S., arising in the ordinary course of its business or otherwise. The Company accrues amounts, to the extent they can be reasonably estimated, that the Company believes will result in a probable loss (including, among other things, probable settlement value), to adequately address any liabilities related to legal proceedings and other loss contingencies. A loss or a range of loss is disclosed when it is reasonably possible that a material loss will incur and can be estimated, or when it is reasonably possible that the amount of a loss, when material, will exceed the recorded provision. The Company did not have material accruals for any currently active legal action in its condensed consolidated balance sheets as of September 30, 2020, as it could not predict the ultimate outcome of these matters, or reasonably estimate the potential exposure.

Indemnification Agreements

The Company enters into standard indemnification arrangements in the ordinary course of business, including for example, service, manufacturing and collaboration agreements. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, including in connection with intellectual property infringement claims by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The Company has entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the extent permissible under applicable law. The maximum potential amount of future payments the Company could be required to make under these arrangements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the estimated fair value of these arrangements is minimal.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the condensed consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q, and in our Securities and Exchange Commission ("SEC") filings, including our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 2, 2020.

FORWARD-LOOKING STATEMENTS

The following discussion and information contained elsewhere in this Quarterly Report on Form 10-Q contain "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"), Section 27A of the Securities Act of 1933, as amended ("Securities Act") and within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors," set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q. The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. New risks emerge from time to time, and it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report on Form 10-Q may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. While we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q and are cautioned not to place undue reliance on such forward-looking statements.

BUSINESS OVERVIEW

We were incorporated in 1993 in Delaware and are headquartered in San Francisco, California, with subsidiary offices in Beijing and Shanghai, People's Republic of China ("China"). We are a leading biopharmaceutical company developing and commercializing a pipeline of first-in-class therapeutics. We apply our pioneering expertise in hypoxia-inducible factor ("HIF"), connective tissue growth factor ("CTGF") biology, and clinical development to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer.

Roxadustat, our most advanced product, is an oral small molecule inhibitor of HIF prolyl hydroxylase ("HIF-PH") activity that has received marketing authorization in China (tradename: □□□®) for the treatment of anemia caused by chronic kidney disease ("CKD") in dialysis and non-dialysis patients. Evrenzo® (roxadustat) is approved in Japan for the treatment of anemia associated with CKD in dialysis patients. In January 2020, Astellas Pharma Inc. ("Astellas") submitted a supplemental New Drug Application ("NDA") in Japan for the treatment of anemia in non-dialysis CKD patients.

Our NDA filing in the United States ("U.S.") for roxadustat for the treatment of anemia in dialysis and non-dialysis CKD patients was accepted by the U.S. Food and Drug Administration ("FDA") in February 2020. In Europe, the Marketing Authorization Application ("MAA") filing for roxadustat for the treatment of anemia in dialysis and non-dialysis CKD patients was accepted for regulatory review by the European Medicines Agency ("EMA") in May 2020.

Roxadustat is in Phase 3 clinical development in the U.S. and Europe and in Phase 2/3 development in China for anemia associated with myelodysplastic syndromes ("MDS"). Roxadustat is in Phase 2 clinical development for chemotherapy-induced anemia.

Pamrevlumab, an anti-CTGF human monoclonal antibody, is in Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer and Duchenne muscular dystrophy ("DMD") and is in Phase 2 development in Severe Acute Respiratory Syndrome Coronavirus 2019 Disease ("COVID-19").

Impact of COVID-19

On March 11, 2020, COVID-19, a disease caused by a novel strain of the coronavirus, was characterized as a pandemic by the World Health Organization. Since December 2019, COVID-19 has spread rapidly. The rapid spread has resulted in authorities implementing numerous measures to contain the virus, such as travel restrictions, social distancing requirements, quarantines, shelter-in-place orders or voluntarily adopted practices, and business shutdowns.

We have taken measures to minimize the health risks of COVID-19 to our staff, patients, healthcare providers and their communities, as their safety and well-being are our top priority. In the U.S., our employees are working remotely when possible, while in China they have returned to work in our offices, manufacturing plants, and are performing medical affairs out in the field. While we have seen some impacts from COVID-19, such as slower enrollment in our clinical trials and some effect on our roxadustat sales in China, particularly in February and March, we do not know if, or to what extent, these effects will continue in the future, as the impact of the COVID-19 pandemic continues to unfold. The effect on our operational and financial performance will depend in large part on future developments with the pandemic, which cannot be predicted with confidence at this time. Future developments include the duration, scope, and severity of the COVID-19 pandemic, the actions taken to contain or mitigate its impact, the impact on governmental programs and budgets, the impact on healthcare systems and operating procedures, the development of treatments or vaccines, and the resumption of widespread economic activity. Due to the inherent uncertainty of the largely unprecedented and rapidly evolving situation, we are unable to predict with any confidence the likely impact of the COVID-19 pandemic on our future operations.

The financial results for the three months ended September 30, 2020 were not significantly impacted by COVID-19 relative to prior quarters. However, we will continue to monitor, and to the extent possible, mitigate the impact of the COVID-19 pandemic on our business.

Financial Highlights

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in thousands, except for per share data)			
Result of Operations				
Revenue	$ 44,032	$ 33,174	$ 111,320	$ 248,603
Operating costs and expenses	11,702	86,028	245,202	237,481
Net income (loss)	33,004	(49,439)	(130,657)	21,153
Net income (loss) per share - basic	0.36	(0.57)	(1.46)	0.24
Net income (loss) per share - diluted	$ 0.35	$ (0.57)	$ (1.46)	$ 0.23

	September 30, 2020	December 31, 2019
	(in thousands)	
Balance Sheet		
Cash and cash equivalents	$ 532,468	$ 126,266
Short-term and long-term investments	155,645	468,609
Accounts receivable	$ 26,252	$ 28,455

Our revenue for the three and nine months ended September 30, 2020 included the revenue recognized related to the following:

- $20.7 million and $59.1 million of development revenue recognized under our collaboration agreements with our partners Astellas and AstraZeneca AB (“AstraZeneca”);
- $22.7 million and 43.3 million of net product revenue from roxadustat commercial sales in China; and
- $0.7 million and $8.9 million of drug product revenue related to roxadustat bulk drug or active pharmaceutical ingredient (“API”) deliveries to AstraZeneca and Astellas.

As comparison, our revenue for the three and nine months ended September 30, 2019 included the revenue recognized related to the following:

- A regulatory milestone of $12.5 million achieved during the third quarter of 2019 associated with the NDA approval in Japan under the collaboration agreement with Astellas for roxadustat as the treatment for dialysis CKD patients;
- Two regulatory milestones totaling $130.0 million associated with the MAA submission to the EMA under the collaboration agreement with Astellas for roxadustat as a treatment for dialysis and non-dialysis CKD patients;

- A $50.0 million regulatory milestone associated with the NDA submission to the FDA under the collaboration agreement with AstraZeneca for roxadustat as a treatment for dialysis and non-dialysis CKD patients; and
- Development revenue recognized under our collaboration agreements with Astellas and AstraZeneca.

Operating costs and expenses for the three months ended September 30, 2020 decreased compared to the same period a year ago primarily, as a result of the net effect of the following:

- Lower sales and marketing expenses due to a reversal in co-promotion expenses with AstraZeneca as a result of the China Amendment (defined below in *Collaboration Partnerships for Roxadustat*) between FibroGen China and AstraZeneca;
- Lower outside services due to lower consulting expenses and scientific contract work related to roxadustat Phase 3 and submission activities; partially offset by:
- Higher clinical trial expenses associated with Phase 3 trials for pamrevlumab and roxadustat post-approval safety studies in China;
- Higher employee-related expenses resulting from higher average compensation level and headcount; and
- Higher stock-based compensation expense, primarily due to the cumulative impact of stock option grant activities.

Operating costs and expenses for the nine months ended September 30, 2020 increased slightly compared to the same period a year ago, as a result of the net effect of the following:

- Higher clinical trial expenses associated with post-approval safety studies in China, and commencement of Phase 3 trials for pamrevlumab, offset by lower activities due to substantial completion of Phase 3 trials for roxadustat;
- Higher legal expenses primarily associated with patent-related activities in the United Kingdom;
- Higher employee-related expenses resulting from higher average compensation level and headcount;
- Higher stock-based compensation expense, primarily due to the cumulative impact of stock option grant activities; partially offset by:
- Lower sales and marketing expenses due to a reversal in co-promotion expenses with AstraZeneca as a result of the China Amendment between FibroGen China and AstraZeneca; and
- Lower outside services due to lower consulting expenses and scientific contract work related to roxadustat Phase 3 and submission activities.

During the three months ended September 30, 2020, we had a net income of $33.0 million, or net income per basic share of $ 0.36 and net income per diluted share of $0.35, as compared to a net loss of $49.4 million for the same period a year ago, due to an increase in revenue and a decrease in operating costs and expenses as discussed above. During the nine months ended September 30, 2020, we had a net loss of $130.7 million, or net loss per basic and diluted share of $1.46, as compared to a net income of $21.2 million for the same period a year ago, due to a decrease in revenue and an increase in operating costs and expenses as discussed above.

Cash and cash equivalents, investments and accounts receivable totaled $714.4 million at September 30, 2020, an increase of $91.1 million from December 31, 2019, primarily due to the cash provided by operations.

Commercial and Development Programs

Roxadustat for the Treatment of Anemia in Chronic Kidney Disease

Roxadustat is our most advanced product, an oral small molecule inhibitor of HIF-PH activity that acts by stimulating the body's natural pathway of erythropoiesis, or red blood cell production.

We continue our commercial launch efforts for roxadustat (tradename: □□□®) in China after receiving marketing authorization for the treatment of anemia caused by CKD in non-dialysis and dialysis patients. Roxadustat was added to the National Reimbursement Drug List ("NRDL"), effective January 1, 2020. Now that China has largely re-opened, we and our partner AstraZeneca continue our strong focus on hospital listings for roxadustat. As of the end of the third quarter, roxadustat was listed at hospitals that represent approximately 55% of the CKD anemia market opportunity in China.

In Japan, our partner Astellas continues the commercial launch of Evrenzo® (roxadustat), which was approved for the treatment of anemia associated with CKD in dialysis patients. In January 2020, Astellas submitted a supplemental NDA in Japan for the treatment of anemia in CKD patients not on dialysis. This supplemental NDA is under review by the Pharmaceuticals and Medical Devices Agency for the use of roxadustat in patients with anemia of CKD not on dialysis, with an anticipated approval decision expected by year-end.

In conjunction with our collaboration partners, AstraZeneca and Astellas, we have completed the Phase 3 trials of roxadustat supporting our NDA in the U.S. and the MAA in the European Union and the United Kingdom (collectively, “Europe”) for the treatment of anemia in CKD.

With respect to our U.S. NDA, we continue to expect an FDA decision on this NDA by the Prescription Drug User Fee Act goal date of December 20, 2020.

In May 2020, our partner Astellas’ MAA for roxadustat for the treatment of anemia in patients with CKD was accepted for regulatory review by the EMA. Our partner Astellas expects an approval decision by the EMA in the middle of 2021.

In addition, in collaboration with AstraZeneca, applications for marketing authorization of roxadustat in CKD anemia have been submitted for Canada, Australia, Mexico, Brazil, Chile, Taiwan, South Korea, Philippines, Singapore, India, Colombia, and Thailand.

Presentations at American Society of Nephrology Kidney Week 2020

In October 2020, we announced additional analyses from roxadustat Phase 3 clinical trials at the American Society of Nephrology Kidney Week 2020.

Consistent Phase 3 Efficacy Data across Multiple CKD Anemia Subgroups

We and our partners made multiple presentations of Phase 3 analyses showing roxadustat’s consistent efficacy at correcting anemia and maintaining hemoglobin levels in multiple sub populations of patients with CKD, including:

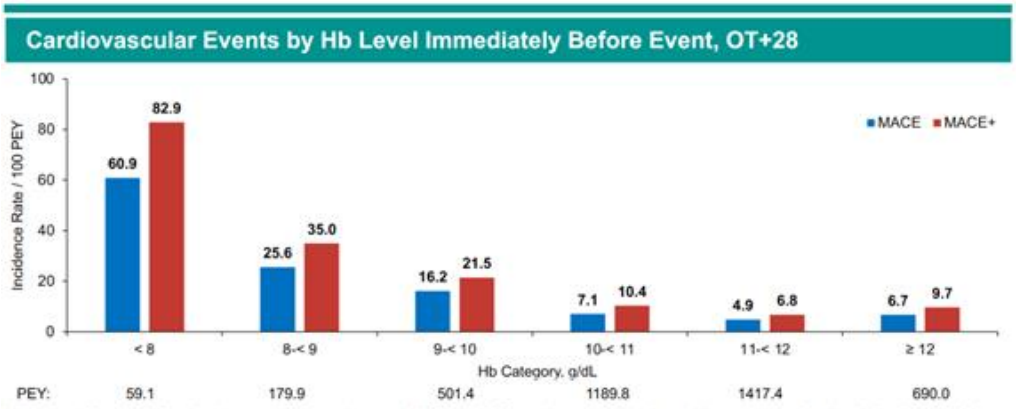
- Patients with or without comorbid heart failure,
- Diabetes patients,
- Patients with or without systematic inflammation (elevated high-sensitivity C-reactive protein) at baseline,
- Patients who were or were not iron replete at baseline,
- Peritoneal dialysis patients,
- Hemodialysis patients,
- Incident dialysis patients, and
- Non-dialysis patients.
    - Among non-dialysis patients still receiving treatment at 4 months, over 90% achieved hemoglobin ≥10 g/dL. Among patients still receiving treatment at 12 months, the cumulative percentage with confirmed hemoglobin ≥10 g/dL was 99% with roxadustat compared to 48% with placebo.

Safety Analyses

In two late-breaking abstracts, we summarized post-hoc pooled analyses of roxadustat Phase 3 studies, examining associations between the achieved hemoglobin levels and cardiovascular outcomes of both non-dialysis-dependent and dialysis-dependent patients with CKD anemia. In both analyses, incidence rates of adjudicated Major Adverse Cardiovascular Events (“MACE”) (all-cause mortality, myocardial infarction, and stroke) and “MACE+” (MACE plus heart failure or unstable angina requiring hospitalization) were evaluated based on hemoglobin level achieved by a patient within four weeks of the event.

In the non-dialysis CKD anemia population:

- Roxadustat corrected anemia and maintained hemoglobin to 11±1 g/dL during Weeks 28–52; and
- MACE and MACE+ rates were highest when hemoglobin was less than 8 g/dL, decreased as hemoglobin increased, and were lowest when achieved hemoglobin levels were greater than or equal to 10 g/dL.



Hb, hemoglobin, MACE, major adverse cardiovascular event; MACE+, MACE plus heart failure and unstable angina requiring hospitalization; OT+28, on-treatment plus 28 days after treatment; PEY, patient exposure–years.

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- Roxadustat corrected anemia and maintained hemoglobin to 11±1 g/dL during Weeks 28–52; and
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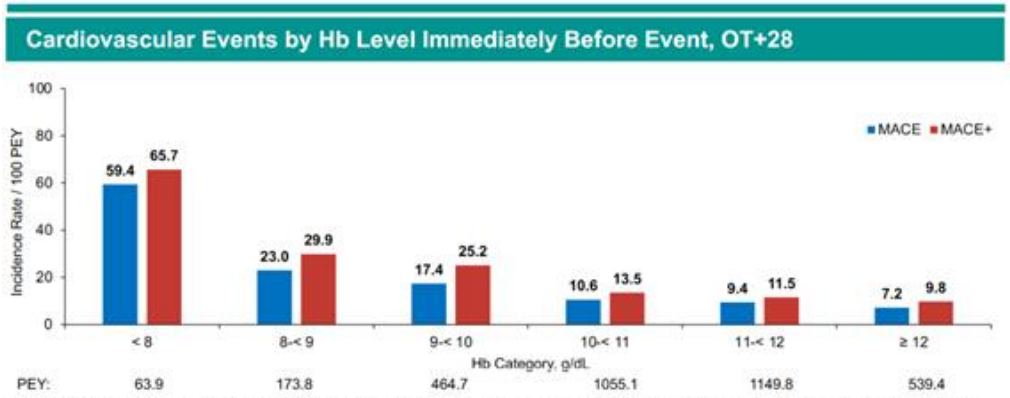


Hb, hemoglobin, MACE, major adverse cardiovascular event; MACE+, MACE plus heart failure and unstable angina requiring hospitalization; OT+28, on-treatment plus 28 days after treatment; PEY, patient exposure–years.

Compared to placebo patients in the non-dialysis Phase 3 trials and compared to ESA patients in the Phase 3 dialysis trials, there were no clinically meaningful between–treatment-group differences in the pooled analyses in:

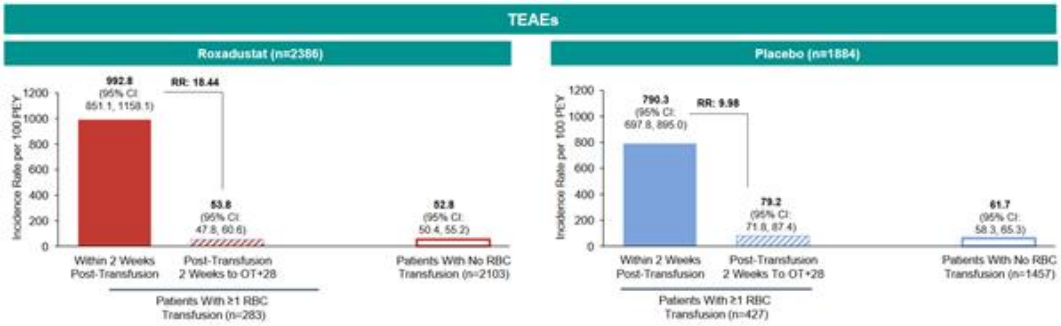
- The exposure-adjusted incidence rate of neoplasm-related treatment-emergent adverse events (“TEAEs”); or
- Blood pressure levels, exacerbation of hypertension, or the incidence of adjudicated hypertensive emergency.

Reduced Risk of Red Blood Cell Transfusions in CKD Patients With Anemia

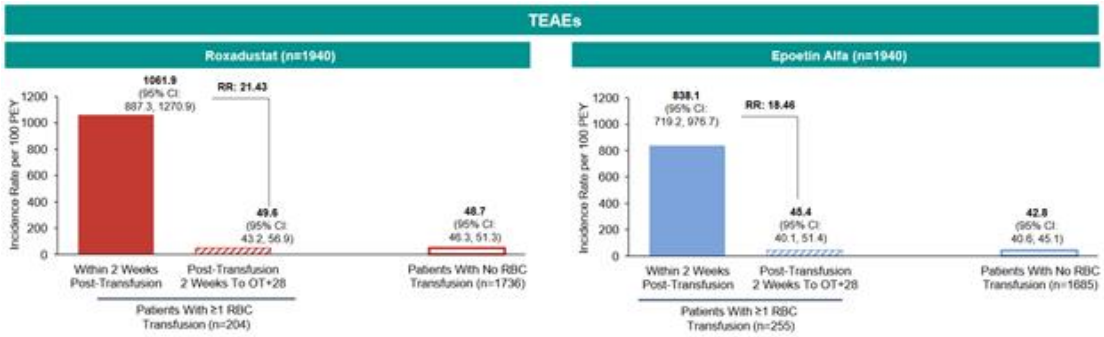
Roxadustat reduced the risk of red blood cell transfusion (5.2% of roxadustat patients) vs placebo (15.4%) in patients with non-dialysis dependent CKD (Hazard Ratio = 0.26 (0.21, 0.32), p<0.001) in the first 52 weeks of treatment. Roxadustat reduced the risk of red blood cell transfusion (9.5% of roxadustat patients) vs epoetin alfa (12.8%) in patients with dialysis-dependent CKD (Hazard Ratio = 0.82 (0.679, 0.997), p=0.046) in the first 52 weeks of treatment.

In a post-hoc analysis of patients not on dialysis and those on dialysis, regardless of treatment assignment, TEAEs (including blood-volume related TEAEs such as heart failure and volume overload) generally occurred at higher rates within the 2-week period after a red blood cell transfusion as compared to patients with no transfusions or during the period two weeks or more after a transfusion, showing the importance of avoiding red blood cell transfusions.

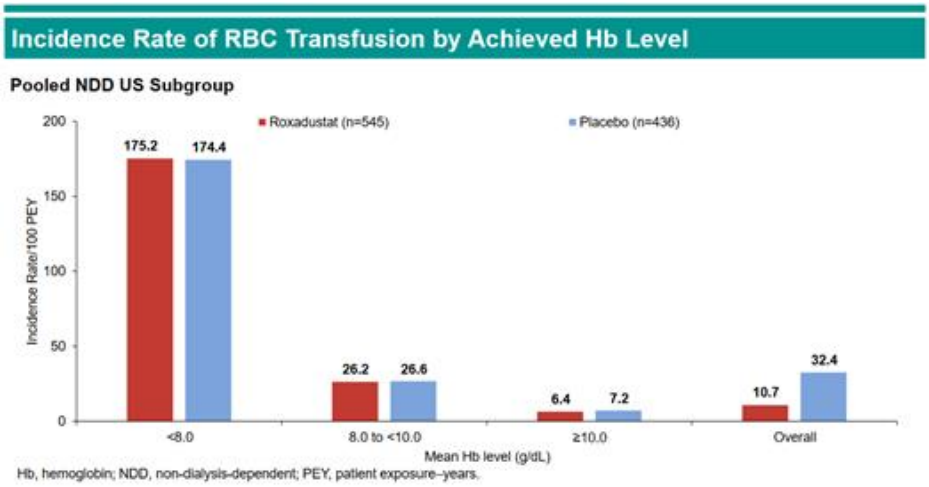
Non-Dialysis Dependent CKD Patients with Anemia



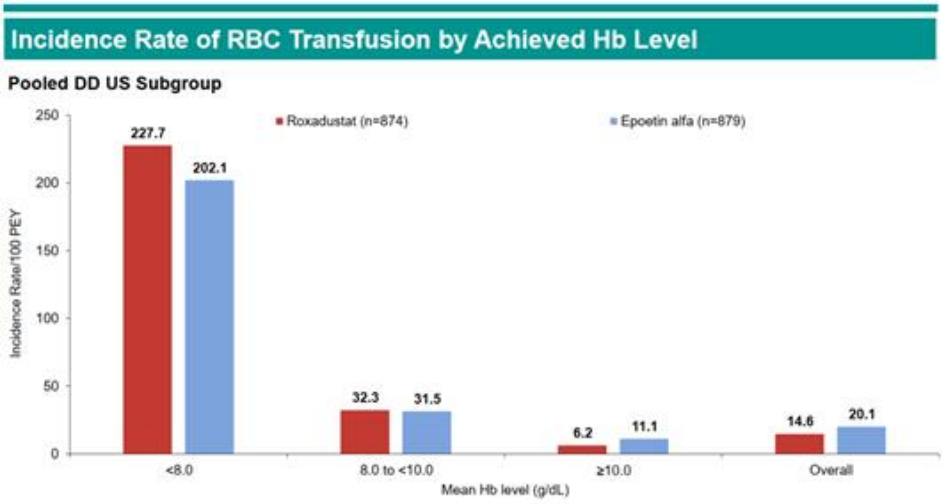
Dialysis-Dependent CKD Patients with Anemia



In addition, in a post-hoc U.S. subgroup analysis, the risk of transfusion increased with lower Hb levels in both roxadustat and in comparator arms in non-dialysis dependent patients and dialysis dependent patients, and was approximately four to five times higher in patients with hemoglobin below 10 g/dL vs those with hemoglobin above 10 g/dL.



Hb, hemoglobin; NDD, non-dialysis-dependent; PEY, patient exposure–years.



DD, dialysis-dependent; Hb, hemoglobin; PEY, patient exposure–years; RBC, red blood cell.

Iron-Metabolism Data

We and our partner AstraZeneca also presented analyses showing that roxadustat treatment is associated with efficient iron utilization.

In non-dialysis patients, roxadustat was as effective in the 40% of patients whose iron stores were below those required for ESA treatment as patients who met the iron requirements ("iron-replete"). Roxadustat increases hemoglobin and mean corpuscular volume without causing clinically significant changes in traditional markers of iron stores, ferritin, and transferrin saturation ("TSAT") as compared with placebo. Roxadustat also increased both serum iron and transferrin, resulting in the long-term clinical stability of TSAT while increasing the absolute amount of iron available for erythropoiesis.

In dialysis patients, roxadustat treated patients required less IV iron supplementation than patients treated with ESA. Roxadustat facilitated iron transport and utilization by increasing both serum iron and iron-carrying capacity (TIBC), whereas these parameters were decreased and unchanged, respectively, with epoetin alfa. We believe these changes were most likely driven by the downstream effects of reduced hepcidin.

Roxadustat for the Treatment of Anemia in Myelodysplastic Syndromes

We are continuing to enroll our global 160-patient double-blind, placebo-controlled Phase 3 clinical study of roxadustat in transfusion-dependent, lower risk MDS patients. Patients are randomized 3:2 to receive roxadustat or placebo three-times-weekly. The primary endpoint is the proportion of patients who achieve 8-week transfusion independence by 28 weeks with safety evaluated up to 52 weeks. We expect topline data from this study in the first half of 2022.

In China, the Phase 2/3 clinical trial to evaluate the safety and efficacy of roxadustat in non-transfusion dependent, lower risk MDS patients with anemia is ongoing.

Roxadustat for the Treatment of Chemotherapy-Induced Anemia

We continue to enroll our Phase 2 clinical trial of roxadustat in the U.S. in chemotherapy-induced anemia. This is a single-arm open label study investigating the efficacy and safety of roxadustat for the treatment of anemia in up to 100 patients receiving myelosuppressive chemotherapy treatment for non-myeloid malignancies, with a treatment duration of 16 weeks. We expect topline data from this study in the second half of 2021.

Pamrevlumab (FG-3019) – Monoclonal Antibody Against Connective Tissue Growth Factor (CTGF)

Pamrevlumab is our human monoclonal antibody that inhibits the activity of CTGF, a central mediator and critical common element in the progression of fibrotic and fibro-proliferative diseases.

In the U.S., the FDA has granted Orphan Drug Designation to pamrevlumab for the treatment of IPF, locally advanced unresectable pancreatic cancer, and DMD. Pamrevlumab has also received Fast Track designation from the FDA for the treatment of both IPF and locally advanced unresectable pancreatic cancer.

Idiopathic Pulmonary Fibrosis

We are conducting ZEPHYRUS, our Phase 3 trial of pamrevlumab in IPF patients, and plan to initiate ZEPHYRUS-2, a second IPF Phase 3 study, as conditions improve with the COVID-19 pandemic. Both studies are double-blind, placebo-controlled Phase 3 trials targeting approximately 340 patients with a primary U.S. efficacy endpoint of change from baseline in forced vital capacity.

Locally Advanced Unresectable Pancreatic Cancer

We continue to enroll LAPIS, our double-blind placebo controlled Phase 3 clinical program for pamrevlumab as a neoadjuvant therapy for locally advanced unresectable pancreatic cancer. We intend to enroll approximately 260 patients, randomized at a 1:1 ratio to receive either pamrevlumab or placebo, in each case in combination with gemcitabine and nab-paclitaxel. We expect topline resection data from this study in the second half of 2022.

Duchenne Muscular Dystrophy

In the third quarter of 2020, we initiated a Phase 3 clinical trial, LELANTOS, evaluating pamrevlumab as a treatment for DMD. LELANTOS is a double-blind, placebo-controlled trial in approximately 90 non-ambulatory DMD patients. Patients will be randomized at a 1:1 ratio to pamrevlumab or placebo and have a treatment period of 52 weeks. The primary endpoint will assess change in upper limb strength and additional endpoints will include pulmonary, performance, cardiac, and fibrosis assessments. We expect topline data from this study in the second half of 2022. We also plan to initiate a Phase 3 clinical trial, LELANTOS 2, evaluating pamrevlumab in 70 ambulatory DMD patients.

Severe Acute Respiratory Syndrome Coronavirus 2019 Disease ("COVID-19")

We are conducting an open-label, randomized, parallel-arm study investigating the efficacy and safety of pamrevlumab versus standard of care in patients with COVID-19 infection in Italy. This study is a Phase 2/3 investigator-initiated clinical trial investigating the efficacy and safety of pamrevlumab in approximately 68 patients hospitalized with COVID-19.

We are also conducting a randomized, double-blind, placebo-controlled Phase 2 study investigating the efficacy and safety of pamrevlumab in hospitalized patients with acute COVID-19 infection in the U.S.

Collaboration Partnerships for Roxadustat

Our current and future research, development, manufacturing and commercialization efforts with respect to roxadustat and our other product candidates currently in development depend on funds from our collaboration agreements with Astellas and AstraZeneca as described below.

Astellas

In June 2005, we entered into a collaboration agreement with Astellas for the development and commercialization (but not manufacture) of roxadustat for the treatment of anemia in Japan ("Japan Agreement"). In April 2006, we entered into the Europe Agreement with Astellas for roxadustat for the treatment of anemia in Europe, the Commonwealth of Independent States, the Middle East, and South Africa. Under these agreements, we provide Astellas the right to develop and commercialize roxadustat for anemia indications in these territories.

We share responsibility with Astellas for clinical development activities required for the U.S. and the EU regulatory approval of roxadustat and share equally those development costs under the agreed development plan for such activities. Astellas will be responsible for clinical development activities and all associated costs required for regulatory approval in all other countries in the Astellas territories. Astellas will own and have responsibility for regulatory filings in its territories. We are responsible, either directly or through our contract manufacturers, for the manufacture and supply of all quantities of roxadustat to be used in development and commercialization under the agreements.

The Astellas agreements will continue in effect until terminated. Either party may terminate the agreements for certain material breaches by the other party. In addition, Astellas will have the right to terminate the agreements for certain specified technical product failures, upon generic sales reaching a particular threshold, upon certain regulatory actions, or upon our entering into a settlement admitting the invalidity or unenforceability of our licensed patents. Astellas may also terminate the agreements for convenience upon advance written notice to us. In the event of any termination of the agreements, Astellas will transfer and assign to us the regulatory filings for roxadustat and will assign or license to us the relevant trademarks used with the products in the Astellas territories. Under certain terminations, Astellas is also obligated to pay us a termination fee.

Consideration under these agreements includes a total of $360.1 million in upfront and non-contingent payments, and milestone payments totaling $557.5 million, of which $542.5 million are development and regulatory milestones and $15.0 million are commercial-based milestones. Total consideration, excluding development cost reimbursement and product sales-related payments, could reach $917.6 million. The aggregate amount of such consideration received through September 30, 2020 totals $630.1 million. Additionally, under these agreements, Astellas pays 100% of the commercialization costs in its territories. Astellas will pay us a transfer price, based on net sales, in the low 20% range for our manufacture and delivery of roxadustat.

During the second quarter of 2019, we received positive topline results from analyses of pooled MACE and MACE+ data from its Phase 3 trials evaluating roxadustat as a treatment for dialysis and non-dialysis CKD patients, enabling Astellas to prepare for an MAA submission to the EMA, following our NDA submission to the FDA in 2019. These milestones became probable of being achieved in the second quarter of 2019, and substantially all of the total consideration of $130.0 million associated with these milestones was included in the transaction price and allocated to performance obligations under the Europe Agreement in the second quarter of 2019, of which $128.8 million was recognized as revenue during 2019, and $0.6 million was recognized as revenue during the nine months ended September 30, 2020, from performance obligations satisfied or partially satisfied. According to the Europe Agreement, these milestone payments were billed to Astellas upon the submission of an MAA in the second quarter of 2020 and the total $130.0 million was received during the same quarter.

In September 2019, Japan's Ministry of Health, Labour and Welfare approved roxadustat for the treatment of anemia associated with dialysis CKD patients. Accordingly, the consideration of $12.5 million associated with this milestone was included in the transaction price and allocated to performance obligations under the Japan Agreement in the third quarter of 2019. This milestone payment was received in October 2019.

In addition, as of September 30, 2020, Astellas had separate investments of $80.5 million in the equity of FibroGen, Inc.

AstraZeneca

In July 2013, we entered into the U.S./RoW Agreement, a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in the U.S. and all territories not previously licensed to Astellas, except China. In July 2013, through our China subsidiary and related affiliates, we entered into the China Agreement, a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in China. Under these agreements, we provide AstraZeneca the right to develop and commercialize roxadustat for anemia in these territories. We share responsibility with AstraZeneca for clinical development activities required for U.S. regulatory approval of roxadustat.

In 2015, we reached the $116.5 million cap on our initial funding obligations (during which time we shared 50% of the joint initial development costs), therefore all development and commercialization costs for roxadustat for the treatment of anemia in CKD in the U.S., Europe, Japan and all other markets outside of China have been paid by Astellas and AstraZeneca since reaching the cap.

In China, FibroGen (China) Medical Technology Development Co., Ltd. ("FibroGen Beijing") will conduct the development work for CKD anemia, will hold all of the regulatory licenses issued by China regulatory authorities, and will be primarily responsible for regulatory, clinical and manufacturing. China development costs are shared 50/50. AstraZeneca is also responsible for 100% of development expenses in all other licensed territories outside of China. Outside of China, we are responsible, through our contract manufacturers, for the manufacture and supply of all quantities of roxadustat to be used in development and commercialization under the AstraZeneca agreements.

Under the AstraZeneca agreements, we will receive upfront and subsequent non-contingent payments totaling $402.2 million. Potential milestone payments under the agreements total $1.2 billion, of which $571.0 million are development and regulatory milestones and $652.5 million are commercial-based milestones. Total consideration under the agreements, excluding development cost reimbursement, transfer price payments, royalties and profit share, could reach $1.6 billion. The aggregate amount of such consideration received through September 30, 2020 totals $516.2 million.

Under the U.S./RoW Agreement, AstraZeneca will pay for all commercialization costs in the U.S. and RoW and AstraZeneca will be responsible for the U.S. commercialization of roxadustat, with FibroGen undertaking specified promotional activities in the end-stage renal disease segment in the U.S. In addition, we will receive a transfer price for delivery of commercial product based on a percentage of net sales in the low- to mid-single digit range and AstraZeneca will pay us a tiered royalty on net sales of roxadustat in the low 20% range.

Under the China Agreement, which is conducted through FibroGen China Anemia Holdings, Ltd., FibroGen Beijing, and FibroGen International (Hong Kong) Limited (collectively, ("FibroGen China"), the commercial collaboration was structured as a 50/50 profit share, which is amended by the China Amendment discussed below in the third quarter of 2020.

Payments under these agreements include over $500.0 million in upfront, non-contingent and other payments received or expected to be received prior to the first U.S. approval, excluding development expense reimbursement.

AstraZeneca may terminate the U.S./RoW Agreement upon specified events, including our bankruptcy or insolvency, our uncured material breach, technical product failure, or upon 180 days prior written notice at will. If AstraZeneca terminates the U.S./RoW Agreement at will, in addition to any unpaid non-contingent payments, it will be responsible for paying for a substantial portion of the post-termination development costs under the agreed development plan until regulatory approval.

AstraZeneca may terminate the China Agreement upon specified events, including our bankruptcy or insolvency, our uncured material breach, technical product failure, or upon advance prior written notice at will. If AstraZeneca terminates our China Agreement at will, it will be responsible for paying for transition costs as well as make a specified payment to FibroGen China.

In the event of any termination of the agreements, but subject to modification upon termination for technical product failure, AstraZeneca will transfer and assign to us any regulatory filings and approvals for roxadustat in the affected territories that they may hold under our agreements, grant us licenses and conduct certain transition activities.

As mentioned above, during the second quarter of 2019, we received positive topline results from analyses of pooled MACE and MACE+ data from its Phase 3 trials for roxadustat, enabling our NDA submission to the FDA. The regulatory milestone payment associated with this NDA submission became probable of being achieved in the second quarter of 2019. Accordingly, the consideration of $50.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the U.S./ RoW Agreement in the second quarter of 2019, of which $42.4 million was recognized as revenue during 2019, and $0.6 million was recognized as revenue during the nine months ended September 30, 2020, from performance obligations satisfied or partially satisfied. We submitted such NDA in December 2019, which was accepted by the FDA for review in February 2020. According to the U.S/RoW Agreement, this milestone payment is billable to AstraZeneca when the NDA is accepted by the FDA. Therefore, this $50.0 million milestone was billed during the first quarter of 2020, the payment of which was fully received in April 2020.

In December 2019, roxadustat was included on the updated NRDL released by China's National Healthcare Security Administration for the treatment of anemia in CKD, covering patients who are non-dialysis-dependent as well as those who are dialysis-dependent. The inclusion on the NRDL triggered a total of $22.0 million milestones payable to us by AstraZeneca. Accordingly, the total consideration of $22.0 million associated with these milestones was included in the transaction price and allocated to performance obligations under the U.S./ RoW Agreement in the fourth quarter of 2019. This milestone payment was fully received during the first quarter of 2020.

China Amendment

On July 8, 2020, FibroGen China and AstraZeneca (together with FibroGen China, the "Parties") entered into an amendment, effective July 1, 2020, to the China Agreement, relating to the development and commercialization of roxadustat in China (the "China Amendment"). While the responsibilities of the Parties under the China Agreement remain largely the same, certain changes are being made under the China Amendment.

The China Amendment provides for the establishment of a jointly owned entity that will perform roxadustat distribution, as well as conduct sales and marketing through AstraZeneca. To prepare for the establishment of this jointly owned entity, in July 2020, FibroGen Beijing acquired Beijing Kangda Yongfu Pharmaceutical Co., LTD ("Kangda"). The purpose of the acquisition was to acquire a distribution license owned by Kangda for commercializing and distributing roxadustat in China. FibroGen Beijing will continue to hold all of the regulatory licenses issued by China regulatory authorities and will continue to be primarily responsible for regulatory, clinical, manufacturing, medical affairs and pharmacovigilance. In September 2020, FibroGen Beijing and AstraZeneca entered into an equity transfer agreement and shareholders agreement related to Kangda. Concurrently with the equity transfer, the two parties renamed Kangda to Beijing Falikang Pharmaceutical Co. Ltd. ("Falikang"). See Note 2, *Acquisition and Variable Interest Entity*, to the condensed consolidated financial statements for details.

As Falikang is a distribution entity for roxadustat and AstraZeneca is the final decision maker for all the roxadustat commercialization activities, we lack the power criterion while AstraZeneca meets both the power and economic criteria under ASC 810, to direct the activities of Falikang that most significantly impact its performance. Therefore, we are not the primary beneficiary of Falikang. As a result, we accounted for our investment in Falikang under the equity method, and Falikang is not consolidated into our condensed consolidated financial statements. In addition, we recognized our proportionate share of the reported profits or losses of Falikang, as other income (loss) in the condensed consolidated statement of operations, and as an adjustment to its investment in unconsolidated subsidiary in the condensed consolidated balance sheet. Falikang has not incurred material profit or loss to date.

In accordance with the China Amendment, we are currently in the interim period. Under the China Amendment, the interim period is defined as the period from April 1, 2020 to the time when Falikang is fully operational, expected in early 2021. During the interim period, FibroGen will continue to sell product directly to the distributors, who remain as our customers. Under the China Amendment, the calculation for profit or loss share has changed related to sales of roxadustat in China for the period from April 1, 2020 onwards. With effect from April 1, 2020, the Parties have changed the method under which commercial expenses incurred by AstraZeneca are calculated and billed. AstraZeneca's co-promotion expenses for their sales and marketing efforts are now subject to a cap of a percentage of net sales. Once AstraZeneca has been fully reimbursed for their sales and marketing costs under the cap, AstraZeneca will bill the co-promotion expenses based on actual costs on a prospective basis. In addition, the China Amendment has allowed for a higher cost of manufacturing incurred by FibroGen Beijing to be included in the profit or loss share calculation, subject to an annual cap, among other changes.

Once Falikang is fully operational, AstraZeneca will bill the co-promotion expenses to Falikang, rather than FibroGen Beijing. In addition, FibroGen Beijing will manufacture and supply commercial product to Falikang based on an agreed upon transfer price. Development costs will continue to be shared 50/50 between the Parties.

As a result, the interim period primarily includes the following activities:

- Co-promotion expenses: The China Amendment revised the payment arrangements and calculation of the historical unpaid co-promotion expenses to AstraZeneca for its sales and marketing efforts associated with the commercial sales for roxadustat in China since the product launch. Under the previous China Agreement, payment of these historical co-promotion expenses was subject to certain profitability and cash flow thresholds. No amount of the historical co-promotion costs had been paid prior to the China Amendment as these thresholds had not yet been met. Under the China Amendment, a portion of the historical unpaid co-promotion expenses was adjusted to reduce the amount owed by FibroGen Beijing and the current period co-promotion expenses are capped at a percentage of net roxadustat sales in China. As a result, in the third quarter of 2020, we reversed approximately $84.4 million of previously accrued co-promotion expenses payable, which was recorded as a reduction to selling, general and administrative expenses, where these expenses were initially recorded during the periods from the initiation of commercial activities in the first quarter of 2019 to the second quarter of 2020. The co-promotion expenses for the three and nine months ended September 30, 2020, capped at a percentage of net roxadustat sales in China, were $8.8 million and $14.8 million, respectively, included in the selling, general and administrative expenses. After this adjustment, as of September 30, 2020, $14.8 million of the recalculated accrued co-promotion expenses was recorded as a current liability, as it is anticipated to be paid within the next 12 months; and $26.3 million of the recalculated accrued co-promotion expenses remained in the long-term liabilities, as it is not anticipated to be paid within the next 12 months.

- Profit share: Profit/loss share between FibroGen China and AstraZeneca is based on a calculation of the current period net roxadustat sales in China and deductible expenses pursuant to the China Agreement. Based on the calculation, a profit was achieved during the third quarter of 2020. As a result, we recorded a profit share liability of $2.0 million to AstraZeneca in the three months ended September 30, 2020 in the condensed consolidated statement of operations.

FibroGen, Inc. and AstraZeneca concurrently amended the U.S./RoW Agreement to reflect minor changes in the governance structure under the China Agreement.

Additional Information Related to Collaboration Agreements

Total cash consideration received through September 30, 2020 and potential cash consideration, other than development cost reimbursement, transfer price payments, royalties and profit share, pursuant to our existing collaboration agreements are as follows:

	Cash Received Through September 30, 2020	Additional Potential Cash Payments	Total Potential Cash Payments
		(in thousands)	
Astellas--related-party:			
Japan Agreement	$ 90,093	$ 82,500	$ 172,593
Europe Agreement	540,000	205,000	745,000
Total Astellas	630,093	287,500	917,593
AstraZeneca:			
U.S. / RoW Agreement	439,000	810,000	1,249,000
China Agreement	77,200	299,500	376,700
Total AstraZeneca	516,200	1,109,500	1,625,700
Total revenue	$ 1,146,293	$ 1,397,000	$ 2,543,293

These collaboration agreements also provide for reimbursement of certain fully burdened research and development costs as well as direct out of pocket expenses.

RESULTS OF OPERATIONS

Revenue

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2020	2019	$	%	2020	2019	$	%
			(dollars in thousands)					
Revenue:								
License revenue	$ —	$ 11,935	$ (11,935)	(100) %	$ —	$ 162,517	$ (162,517)	(100) %
Development and other revenue	20,663	20,660	3	— %	59,065	85,507	(26,442)	(31) %
Product revenue, net	22,683	579	22,104	3,818 %	43,331	579	42,752	7,384 %
Drug product revenue	686	—	686	100 %	8,924	—	8,924	100 %
Total revenue	$ 44,032	$ 33,174	$ 10,858	33 %	$ 111,320	$ 248,603	$ (137,283)	(55) %

Our revenue to date has been generated substantially from our collaboration agreements with Astellas and AstraZeneca. In addition, we started roxadustat commercial sales in China in the third quarter of 2019.

Under our revenue recognition policy, license revenue includes amounts from upfront, non-refundable license payments and amounts allocated pursuant to the standalone selling price method from other consideration received during the periods. This revenue is generally recognized as deliverables are met and services are performed. We did not have any license revenue for the three and nine months ended September 30, 2020.

Development and other revenue includes co-development and other development related services. Co-development services are recognized as revenue in the period in which they are billed to our partners, excluding China. For China co-development services, revenue is deferred until the end of the development period once all performance obligations have been satisfied. Other development related services are recognized as revenue over the non-contingent development period based on a proportional performance method. As of September 30, 2020, the future non-contingent development periods range from 12 to 60 months. Other revenues consist of sales of research and development material and have been included with development and other revenue in the consolidated statements of operations, as they have not been material for any of the periods presented.

Product revenue is recognized when our customer obtains control of promised goods or services in an amount that reflects the consideration we expect to receive in exchange for those goods or services.

Drug product revenue includes commercial-grade API sales to AstraZeneca in support of pre-commercial validation work prior to the NDA approval, and to Astellas for purpose of roxadustat commercial launch in Japan, and is recognized when we fulfill all the delivery obligations.

In the future, we will continue generating revenue from collaboration agreements in the form of license fees, milestone payments, reimbursements for collaboration services and royalties on drug product sales, and from product sales. We expect that any revenues we generate will fluctuate from quarter to quarter due to the uncertain timing and amount of such payments and sales.

In addition, for the nine months ended September 30, 2020, our $43.3 million of net product revenue from roxadustat sales in China was affected by the COVID-19 pandemic and by the fact that patient and physician interaction was limited during a significant portion of the time, particularly in February and March. However, since we have limited history of roxadustat product revenue, it is difficult to estimate how much sales were affected by COVID-19.

Total revenue increased $10.9 million, or 33% for the three months ended September 30, 2020, and decreased $137.3 million, or 55% for the nine months ended September 30, 2020, compared to the same periods a year ago for the reasons discussed in the sections below.

License Revenue

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2020	2019	$	%	2020	2019	$	%
	(dollars in thousands)							
License revenue:								
Astellas	$ —	$ 11,935	$ (11,935)	(100) %	$ —	$ 129,405	$ (129,405)	(100) %
AstraZeneca	—	—	—	— %	—	33,112	(33,112)	(100) %
Total license revenue	$ —	$ 11,935	$ (11,935)	(100) %	$ —	$ 162,517	$ (162,517)	(100) %

We did not have any license revenue for the three and nine months ended September 30, 2020.

License revenue recognized under our collaboration agreements with Astellas in the three and nine months ended September 2019 was related to a regulatory milestone of $12.5 million associated with the NDA approval in Japan achieved during the third quarter of 2019. Of this amount, $11.9 million was allocated to license revenue and recognized during the third quarter of 2019. License revenue recognized under our collaboration agreements with Astellas in the nine months ended September 2019 was also related to two regulatory milestones totaling $130.0 million associated with the planned MAA submission in Europe that were included in the transaction price during the second quarter of 2019 when these milestones became probable of being achieved. Of this amount, $117.5 million was allocated to license revenue and recognized during the second quarter of 2019.

License revenue recognized under our collaboration agreements with AstraZeneca in the three and nine months ended September 2019 was related to a regulatory milestone of $50.0 million associated with the planned NDA submission in the U.S. that was included in the transaction price during the second quarter of 2019 when this milestone became probable of being achieved. Of this amount, $33.1 million was allocated to license revenue and recognized during the second quarter of 2019.

Development and Other Revenue

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2020	2019	$	%	2020	2019	$	%
	(dollars in thousands)							
Development revenue:								
Astellas	$ 4,737	$ 3,533	$ 1,204	34 %	$ 14,240	$ 25,614	$ (11,374)	(44) %
AstraZeneca	15,926	17,125	(1,199)	(7) %	44,825	59,891	(15,066)	(25) %
Total development revenue	20,663	20,658	5	— %	59,065	85,505	(26,440)	(31) %
Other revenue	—	2	(2)	(100) %	—	2	(2)	(100) %
Total development and other revenue	$ 20,663	$ 20,660	$ 3	— %	$ 59,065	$ 85,507	$ (26,442)	(31) %

Development and other revenue remained flat for the three months ended September 30, 2020, Development and other revenue decreased $26.4 million, or 31% for the nine months ended September 30, 2019, compared to the same period a year ago.

Development revenue recognized under our collaboration agreements with Astellas for the three and nine months ended September 30, 2020 increased related to higher medical affairs activities under the Europe Agreement.

Development revenue recognized under our collaboration agreements with Astellas for the nine months ended September 30, 2019 included the allocated revenue of $11.6 million related to the above-mentioned $130.0 million associated with the regulatory milestones of the planned MAA submission in Europe.

Development revenue recognized under our collaboration agreements with AstraZeneca for the nine months ended September 30, 2019 included the allocated revenue of $9.0 million related to the above-mentioned $50.0 million associated with the regulatory milestone of the planned NDA submission in the U.S.

In addition, development revenue recognized under our collaboration agreements for the three and nine months ended September 30, 2020 decreased in co-development billings related to the development of roxadustat as a result of the substantial completion of Phase 3 trials for roxadustat.

Product Revenue, Net

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2020	2019	$	%	2020	2019	$	%
	(dollars in thousands)							
Gross revenue	$ 27,900	$ 622	$ 27,278	4,386 %	$ 53,105	$ 622	$ 52,483	8,438 %
Non-key account hospital listing award	(2,930)	—	(2,930)	100 %	(5,495)	—	(5,495)	100 %
Contractual sales rebate	(1,966)	(43)	(1,923)	4,472 %	(3,714)	(43)	(3,671)	8,537 %
Other discounts and rebates	(313)	—	(313)	100 %	(512)	—	(512)	100 %
Sales return	(8)	—	(8)	100 %	(53)	—	(53)	100 %
Product revenue, net	$ 22,683	$ 579	$ 22,104	3,818 %	$ 43,331	$ 579	$ 42,752	7,384 %

We started roxadustat commercial sales in China in the third quarter of 2019; therefore the year-over-year comparison would not be meaningful as the prior year period was the first period of such sales with limited sales volume. Product revenue is recognized in an amount that reflects the consideration to which we expect to be entitled in exchange for those products, net of various sales rebates and discounts.

The gross product revenue for the three and nine months ended September 30, 2020 was $27.9 million and $53.1 million, respectively.

In the second quarter of 2020, we amended the agreement with our pharmaceutical distributors, which triggered accounting modifications particularly related to non-key account hospital listing award. During the three and nine months ended September 30, 2020, non-key account hospital listing award was $2.9 million and $5.5 million, respectively, recorded as a reduction to the revenue, which was calculated based on eligible non-key account hospital listing to date achieved by each distributor with certain requirements met during the period.

The contractual sales rebate for the three and nine months ended September 30, 2020 was $2.0 million and $3.7 million, respectively, which was calculated based on the stated percentage of gross sales by each distributor in the distribution agreement entered between us and each distributor. All other rebates and discounts, and sales return allowance, were immaterial for the periods.

Drug Product Revenue

	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2020
	(dollars in thousands)	
Drug product revenue:		
Astellas	$ (3,957)	$ 4,281
AstraZeneca	4,643	4,643
Total drug product revenue:	$ 686	$ 8,924

In 2018, FibroGen and Astellas entered into an amendment to the Japan Agreement that allows Astellas to manufacture roxadustat drug product for commercialization in Japan (the "Japan Amendment"). Under this amendment, FibroGen would continue to manufacture and deliver to Astellas roxadustat API for the roxadustat commercial launch in Japan. Related to the API shipments in 2018 under the Japan Amendment, during the three months ended September 30, 2020, we recorded a $4.0 million reduction to drug product revenue, related to a change in estimated variable consideration incurred in the first quarter of 2020. Specially, the change in estimated variable consideration was based on Astellas' inventory level at March 31, 2020, with the updated listed price for roxadustat issued by the Japanese Ministry of Health, Labour and Welfare, adjusted for estimated bulk product strength mix intended to be manufactured by Astellas, estimated cost to convert the API to bulk product tablets, and estimated yield from the manufacture of bulk product tablets, among others.

During the three months ended June 30, 2020, we fulfilled the delivery obligations under the term of the Japan Amendment, and recognized the related drug product revenue of $8.2 million in the same period. The amount represents variable consideration and was estimated based on the quantity of product shipped, actual listed price for roxadustat issued by the Japanese Ministry of Health, Labour and Welfare and possible future changes to the listed price, adjusted for estimated bulk product strength mix intended to be manufactured by Astellas, estimated cost to convert the API to bulk product tablets, and estimated yield from the manufacture of bulk product tablets, among others.

Under the U.S./RoW Agreement, we would manufacture and deliver to AstraZeneca roxadustat bulk drug product in support of commercial supplies. We delivered process validation product to AstraZeneca as pre-commercial supply in the three months ended March 31, 2020, June 30, 2020 and September 30, 2020, respectively. The related drug product revenue of $4.6 million was recognized in the three months ended September 30, 2020. The drug product revenue amount represents variable consideration and was estimated based on the quantity of product shipped and an estimated price.

The amount of variable consideration that is included in the transaction price may be constrained, and is included in the drug product revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received in the future may differ from our estimates, for which we will adjust these estimates and affect the drug product revenue in the period such variances become known.

Operating Costs and Expenses

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2020	2019	$	%	2020	2019	$	%
	(dollars in thousands)							
Operating costs and expenses								
Cost of goods sold	$ 2,207	$ 242	$ 1,965	812 %	$ 6,253	$ 242	$ 6,011	2,484 %
Research and development	58,476	49,963	8,513	17 %	174,792	152,467	22,325	15 %
Selling, general and administrative	(48,981)	35,823	(84,804)	(237) %	64,157	84,772	(20,615)	(24) %
Total operating costs and expenses	$ 11,702	$ 86,028	$ (74,326)	(86) %	$ 245,202	$ 237,481	$ 7,721	3 %

We have taken measures to minimize the health risks of COVID-19 to our staff, patients, healthcare providers and their communities, as their safety and well-being are our top priority. In the U.S., our employees are working remotely when possible, while in China they have returned to work in our offices, manufacturing plants, and are performing medical affairs out in the field. We have also seen some reduced enrollment in our clinical trials, particularly for our IPF pamrevlumab trial. However, the overall impact of COVID-19 on our expenses was not significant. In the three and nine months ended September 30, 2020, some reduction in expenses, such as due to reduced travel and paused or slowed enrollment for trials, were offset by some increased expenses, such as in patient care.

Total operating costs and expenses decreased $74.3 million, or 86% for the three months ended September 30, 2020, and increased $7.7 million, or 3%, compared to the same periods a year ago, for the reason discussed in the sections below.

Cost of Goods Sold

Cost of goods sold, associated with the roxadustat commercial sales in China, consists of direct costs to manufacture commercial product, as well as indirect costs including factory overhead, storage, shipping, quality assurance, idle capacity charges, and inventory valuation reserve. The year-over-year comparison would not be meaningful as the prior year period was the first period for roxadustat commercial sales with limited sales volume. Cost of goods sold was $2.2 million and $6.3 million for the three and nine months ended September 30, 2020, primarily consisted of costs associated with the manufacturing of roxadustat product.

Research and Development Expenses

Research and development expenses consist of third-party research and development costs and the fully-burdened amount of costs associated with work performed under collaboration agreements. Research and development costs include employee-related expenses for research and development functions, expenses incurred under agreements with clinical research organizations, other clinical and preclinical costs and allocated direct and indirect overhead costs, such as facilities costs, information technology costs and other overhead. Research and development costs are expensed as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

The following table summarizes our research and development expenses incurred during the three and nine months ended September 30, 2020 and 2019:

Product Candidate	Phase of Development	Three Months Ended September 30,		Nine Months Ended September 30,	
		2020	2019	2020	2019
		(in thousands)			
Roxadustat	Phase 3	$ 31,222	$ 27,686	$ 91,586	$ 91,733
Pamrevlumab	Phase 2/3	24,959	16,152	70,374	45,310
FG-5200	Preclinical	942	1,302	2,999	4,070
Other research and development expenses		1,353	4,823	9,833	11,354
Total research and development expenses		$ 58,476	$ 49,963	$ 174,792	$ 152,467

The program-specific expenses summarized in the table above include costs we directly attribute to our product candidates. We allocate research and development salaries, benefits, stock-based compensation and other indirect costs to our product candidates on a program-specific basis, and we include these costs in the program-specific expenses. We expect our research and development expenses to increase in the future as we advance our product candidates through clinical trials and expand our product candidate portfolio.

Research and development expenses increased $8.5 million, or 17% for the three months ended September 30, 2020, compared to the same period a year ago, as a result of the net effect of the following:

- Increase of $8.0 million in clinical trials costs, primarily due to Phase 3 trials for pamrevlumab and roxadustat post-approval safety studies in China;
- Increase of $1.7 million in employee-related costs primarily due to higher headcount in the research and development functions in China and higher compensation levels;
- Increase of $1.1 million in facility related expense, primarily due to higher allocated overhead costs, higher depreciation expenses related to China facilities and general maintenance expenses; and partially offset by:
- Decrease of $2.8 million in outside services due to lower consulting expenses and scientific contract work related to roxadustat Phase 3 and submission activities.

Research and development expenses increased $22.3 million, or 15% for the nine months ended September 30, 2020, compared to the same period a year ago, as a result of the net effect of the following:

- Increase of $20.9 million in clinical trials costs, primarily due to post-approval safety studies in China, and commencement of Phase 3 trials for pamrevlumab, partially offset by the substantial completion of Phase 3 trials for roxadustat and lower activities related to NDA preparation as it was submitted in December 2019;
- Increase of $5.3 million in facility related expense, primarily due to higher allocated overhead costs, higher depreciation expenses related to China facilities and general maintenance expenses;
- Increase of $2.4 million in drug development expenses, primarily due to higher drug substance manufacturing activities and supplies related to pamrevlumab, and higher drug substance manufacturing activities related to roxadustat in its global program, partially offset by lower drug product manufacturing activities related to pamrevlumab;
- Increase of $2.4 million in stock-based compensation expense, primarily due to the cumulative impact of stock option grant activities;
- Increase of $1.9 million in employee-related costs primarily due to higher headcount in the research and development functions in China and higher compensation levels; partially offset by:
- Decrease of $5.4 million due to capitalization of inventory manufacturing costs associated with roxadustat production; and
- Decrease of $5.2 million in outside services due to lower consulting expenses and scientific contract work related to roxadustat Phase 3 and submission activities.

Selling, General and Administrative Expenses

We started to incur sales and marketing expenses in the first quarter of 2019 in China to prepare for commercial operations. Selling, general and administrative (“SG&A”) expenses consist primarily of employee-related expenses for executive, operational, finance, legal, compliance, and human resource functions. SG&A expenses also include facility-related costs, professional fees, accounting and legal services, other outside services including co-promotion expenses, recruiting fees and expenses associated with obtaining and maintaining patents.

We anticipate that our SG&A expenses will increase in the future as we anticipate an increase in payroll and related expenses associated with an increase in headcount to support the growth of the business in connection with potential commercialization of our product candidates.

SG&A expenses decreased $84.8 million, or 237% for the three months ended September 30, 2020 compared to the same period a year ago, as a result of the net effect of the following:

- Decrease of $89.8 million in outside service expenses, resulting from the China Amendment between FibroGen China and AstraZeneca in the third quarter of 2020. Under China Amendment, a portion of the historical unpaid co-promotion expenses was adjusted to reduce the amount owed by FibroGen Beijing and the current period co-promotion expenses are capped at a percentage of net roxadustat sales in China. As a result, in the third quarter of 2020, we reversed approximately $84.4 million of previously accrued co-promotion expenses payable, which was recorded as a reduction to selling, general and administrative expenses; partially offset by:
- Increase of $2.6 million in employee-related costs primarily due to higher headcount in the sales and marketing functions in China and higher compensation levels; and
- Increase of $2.0 million in stock-based compensation expense, primarily due to the cumulative impact of stock option grant activities.

SG&A expenses decreased $20.6 million, or 24% for the nine months ended September 30, 2020 compared to the same period a year ago, as a result of the net effect of the following:

- Decrease of $32.8 million in outside service expenses, resulting from the above-mentioned reversal of previously accrued co-promotion expenses payable, which was recorded as a reduction to selling, general and administrative expenses. In addition, current year co-promotion expenses are capped at a percentage of net sales; partially offset by:
- Increase of $6.0 million in employee-related costs primarily due to higher headcount in the sales and marketing functions in China and higher compensation levels; and
- Increase of $5.1 million in legal expenses primarily associated with patent-related activities in United Kingdom.

Interest and Other, Net

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2020	2019	$	%	2020	2019	$	%
	(dollars in thousands)							
Interest and other, net:								
Interest expense	$ (580)	$ (702)	$ 122	(17) %	$ (1,864)	$ (2,209)	$ 345	(16) %
Interest income and other, net	1,469	4,193	(2,724)	(65) %	5,279	12,496	(7,217)	(58) %
Total interest and other, net	$ 889	$ 3,491	$ (2,602)	(75) %	$ 3,415	$ 10,287	$ (6,872)	(67) %

Interest Expense

Interest expense relates to our finance lease liabilities accretion primarily for our leased facilities in San Francisco and China. Interest expense also includes interest related to the Technology Development Center of the Republic of Finland product development obligations.

Interest Income and Other, Net

Interest income and other, net primarily include interest income earned on our cash, cash equivalents and investments, foreign currency transaction gains (losses), remeasurement of certain monetary assets and liabilities in non-functional currency of our subsidiaries into the functional currency, realized gains (losses) on sales of investments.

Interest income and other, net decreased $2.7 million, or 65% for the three months ended September 30, 2020, and $7.2 million, or 58% for the nine months ended September 30, 2020, compared to the same periods a year ago, primarily due to lower interest earned on our cash, cash equivalents and investments of $2.7 million and $6.9 million, respectively, associated with the lower average balances.

On April 1, 2020, FibroGen Beijing adopted Renminbi Yuan (“CNY”) as its functional currency based on reassessment of the primary economic environment in which FibroGen Beijing operates, as such environment was mainly associated with its growing manufacturing and product sales activities conducted in CNY. Prior to April 1, 2020, FibroGen Beijing’s functional currency was the U.S. dollar. This change did not result in material impact to unrealized foreign currency gain or loss during the three and nine months ended September 30, 2020.

Income Taxes

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(dollars in thousands)			
Income (loss) before income taxes	$ 33,219	$ (49,363)	$ (130,467)	$ 21,409
Provision for income taxes	215	76	190	256
Effective tax rate	0.6%	(0.2)%	(0.1)%	1.2%

Provision for income tax for the three and nine months ended September 30, 2020 and 2019 were primarily due to foreign taxes.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”) was enacted and signed into law. The CARES Act includes changes to the tax provisions that benefits business entities, and makes certain technical corrections to the 2017 Tax Cuts and Jobs Act. U.S. GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date. We evaluated and determined that the impact is immaterial.

Based upon the weight of available evidence, which includes our historical operating performance, reported cumulative net losses since inception, we have established and continue to maintain a full valuation allowance against our deferred tax assets as we do not currently believe that realization of those assets is more likely than not.

LIQUIDITY AND CAPITAL RESOURCES

Financial Conditions

We have historically funded our operations principally from the sale of common stock (including our public offering proceeds) and from the execution of certain collaboration agreements involving license payments, milestones and reimbursement for development services.

As of September 30, 2020, we had cash and cash equivalents of $532.5 million. Cash is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting of available-for-sale debt investments, marketable equity investments, and certificate of deposit, and stated at fair value, are also available as a source of liquidity. As of September 30, 2020, we had short-term and long-term investments of $155.4 million and $0.2 million, respectively. As of September 30, 2020, a total of $51.2 million of our cash and cash equivalents was held outside of the U.S. in our foreign subsidiaries, including $29.5 million of our cash and cash equivalents is held in China, to be used primarily for our China operations.

Operating Capital Requirements

In the third quarter of 2019, we started generating revenue from commercial sales of roxadustat product in China. Even with the expectation of increases in revenue from product sales, we anticipate that we will continue to generate losses for the foreseeable future. We expect increase in our operating expenses as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. To date, we have funded certain portions of our research and development and manufacturing efforts in China and Europe through outside parties. There is no guarantee that sufficient funds will be available to continue to fund these development efforts through commercialization or otherwise. Although our share of expenses for roxadustat will decrease as a result of AstraZeneca funding all non-China collaboration expenses not reimbursed by Astellas, we expect our research and development expenses to continue to increase as we invest in our other programs. We are subject to all the risks related to the development and commercialization of novel therapeutics, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business, such as from the COVID-19 pandemic or other factors outlined under Part II, Item 1A "*Risk Factors*" in this Quarterly Report on Form 10-Q. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We believe that our existing cash and cash equivalents, short-term and long-term investments and accounts receivable will be sufficient to meet our anticipated cash requirements for at least the next 12 months from the date of this Quarterly Report on Form 10-Q. However, our liquidity assumptions may change over time, and we could utilize our available financial resources sooner than we currently expect. In addition, we may elect to raise additional funds at any time through equity, equity-linked or debt financing arrangements. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements and the adequacy of available funds will depend on many factors, including those set forth under Part II, Item 1A "*Risk Factors*" in this Quarterly Report on Form 10-Q. We may not be able to secure additional financing to meet our operating requirements on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, the ownership of our existing stockholders will be diluted. If we raise additional financing by the incurrence of indebtedness, we will be subject to increased fixed payment obligations and could also be subject to restrictive covenants, such as limitations on our ability to incur additional debt, and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to obtain needed additional funds, we will have to reduce our operating costs and expenses, which would impair our growth prospects and could otherwise negatively impact our business.

Cash Sources and Uses

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods set forth below:

	Nine Months Ended September 30,	
	2020	2019
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ 88,830	$ (33,655)
Investing activities	308,719	145,051
Financing activities	7,684	(4,016)
Effect of exchange rate changes on cash and cash equivalents	969	(46)
Net increase in cash and cash equivalents	$ 406,202	$ 107,334

Operating Activities

Net cash provided by operating activities was $88.8 million for the nine months ended September 30, 2020 and consisted primarily of net loss of $130.7 million adjusted for non-cash items of $69.4 million, offset by a net increase in operating assets and liabilities of $150.1 million. The significant non-cash items included stock-based compensation expense of $52.5 million, depreciation expense of $8.7 million and amortization of finance lease ROU of $7.9 million. The significant items in the changes in operating assets and liabilities included the increases resulting from the following:

- Prepaid expenses and other current assets of $121.9 million and Deferred revenue of $45.9 million, primarily related to the billing and receipt of $130.0 million in regulatory milestones under the Europe Agreement with Astellas associated with the MAA submission in Europe; and the billing and receipt of $50.0 million regulatory milestone under the U.S./RoW Agreement with AstraZeneca associated with the NDA submission for review in the U.S. These milestones were not billable as of December 31, 2019, and was net of the associated deferred revenues of $4.8 million and $50.0 million, respectively. The change in deferred revenue was also driven by the recognition of revenues under our collaboration agreements with Astellas and AstraZeneca;
- Other assets of $7.6 million, primarily related to the return and consumption of input value added tax by FibroGen Beijing;
- Accrued and other liabilities of $3.2 million, primarily driven by $14.8 million of the accrued co-promotion expenses at September 30, 2020 that is anticipated to be paid within the next 12 months resulting from the China Amendment in the third quarter of 2020, as well as driven by the timing of invoicing and payment; offset by the payment of $36.3 million that was accrued at December 31, 2019, related to the change in estimated variable consideration associated with the API delivery; and
- Accounts receivable of $2.5 million, primarily driven by the timing of the receipt of upfront payments and the recognition of revenues under our collaboration agreements with Astellas and AstraZeneca; offset by the increase in accounts receivable from customers in China for roxadustat sales.

The increases were partially offset by the decreases resulting from the following:

- Other long-term liabilities of $27.1 million, primarily due to the adjustment in long-term co-promotion expenses payable to AstraZeneca for its sales and marketing efforts related to the commercial sales of roxadustat in China resulting from the China Amendment in the third quarter of 2020; and
- Inventories of $5.2 million, driven by the increased inventory level primarily related to FibroGen Beijing’s productions of roxadustat for commercial sales purposes.

Net cash used in operating activities was $33.7 million for the nine months ended September 30, 2019 and consisted primarily of net income of $21.2 million adjusted for non-cash items of $61.9 million, offset by a net decrease in operating assets and liabilities of $116.7 million. The significant non-cash items included stock-based compensation expense of $48.9 million, depreciation expense of $8.7 million, amortization of finance lease ROU of $7.7 million, and net amortization of premium and discount on investments of $3.4 million. The significant items in the changes in operating assets and liabilities included decreases resulting from the following:

- Prepaid expenses and other current assets of $128.9 million and deferred revenue of $50.9 million, primarily driven by the above mentioned unbilled contract assets including $130.0 million regulatory milestones under the Europe Agreement with Astellas and a $50.0 million regulatory milestone under the U.S./RoW Agreement with AstraZeneca, which were not billable to Astellas or AstraZeneca as of September 30, 2019, net of the associated deferred revenues of $4.0 million and $50.0 million, respectively. The change in deferred revenue was also related to the recognition of revenues under our collaboration agreements with Astellas and AstraZeneca.
- Accounts payable of $5.1 million primarily driven by the timing of invoicing and payments; and
- Inventories of $4.9 million due to the capitalization of inventory costs starting in June 2019 when FibroGen Beijing began productions of roxadustat for commercial sales purposes.

The decreases were partially offset by increases resulting from the following:

- Accounts receivable of $44.5 million, primarily related to the collection of $43.9 million from Astellas for the roxadustat API delivery in December 2018 under the Japan Amendment, as well as the timing of the receipt of upfront payments and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca;
- Other long-term liabilities of $24.1 million primarily due to the accrual of co-promotion expenses for our preparation for commercial operation that is not expected to be paid in the next year; and
- Accrued and other liabilities of $5.5 million primarily driven by the timing of invoicing and payments.

Investing Activities

Investing activities primarily consist of purchases of property and equipment, purchases of investments, and proceeds from the maturity and sale of investments.

Net cash provided by investing activities was $308.7 million for the nine months ended September 30, 2020 and consisted primarily of $301.9 million of proceeds from maturities of investments, and $10.6 million of proceeds from sales of available-for-sale securities, partially offset by $2.1 million of purchases of property and equipment, and $1.6 million of payment made for acquisition of Kangda.

Net cash provided by investing activities was $145.1 million for the nine months ended September 30, 2019 and consisted of $305.0 million of proceeds from maturities of investments, partially offset by $155.9 million of cash used in purchases of available-for-sale securities and term deposit, and $4.0 million of purchase of property and equipment.

Financing Activities

Financing activities primarily reflect proceeds from the issuance of our common stock, cash paid for payroll taxes on restricted stock unit releases, and repayments of our lease liability.

Net cash provided by financing activities was $7.7 million for the nine months ended September 30, 2020 and consisted primarily of $26.2 million of proceeds from the issuance of common stock upon exercise of stock options and purchases under our Employee Share Purchase Plan (“ESPP”), partially offset by $9.0 million of cash paid for payroll taxes on restricted stock unit releases, and $9.3 million of repayments of finance lease liabilities.

Net cash used in financing activities was $4.0 million for the nine months ended September 30, 2019 and consisted primarily of $10.6 million of cash paid for payroll taxes on restricted stock unit releases and $8.8 million of repayments of finance lease liabilities, partially offset by $15.7 million of proceeds from the issuance of common stock upon exercise of stock options and purchases under our 2014 ESPP.

Off-Balance Sheet Arrangements

During the three and nine months ended September 30, 2020, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements.

Contractual Obligations and Commitments

During the first quarter of 2020, we entered into a Master Supply Agreement with Shanghai SynTheAll Pharmaceutical Co., Ltd. and STA Pharmaceutical Hong Kong Limited for the manufacture and supply of bulk roxadustat (as API), and other intermediates for use in the commercialization and development of products containing roxadustat.

As of September 30, 2020, we had outstanding total non-cancelable contract obligations of $33.1 million, including $16.7 million for manufacture and supply of roxadustat (including $14.4 million for the above-mentioned agreement), $10.9 million for future milestone payments for research and pre-clinical stage development programs, and $5.5 million for other purchases. We expect to fulfill our commitments under these agreements in the normal course of business, and as such, no liability has been recorded.

Recently Issued and Adopted Accounting Guidance

In August 2018, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.* This guidance requires capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). This guidance was effective for annual reporting periods beginning after December 15, 2019, including interim periods. We adopted this guidance on January 1, 2020 using the prospective method, and the adoption of this guidance did not have material impact to our consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). This guidance is intended to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. This guidance requires the measurement of financial assets with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. This guidance requires an impairment model, known as the current expected credit loss model, which is based on expected losses rather than incurred losses. Entities are required to carry an allowance for expected credit losses for financial assets, including most debt instruments (except those carried at fair value) and trade receivables. In November 2019, the FASB issued ASU No. 2019-11, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses* ("ASU 2019-11"), which has the same effective dates and transition requirements as ASU 2016-13. ASU 2016-13 and ASU 2019-11 were effective for annual reporting periods beginning after December 15, 2019 including interim periods. Our investment portfolio primarily consists of U.S. Treasury bills and notes carried at fair value, which is required to follow the impairment model under Topic 326. We adopted this guidance on January 1, 2020. Based on the composition of our trade receivables and investment portfolio, economic conditions and historical credit loss activity, the adoption of this guidance did not have material impact to our consolidated financial statements.

Recently Issued Accounting Guidance Not Yet Adopted

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. This guidance simplifies the accounting for income taxes by clarifying and amending existing guidance related to the recognition of franchise tax, the evaluation of a step up in the tax basis of goodwill, and the effects of enacted changes in tax laws or rates in the effective tax rate computation, among other clarifications. This guidance is effective for annual reporting periods beginning after December 15, 2020 including interim periods, with early adoption permitted. We do not plan to early adopt this guidance and do not anticipate a material impact to our consolidated financial statements upon adoption of this guidance.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes in our critical accounting policies, estimates and judgments during the three and nine months ended September 30, 2020 compared with the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2019, except for the following:

Revenue Recognition - *Product revenue, net*

We sell roxadustat in China through a number of pharmaceutical distributors located in China. These pharmaceutical distributors are our customers. Hospitals order roxadustat through a distributor and we ship the product directly to the distributors. The delivery of roxadustat to a distributor represents a single performance obligation. Distributors are responsible for delivering product to end users, primarily hospitals. Distributors bear inventory risk once they receive and accept the product. Product revenue is recognized when control of the promised good is transferred to the customer in an amount that reflects the consideration to which we expect to be entitled to in exchange for the product.

The period between the transfer of control of the promised goods and when we receive payment is based on a general 60-day payment term. As such, product revenue is not adjusted for the effects of a significant financing component.

Product drug revenue is recorded at the net sales prices (transaction price) which includes the following estimates of variable consideration:

- Price adjustment: In December 2019, China's National Healthcare Security Administration released price guidance for roxadustat under NRDL, effective January 1, 2020. Any channel inventories as of January 1, 2020 that had not been sold to hospitals by distributors, or to patients by hospitals, were eligible for a price adjustment under the price protection. The price adjustment is calculated based on estimated channel inventory levels at January 1, 2020. If price guidance changes in the future, the price adjustment will be calculated in the same manner;

- Contractual sales rebate: The contractual sales rebate is calculated based on the stated percentage of gross sales by each distributor in the distribution agreement entered between FibroGen and each distributor. The contractual sales rebate is recorded as a reduction to revenue at the point of sale to the distributor;
- Key account hospital sales rebate: An additional sales rebate is provided to a distributor for product sold to key account hospitals as a percentage of gross sales made by the distributor to eligible hospitals. This additional rebate is recorded as a reduction to revenue at the point of sale to the distributor;
- Transfer fee discount: The transfer fee discount is offered to a distributor who has its downstream distributors supply to eligible hospitals. This discount is calculated based on a percentage of gross sales made to the downstream distributors, and recorded as a reduction to revenue as incurred;
- Sales return: Distributors can request to return product to us only due to quality issues and for product within one year of the product's expiration date. We, at our sole discretion, decides whether to accept such return request; and
- Non-key account hospital listing award: A one-time fixed-amount award is offered to a distributor who successfully lists the product with an eligible hospital, and meets certain requirements. We consider this particular award to be an upfront payment to a customer within the definitions of ASC 606. The non-key account hospital listing award is capitalized when the distributor meets eligibility requirements, and amortized as reduction to product revenue over future sales orders made by the distributor until exhausted.

The calculation of the above variable consideration is based on gross sales to the distributor, or estimated utilizing best available information from the distributor, maximum known exposures and other available information including estimated channel inventory levels and estimated sales made by the distributor to hospitals, which involve a substantial degree of judgment.

The above rebates and discounts all together are eligible to be applied against the distributor's future sales order, limited to certain maximums until such rebates and discounts are exhausted. These rebates and discounts are recorded as contract liabilities at the time they become eligible in the same period that the related revenue is recorded. Due to the distributor's legal right to offset, at each balance sheet date, the rebates and discounts are presented as reductions of gross accounts receivable from the distributor, or as a current liability to the distributor to the extent that the total amount exceeds the gross accounts receivable. The distributor's legal right of offset is calculated at the individual distributor level.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We believe there has been no material change in our exposure to market risks as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019, other than as a result of the COVID-19 pandemic and described in the section above titled "*Risks and Uncertainties*".

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to the company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of September 30, 2020 because of the material weaknesses in our internal control over financial reporting described below.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

As of September 30, 2020, we have identified a material weakness in the risk assessment component of internal control as we did not appropriately design and maintain an effective risk assessment process at a precise enough level to identify new and evolving risks of material misstatement to the financial statements as a result of changes in our business operation. This material weakness gave rise to the following additional control deficiencies, which we also determined to be material weaknesses. We did not design and maintain effective controls related to the timely identification of shipments associated with drug product revenue, and we did not design and maintain effective controls related to the timely identification of changes in estimated variable consideration related to drug product revenue.

Each of these material weaknesses could result in material misstatements in the drug product revenue, contract asset or contract liability account balances or disclosures in our annual or interim consolidated financial statements that would not be prevented or detected.

The material weaknesses described above did not result in any material misstatements of our consolidated financial statements or disclosures, but did result in immaterial out-of-period adjustments to drug product revenue related to pre-commercial shipments of drug product, contract assets and contract liabilities, and related financial statement disclosures during the quarter ended September 30, 2020.

Plan for Remediation

Our Board of Directors and management are committed to maintaining a strong internal control environment. While we are still developing a full detailed remediation plan and are in the early phase of what will be a multi-step remediation process to fully remediate the material weaknesses described above, we are devoting substantial effort in performing a comprehensive risk assessment process to identify, design, implement, and re-evaluate our control activities related to the above mentioned material weaknesses in our internal control over financial reporting. We plan to conduct a comprehensive review and, as applicable, update our existing internal control framework to ensure that it has identified, developed and deployed the appropriate business process controls to meet the objectives and address the risks identified.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below in addition to the other information included or incorporated by reference in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Although we have discussed all known material risks, the risks described below are not the only ones that we may face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from the risks described under Part I, Item 1A *"Risk Factors"* included in our Annual Report on Form 10-K for the year ended December 31, 2019.

SUMMARY RISK FACTOR

The success of the Company will depend on a number of factors, many of which are beyond our control and involve risks, including but not limited to the following:*

Risks Related to the Development and Commercialization of Our Product Candidates

- We are substantially dependent on the success of our lead product, roxadustat, and our second compound in development, pamrevlumab.
- As a company, we have limited commercialization experience, and the time and resources to develop such experience are significant. If we fail to achieve and sustain commercial success for roxadustat with our collaboration partners, our business would be harmed.
- Although regulatory approval has been obtained for roxadustat in China and Japan, we may be unable to obtain regulatory approval for other countries, or such approval may be delayed or limited, due to a number of factors, many of which are beyond our control.
- Preclinical, Phase 1 and Phase 2 clinical trial results may not be indicative of the results that may be obtained in larger clinical trials.
- We do not know whether our ongoing or planned clinical trials of roxadustat or pamrevlumab will need to be redesigned based on interim results or if we will be able to achieve sufficient patient enrollment or complete planned clinical trials on schedule.
- Our product candidates may cause or have attributed to them undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.
- Clinical trials of our product candidates may not uncover all possible adverse effects that patients may experience.
- If we or our manufacturers cannot properly manufacture sufficient product, we may experience delays in development, regulatory approval, launch or successful commercialization.
- Regulatory authorities will do their own benefit risk analysis and may reach a different conclusion than we or our partners have, and these regulatory authorities may base their approval decision on different analyses, data, and statistical methods than ours.
- Even if we are able to obtain regulatory approval of our product candidates, the label we obtain may limit the indicated uses for which our product candidates may be marketed.
- We face substantial competition in the discovery, development and commercialization of product candidates.
- No or limited reimbursement or insurance coverage of our approved products, if any, by third-party payors may render our products less attractive to patients and healthcare providers.

Risks Related to Severe Acute Respiratory Syndrome Coronavirus 2019 Disease ("COVID-19")

- Our business could be adversely affected by the ongoing COVID-19 global pandemic.

Risks Related to Our Reliance on Third Parties

- If our collaborations were terminated or if Astellas or AstraZeneca were to prioritize other initiatives over their collaborations with us, our ability to successfully develop and commercialize our product candidates would suffer.
- If our preclinical and clinical trial contractors do not properly perform their agreed upon obligations, we may not be able to obtain or may be delayed in receiving regulatory approvals for our product candidates.
- We currently rely, and expect to continue to rely, on third parties to conduct many aspects of our product manufacturing and distribution, and these third parties may terminate these agreements or not perform satisfactorily.

- Certain components of our products are acquired from single-source suppliers or without long-term supply agreements. The loss of these suppliers, or their failure to supply, would materially and adversely affect our business.

Risks Related to Our Intellectual Property

- If our efforts to protect our proprietary technologies are not adequate, we may not be able to compete effectively in our market.
- Intellectual property disputes may be costly and time consuming, and may negatively affect our competitive position.
- Our reliance on third parties and agreements with collaboration partners requires us to share our trade secrets, which increases the possibility that a competitor may discover them or that our trade secrets will be misappropriated or disclosed.
- The cost of maintaining our patent protection is high and requires continuous review and diligence. We may not be able to effectively maintain our intellectual property position throughout the major markets of the world.
- The laws of some foreign countries do not protect proprietary rights to the same extent as do the laws of the U.S., and we may encounter significant problems in securing and defending our intellectual property rights outside the U.S.
- Intellectual property rights do not address all potential threats to any competitive advantage we may have.
- The existence of counterfeit pharmaceutical products in pharmaceutical markets may compromise our brand and reputation and have a material adverse effect on our business, operations and prospects.

Risks Related to Government Regulation

- The regulatory approval process is highly uncertain and we may not obtain regulatory approval for our product candidates.
- Our product candidates could fail to receive regulatory approval from the FDA or other regulatory authorities.
- Our current and future relationships with customers, physicians, and third-party payors are subject to healthcare fraud and abuse laws, false claims laws, transparency laws, privacy and security laws, and other regulations. If we are unable to comply with such laws, we could face substantial penalties.
- We are subject to laws and regulations governing corruption, which will require us to maintain costly compliance programs.
- We have identified material weaknesses in our internal controls over financial reporting. If we are unable to remediate these, or if we otherwise fail to maintain an effective system of internal controls, it may result in material misstatements in our financial statements.
- The impact of recent U.S. healthcare reform, its potential partial or full repeal, and other changes in the healthcare industry and in healthcare spending is currently unknown, and may adversely affect our business model.
- Roxadustat is considered a Class 2 substance on the 2019 World Anti-Doping Agency Prohibited List that could limit sales and increase security and distribution costs for our partners and us.
- Our employees may engage in misconduct or improper activities, which could result in significant liability or harm our reputation.
- If we fail to comply with environmental, health or safety laws and regulations, we could incur fines, penalties or other costs.

Risks Related to Our International Operations

- We have established operations in China and are seeking approval to commercialize our product candidates outside of the U.S., and a number of risks associated with international operations could materially and adversely affect our business.
- The pharmaceutical industry in China is highly regulated and such regulations are subject to change.
- We use our own manufacturing facilities in China to produce roxadustat API and drug product. We have limited experience with manufacturing plants and may not be able to continually meet regulatory requirements.
- As a company, we have limited experience in pharmacovigilance, medical affairs, and management of the third-party distribution logistics, and cannot assure you we will be able to meet regulatory requirements or operate in these capacities successfully.
- We and our collaboration partner in China, AstraZeneca, may experience difficulties in successfully generating sales of roxadustat in China.
- The retail prices of any product candidates that we develop may be subject to pricing control in China and elsewhere.
- FibroGen (China) Medical Technology Development Co., Ltd. (“FibroGen Beijing”) would be subject to restrictions on paying dividends or making other payments to us, which may restrict our ability to satisfy our liquidity requirements.
- Any capital contributions from us to FibroGen Beijing must be approved by the Ministry of Commerce in China, and failure to obtain such approval may materially and adversely affect the liquidity position of FibroGen Beijing.
- We may be subject to currency exchange rate fluctuations and currency exchange restrictions with respect to our operations in China, which could adversely affect our financial performance.
- Because FibroGen Beijing’s funds are held in banks that do not provide insurance, the failure of any bank in which FibroGen Beijing deposits its funds could adversely affect our business.
- We may be subject to tax inefficiencies associated with our offshore corporate structure.
- Our foreign operations, particularly those in China, are subject to significant risks involving the protection of intellectual property.
- Uncertainties with respect to the China legal system could have a material adverse effect on us.
- Changes in China’s economic, governmental, or social conditions could have a material adverse effect on our business.
- Our operations in China subject us to various Chinese labor and social insurance laws, and our failure to comply with such laws may materially and adversely affect our business, financial condition and results of operations.
- Developments relating to the United Kingdom’s referendum vote in favor of leaving the European Union could adversely affect us.

Risks Related to the Operation of Our Business

- We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future and may never achieve or sustain profitability. We may require additional financings in order to fund our operations.
- Most of our recent revenue has been earned from collaboration partners for our product candidates under development.
- We may encounter difficulties in managing our growth and expanding our operations successfully.
- Loss of senior management and key personnel could adversely affect our business.
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may have to limit commercial operations.
- Our business and operations would suffer in the event of computer system failures.
- We depend on sophisticated information technology systems and we could face a cyber-attack or other breach of these systems.
- Our headquarters are located near known earthquake fault zones.

Risks Related to Our Common Stock

- The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above your purchase price.
- Our principal stockholders own a significant percentage of our stock and will be able to exercise influence over stockholder approvals.
- We may engage in acquisitions that could dilute stockholders and harm our business.
- Provisions in our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, and may prevent attempts by our stockholders to replace or remove our current directors or management.
- Changes in our tax provision or exposure to additional tax liabilities could adversely affect our earnings and financial condition.
- Tariffs imposed by the U.S. and those imposed in response by other countries could have a material adverse effect on our business.
- Our certificate of incorporation designates courts located in Delaware as the sole forum for certain proceedings, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.
- We do not plan to pay dividends. Capital appreciation will be your sole possible source of gain, which may never occur.

Risks Related to the Development and Commercialization of Our Product Candidates

We are substantially dependent on the success of our lead product, roxadustat, and our second compound in development, pamrevlumab.*

To date, we have invested a substantial portion of our efforts and financial resources in the research and development of roxadustat and pamrevlumab. While we have received approval of our New Drug Applications ("NDA") for roxadustat in the People's Republic of China ("China") for chronic kidney disease ("CKD") anemia for patients on dialysis and not on dialysis, and for roxadustat in Japan for CKD anemia in dialysis patients, we and our partners will need to make substantial additional investments in the development of roxadustat worldwide and in various indications. Our near-term prospects, including maintaining our existing collaborations with Astellas Pharma Inc. ("Astellas") and AstraZeneca AB ("AstraZeneca"), will depend heavily on successful development and commercialization of roxadustat, including obtaining additional regulatory approvals for the commercialization of roxadustat for anemia associated with CKD.

Our other lead product candidate, pamrevlumab, is currently in clinical development for idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer, Duchenne muscular dystrophy ("DMD"), and COVID-19. Pamrevlumab requires substantial further development and investment and we do not have a collaboration partner for support of this compound. In addition, pamrevlumab is a monoclonal antibody, which may require greater financial resources than for our small molecule, roxadustat.

As a company, we have limited commercialization experience, and the time and resources to develop such experience are significant. If we fail to achieve and sustain commercial success for roxadustat with our collaboration partners, our business would be harmed.*

We do not have a sales or marketing infrastructure and have limited experience in the sales, marketing or distribution of pharmaceutical products in any country. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish sales and marketing capabilities or make and maintain our existing arrangements with third parties to perform these services at a level sufficient to support our commercialization efforts.

To the extent that we would undertake sales and marketing of any of our products directly, there are risks involved with establishing our own sales, marketing and distribution capabilities. Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;

- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- our inability to effectively manage geographically dispersed sales and marketing teams;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

With respect to roxadustat, we are dependent on the commercialization capabilities of our collaboration partners, AstraZeneca and Astellas. If either such partner were to terminate its agreement with us, we would have to commercialize on our own or with another third party. We will have limited control over the commercialization efforts of such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products, if any, effectively. If they are not successful in commercializing our product candidates, our business and financial condition would suffer.

Commercializing roxadustat requires us to establish commercialization systems, including but not limited to, medical affairs, sales, pharmacovigilance, supply-chain, and distribution capabilities to perform our portion of the collaborative efforts. These efforts require resources and time. If we, along with Astellas and AstraZeneca, are not successful in our marketing, pricing and reimbursement strategies, facilitating adoption by dialysis organizations, health care professionals, and physicians, recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing roxadustat, which would adversely affect our business and financial condition.

Although regulatory approval has been obtained for roxadustat in China and Japan, we may be unable to obtain regulatory approval in other countries, or such approval may be delayed or limited, due to a number of factors, many of which are beyond our control.*

The clinical trials and the manufacturing of our product candidates are and will continue to be, and the marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States ("U.S.") and in other countries where we intend to develop and, if approved, market any product candidates. Before obtaining regulatory approval for the commercial sale of any product candidate, we must demonstrate through extensive preclinical trials and clinical trials that the product candidate is safe and effective for use in each indication for which approval is sought. The regulatory review and approval process is expensive and requires substantial resources and time, and in general, very few product candidates that enter development receive regulatory approval. In addition, our collaboration partners for roxadustat have final control over development decisions in their respective territories and they may make decisions with respect to development or regulatory authorities that delay or limit the potential approval of roxadustat, or increase the cost of development or commercialization. Accordingly, we may be unable to successfully develop or commercialize roxadustat, pamrevlumab, or any of our other product candidates in one or more indications and jurisdictions.

Moreover, for any Phase 3 clinical trial to support an NDA/Biologics License Application submission for approval, the U.S. Food and Drug Administration ("FDA") and foreign regulatory authorities require compliance with regulations and standards (including good clinical practices ("GCP") requirements for designing, conducting, monitoring, recording, analyzing, and reporting the results of clinical trials) to ensure that (1) the data and results from trials are credible and accurate; and (2) that the rights, integrity and confidentiality of trial participants are protected. Although we rely on third parties to conduct our clinical trials, we as the sponsor remain responsible for ensuring that each of these clinical trials is conducted in accordance with its general investigational plan and protocol under legal and regulatory requirements, including GCP. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our clinical research organizations ("CROs"), trial sites, principal investigators or other third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable. Accordingly, the FDA or other regulatory authorities may require us to exclude the use of patient data from these unreliable clinical trials, or perform additional clinical trials before approving our marketing applications. The FDA or other regulatory authorities may even reject our application for approval or refuse to accept our future applications.

Regulatory authorities may take actions or impose requirements that delay, limit or deny approval of our product candidates for many reasons, including, among others:

- our failure to adequately demonstrate to the satisfaction of regulatory authorities that roxadustat is safe and effective in treating anemia in CKD or that pamrevlumab is safe and effective in treating IPF, pancreatic cancer, DMD or COVID-19;
- our failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

- our failure of clinical trials to meet the level of statistical significance required for approval;
- the determination by regulatory authorities that additional clinical trials are necessary to demonstrate the safety and efficacy of roxadustat or pamrevlumab, or that ongoing clinical trials need to be modified in design, size, conduct or implementation;
- our product candidates may exhibit an unacceptable safety signal as they advance through clinical trials, in particular controlled Phase 3 trials;
- the CROs that conduct clinical trials on our behalf may take actions outside of our control that materially adversely impact our clinical trials;
- we or third-party contractors manufacturing our product candidates may not maintain current good manufacturing practices ("cGMP"), successfully pass inspection or meet other applicable manufacturing regulatory requirements;
- regulatory authorities may not agree with our interpretation of the data from our preclinical trials and clinical trials; or
- collaboration partners may not perform or complete their clinical programs in a timely manner, or at all.

Any of these factors, many of which are beyond our control, could jeopardize our or our collaboration partners' abilities to obtain regulatory approval for our product candidates in one or more indications.

The FDA or other regulatory authorities may require more information (including additional preclinical or clinical data to support approval), which may delay or prevent approval or cause us to abandon the development program altogether. In addition, if our product candidates produce undesirable side effects or safety issues, the FDA may require the establishment of Risk Evaluation and Mitigation Strategy ("REMS") (or other regulatory authorities may require the establishment of a similar strategy), that may restrict distribution of our approved products, if any, and impose burdensome implementation requirements on us.

Preclinical, Phase 1 and Phase 2 clinical trial results may not be indicative of the results that may be obtained in larger clinical trials.

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical and early clinical trials, which are often highly variable and use small sample sizes, may not be predictive of similar results in humans or in larger, controlled clinical trials, and successful results from clinical trials in one indication may not be replicated in other indications.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we may face similar setbacks.

We do not know whether our ongoing or planned clinical trials of roxadustat or pamrevlumab will need to be redesigned based on interim results or if we will be able to achieve sufficient patient enrollment or complete planned clinical trials on schedule.*

Clinical trials can be delayed or terminated for a variety of reasons, including delay or failure to:

- address any physician or patient safety concerns that arise during the course of the trial;
- obtain required regulatory or institutional review board approval or guidance;
- reach timely agreement on acceptable terms with prospective CROs and clinical trial sites;
- recruit, enroll and retain patients through the completion of the trial, including for the duration of the COVID-19 pandemic;
- maintain clinical sites in compliance with clinical trial protocols;
- initiate or add a sufficient number of clinical trial sites; and
- manufacture sufficient quantities of product candidate for use in clinical trials.

In particular, identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the rate at which we can recruit and enroll patients in testing our product candidates. Patients may be unwilling to participate in clinical trials of our product candidates for a variety of reasons, some of which may be beyond our control, including:

- severity of the disease under investigation;
- availability of alternative treatments;
- size and nature of the patient population;
- eligibility criteria for and design of the study in question;
- perceived risks and benefits of the product candidate under study;
- ability to enroll patients in clinical trials during the COVID-19 pandemic (particularly for IPF);
- ongoing clinical trials of competitive agents;
- physicians' and patients' perceptions of the potential advantages of our product candidates being studied in relation to available therapies or other products under development;
- our CRO's and our trial sites' efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients and collect patient data adequately during and after treatment.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate on-going or planned clinical trials.

In addition, we could encounter delays if a clinical trial is suspended or terminated by us, by the relevant institutional review boards at the sites at which such trials are being conducted, or by the FDA or other regulatory authorities. A suspension or termination of clinical trials may result from any number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, changes in laws or regulations, or a principal investigator's determination that a serious adverse event could be related to our product candidates. Any delays in completing our clinical trials will increase the costs of the trial, delay the product candidate development and approval process and jeopardize our ability to commence marketing and generate revenues. Any of these occurrences may materially and adversely harm our business, operations, and prospects.

Our product candidates may cause or have attributed to them undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.

Undesirable side effects caused by our product candidates or that may be identified as related to our product candidates by physician investigators conducting our clinical trials or even competing products in development that utilize a similar mechanism of action or act through a similar biological disease pathway could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. If we determine that there is a likely causal relationship between a serious adverse event and our product candidate, and such safety event is material or significant enough, it may result in:

- our clinical trial development plan becoming longer and more extensive;
- regulatory authorities increasing the data and information required to approve our product candidates and imposing other requirements; and
- our collaboration partners terminating our existing agreements.

The occurrence of any or all of these events may cause the development of our product candidates to be delayed or terminated, which could materially and adversely affect our business and prospects. Refer to "*Business — Overview*" in our Annual Report on Form 10-K for the year ended December 31, 2019 for a discussion of the adverse events and serious adverse events that have emerged in clinical trials of roxadustat and pamrevlumab.

Clinical trials of our product candidates may not uncover all possible adverse effects that patients may experience.

Clinical trials are conducted in representative samples of the potential patient population, which may have significant variability. Clinical trials are by design based on a limited number of subjects and of limited duration for exposure to the product used to determine whether, on a potentially statistically significant basis, the planned safety and efficacy of any product candidate can be achieved. As with the results of any statistical sampling, we cannot be sure that all side effects of our product candidates may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to the product candidate for a longer duration, that a more complete safety profile is identified. Further, even larger clinical trials may not identify rare serious adverse effects or the duration of such studies may not be sufficient to identify when those events may occur. There have been other products, including erythropoiesis stimulating agents ("ESAs"), for which safety concerns have been uncovered following approval by regulatory authorities. Such safety concerns have led to labeling changes or withdrawal of ESAs products from the market. While our most advanced product candidate is chemically unique from ESAs, it or any of our product candidates may be subject to known or unknown risks. Patients treated with our products, if approved, may experience adverse reactions and it is possible that the FDA or other regulatory authorities may ask for additional safety data as a condition of, or in connection with, our efforts to obtain approval of our product candidates. If safety problems occur or are identified after our product candidates reach the market, we may, or regulatory authorities may require us to amend the labeling of our products, recall our products or even withdraw approval for our products.

If we or our manufacturers cannot properly manufacture sufficient product, we may experience delays in development, regulatory approval, launch or successful commercialization.*

Completion of our clinical trials and commercialization of our products require access to, or development of, facilities to manufacture and manage our product candidates at sufficient yields, quality and at commercial scale. Although we have entered into commercial supply agreements for the manufacture of some of our drug candidates, active pharmaceutical ingredients ("API"), intermediates or raw materials, we will need to enter into additional commercial supply agreements, including for backup or second source third-party manufacturers. We may not be able to enter into these agreements with satisfactory terms or on a timely manner.

We have limited experience manufacturing or managing third parties in manufacturing any of our product candidates in the volumes that are expected to be necessary to support large-scale clinical trials and sales. In addition, we have limited experience forecasting supply requirements or coordinating supply chain (including export management) for launch or commercialization, which is a complex process involving our third-party manufacturers and logistics providers, and for roxadustat, our collaboration partners. We may not be able to accurately forecast supplies for commercial launch, or do so in a timely manner and our efforts to establish these manufacturing and supply chain management capabilities may not meet our requirements as to quantities, scale-up, yield, cost, potency or quality in compliance with cGMP, particularly if the marketing authorization or market uptake is more rapid than anticipated or we have an unanticipated surge in demand.

We have a limited amount of roxadustat and pamrevlumab in storage, limited capacity reserved at our third-party manufacturers, and, even if we have or are able to put supply agreements in place for our products, there are long lead times required to manufacture and scale-up the manufacture of additional supply, as required for both late-stage clinical trials, post-approval trials, and commercial supply. If we are unable to forecast, order or manufacture sufficient quantities of roxadustat or pamrevlumab on a timely basis, it may delay our development, launch or commercialization in some or all indications we are currently pursuing. Any delay or interruption in the supply of our product candidates or products could have a material adverse effect on our business and operations.

Our commercial drug product and the product we use for clinical trials must be produced under applicable cGMP regulations. Failure to comply with these regulations may require us to recall commercial product or repeat clinical trials, which would impact sales revenue or delay the regulatory approval process.

We may add or change manufacturers for our products. We may also make changes to our manufacturing processes or to our product specifications, including in order to accommodate changes in regulations, manufacturing equipment or to account for different processes at new or second source suppliers. If we make any such changes with respect to roxadustat or pamrevlumab we will need to demonstrate comparability to the products and processes already approved or in approval by various regulatory authorities, including potentially through the conduct of additional clinical trials. Even if we do demonstrate comparability, a regulatory agency could challenge that result which could delay our development or commercialization progress. Any of these occurrences may materially impact our operations and potential profitability.

We, and even an experienced third-party manufacturer, may encounter difficulties in production. Difficulties may include:

- costs and challenges associated with scale-up and attaining sufficient manufacturing yields, in particular for biologic products such as pamrevlumab, which is a monoclonal antibody;
- contracting with additional suppliers and validation/qualification of additional facilities to meet growing demand;

- supply chain issues, including coordination of multiple contractors in our supply chain and securing necessary licenses (such as export licenses);
- the timely availability and shelf life requirements of raw materials and supplies;
- equipment maintenance issues or failure;
- quality control and quality assurance issues;
- shortages of qualified personnel and capital required to manufacture large quantities of product;
- compliance with regulatory requirements that vary in each country where a product might be sold;
- capacity or forecasting limitations and scheduling availability in contracted facilities; and
- natural disasters, such as pandemics, including the COVID-19 pandemic, floods, storms, earthquakes, tsunamis, and droughts, or accidents such as fire, that affect facilities, possibly limit or postpone production, and increase costs.

Regulatory authorities will do their own benefit risk analysis and may reach a different conclusion than we or our partners have, and these regulatory authorities may base their approval decision on different analyses, data, and statistical methods than ours.

Even if we believe we have achieved positive clinical results, such as superiority or non-inferiority, in certain endpoints, populations or subpopulations, or using certain statistical methods of analysis, the FDA and European Medicines Agency ("EMA") will each conduct their own benefit-risk analysis and may reach different conclusions, using different statistical methods, different endpoints or definitions thereof, or different patient populations or sub-populations, and regulatory authorities may change their approvability criteria based on their internal analyses and discussions with expert advisors. Regulatory authorities may approve roxadustat for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-approval clinical trials. While we will present to regulatory authorities certain pre-specified and not pre-specified sub-populations and sub-group analyses (for example, incident dialysis), multiple secondary endpoints, and multiple analytical methods (such as long-term follow up analyses), including adjusted and censored data, regulatory authorities may reject these analyses, methods, or even parts of our trial design or certain data from our studies, the rationale for our pre-specified non-inferiority margins or other portions of our statistical analysis plans. In addition, even if we are able to provide positive data with respect to certain analyses, such as incident dialysis, estimated glomerular filtration rate, hepcidin, or quality of life measures, regulatory authorities may not include such claims on any approved labeling for roxadustat, which may limit the commercialization or market opportunity for roxadustat. The failure to obtain regulatory approval, or any label, population or other approval limitations in any jurisdiction, may significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenue.

Even if we are able to obtain regulatory approval of our product candidates, the label we obtain may limit the indicated uses for which our product candidates may be marketed.

With respect to roxadustat, regulatory approvals obtained, could limit the approved indicated uses for which roxadustat may be marketed. For example, our label approved in Japan, includes the following warning: "Serious thromboembolism such as cerebral infarction, myocardial infarction, and pulmonary embolism may occur, possibly resulting in death, during treatment with roxadustat." Additionally, in the U.S., ESAs have been subject to significant safety warnings, including the "Black Box" warnings on their labels. The safety concerns relating to ESAs may result in labeling for roxadustat containing similar warnings even if our Phase 3 clinical trials do not suggest that roxadustat has similar safety issues. Even if the label for roxadustat does not contain all of the warnings contained in the "Black Box" warning for ESAs, the label for roxadustat may contain other warnings or limit the market opportunity or approved indications for roxadustat. These warnings could include warnings against exceeding specified hemoglobin targets and other warnings that derive from the lack of clarity regarding the safety issues associated with ESAs, even if our Phase 3 clinical trials do not themselves raise safety concerns.

We face substantial competition in the discovery, development and commercialization of product candidates.*

The development and commercialization of new pharmaceutical products is highly competitive. Our future success depends on our ability and/or the ability of our collaboration partners to achieve and maintain a competitive advantage with respect to the development and commercialization of our product candidates. Our objective is to discover, develop and commercialize new products with superior efficacy, convenience, tolerability, and safety. We expect that in many cases, the products that we commercialize will compete with existing, market-leading products of companies that have large, established commercial organizations.

If roxadustat is approved and launched commercially, competing drugs are expected to include ESAs, particularly in those patient segments where ESAs are used. Currently available ESAs include epoetin alfa (EPOGEN®, marketed by Amgen Inc. in the U.S., Procrit® and Erypo®/Eprex®, marketed by Johnson & Johnson Inc., and Espo® marketed by Kyowa Hakko Kirin in Japan and China), darbepoetin (Amgen/Kyowa Hakko Kirin's Aranesp® and NESP®) and Mircera® marketed by Hoffmann-La Roche ("Roche") outside of the U.S. and by Vifor Pharma, a Roche licensee, in the U.S. and Puerto Rico, as well as biosimilar versions of these currently marketed ESA products. ESAs have been used in the treatment of anemia in CKD for more than 30 years, serving a significant majority of dialysis CKD patients. While non-dialysis CKD patients who are not under the care of nephrologists, including those with diabetes and hypertension, do not typically receive ESAs and are often left untreated, some non-dialysis patients under nephrology care may be receiving ESA therapy. It may be difficult to encourage healthcare providers and patients to switch to roxadustat from products with which they have become familiar.

We may also face competition from potential new anemia therapies currently in clinical development, including in those patient segments not currently addressed by ESAs. Companies that are currently developing hypoxia-inducible factor ("HIF") prolyl hydroxylase ("HIF-PH") inhibitors for anemia in CKD indications include GlaxoSmithKline plc ("GSK"), Bayer Corporation ("Bayer"), Akebia Therapeutics, Inc. ("Akebia"), Japan Tobacco, and Zydus Cadila. Akebia is currently conducting Phase 3 studies in CKD patients on dialysis and not on dialysis, as well as a Phase 2 study evaluating pharmacokinetics and pharmacodynamics in dialysis patients with three-times weekly versus once-a-day dosing. In Japan, Mitsubishi Tanabe Pharmaceutical Corporation, Akebia's collaboration partner, received approval for vadadustat on June 29, 2020 for the treatment of anemia of CKD patients on and not on dialysis. GSK received approval for daprodustat in Japan on June 29, 2020 for the treatment of anemia of CKD patients on and not on dialysis. Price listing for the launch in Japan of both vadadustat and daprodustat occurred in the third quarter of 2020, with pricing in line with roxadustat pricing. GSK is also conducting global Phase 3 studies in CKD patients on dialysis and not on dialysis, and expects to complete those studies by March 2022. GSK and Kyowa Hakko Kirin announced in November 2018 that the two companies signed a strategic commercialization deal in Japan for daprodustat. Bayer has completed global Phase 2 studies and its HIF-PH inhibitor is now in Phase 3 development in CKD populations on dialysis and not on dialysis in Japan. Japan Tobacco received approval in Japan for enarodustat for the treatment of anemia in CKD patients on dialysis and not on dialysis, to be sold by Torii Pharmaceuticals Ltd as ENAROY®. Japan Tobacco and its partner JW Pharmaceuticals started a Phase 3 study in dialysis patients in Korea in 2019. Zydus Cadila (India) started Phase 3 studies in dialysis and non-dialysis CKD patients in India in 2019. In July 2020, Zydus received approval from the FDA to begin studies of desidustat for the treatment of chemotherapy-induced anemia, which could potentially be competitive with roxadustat within this indication.

In addition, there are other companies developing or that have developed biologic therapies for the treatment of other anemia indications that we may also seek to pursue in the future, including anemia of myelodysplastic syndromes ("MDS"). For example, Acceleron Pharma, Inc., in partnership with Celgene Corporation, a Bristol-Myers Squibb company ("Celgene"), developed Reblozyl® (luspatercept), a protein therapeutic. Reblozyl was approved for treatment of anemia in adult patients with ß-thalassemia in November 2019, and in April 2020 for treatment of anemia failing an ESA therapy and requiring two or more red blood cell transfusions over eight weeks in adult patients with very low- to intermediate-risk MDS with ring sideroblast or with myelodysplastic or myeloproliferative neoplasm with ring sideroblasts and thrombocytosis. In June 2020, Acceleron received European Commission approval for luspatercept for the treatment of transfusion-dependent anemia in adult patients with MDS or ß-thalassemia. In Japan, Celgene started a luspatercept Phase 2 study in May 2019. We may face competition for patient recruitment, enrollment for clinical trials, and potentially in commercial sales. There may also be new therapies for renal-related diseases that could limit the market or level of reimbursement available for roxadustat if and when it is commercialized.

In China, locally manufactured epoetin alfa are offered by Chinese pharmaceutical companies such as EPIAO marketed by 3SBio Inc. as well as more than 15 other local manufacturers. We may also face competition by HIF-PH inhibitors from other companies such as Akebia, Bayer, and GSK, which was authorized by the National Medical Products Administration ("NMPA") to conduct trials in China to support its ex-China regulatory filings. A number of domestic companies, including Jiangsu Hengrui Medicine Co., Ltd., Guandong Sunshine Health Investment Co., Ltd., 3SBio Inc., and Hangzhou Andao Pharmaceutical Co. have been permitted by the NMPA to conduct clinical trials in their locally-developed HIF-PH inhibitor investigational compounds for the treatment of anemia in CKD. Another domestic company, China Medical System, in-licensed desidustat, a compound that is currently in Phase 3 trials in India, from Zydus Cadila for greater China in January 2020. Shenzhen Salubris Pharmaceutical Co., Ltd., a domestic company in China, has in-licensed enarodustat from Japan Tobacco and received NMPA approval in the third quarter of 2020 to initiate Phase 3 studies. Akebia announced in December 2015 that it had entered into a development and commercialization partnership with Mitsubishi Tanabe Pharmaceutical Corporation for its HIF-PH inhibitor vadadustat in Japan, Taiwan, South Korea, India and certain other countries in Asia, and announced in April 2017 an expansion of their U.S. collaboration with Otsuka to add markets, including China. 3SBio Inc. announced in 2016 its plan to begin a Phase 1 clinical trial of a HIF-PH inhibitor for the China market.

The first biosimilar ESA, Pfizer's Retacrit® (epoetin zeta), entered the U.S. market in November 2018. Market penetration of Retacrit and the potential addition of other biosimilar ESAs currently under development may alter the competitive and pricing landscape of anemia therapy in CKD patients on dialysis under the end-stage renal disease bundle. The patents for Amgen's EPOGEN® (epoetin alfa) expired in 2004 in Europe, and the final material patents in the U.S. expired in May 2015. Several biosimilar versions of currently marketed ESAs are available for sale in Europe, China and other territories. In the U.S., a few ESA biosimilars are currently under development. Sandoz, a division of Novartis, markets Binocrit® (epoetin alfa) in Europe and may file a biosimilar Biologics License Application in the U.S.

The majority of the current CKD anemia market focuses on dialysis patients, who visit dialysis centers on a regular basis, typically three times a week, and anemia therapies are administered as part of the visit. Two of the largest operators of dialysis clinics in the U.S., DaVita Healthcare Partners Inc. ("DaVita"), and Fresenius Medical Care AG & Co. KGaA ("Fresenius"), collectively provide dialysis care to more than 80% of U.S. dialysis patients, and therefore have historically executed long-term contracts including rebate terms with Amgen. Successful penetration in this market will likely require a definitive agreement with Fresenius and/or DaVita, on favorable terms and on a timely basis.

If approved and launched commercially to treat IPF, pamrevlumab is expected to compete with Roche's Esbriet® (pirfenidone), and Boehringer Ingelheim's Ofev® (nintedanib). We believe that if pamrevlumab can be shown to safely stabilize or reverse lung fibrosis, and thus stabilize or improve lung function in IPF patients, it can compete with pirfenidone and nintedanib for market share in IPF. However, it may be difficult to encourage treatment providers and patients to switch to pamrevlumab from an oral product with which they are already familiar to a product delivered via in-office infusion. Furthermore, pirfenidone and nintedanib may be produced as generics in the near future. We may also face competition from potential new IPF therapies in recruitment and enrollment in our clinical trials and potentially in commercialization.

Pamrevlumab is a monoclonal antibody which may be more expensive and less convenient than oral small molecules such as nintedanib and pirfenidone. Other potential competitive product candidates in various stages of development for IPF include Galapagos NV's GLPG1690 and GLPG1205, Kadmon Holdings, Inc.'s KD025, Liminal BioSciences' PBI-4050, and Roche/Promedior, Inc.'s PRM-151. In particular, GLPG1690 is in a Phase 3 program consisting of two clinical trials with 750 subjects each, intended to support both the U.S. NDA and Marketing Authorization Application ("MAA") in Europe.

If pamrevlumab is approved and launched commercially to treat locally advanced pancreatic cancer patients who are not candidates for surgical resection, pamrevlumab may face competition from products currently used for pancreatic cancer. These include FOLFRINOX, a combination chemotherapy regimen of folic acid, 5-fluouracil, oxaliplatin and irinotecan, and agents seeking approval in combination with gemcitibine and nab-paclitaxel from companies such as Rafael Pharma's defactinib/CPI-613 and Merrimack's istiratumab. Gemcitabine and/or nab-paclitaxel are the current standard of care in the first-line treatment of metastatic pancreatic cancer.

Celgene Corporation's Abraxane® (nab-paclitaxel) was launched in the U.S. and Europe in 2013 and 2014, and was the first drug approved in this disease in nearly a decade.

If approved and launched commercially to treat DMD, pamrevlumab is expected to face competition from drugs that have been approved in major markets such as the U.S., EU, and Japan. On September 19, 2016, the FDA approved Sarepta Therapeutics Inc.'s ("Sarepta") Exondys 51™ (eteplirsen). This was the first drug approved to treat DMD. Exondys 51 is approved to treat patients who have a mutation of the dystrophin gene amenable to exon 51 skipping, representing approximately 13% of patients with DMD. In Europe, Sarepta received a negative opinion for its marketing application for eteplirsen from the EMA in September 2018. Sarepta has reported a full year Exondys 51 revenue of $380 million in 2019. Sarepta's Vyondys 53™ (golodirsen) was also approved by the FDA in December 2019 for patients with a confirmed genetic mutation that is amenable to exon 53 skipping, which accounts for 8% of the DMD population.

PTC Therapeutics' product Translarna ™ received a conditional approval in Europe in 2014, which was renewed in November 2016 with a request for a new randomized placebo-controlled 18-month study by the Committee for Medicinal Products for Human Use of the EMA; however, the FDA informed the sponsor in a complete response letter in October 2017, as well as in its response to PTC Therapeutics' appeal, that the FDA is unable to approve the application in its current form. An additional Phase 3 study is currently ongoing. While Translarna ™ targets a different set of DMD patients from those targeted by Sarepta's Exondys 51®, it is also limited to a subset of patients who carry a specific mutation. Conversely, pamrevlumab is intended to treat DMD patients without limitation to type of mutation.

Pamrevlumab may also face competition from other drugs currently in clinical development in patient recruiting and enrollment in clinical trials, and, if approved, in commercialization. Examples of those compounds currently under clinical development are the drug candidates from Pfizer, Pliant, Galecto, and Sarepta. Pfizer initiated a Phase 3 study with PF-06939926, its AAV9 mini-dystrophin gene therapy for DMD in February 2020. Pliant's PLN-74809 and Galecto's lead candidate GB0139, are in Phase 2 development for IPF.

The success of any or all of these potential competitive products may negatively impact the development and potential for success of pamrevlumab. In addition, any competitive products that are on the market or in development may compete with pamrevlumab for patient recruitment and enrollment for clinical trials or may force us to change our clinical trial design, including, in order to compare pamrevlumab against another drug, which may be the new standard of care.

Moreover, many of our competitors have significantly greater resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients, manufacturing pharmaceutical products, and commercialization. In the potential anemia market for roxadustat, for example, large and established companies such as Amgen and Roche, among others, compete aggressively to maintain their market shares. In particular, the currently marketed ESA products are supported by large pharmaceutical companies that have greater experience and expertise in commercialization in the anemia market, including in securing reimbursement, government contracts and relationships with key opinion leaders; conducting testing and clinical trials; obtaining and maintaining regulatory approvals and distribution relationships to market products; and marketing approved products. These companies also have significantly greater scale, research and marketing capabilities than we do and may also have products that have been approved or are in later stages of development and have collaboration agreements in our target markets with leading dialysis companies and research institutions. If we and our collaboration partners are not able to compete effectively against existing and potential competitors, our business and financial condition may be materially and adversely affected.

No or limited reimbursement or insurance coverage of our approved products, if any, by third-party payors may render our products less attractive to patients and healthcare providers.*

Market acceptance and sales of any approved products will depend significantly on reimbursement or coverage of our products by government or third-party payors and may be affected by existing and future healthcare reform measures or prices of related products for which the government or third-party reimbursement applies. Coverage and reimbursement by the government or a third-party payor may depend upon a number of factors, including the payor's determination that use of a product is:

- a covered benefit under applicable health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor, which we may not be able to provide. Furthermore, the reimbursement policies of third-party payors may significantly change in a manner that renders our clinical data insufficient for adequate reimbursement or otherwise limits the successful marketing of our products. Even if we obtain coverage for our product candidates, third-party payors may not establish adequate reimbursement amounts, which may reduce the demand for, or the price of, our products. For example, the initial roxadustat reimbursement prices set by the Ministry of Health, Labour and Welfare in Japan in November 2019 did not reflect innovation premium over the current ESA therapy, despite roxadustat's advantages observed in our clinical programs. We believe the Japanese authority's decision was primarily based on the comparability of roxadustat shown in the Japan Phase 3 studies that supported the Japan NDA, that was not designed to evaluate the outcome and additional efficacy and safety data observed in the large global Phase 3 programs that included over 8,000 patients. We have no control over whether the agency will revisit the pricing once they review the comprehensive data from the global Phase 3 program including the major adverse cardiac event /major adverse cardiac event plus hospitalized unstable angina and hospitalized congestive heart failure outcomes. If reimbursement is not available or is available only to limited levels or only in subsets of the dialysis and non-dialysis populations, we may not be able to successfully commercialize certain of our products, or in particular jurisdictions.

Price controls may limit the price at which products such as roxadustat, if approved, are sold. For example, reference pricing is used by various Europe member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, our partner or we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available products in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unacceptable levels, we or our partner may elect not to commercialize our products in such countries, and our business and financial condition could be adversely affected.

Risks Related to COVID-19

Our business could be adversely affected by the ongoing COVID-19 global pandemic.*

Our business could be adversely affected by the effects of the COVID-19 pandemic, which has resulted in various and evolving restrictions in order to reduce the spread of the disease.

The effects of the COVID-19 pandemic, the associated government-mandated restrictions and the other effects on healthcare systems, the economy, and society as a whole, may negatively impact productivity, disrupt our business, and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the progression of the disease, the length and severity of the restrictions, and other impacts and limitations on our ability to conduct our business in the ordinary course. These disruptions in our operations could negatively impact our business, operating results, and financial condition. The number of COVID-19 cases has recently been increasing in the U.S., Europe and certain other territories, and certain jurisdictions have begun re-opening only to return to restrictions due to increasing numbers of COVID-19 cases. The extent of the impact on the COVID-19 pandemic on our business and financial results will continue to depend on numerous evolving factors that we are not able to accurately predict and which will vary by market, including the duration and scope of the pandemic, global economic conditions during and after the pandemic, and governmental actions that have been taken, or may be taken in the future, in response to the pandemic.

We have taken measures to minimize the health risks of COVID-19 to our staff, patients, healthcare providers, and their communities, as their safety and well-being are our top priority. Despite these efforts, there is a risk that one or more of our employees, including members of senior management, could contract COVID-19. Our U.S. employees are working remotely when possible, and we may experience reduced productivity due to the remote work environment. In addition, there are other risks from remote work including but not limited to the potential for reduced oversight of third parties we work with, such as manufacturing and clinical sites.

In China, most of our partner's and our activities have been resumed after the government shutdown during February and March of 2020. However, if there are any further COVID-19 outbreaks, we or our partners may need to re-institute or tighten restrictions on our operations.

Our clinical trials for MDS, chemotherapy-induced anemia and locally advanced pancreatic cancer have continued to enroll and enrollment for IPF has resumed. However, we have seen impacts from COVID-19 on all of our clinical trials to varying degrees. There is a risk that any or all of our clinical trials will be delayed due to a continued or further outbreak slowing or pausing enrollment or site initiation, and direct COVID-19 impacts to clinical sites and clinical service providers. In addition, while we are trying to mitigate the effect of COVID-19 on existing patients, it is possible that some patients may not be able to continue to comply with protocols, which could further delay our clinical trial progress.

We believe we have sufficient roxadustat and pamrevlumab supplies for our expected commercial and clinical requirements over the next year and we and our manufacturing partners are currently continuing manufacturing operations. However, we only have a limited stockpile of these drug supply products, and therefore, if there is a greater impact from the COVID-19 pandemic than we have expected, or if manufacturing operations are halted again, or if drug product expires due to slowed clinical trials, we could face shortages in our global supply chains. We could also face additional competition to use available capacity at our manufacturing partners or for manufacturing supplies including reagents and media. Any such supply disruptions could adversely impact our clinical development and ability to generate revenues from our approved products and our business, financial condition, results of operations and growth prospects could be materially adversely affected. There may be unexpected regulatory delays due to the COVID-19 pandemic including due to travel restrictions impacting pre-approval inspections.

Due to these and potentially additional business disruptions, there may be delays to any of our business areas including our drug supply chains, problems with our distribution or warehousing vendors, or delays to our (and our partners') clinical trials or other development efforts, or commercialization and launch activities. The full extent of these effects are unknown, but all of them could have a material impact on our operations and revenue.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "*Risk Factors*" section.

Risks Related to Our Reliance on Third Parties

If our collaborations were terminated or if Astellas or AstraZeneca were to prioritize other initiatives over their collaborations with us, our ability to successfully develop and commercialize our product candidates would suffer.*

We have entered into collaboration agreements with respect to the development and commercialization of our lead product candidate, roxadustat, with Astellas and AstraZeneca. These agreements provide for reimbursement of our development costs by our collaboration partners and also provide for commercialization of roxadustat throughout the major territories of the world.

Our agreements with Astellas and AstraZeneca provide each of them with the right to terminate their respective agreements with us, upon the occurrence of negative clinical results, delays in the development and commercialization of our product candidates or adverse regulatory requirements or guidance. The termination of any of our collaboration agreements would require us to fund and perform the further development and commercialization of roxadustat in the affected territory, or pursue another collaboration, which we may be unable to do, either of which could have an adverse effect on our business and operations. In addition, each of those agreements provides our respective partners the right to terminate any of those agreements upon written notice for convenience. Moreover, if Astellas or AstraZeneca, or any successor entity, were to determine that their collaborations with us are no longer a strategic priority, or if either of them or a successor were to reduce their level of commitment to their collaborations with us, our ability to develop and commercialize roxadustat could suffer. In addition, some of our collaborations are exclusive and preclude us from entering into additional collaboration agreements with other parties in the area or field of exclusivity.

If we do not establish and maintain strategic collaborations related to our product candidates, we will bear all of the risk and costs related to the development and commercialization of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise at significant cost. This in turn may negatively affect the development of our other product candidates as we direct resources to our most advanced product candidates.

Our collaboration partners also have certain rights to control decisions regarding the development and commercialization of our product candidates with respect to which they are providing funding. If we have a disagreement over strategy and activities with our collaboration partners, our plans for obtaining approval may be revised and negatively affect the anticipated timing and potential for success of our product candidates. Even if a product under a collaboration agreement is approved, we will remain substantially dependent on the commercialization strategy and efforts of our collaboration partners, and neither of our collaboration partners has experience in commercialization of an anemia drug, or novel drug such as roxadustat in the dialysis market. If our collaboration partners are unsuccessful in their commercialization efforts, our results will be affected.

With respect to our collaboration agreements for roxadustat, there are additional complexities in that our collaboration partners, Astellas and AstraZeneca, and we must reach consensus on our development programs and regulatory activities, including for the NDA in the U.S. and the MAA in Europe. In addition, there are aspects of commercial operations that require cooperation among the collaboration partners, including safety data reporting. Multi-party decision-making is complex and involves significant time and effort, and there can be no assurance that the parties will cooperate or reach consensus, or that one or both of our partners will not ask to proceed independently in some or all of their respective territories or functional areas of responsibility in which the applicable collaboration partner would otherwise be obligated to cooperate with us. Any disputes or lack of cooperation with us by either Astellas or AstraZeneca may negatively impact the timing or success of our regulatory approval applications.

We intend to conduct proprietary research programs in specific disease areas that are not covered by our collaboration agreements. Our pursuit of such opportunities could, however, result in conflicts with our collaboration partners in the event that any of our collaboration partners takes the position that our internal activities overlap with those areas that are exclusive to our collaboration agreements. Moreover, disagreements with our collaboration partners could develop over rights to our intellectual property, including the enforcement of those rights. In addition, our collaboration agreements may have provisions that give rise to disputes regarding the rights and obligations of the parties. Any conflict with our collaboration partners could lead to the termination of our collaboration agreements, delay collaborative activities, reduce our ability to renew agreements or obtain future collaboration agreements or result in litigation or arbitration and would negatively impact our relationship with existing collaboration partners, and could impact our commercial results.

Certain of our collaboration partners could also become our competitors in the future. If our collaboration partners develop competing products, fail to obtain necessary regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the development and commercialization of our product candidates, the development and commercialization of our product candidates and products could be delayed.

If our preclinical and clinical trial contractors do not properly perform their agreed upon obligations, we may not be able to obtain or may be delayed in receiving regulatory approvals for our product candidates.*

We rely heavily on university, hospital, dialysis centers and other institutions and third parties, including the principal investigators and their staff, to carry out our clinical trials in accordance with our clinical protocols and designs. We also rely on a number of third-party CROs to assist in undertaking, managing, monitoring and executing our ongoing clinical trials, including those for roxadustat. We expect to continue to rely on CROs, clinical data management organizations, medical institutions and clinical investigators to conduct our development efforts in the future, including our continued development of roxadustat. We compete with many other companies for the resources of these third parties, and large pharmaceutical companies often have significantly more extensive agreements and relationships with such third-party providers, and such third-party providers may prioritize the requirements of such large pharmaceutical companies over ours. The third parties on whom we rely may terminate their engagements with us at any time, which may cause delay in the development and commercialization of our product candidates. If any such third party terminates its engagement with us or fails to perform as agreed, we may be required to enter into alternative arrangements, which would result in significant cost and delay to our product development program. Moreover, our agreements with such third parties generally do not provide assurances regarding employee turnover and availability, which may cause interruptions in the research on our product candidates by such third parties.

Moreover, while our reliance on these third parties for certain development and management activities will reduce our control over these activities, it will not relieve us of our responsibilities. For example, the FDA and foreign regulatory authorities require compliance with regulations and standards, including GCP requirements for designing, conducting, monitoring, recording, analyzing and reporting the results of clinical trials to ensure that the data and results from trials are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Although we rely on third parties to conduct our clinical trials, we, as the sponsor, remain responsible for ensuring that each of these clinical trials is conducted in accordance with its general investigational plan and protocol under legal and regulatory requirements, including GCP. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites.

If any of our CROs, trial sites, principal investigators or other third parties fail to comply with applicable GCP requirements, other regulations, trial protocol or other requirements under their agreements with us, the quality or accuracy of the data they obtain may be compromised or unreliable, and the trials of our product candidates may not meet regulatory requirements. If trials do not meet regulatory requirements or if these third parties need to be replaced, the development of our product candidates may be delayed, suspended or terminated, regulatory authorities may require us to exclude the use of patient data from our approval applications or perform additional clinical trials before approving our marketing applications. Regulatory authorities may even reject our application for approval or refuse to accept our future applications for an extended period of time. We cannot assure that upon inspection by a regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements or that our results may be used in support of our regulatory submissions. If any of these events occur, we may not be able to obtain regulatory approval for our product candidates on a timely basis, at a reasonable cost, or at all.

We currently rely, and expect to continue to rely, on third parties to conduct many aspects of our product manufacturing and distribution, and these third parties may terminate these agreements or not perform satisfactorily.*

We do not have operating manufacturing facilities at this time other than our roxadustat manufacturing facilities in China, and our current commercial manufacturing plans in China are not expected to satisfy the requirements necessary to support development and commercialization outside of China. Other than in and for China specifically, we do not expect to independently manufacture our products. We currently rely, and expect to continue to rely, on third parties to scale-up, manufacture and supply roxadustat and our other product candidates outside of China. We also rely entirely on third parties for distribution in China. Risks arising from our reliance on third-party manufacturers include:

- reduced control and additional burdens of oversight as a result of using third-party manufacturers and distributors for all aspects of manufacturing activities, including regulatory compliance and quality control and quality assurance;
- termination of manufacturing agreements, termination fees associated with such termination, or nonrenewal of manufacturing agreements with third parties may negatively impact our planned development and commercialization activities;
- the possible misappropriation of our proprietary technology, including our trade secrets and know-how; and
- disruptions to the operations of our third-party manufacturers, distributors or suppliers unrelated to our product, including the merger, acquisition, or bankruptcy of a manufacturer or supplier or a catastrophic event, including disruption resulting from the COVID-19 pandemic, affecting our manufacturers, distributors or suppliers.

Any of these events could lead to development delays or failure to obtain regulatory approval or affect our ability to successfully commercialize our product candidates. Some of these events could be the basis for action by the FDA or another regulatory authority, including injunction, recall, seizure or total or partial suspension of production.

The facilities used by our contract manufacturers to manufacture our product candidates must pass inspections by the FDA and other regulatory authorities. Although, except for China, we do not control the manufacturing operations of, and expect to remain completely dependent on, our contract manufacturers for manufacture of drug substance and finished drug product, we are ultimately responsible for ensuring that our product candidates are manufactured in compliance with cGMP requirements. If our contract manufacturers cannot successfully manufacture material that conforms to our or our collaboration partners' specifications, or the regulatory requirements of the FDA or other regulatory authorities, we may not be able to secure and/or maintain regulatory approval for our product candidates and our development or commercialization plans may be delayed. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. In addition, although our longer-term agreements are expected to provide for requirements to meet our quantity and quality requirements to manufacture our products candidates for clinical studies and commercial sale, we will have minimal direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel and we expect to rely on our audit rights to ensure that those qualifications are maintained to meet our requirements. If our contract manufacturers' facilities do not pass inspection by regulatory authorities, or if regulatory authorities do not approve these facilities for the manufacture of our products, or withdraw any such approval in the future, we would need to identify and qualify alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products, if approved. Moreover, any failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us or adverse regulatory consequences, including clinical holds, warnings or untitled letters, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which would be expected to significantly and adversely affect supplies of our products to us and our collaboration partners.

We have not yet entered into any commercial supply agreements for the manufacture of pamrevlumab drug substance or drug products, and our third party manufacturer could terminate their engagement with us at any time. With respect to roxadustat, AstraZeneca and Astellas have certain rights to assume manufacturing of roxadustat and the existence of those rights may limit our ability to enter into favorable long-term supply agreements, if at all, with other third-party manufacturers. In addition, our product candidates and any products that we may develop may compete with other product candidates and products for access and prioritization to manufacture. Certain third-party manufacturers may be contractually prohibited from manufacturing our product due to non-compete agreements with our competitors or a commitment to grant another party priority relative to our products. There are a limited number of third-party manufacturers that operate under cGMP and that might be capable of manufacturing to meet our requirements. Due to the limited number of third-party manufacturers with the contractual freedom, expertise, required regulatory approvals and facilities to manufacture our products on a commercial scale, identifying and qualifying a replacement third-party manufacturer would be expensive and time-consuming and may cause delay or interruptions in the production of our product candidates or products, which in turn may delay, prevent or impair our development and commercialization efforts.

We have a letter agreement with IRIX Pharmaceuticals, Inc. (“IRIX”), a third-party manufacturer that we have used in the past, pursuant to which we agreed to negotiate a single source manufacturing agreement that included a right of first negotiation for the cGMP manufacture of HIF-PH inhibitors, including roxadustat, provided that IRIX is able to match any third-party bids within 5%. The exclusive right to manufacture extends for five years after approval of an NDA for those compounds, and any agreement would provide that no minimum amounts would be specified until appropriate by forecast and that we and a commercialization partner would have the rights to contract with independent third parties that exceed IRIX’s internal manufacturing capabilities or in the event that we or our commercialization partner determines for reasons of continuity of supply and security that such a need exists, provided that IRIX would supply no less than 65% of the product if it is able to provide this level of supply. Subsequent to the letter agreement, we and IRIX have entered into several additional service agreements. IRIX has requested in writing that we honor the letter agreement with respect to the single source manufacturing agreement, and if we were to enter into any such exclusive manufacturing agreement, there can be no assurance that IRIX will not assert a claim for right to manufacture roxadustat or that IRIX could manufacture roxadustat successfully and in accordance with applicable regulations for a commercial product and the specifications of our collaboration partners. In 2015, Patheon Pharmaceuticals Inc., a business unit of DPx Holdings B.V. (“Patheon”), acquired IRIX, and in 2017, ThermoFisher Scientific Inc. acquired Patheon.

If any third-party manufacturer terminates its engagement with us or fails to perform as agreed, we may be required to find replacement manufacturers, which would result in significant cost and delay to our development programs. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur significant delays and added costs in identifying, qualifying and contracting with any such third party or potential second source manufacturer. In any event, with any third-party manufacturer we expect to enter into technical transfer agreements and share our know-how with the third-party manufacturer, which can be time-consuming and may result in delays. These delays could result in a suspension or delay of marketing roxadustat.

Certain components of our products are acquired from single-source suppliers or without long-term supply agreements. The loss of these suppliers, or their failure to supply, would materially and adversely affect our business.

We do not have an alternative supplier of certain components of our product candidates. We may be unable to enter into long-term commercial supply arrangements for some of our products, or do so on commercially reasonable terms, which could have a material adverse impact upon our business. In addition, we currently rely on our contract manufacturers to purchase from third-party suppliers some of the materials necessary to produce our product candidates. We do not have direct control over the acquisition of those materials by our contract manufacturers.

The logistics of our supply chain, which include shipment of materials and intermediates from countries such as China and India add additional time and risk (including risk of loss) to the manufacture of our product candidates. While we have in the past maintained sufficient inventory of materials, API, and drug product to meet our and our collaboration partners’ needs for roxadustat to date, the lead-time and regulatory approvals required to source from and into countries outside of the U.S. increase the risk of delay and potential shortages of supply.

Risks Related to Our Intellectual Property

If our efforts to protect our proprietary technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection, and contractual arrangements to protect the intellectual property related to our technologies. We will only be able to protect our products and proprietary information and technology by preventing unauthorized use by third parties to the extent that our patents, trade secrets, and contractual position allow us to do so. Any disclosure to or misappropriation by third parties of our trade secrets or confidential information could compromise our competitive position. Moreover, we are involved in, have in the past been involved in, and may in the future be involved in legal or administrative proceedings involving our intellectual property initiated by third parties, and which proceedings can result in significant costs and commitment of management time and attention. As our product candidates continue in development, third parties may attempt to challenge the validity and enforceability of our patents and proprietary information and technologies.

We also are involved in, have in the past been involved in, and may in the future be involved in initiating legal or administrative proceedings involving the product candidates and intellectual property of our competitors. These proceedings can result in significant costs and commitment of management time and attention, and there can be no assurance that our efforts would be successful in preventing or limiting the ability of our competitors to market competing products.

Composition-of-matter patents relating to the API are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection not limited to any one method of use. Method-of-use patents protect the use of a product for the specified method(s), and do not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. We rely on a combination of these and other types of patents to protect our product candidates, and there can be no assurance that our intellectual property will create and sustain the competitive position of our product candidates.

Biotechnology and pharmaceutical product patents involve highly complex legal and scientific questions and can be uncertain. Any patent applications that we own or license may fail to result in issued patents. Even if patents do successfully issue from our applications, third parties may challenge their validity or enforceability, which may result in such patents being narrowed, invalidated, or held unenforceable. Even if our patents and patent applications are not challenged by third parties, those patents and patent applications may not prevent others from designing around our claims and may not otherwise adequately protect our product candidates. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, competitors with significantly greater resources could threaten our ability to commercialize our product candidates. Discoveries are generally published in the scientific literature well after their actual development, and patent applications in the U.S. and other countries are typically not published until 18 months after their filing, and in some cases are never published. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or patent applications, or that we or our licensors were the first to file for patent protection covering such inventions. Subject to meeting other requirements for patentability, for U.S. patent applications filed prior to March 16, 2013, the first to invent the claimed invention is entitled to receive patent protection for that invention while, outside the U.S., the first to file a patent application encompassing the invention is entitled to patent protection for the invention. The U.S. moved to a “first to file” system under the Leahy-Smith America Invents Act, effective March 16, 2013. This system also includes procedures for challenging issued patents and pending patent applications, which creates additional uncertainty. We may become involved in opposition or interference proceedings challenging our patents and patent applications or the patents and patent applications of others, and the outcome of any such proceedings are highly uncertain. An unfavorable outcome in any such proceedings could reduce the scope of or invalidate our patent rights, allow third parties to commercialize our technology and compete directly with us, or result in our inability to manufacture, develop or commercialize our product candidates without infringing the patent rights of others.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how, information, or technology that is not covered by our patents. Although our agreements require all of our employees to acknowledge ownership by us of inventions conceived as a result of employment from the point of conception and, to the extent necessary, perfect such ownership by assignment, and we require all of our employees, consultants, advisors and any third parties who have access to our trade secrets, proprietary know-how and other confidential information and technology to enter into appropriate confidentiality agreements, we cannot be certain that our trade secrets, proprietary know-how and other confidential information and technology will not be subject to unauthorized disclosure or that our competitors will not otherwise gain access to or independently develop substantially equivalent trade secrets, proprietary know-how and other information and technology. Furthermore, the laws of some foreign countries, in particular, China, where we have operations, do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property globally. If we are unable to prevent unauthorized disclosure of our intellectual property related to our product candidates and technology to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business and operations.

Intellectual property disputes may be costly and time consuming, and may negatively affect our competitive position.*

Our commercial success may depend on our avoiding infringement of the patents and other proprietary rights of third parties as well as on enforcing our patents and other proprietary rights against third parties. Pharmaceutical and biotechnology intellectual property disputes are characterized by complex, lengthy and expensive litigation over patents and other intellectual property rights. We may initiate or become party to or be threatened with future litigation or other proceedings regarding intellectual property rights with respect to our product candidates and competing products.

As our product candidates progress toward commercialization, our collaboration partners or we may be subject to patent infringement claims from third parties. We attempt to ensure that our product candidates do not infringe third-party patents and other proprietary rights. However, the patent landscape in competitive product areas is highly complex, and there may be patents of third parties of which we are unaware that may result in claims of infringement. Accordingly, there can be no assurance that our product candidates do not infringe proprietary rights of third parties, and parties making claims against us may seek and obtain injunctive or other equitable relief, which could potentially block further efforts to develop and commercialize our product candidates including roxadustat or pamrevlumab. Any litigation involving defense against claims of infringement, regardless of the merit of such claims, would involve substantial litigation expense and would be a substantial diversion of management time.

We may consider administrative proceedings and other means for challenging third-party patents and patent applications. An unfavorable outcome in any such challenge could require us to cease using the related technology and to attempt to license rights to it from the prevailing third party, which may not be available on commercially reasonable terms, if at all, in which case our business could be harmed.

We intend, if necessary, to vigorously enforce our intellectual property in order to protect the proprietary position of our product candidates, including roxadustat and pamrevlumab. In addition, our collaboration partners who have been granted licenses to our patents may also have rights related to enforcement of those patents. Active efforts to enforce our patents by us or by our partners may include litigation, administrative proceedings, or both, depending on the potential benefits that might be available from those actions and the costs associated with undertaking those efforts against third parties. We carefully review and monitor publicly available information regarding products that may be competitive with our product candidates and assert our intellectual property rights where appropriate.

Third parties may also challenge our patents and patent applications, through interference, reexamination, *inter partes* review, and post-grant review proceedings before the U.S. Patent and Trademark Office ("USPTO") or through comparable proceedings in other territories. For example, various administrative and court challenges have been filed in several territories including the U.S., Europe, the United Kingdom, Canada, and Japan, against our HIF anemia-related technologies patent portfolio. In the U.S., we have previously prevailed in administrative challenges to various patents in in this portfolio that are owned or exclusively licensed by us, maintaining our intellectual property in all relevant scope.

On April 20, 2020, in response to an invalidation action brought against certain FibroGen United Kingdom patents by Akebia, the United Kingdom court handed down a decision invalidating United Kingdom designations of European Patent Nos. 1463823, 1633333, 2298301, 2322153, and 2322155. The United Kingdom designation to European Patent No. 2289531 was held to be valid in amended form, but not infringed by Akebia. We and our partner Astellas have filed an appeal of the decision in the United Kingdom Court of Appeal. Notwithstanding the final outcome of this action, the potential narrowing or revocation of any of the HIF anemia-related technology patents does not affect our exclusivity for roxadustat or our freedom-to-operate with respect to use of roxadustat for the treatment of anemia in these or other territories.

Oppositions have also recently been filed against our European Patent No. 2872488, which claims a crystalline form of roxadustat. Final resolution of the opposition proceedings will take considerable time, and we cannot be assured of the breadth of the claims that will remain in the '488 European patent or that the patent will not be revoked in its entirety.

Furthermore, there is a risk that any public announcements concerning the status or outcomes of intellectual property litigation or administrative proceedings may adversely affect the price of our stock. If securities analysts or our investors interpret such status or outcomes as negative or otherwise creating uncertainty, our common stock price may be adversely affected.

Our reliance on third parties and agreements with collaboration partners requires us to share our trade secrets, which increases the possibility that a competitor may discover them or that our trade secrets will be misappropriated or disclosed.

Our reliance on third-party contractors to develop and manufacture our product candidates is based upon agreements that limit the rights of the third parties to use or disclose our confidential information, including our trade secrets and know-how. Despite the contractual provisions, the need to share trade secrets and other confidential information increases the risk that such trade secrets and information are disclosed or used, even if unintentionally, in violation of these agreements. In the highly competitive markets in which our product candidates are expected to compete, protecting our trade secrets, including our strategies for addressing competing products, is imperative, and any unauthorized use or disclosure could impair our competitive position and may have a material adverse effect on our business and operations.

In addition, our collaboration partners are larger, more complex organizations than ours, and the risk of inadvertent disclosure of our proprietary information may be increased despite their internal procedures and contractual obligations in place with our collaboration partners. Despite our efforts to protect our trade secrets and other confidential information, a competitor's discovery of such trade secrets and information could impair our competitive position and have an adverse impact on our business.

The cost of maintaining our patent protection is high and requires continuous review and diligence. We may not be able to effectively maintain our intellectual property position throughout the major markets of the world.

The USPTO and foreign patent authorities require maintenance fees and payments as well as continued compliance with a number of procedural and documentary requirements. Noncompliance may result in abandonment or lapse of the subject patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance may result in reduced royalty payments for lack of patent coverage in a particular jurisdiction from our collaboration partners or may result in competition, either of which could have a material adverse effect on our business.

We have made, and will continue to make, certain strategic decisions in balancing costs and the potential protection afforded by the patent laws of certain countries. As a result, we may not be able to prevent third parties from practicing our inventions in all countries throughout the world, or from selling or importing products made using our inventions in and into the U.S. or other countries. Third parties may use our technologies in territories in which we have not obtained patent protection to develop their own products and, further, may infringe our patents in territories which provide inadequate enforcement mechanisms, even if we have patent protection. Such third-party products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some foreign countries do not protect proprietary rights to the same extent as do the laws of the U.S., and we may encounter significant problems in securing and defending our intellectual property rights outside the U.S.*

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain countries. The legal systems of certain countries do not always favor the enforcement of patents, trade secrets, and other intellectual property rights, particularly those relating to pharmaceutical and biotechnology products, which could make it difficult for us to stop infringement of our patents, misappropriation of our trade secrets, or marketing of competing products in violation of our proprietary rights. In China, our intended establishment of significant operations will depend in substantial part on our ability to effectively enforce our intellectual property rights in that country. Proceedings to enforce our intellectual property rights in foreign countries could result in substantial costs and divert our efforts and attention from other aspects of our business, and could put our patents in these territories at risk of being invalidated or interpreted narrowly, or our patent applications at risk of not being granted, and could provoke third parties to assert claims against us. We may not prevail in all legal or other proceedings that we may initiate and, if we were to prevail, the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Intellectual property rights do not address all potential threats to any competitive advantage we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are the same as or similar to our current or future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- The prosecution of our pending patent applications may not result in granted patents.
- Granted patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product.
- Our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates.

The existence of counterfeit pharmaceutical products in pharmaceutical markets may compromise our brand and reputation and have a material adverse effect on our business, operations and prospects.

Counterfeit products, including counterfeit pharmaceutical products, are a significant problem, particularly in China. Counterfeit pharmaceuticals are products sold or used for research under the same or similar names, or similar mechanism of action or product class, but which are sold without proper licenses or approvals, and are often lower cost, lower quality, different potency, or have different ingredients or formulations, and have the potential to damage the reputation for quality and effectiveness of the genuine product. Such products may be used for indications or purposes that are not recommended or approved or for which there is no data or inadequate data with regard to safety or efficacy. Such products divert sales from genuine products. If counterfeit pharmaceuticals illegally sold or used for research result in adverse events or side effects to consumers, we may be associated with any negative publicity resulting from such incidents. Consumers may buy counterfeit pharmaceuticals that are in direct competition with our pharmaceuticals, which could have an adverse impact on our revenues, business and results of operations. In addition, the use of counterfeit products could be used in non-clinical or clinical studies, or could otherwise produce undesirable side effects or adverse events that may be attributed to our products as well, which could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. With respect to China, although the government has recently been increasingly active in policing counterfeit pharmaceuticals, there is not yet an effective counterfeit pharmaceutical regulation control and enforcement system in China. As a result, we may not be able to prevent third parties from selling or purporting to sell our products in China. The proliferation of counterfeit pharmaceuticals has grown in recent years and may continue to grow in the future. The existence of and any increase in the sales and production of counterfeit pharmaceuticals, or the technological capabilities of counterfeiters, could negatively impact our revenues, brand reputation, business and results of operations.

Risks Related to Government Regulation

The regulatory approval process is highly uncertain and we may not obtain regulatory approval for our product candidates.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Except for roxadustat in China for patients on dialysis and not on dialysis, and Japan for patients on dialysis, we have not obtained regulatory approval for any product candidate, and it is possible that neither roxadustat nor pamrevlumab, nor any future product candidates we may discover, in-license or acquire and seek to develop in the future, will obtain regulatory approval in additional countries.

Our product candidates could fail to receive regulatory approval from the FDA or other regulatory authorities for many reasons, including:

- disagreement over the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement over our interpretation of data from preclinical studies or clinical trials;
- disagreement over whether to accept efficacy results from clinical trial sites outside the U.S. where the standard of care is potentially different from that in the U.S.;
- the insufficiency of data collected from clinical trials of our present or future product candidates to support the submission and filing of an NDA or other submission or to obtain regulatory approval;
- disapproval of the manufacturing processes or facilities of either our manufacturing plant or third party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or other regulatory authorities may require more information, including additional preclinical or clinical data to support approval, or different analyses, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program altogether. Even if we do obtain regulatory approval, our product candidates may be approved for fewer or more limited indications than we request, approval may be contingent on the performance of costly post-marketing clinical trials, or approval may require labeling that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. In addition, if our product candidates produce undesirable side effects or safety issues, the FDA may require the establishment of REMS or other regulatory authorities may require the establishment of a similar strategy, that may restrict distribution of our approved products, if any, and impose burdensome implementation requirements on us. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Even if we believe our clinical trials are successful, regulatory authorities may not agree that our completed clinical trials provide adequate data on safety or efficacy. Approval by one regulatory authority does not ensure approval by any other regulatory authority. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. We may not be able to file for regulatory approvals and even if we file we may not receive the necessary approvals to commercialize our product candidates in any market.

Our current and future relationships with customers, physicians, and third-party payors are subject to healthcare fraud and abuse laws, false claims laws, transparency laws, privacy and security laws, and other regulations. If we are unable to comply with such laws, we could face substantial penalties.

Our current and future relationships with customers, physicians, and third-party payors are subject to health care laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market and distribute any products for which we obtain marketing approval. If we obtain approval in the U.S. for any of our product candidates, the regulatory requirements applicable to our operations, in particular our sales and marketing efforts, will increase significantly with respect to our operations and the potential for administrative, civil and criminal enforcement by the federal government and the states and foreign governments will increase with respect to the conduct of our business. The laws that may affect our operations in the U.S. include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes certain requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors relating to the privacy, security, and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “PPACA”), which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services (“CMS”), information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;

- foreign and state law equivalents of each of the above federal laws, such as the U.S. Foreign Corrupt Practices Act ("FCPA"), anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts; and
- the Trade Agreements Act ("TAA"), which requires that drugs sold to the U.S. Government must be manufactured in the U.S. or in TAA approved and designated countries. Drugs manufactured in countries not approved under the TAA, may not be sold to the U.S. without specific regulatory approval. We have little experience with this regulation and there is a risk that drugs made from Chinese-made API may not be sold to an entity of the U.S. such as the Veterans Health Administration ("VA") due to our inability to obtain regulatory approval. While there have been recent VA policy changes that appear to allow for sale of drugs from non-TAA approved countries, this policy may change or there may be additional policies or legislation that affect our ability to sell drug to the U.S. Government.

The scope of these laws and our lack of experience in establishing the compliance programs necessary to comply with this complex and evolving regulatory environment increases the risks that we may unknowingly violate the applicable laws and regulations. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could materially adversely affect our ability to operate our business and our financial results.

Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have a material adverse effect on our ability to compete in the marketplace.

We are subject to laws and regulations governing corruption, which will require us to maintain costly compliance programs.

We must comply with a wide range of laws and regulations to prevent corruption, bribery, and other unethical business practices, including the FCPA, anti-bribery and anti-corruption laws in other countries, particularly China. The implementation and maintenance of compliance programs is costly and such programs may be difficult to enforce, particularly where reliance on third parties is required.

Anti-bribery laws prohibit us, our employees, and some of our agents or representatives from offering or providing any personal benefit to covered government officials to influence their performance of their duties or induce them to serve interests other than the missions of the public organizations in which they serve. Certain commercial bribery rules also prohibit offering or providing any personal benefit to employees and representatives of commercial companies to influence their performance of their duties or induce them to serve interests other than their employers. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with these anti-bribery laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the anti-bribery laws present particular challenges in the pharmaceutical industry because in many countries including China, hospitals are state-owned or operated by the government, and doctors and other hospital employees are considered foreign government officials. Furthermore, in certain countries (China in particular), hospitals and clinics are permitted to sell pharmaceuticals to their patients and are primary or significant distributors of pharmaceuticals. Certain payments to hospitals in connection with clinical studies, procurement of pharmaceuticals and other work have been deemed to be improper payments to government officials that have led to vigorous anti-bribery law enforcement actions and heavy fines in multiple jurisdictions, particularly in the U.S. and China.

It is not always possible to identify and deter violations, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

In the pharmaceutical industry, corrupt practices include, among others, acceptance of kickbacks, bribes or other illegal gains or benefits by the hospitals and medical practitioners from pharmaceutical manufacturers, distributors or their third-party agents in connection with the prescription of certain pharmaceuticals. If our employees, affiliates, distributors or third-party marketing firms violate these laws or otherwise engage in illegal practices with respect to their sales or marketing of our products or other activities involving our products, we could be required to pay damages or heavy fines by multiple jurisdictions where we operate, which could materially and adversely affect our financial condition and results of operations. The Chinese government has also sponsored anti-corruption campaigns from time to time, which could have a chilling effect on any future marketing efforts by us to new hospital customers. There have been recent occurrences in which certain hospitals have denied access to sales representatives from pharmaceutical companies because the hospitals wanted to avoid the perception of corruption. If this attitude becomes widespread among our potential customers, our ability to promote our products to hospitals may be adversely affected.

As we expand our operations in China and other jurisdictions internationally, we will need to increase the scope of our compliance programs to address the risks relating to the potential for violations of the FCPA and other anti-bribery and anti-corruption laws. Our compliance programs will need to include policies addressing not only the FCPA, but also the provisions of a variety of anti-bribery and anti-corruption laws in multiple foreign jurisdictions, including China, provisions relating to books and records that apply to us as a public company, and include effective training for our personnel throughout our organization. The creation and implementation of anti-corruption compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required. Violation of the FCPA and other anti-corruption laws can result in significant administrative and criminal penalties for us and our employees, including substantial fines, suspension or debarment from government contracting, prison sentences, or even the death penalty in extremely serious cases in certain countries. The SEC also may suspend or bar us from trading securities on U.S. exchanges for violation of the FCPA's accounting provisions. Even if we are not ultimately punished by government authorities, the costs of investigation and review, distraction of our personnel, legal defense costs, and harm to our reputation could be substantial and could limit our profitability or our ability to develop or commercialize our product candidates. In addition, if any of our competitors are not subject to the FCPA, they may engage in practices that will lead to their receipt of preferential treatment from foreign hospitals and enable them to secure business from foreign hospitals in ways that are unavailable to us.

We have identified material weaknesses in our internal controls over financial reporting. If we are unable to remediate these, or if we otherwise fail to maintain an effective system of internal controls, it may result in material misstatements in our financial statements.*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for evaluating and reporting on the effectiveness of our system of internal control. Our internal controls over financial reporting is a process designed to provide reasonable assurances regarding the reliability of our financial reporting and the preparation of financial statements for external reporting purposes in accordance with accounting principles generally accepted in the U.S. As a public company, we are required to comply with the Sarbanes-Oxley Act and other rules that govern public companies.

As of September 30, 2020, we have identified a material weakness in the risk assessment component of internal control as we did not appropriately design and maintain an effective risk assessment process at a precise enough level to identify new and evolving risks of material misstatement to the financial statements as a result of changes in our business operation. This material weakness gave rise to the following additional control deficiencies, which we also determined to be material weaknesses. We did not design and maintain effective controls related to the timely identification of shipments associated with drug product revenue and we did not design and maintain effective controls related to the timely identification of changes in estimated variable consideration related to drug product revenue. Each of these material weaknesses could result in material misstatements in the drug product revenue, contract asset, or contract liability account balances or disclosures in our annual or interim consolidated financial statements that would not be prevented or detected. The material weaknesses described above did not result in any material misstatements of our consolidated financial statements or disclosures, but did result in immaterial out-of-period adjustments to drug product revenue related to pre-commercial shipments of drug product, contract assets and contract liabilities, and related financial statement disclosures during the quarter ended September 30, 2020.

We are taking certain remedial steps to improve our related internal controls over financial reporting. For further discussion of the material weaknesses identified and our remedial efforts, see Part I, Item 4, "*Controls and Procedures"* in this Quarterly Report on Form 10-Q.

Remediation efforts place a significant burden on management and add increased pressure on our financial resources and processes. If we are unable to successfully remediate our existing or any future material weaknesses or other deficiencies in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected, our liquidity, our access to capital markets may be adversely affected, we may be unable to maintain or regain compliance with applicable securities laws, and the Nasdaq Stock Market LLC listing requirements, we may be subject to regulatory investigations and penalties, investors may lose confidence in our financial reporting, and our stock price may decline.

The impact of recent U.S. healthcare reform, its potential partial or full repeal, and other changes in the healthcare industry and in healthcare spending is currently unknown, and may adversely affect our business model.*

The commercial potential for our approved products could be affected by changes in healthcare spending and policy in the U.S. and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") altered Medicare coverage and payments for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. The MMA also provided authority for limiting the number of drugs that will be covered in any therapeutic class and as a result, we expect that there will be additional pressure to reduce costs. For example, the CMS in implementing the MMA has enacted regulations that reduced capitated payments to dialysis providers. These cost reduction initiatives and other provisions of the MMA could decrease the scope of coverage and the price that may be received for any approved dialysis products and could seriously harm our business and financial condition. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may cause a similar reduction in payments from private payors. Similar regulations or reimbursement policies have been enacted in many international markets that could similarly impact the commercial potential for our products.

Under the Medicare Improvements for Patients and Providers Act ("MIPPA"), a basic case-mix adjusted composite, or bundled, payment system commenced in January 2011 and transitioned fully by January 2014 to a single reimbursement rate for drugs and all services furnished by renal dialysis centers for Medicare beneficiaries with end-stage renal disease. Specifically, under MIPPA the bundle now covers drugs, services, lab tests and supplies under a single treatment base rate for reimbursement by the CMS based on the average cost per treatment, including the cost of ESAs and IV iron doses, typically without adjustment for usage. It is unknown whether roxadustat, if approved in the U.S., will be included in the payment bundle. Under MIPPA, agents that have no IV equivalent in the bundle are currently expected to be excluded from the bundle until 2025. If roxadustat were included in the bundle, it may reduce the price that could be charged for roxadustat, and therefore potentially limit our profitability. Based on roxadustat's differentiated mechanism of action and therapeutic effects, and discussions with our collaboration partner, we currently believe that roxadustat might not be included in the bundle and would instead be eligible for a Transitional Drug Add-on Payment Adjustment ("TDAPA") for a 24-month period. After this 24-month period, CMS would determine if roxadustat should be included in the bundle and, if so, what changes to end-stage renal disease prospective payment system reimbursement should be made. If roxadustat is not included in the bundle after the TDAPA period, and would therefore be reimbursed outside of the bundle, it may potentially limit further market penetration of roxadustat.

In March 2010, the PPACA was passed, which substantially changed the way healthcare is financed by both governmental and private payors in the U.S. There remain judicial and Congressional challenges to certain aspects of the PPACA as well as efforts by the Trump administration to repeal or replace certain aspects of the PPACA. For example, the Tax Cuts and Jobs Act of 2017, (the "Tax Act"), was enacted, which includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Additionally, on December 15, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case. It is unclear how such litigation and other efforts to repeal and replace the PPACA will impact the PPACA and our business.

Further, in the U.S. there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. At the federal level, the Trump administration's budget proposals for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. In addition, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services has solicited feedback on some of these measures and has implemented others under its existing authority. Additionally, on July 24, 2020, President Trump announced four executive orders related to prescription drug pricing that attempt to implement several of the Trump administration proposals, including (i) a policy that would tie certain Medicare Part B drug prices to international drug prices, or the "most favored nation price," the details of which were released on September 13, 2020 and also expanded the policy to cover certain Part D drugs; (ii) an order that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; (iii) an order that directs HHS to finalize the rulemaking process on modifying the Anti-Kickback Statute safe harbors for discounts for plans, pharmacies, and pharmaceutical benefit managers; (iv) a policy that reduces costs of insulin and epipens to patients of federally qualified health centers. The FDA also recently released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. While some of these measures may require additional authorization to become effective, the U.S. Congress and the Trump administration have indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional U.S. healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for any future products or additional pricing pressures.

Roxadustat is considered a Class 2 substance on the 2019 World Anti-Doping Agency Prohibited List that could limit sales and increase security and distribution costs for our partners and us.*

Roxadustat is considered a Class 2 substance on the World Anti-Doping Agency Prohibited List. There are enhanced security and distribution procedures we and our collaboration partners and third-party contractors will have to take to limit the risk of loss of product in the supply chain. As a result, our distribution, manufacturing and sales costs for roxadustat, as well as for our partners, will be increased which will reduce profitability. In addition, there is a risk of reduced sales due to patient access to this drug.

Our employees may engage in misconduct or improper activities, which could result in significant liability or harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failure to:

- comply with FDA regulations or similar regulations of comparable foreign regulatory authorities;
- provide accurate information to the FDA or comparable foreign regulatory authorities;
- comply with manufacturing standards we have established;
- comply with privacy laws protecting personal information;
- comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities;
- comply with the FCPA and other anti-bribery laws;
- report financial information or data accurately; or
- disclose unauthorized activities to us.

Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions, delays in clinical trials, or serious harm to our reputation. We have adopted a code of conduct for our directors, officers and employees, but it is not always possible to identify and deter employee misconduct. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could harm our business, results of operations, financial condition and cash flows, including through the imposition of significant fines or other sanctions.

If we fail to comply with environmental, health or safety laws and regulations, we could incur fines, penalties or other costs.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations applicable to our operations in the U.S. and foreign countries. These current or future laws and regulations may impair our research, development or manufacturing efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Our International Operations

We have established operations in China and are seeking approval to commercialize our product candidates outside of the U.S., and a number of risks associated with international operations could materially and adversely affect our business.*

We expect to be subject to a number of risks related with our international operations, many of which may be beyond our control. These risks include:

- different regulatory requirements for drug approvals in different countries;
- different standards of care in various countries that could complicate the evaluation of our product candidates;
- different U.S. and foreign drug import and export rules;
- reduced protection for intellectual property rights in certain countries;
- changes in tariffs, trade barriers and regulatory requirements;

- different reimbursement systems and different competitive drugs indicated to treat the indications for which our product candidates are being developed;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- compliance with the FCPA, and other anti-corruption and anti-bribery laws;
- U.S. and foreign taxes, including income, excise, customs, consumption, withholding, and payroll taxes;
- foreign currency fluctuations, which could result in increased operating costs and expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- a reliance on CROs, clinical trial sites, principal investigators and other third parties that may be less experienced with clinical trials or have different methods of performing such clinical trials than we are used to in the U.S.;
- potential liability resulting from development work conducted by foreign distributors; and
- business interruptions resulting from geopolitical actions specific to an international region, including war and terrorism, or natural disasters, including the differing impact of the COVID-19 pandemic on each region.

The pharmaceutical industry in China is highly regulated and such regulations are subject to change.*

The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. Refer to "*Business — Government Regulation — Regulation in China*" in our Annual Report on Form 10-K for the year ended December 31, 2019 for a discussion of the regulatory requirements that are applicable to our current and planned business activities in China. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. For example, the Chinese government has implemented regulations that impact distribution of pharmaceutical products in China. These regulations generally require that at most two invoices may be issued throughout the distribution chain. Failure to comply with the "Two-Invoices" regulations would prevent us from accessing the market in China. We have established a jointly owned entity with AstraZeneca to manage distribution in China, and there are complexities involved in establishing proper systems to perform distribution with which we have limited experience. We expect to continue to manage distribution in certain provinces in China. We have limited experience managing distribution of pharmaceutical products, and this new distribution structure may impose higher costs or limit or delay our ability to sell products to our principal customers, and may limit the near term sales of our products. Any other such changes or amendments may result in increased compliance costs to our business or cause delays in or prevent the successful development or commercialization of our product candidates in China. Any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China.

We use our own manufacturing facilities in China to produce roxadustat API and drug product. We have limited experience with manufacturing plants and may not be able to continually meet regulatory requirements.*

We have two manufacturing facilities in China, with one located in Beijing and the other in Cangzhou, Hebei. However, as an organization, we have limited experience licensing and operating commercial manufacturing facilities.

We will be obligated to comply with continuing cGMP requirements and there can be no assurance that we will maintain all of the appropriate licenses required to manufacture our product candidates for clinical and commercial use in China. In addition, we and our product suppliers must continually spend time, money and effort in production, record-keeping and quality assurance and appropriate controls in order to ensure that any products manufactured in our facilities meet applicable specifications and other requirements for product safety, efficacy and quality and there can be no assurance that our efforts will continue to be successful in meeting these requirements.

Manufacturing facilities in China are subject to periodic unannounced inspections by the NMPA and other regulatory authorities. We expect to depend on these facilities for our product candidates and business operations in China. Natural disasters or other unanticipated catastrophic events, including power interruptions, water shortages, storms, fires, pandemics (including the COVID-19 pandemic), earthquakes, terrorist attacks, government appropriation of our facilities, and wars, could significantly impair our ability to operate our manufacturing facilities. Certain equipment, records and other materials located in these facilities would be difficult to replace or would require substantial replacement lead-time that would impact our ability to successfully commercialize our product candidates in China. The occurrence of any such event could materially and adversely affect our business, financial condition, results of operations, cash flows and prospects.

As a company, we have limited experience in pharmacovigilance, medical affairs, and management of the third-party distribution logistics, and cannot assure you we will be able to meet regulatory requirements or operate in these capacities successfully.

We are responsible for commercial manufacturing, pharmacovigilance, medical affairs, and management of the third-party distribution logistics (with AstraZeneca through a jointly owned entity that will perform roxadustat distribution) for roxadustat commercial activities in China. While we have been increasing our staffing in these areas, as a company, we have no experience managing or operating these functions for a commercial product and there can be no guarantee that we will do so efficiently or effectively. Mistakes or delays in these areas could limit our ability to successfully commercialize roxadustat in China, could limit our eventual market penetration, sales and profitability, and could subject us to significant liability in China.

We and our collaboration partner in China, AstraZeneca, may experience difficulties in successfully generating sales of roxadustat in China.

We and AstraZeneca have a profit sharing arrangement with respect to roxadustat in China and any difficulties we may experience in generating sales will affect our bottom line. Difficulties may be related to our ability to maintain reasonable pricing and reimbursement, obtain hospital listing, or other difficulties related to distribution, marketing, and sales efforts in China. For example, our current National Reimbursement Drug List reimbursement pricing is effective for a standard two-year period (between January 1, 2020 to December 31, 2021), after which time we will have to renegotiate a new price for roxadustat, which may be lower. Sales of roxadustat in China may be limited due to the complex nature of the healthcare system, low average personal income, pricing controls, still developing infrastructure and potentially rapid competition from other products. The hospital listing process is critical to roxadustat's near-term commercial success in China and may take many years to obtain the majority of hospital listings.

The retail prices of any product candidates that we develop may be subject to pricing control in China and elsewhere.

The price for pharmaceutical products is highly regulated in China, both at the national and provincial level. Price controls may reduce prices to levels significantly below those that would prevail in less regulated markets or limit the volume of products that may be sold, either of which may have a material and adverse effect on potential revenues from sales of roxadustat in China. Moreover, the process and timing for the implementation of price restrictions is unpredictable, which may cause potential revenues from the sales of roxadustat to fluctuate from period to period.

FibroGen Beijing would be subject to restrictions on paying dividends or making other payments to us, which may restrict our ability to satisfy our liquidity requirements.*

We plan to conduct all of our business in China through FibroGen China Anemia Holdings, Ltd. and FibroGen Beijing. We may rely on dividends and royalties paid by FibroGen Beijing for a portion of our cash needs, including the funds necessary to service any debt we may incur and to pay our operating costs and expenses. The payment of dividends by FibroGen Beijing is subject to limitations. Regulations in China currently permit payment of dividends only out of accumulated profits as determined in accordance with accounting standards and regulations in China. FibroGen Beijing is not permitted to distribute any profits until losses from prior fiscal years have been recouped and in any event must maintain certain minimum capital requirements. FibroGen Beijing is also required to set aside at least 10.0% of its after-tax profit based on Chinese accounting standards each year to its statutory reserve fund until the cumulative amount of such reserves reaches 50.0% of its registered capital. Statutory reserves are not distributable as cash dividends. In addition, if FibroGen Beijing incurs debt on its own behalf in the future, the agreements governing such debt may restrict its ability to pay dividends or make other distributions to us. As of September 30, 2020, approximately $29.5 million of our cash and cash equivalents is held in China.

Any capital contributions from us to FibroGen Beijing must be approved by the Ministry of Commerce in China, and failure to obtain such approval may materially and adversely affect the liquidity position of FibroGen Beijing.

The Ministry of Commerce in China or its local counterpart must approve the amount and use of any capital contributions from us to FibroGen Beijing, and there can be no assurance that we will be able to complete the necessary government registrations and obtain the necessary government approvals on a timely basis, or at all. If we fail to do so, we may not be able to contribute additional capital to fund our Chinese operations, and the liquidity and financial position of FibroGen Beijing may be materially and adversely affected.

We may be subject to currency exchange rate fluctuations and currency exchange restrictions with respect to our operations in China, which could adversely affect our financial performance.

Most of our product sales will occur in local Chinese currency and our operating results will be subject to volatility from currency exchange rate fluctuations. To date, we have not hedged against the risks associated with fluctuations in exchange rates and, therefore, exchange rate fluctuations could have an adverse impact on our future operating results. Changes in value of the Renminbi against the U.S. dollar, Euro and other currencies is affected by, among other things, changes in China's political and economic conditions. Currently, the Renminbi is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. Any significant currency exchange rate fluctuations may have a material adverse effect on our business and financial condition.

In addition, the Chinese government imposes controls on the convertibility of the Renminbi into foreign currencies and the remittance of foreign currency out of China for certain transactions. Shortages in the availability of foreign currency may restrict the ability of FibroGen Beijing to remit sufficient foreign currency to pay dividends or other payments to us, or otherwise satisfy their foreign currency-denominated obligations. Under existing Chinese foreign exchange regulations, payments of current account items, including profit distributions, interest payments and balance of trade, can be made in foreign currencies without prior approval from the State Administration of Foreign Exchange by complying with certain procedural requirements. However, approval from State Administration of Foreign Exchange or its local branch is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. The Chinese government may also at its discretion restrict access in the future to foreign currencies for current account transactions. If the foreign exchange control system prevents us from obtaining sufficient foreign currency to satisfy our operational requirements, our liquidity and financial position may be materially and adversely affected.

Because FibroGen Beijing's funds are held in banks that do not provide insurance, the failure of any bank in which FibroGen Beijing deposits its funds could adversely affect our business.

Banks and other financial institutions in China do not provide insurance for funds held on deposit. As a result, in the event of a bank failure, FibroGen Beijing may not have access to funds on deposit. Depending upon the amount of money FibroGen Beijing maintains in a bank that fails, its inability to have access to cash could materially impair its operations.

We may be subject to tax inefficiencies associated with our offshore corporate structure.*

The tax regulations of the U.S. and other jurisdictions in which we operate are extremely complex and subject to change. New laws, new interpretations of existing laws, such as the Base Erosion Profit Shifting project initiated by the Organization for Economic Co-operation and Development, and any legislation proposed by the relevant taxing authorities, or limitations on our ability to structure our operations and intercompany transactions may lead to inefficient tax treatment of our revenue, profits, royalties, and distributions, if any are achieved.

In addition, our foreign subsidiaries and we have various intercompany transactions. We may not be able to obtain certain benefits under relevant tax treaties to avoid double taxation on certain transactions among our subsidiaries. If we are not able to avail ourselves to the tax treaties, we could be subject to additional taxes, which could adversely affect our financial condition and results of operations.

On December 22, 2017, the Tax Cuts and Jobs Act (Tax Act) was enacted which instituted various changes to the taxation of multinational corporations. Since inception, various regulations and interpretations have been issued by governing authorities and we continue to examine the impacts to our business, which could potentially have a material adverse effect on our business, results of operations or financial conditions.

Our foreign operations, particularly those in China, are subject to significant risks involving the protection of intellectual property.

We seek to protect the products and technology that we consider important to our business by pursuing patent applications in China and other countries, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. We note that the filing of a patent application does not mean that we will be granted a patent, or that any patent eventually granted will be as broad as requested in the patent application or will be sufficient to protect our technology. There are a number of factors that could cause our patents, if granted, to become invalid or unenforceable or that could cause our patent applications not to be granted, including known or unknown prior art, deficiencies in the patent application, or lack of originality of the technology. Furthermore, the terms of our patents are limited. The patents we hold and the patents that may be granted from our currently pending patent applications have, absent any patent term adjustment or extension, a twenty-year protection period starting from the date of application.

Intellectual property rights and confidentiality protections in China may not be as effective as those in the U.S. or other countries for many reasons, including lack of procedural rules for discovery and evidence, low damage awards, and lack of judicial independence. Implementation and enforcement of China intellectual property laws have historically been deficient and ineffective and may be hampered by corruption and local protectionism. Policing unauthorized use of proprietary technology is difficult and expensive, and we may need to resort to litigation to enforce or defend patents issued to us or to determine the enforceability and validity of our proprietary rights or those of others. The experience and capabilities of China courts in handling intellectual property litigation varies and outcomes are unpredictable. An adverse determination in any such litigation could materially impair our intellectual property rights and may harm our business.

Uncertainties with respect to the China legal system could have a material adverse effect on us.

The legal system of China is a civil law system primarily based on written statutes. Unlike in a common law system, prior court decisions may be cited for reference but are not binding. Because the China legal system continues to rapidly evolve, the interpretations of many laws, regulations and rules are not always uniform and enforcement of these laws, regulations and rules involve uncertainties, which may limit legal protections available to us. Moreover, decision makers in the China judicial system have significant discretion in interpreting and implementing statutory and contractual terms, which may render it difficult for FibroGen Beijing to enforce the contracts it has entered into with our business partners, customers and suppliers. Different government departments may have different interpretations of certain laws and regulations, and licenses and permits issued or granted by one government authority may be revoked by a higher government authority at a later time. Navigating the uncertainty and change in the China legal system will require the devotion of significant resources and time, and there can be no assurance that our contractual and other rights will ultimately be enforced.

Changes in China's economic, governmental, or social conditions could have a material adverse effect on our business.

Chinese society and the Chinese economy continue to undergo significant change. Changes in the regulatory structure, regulations, and economic policies of the Chinese government could have a material adverse effect on the overall economic growth of China, which could adversely affect our ability to conduct business in China. The Chinese government continues to adjust economic policies to promote economic growth. Some of these measures benefit the overall Chinese economy, but may also have a negative effect on us. For example, our financial condition and results of operations in China may be adversely affected by government control over capital investments or changes in tax regulations. As the Chinese pharmaceutical industry grows and evolves, the Chinese government may also implement measures to change the regulatory structure and structure of foreign investment in this industry. We are unable to predict the frequency and scope of such policy changes and structural changes, any of which could materially and adversely affect FibroGen Beijing's development and commercialization timelines, liquidity, access to capital, and its ability to conduct business in China. Any failure on our part to comply with changing government regulations and policies could result in the loss of our ability to develop and commercialize our product candidates in China. In addition, the changing government regulations and policies could result in delays and cost increases to our development, manufacturing, approval, and commercialization timelines in China.

Our operations in China subject us to various Chinese labor and social insurance laws, and our failure to comply with such laws may materially and adversely affect our business, financial condition and results of operations.

We are subject to China Labor Contract Law, which provides strong protections for employees and imposes many obligations on employers. The Labor Contract Law places certain restrictions on the circumstances under which employers may terminate labor contracts and require economic compensation to employees upon termination of employment, among other things. In addition, companies operating in China are generally required to contribute to labor union funds and the mandatory social insurance and housing funds. Any failure by us to comply with Chinese labor and social insurance laws may subject us to late fees, fines and penalties, or cause the suspension or termination of our ability to conduct business in China, any of which could have a material and adverse effect on business, results of operations and prospects.

Developments relating to the United Kingdom's referendum vote in favor of leaving the European Union could adversely affect us.

Effective January 31, 2020, the United Kingdom commenced an exit from the European Union, commonly referred to as "Brexit." During a transition period (set to expire on December 31, 2020), the British government will continue to negotiate the terms of the United Kingdom's future relationship with the European Union. The outcome of these negotiations is uncertain, and we do not know to what extent Brexit will ultimately impact the business and regulatory environment in the United Kingdom, the rest of Europe, or other countries. The effects of the United Kingdom's withdrawal from the European Union, and the perceptions as to its impact, are expected to be far-reaching and may adversely affect business activity and economic conditions in Europe and globally and could continue to contribute to instability in global financial markets, including foreign exchange markets. The United Kingdom's withdrawal from the European Union could also have the effect of disrupting the free movement of goods, services and people between the United Kingdom and Europe and could also lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which European laws to replace or replicate, including laws that could impact our ability, or our collaborator's ability in the case of roxadustat, to obtain approval of our products or sell our products in the United Kingdom. Changes impacting our ability to conduct business in the United Kingdom or other European countries, or changes to the regulatory regime applicable to our operations in those countries (such as with respect to the approval of our product candidates), may materially and adversely impact our business, prospects, operating results, and financial condition.

Risks Related to the Operation of Our Business

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future and may never achieve or sustain profitability. We may require additional financings in order to fund our operations.*

We are a biopharmaceutical company with two lead product candidates in clinical development, roxadustat in anemia in CKD, MDS, and chemotherapy-induced anemia, and pamrevlumab in IPF, pancreatic cancer, DMD, and COVID-19. Most of our revenue generated to date has been based on our collaboration agreements and we have limited commercial drug product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. Our net loss for the year ended December 31, 2019, 2018 and 2017 were $77.0 million, $86.4 million and $120.9 million, respectively. As of September 30, 2020, we had an accumulated deficit of $915.4 million. As of September 30, 2020, we had capital resources consisting of cash, cash equivalents and short-term investments of $687.9 million plus $0.2 million of long-term investments classified as available for sale securities. Despite contractual development and cost coverage commitments from our collaboration partners, AstraZeneca and Astellas, and the potential to receive milestone and other payments from these partners, and despite commercialization efforts in the China and Japan for roxadustat for the treatment of anemia caused by CKD, we anticipate we will continue to incur losses on an annual basis for the foreseeable future. If we do not successfully develop and continue to obtain regulatory approval for our existing or any future product candidates and effectively manufacture, market and sell the product candidates that are approved, we may never achieve or sustain profitability on a quarterly or annual basis. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

We believe that we will continue to expend substantial resources for the foreseeable future as we continue late-stage clinical development of roxadustat, grow our operations in China, expand our clinical development efforts on pamrevlumab, continue to seek regulatory approval, launch commercialization of our product candidates, and pursue additional indications. These expenditures will include costs associated with research and development, conducting preclinical trials and clinical trials, obtaining regulatory approvals in various jurisdictions, and manufacturing and supplying products and product candidates for ourselves and our partners. The outcome of any clinical trial and/or regulatory approval process is highly uncertain and we are unable to fully estimate the actual costs necessary to successfully complete the development and regulatory approval process for our compounds in development and any future product candidates. We believe that the net proceeds from our 2017 public offerings, our existing cash and cash equivalents, short-term and long-term investments and accounts receivable, and expected third-party collaboration revenues will allow us to fund our operating plans through at least the next 12 months. Our operating plans or third-party collaborations may change as a result of many factors, including the success of our development and commercialization efforts, operations costs (including manufacturing and regulatory), competition, and other factors that may not currently be known to us, and we therefore may need to seek additional funds sooner than planned, through offerings of public or private securities, debt financings or other sources, such as royalty monetization or other structured financings. Such financings may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may adversely affect our business. We may also seek additional capital due to favorable market conditions or strategic considerations even if we currently believe that we have sufficient funds for our current or future operating plans.

Additional funds may not be available when we require them, or on terms that are acceptable to us. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate our research and development efforts or other operations or activities that may be necessary to commercialize our product candidates.

Most of our recent revenue has been earned from collaboration partners for our product candidates under development.

If either or both of our Astellas and AstraZeneca collaborations were to be terminated, we could require significant additional capital in order to proceed with development and commercialization of our product candidates, including with respect to our commercialization of roxadustat for the treatment of anemia caused by CKD, or we may require additional partnering in order to help fund such development and commercialization. If adequate funds or partners are not available to us on a timely basis or on favorable terms, we may be required to delay, limit, reduce or terminate our development or commercialization efforts or other operations.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, commercialization and administration capabilities or contract with third parties to provide these capabilities for us. As our operations expand and we continue to undertake the efforts and expense to operate as a public reporting company, we expect that we will need to increase the responsibilities on members of management in order to manage any future growth effectively. Our failure to accomplish any of these steps could prevent us from successfully implementing our strategy and maintaining the confidence of investors in us.

Loss of senior management and key personnel could adversely affect our business.*

We are highly dependent on members of our senior management team, including Enrique Conterno, our Chief Executive Officer. The loss of the services of Mr. Conterno or any of our senior management could significantly impact the development and commercialization of our products and product candidates and our ability to successfully implement our business strategy.

Recruiting and retaining qualified commercial, development, scientific, clinical, and manufacturing personnel are and will continue to be critical to our success, particularly as we expand our commercialization operations. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize product candidates. We may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the intense competition among numerous biopharmaceutical companies for similar personnel.

There is also significant competition, in particular in the San Francisco Bay Area, for the hiring of experienced and qualified personnel, which increases the importance of retention of our existing personnel. If we are unable to continue to attract and retain personnel with the quality and experience applicable to our product candidates, our ability to pursue our strategy will be limited and our business and operations would be adversely affected.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may have to limit commercial operations.

We face an inherent risk of product liability as a result of the clinical testing, manufacturing and commercialization of our product candidates. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in a product, negligence, strict liability or breach of warranty. Claims could also be asserted under state consumer protection acts. If we are unable to obtain insurance coverage at levels that are appropriate to maintain our business and operations, or if we are unable to successfully defend ourselves against product liability claims, we may incur substantial liabilities or otherwise cease operations. Product liability claims may result in:

- termination of further development of unapproved product candidates or significantly reduced demand for any approved products;
- material costs and expenses to defend the related litigation;
- a diversion of time and resources across the entire organization, including our executive management;
- product recalls, withdrawals or labeling restrictions;
- termination of our collaboration relationships or disputes with our collaboration partners; and
- reputational damage negatively impacting our other product candidates in development.

If we fail to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims, we may not be able to continue to develop our product candidates. We maintain product liability insurance in a customary amount for the stage of development of our product candidates. Although we believe that we have sufficient coverage based on the advice of our third-party advisors, there can be no assurance that such levels will be sufficient for our needs. Moreover, our insurance policies have various exclusions, and we may be in a dispute with our carrier as to the extent and nature of our coverage, including whether we are covered under the applicable product liability policy. If we are not able to ensure coverage or are required to pay substantial amounts to settle or otherwise contest the claims for product liability, our business and operations would be negatively affected.

Our business and operations would suffer in the event of computer system failures.

Despite the implementation of security measures, our internal computer systems, and those of our CROs, collaboration partners, and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We upgraded our disaster and data recovery capabilities in 2017, however, to the extent that any disruption or security breach, in particular with our partners' operations, results in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and it could result in a material disruption and delay of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

We depend on sophisticated information technology systems and could face a cyber-attack or other breach of these systems.

We rely on information technology systems to process, transmit and store electronic information in our day-to-day operations. The size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption. While we have recently upgraded our disaster data recovery program, a successful attack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyber-attacks are becoming more sophisticated and frequent. We have invested in our systems and the protection and recoverability of our data to reduce the risk of an intrusion or interruption, and we monitor and test our systems on an ongoing basis for any current or potential threats. There can be no assurance that these measures and efforts will prevent future interruptions or breakdowns. If we fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to these systems, we could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating costs and expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows.

Our headquarters are located near known earthquake fault zones. *

We and some of the third-party service providers on which we depend for various support functions are vulnerable to damage from catastrophic events, such as power loss, natural disasters, terrorism and similar unforeseen events beyond our control. Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes and fires, and has been affected by the COVID-19 pandemic, including economic disruption resulting from the related shelter-in-place and stay-at-home governmental orders.

After a comprehensive earthquake risk analysis conducted by Marsh Risk, we decided not to purchase earthquake or flood insurance. Based upon (among other factors) the Marsh Risk analysis, the design and construction of our building, the expected potential loss, and the costs and deductible associated with earthquake and flood insurance, we chose to self-insure. However, earthquakes or other natural disasters could severely disrupt our operations, or have a larger cost than expected, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, or otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place are unlikely to provide adequate protection in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events, such as the COVID-19 pandemic. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

Risks Related to Our Common Stock

The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above your purchase price.

In general, pharmaceutical, biotechnology and other life sciences company stocks have been highly volatile in the current market. The volatility of pharmaceutical, biotechnology and other life sciences company stocks is sometimes unrelated to the operating performance of particular companies and biotechnology and life science companies stocks often respond to trends and perceptions rather than financial performance. In particular, the market price of shares of our common stock could be subject to wide fluctuations in response to the following factors:

- results of clinical trials of our product candidates, including roxadustat and pamrevlumab;
- the timing of the release of results of and regulatory updates regarding our clinical trials;
- the level of expenses related to any of our product candidates or clinical development programs;
- results of clinical trials of our competitors' products;
- safety issues with respect to our product candidates or our competitors' products;
- regulatory actions with respect to our product candidates and any approved products or our competitors' products;
- fluctuations in our financial condition and operating results, which will be significantly affected by the manner in which we recognize revenue from the achievement of milestones under our collaboration agreements;
- adverse developments concerning our collaborations and our manufacturers;
- the termination of a collaboration or the inability to establish additional collaborations;
- the inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- changes in legislation or other regulatory developments affecting our product candidates or our industry;
- fluctuations in the valuation of the biotechnology industry and particular companies perceived by investors to be comparable to us;
- speculation in the press or investment community;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- activities of the government of China, including those related to the pharmaceutical industry as well as industrial policy generally;
- performance of other U.S. publicly traded companies with significant operations in China;
- changes in market conditions for biopharmaceutical stocks; and
- the other factors described in this "*Risk Factors*" section.

As a result of fluctuations caused by these and other factors, comparisons of our operating results across different periods may not be accurate indicators of our future performance. Any fluctuations that we report in the future may differ from the expectations of market analysts and investors, which could cause the price of our common stock to fluctuate significantly. Moreover, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources and could also require us to make substantial payments to satisfy judgments or to settle litigation.

Our principal stockholders own a significant percentage of our stock and will be able to exercise influence over stockholder approvals.*

As of October 31, 2020, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 46.42% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after such date and shares issuable upon settlement of restricted stock units that will vest within 60 days after such date. This percentage is based upon information supplied by officers, directors and principal stockholders and Schedules 13D and 13G, if any, filed with the SEC, which information may not be accurate as of January 31, 2020. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. The interests of this group may differ from those of other stockholders and they may vote their shares in a way that is contrary to the way other stockholders vote their shares. This concentration of ownership could have the effect of entrenching our management and/or the board of directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

We may engage in acquisitions that could dilute stockholders and harm our business.

We may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our present or future product candidates and business or otherwise offer opportunities for us. In connection with these acquisitions or investments, we may:

- issue stock that would dilute our existing stockholders' percentage of ownership;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We may not be able to complete acquisitions on favorable terms, if at all. If we do complete an acquisition, we cannot assure you that it will ultimately strengthen our competitive position or that it will be viewed positively by customers, financial markets or investors. Furthermore, future acquisitions could pose numerous additional risks to our operations, including:

- problems integrating the purchased business, products or technologies, or employees or other assets of the acquisition target;
- increases to our expenses;
- disclosed or undisclosed liabilities of the acquired asset or company;
- diversion of management's attention from their day-to-day responsibilities;
- reprioritization of our development programs and even cessation of development and commercialization of our current product candidates;
- harm to our operating results or financial condition;
- entrance into markets in which we have limited or no prior experience; and
- potential loss of key employees, particularly those of the acquired entity.

We may not be able to complete any acquisitions or effectively integrate the operations, products or personnel gained through any such acquisition.

Provisions in our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, and may prevent attempts by our stockholders to replace or remove our current directors or management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors pursuant to a resolution adopted by a majority of the total number of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that our directors may be removed prior to the end of their term only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- require a supermajority vote of the holders of our common stock or the majority vote of our board of directors to amend our bylaws; and
- require a supermajority vote of the holders of our common stock to amend the classification of our board of directors into three classes and to amend certain other provisions of our certificate of incorporation.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Moreover, because we are incorporated in Delaware, we are governed by certain anti-takeover provisions under Delaware law which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. We are subject to the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, our amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Changes in our tax provision or exposure to additional tax liabilities could adversely affect our earnings and financial condition.*

As a multinational corporation, we are subject to income taxes in the U.S. and various foreign jurisdictions. Significant judgment is required in determining our global provision for income taxes and other tax liabilities. In the ordinary course of a global business, there are intercompany transactions and calculations where the ultimate tax determination is uncertain. Our income tax returns are subject to audits by tax authorities. Although we regularly assess the likelihood of adverse outcomes resulting from these examinations to determine our tax estimates, a final determination of tax audits or tax disputes could have an adverse effect on our results of operations and financial condition.

We are also subject to non-income taxes, such as payroll, excise, customs and duties, sales, use, value-added, net worth, property, gross receipts, and goods and services taxes in the U.S., state and local, and various foreign jurisdictions. We are subject to audit and assessments by tax authorities with respect to these non-income taxes and may have exposure to additional non-income tax liabilities, which could have an adverse effect on our results of operations and financial condition.

In addition, our judgment in providing for the possible impact of the Tax Act remains subject to developing interpretations of the provisions of the Tax Act. As regulations and guidance evolve with respect to the Tax Act, we continue to examine the impact to our tax provision or exposure to additional tax liabilities, which could have a material adverse effect on our business, results of operations or financial condition.

Tariffs imposed by the U.S. and those imposed in response by other countries could have a material adverse effect on our business.

Changes in U.S. and foreign governments' trade policies have resulted in, and may continue to result in, tariffs on imports into and exports from the U.S. Throughout 2018 and 2019, the U.S. imposed tariffs on imports from several countries, including China. In response, China has proposed and implemented their own tariffs on certain products, which may impact our supply chain and our costs of doing business. If we are impacted by the changing trade relations between the U.S. and China, our business and results of operations may be negatively impacted. Continued diminished trade relations between the U.S. and other countries, including potential reductions in trade with China and others, as well as the continued escalation of tariffs, could have a material adverse effect on our financial performance and results of operations.

Our certificate of incorporation designates courts located in Delaware as the sole forum for certain proceedings, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.*

Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the state and federal courts located in the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated by-laws, or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. If a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

We do not plan to pay dividends. Capital appreciation will be your sole possible source of gain, which may never occur.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future and investors seeking cash dividends should not purchase our common stock. We plan to retain any earnings to invest in our product candidates and maintain and expand our operations. Therefore, capital appreciation, or an increase in your stock price, which may never occur, may be the only way to realize any return on your investment.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

Use of Proceeds from Initial Public Offering of Common Stock

On November 13, 2014, our Registration Statement on Form S-1, as amended (Reg. Nos. 333-199069 and 333-200189) was declared effective in connection with the initial public offering of our common stock. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on November 14, 2014.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of FibroGen, Inc.	8-K	001-36740	3.1	11/21/2014
3.2	Amended and Restated Bylaws of FibroGen, Inc.	S-1/A	333-199069	3.4	10/23/2014
4.1	Form of Common Stock Certificate.	8-K	001-36740	4.1	11/21/2014
4.2	Shareholders' Agreement by and among FibroGen International (Cayman) Limited and certain of its shareholders, dated as of September 8, 2017.	10-Q	001-36740	4.6	11/8/2017
4.3	Common Stock Purchase Agreement by and between FibroGen, Inc. and AstraZeneca AB, dated as of October 20, 2014.	S-1/A	333-199069	4.17	10/24/2014
10.1*†	Collaboration Agreement by and between FibroGen, Inc. and Astellas Pharma Inc., effective June 1, 2005.	—	—	—	—
10.2*†	Amended and Restated License, Development and Commercialization Agreement (for the U.S. and Certain Other Territories) by and between FibroGen, Inc. and AstraZeneca AB, effective as of July 30, 2013.	—	—	—	—
10.3*†	Amended and Restated License, Development and Commercialization Agreement (China) by and among FibroGen China Anemia Holdings, Ltd., Beijing FibroGen Medical Technology Development Co., Ltd., FibroGen International (Hong Kong) Limited and AstraZeneca AB, effective July 30, 2013.	—	—	—	—
10.4*†	License Agreement by and between FibroGen, Inc. and the University of Miami and its School of Medicine, effective as of May 23, 1997.	—	—	—	—
10.5*†	First Amendment to May 23, 1997 License Agreement by and between FibroGen, Inc. and the University of Miami, effective as of July 29, 1999.	—	—	—	—
10.6*†	Amendment No. 2 to Research and Commercialization Agreement by and among FibroGen, Inc., Medarex, Inc., GenPharm International Inc., and FibroPharma, Inc., effective as of January 28, 2002.	—	—	—	—
10.7*†	License Agreement by and between FibroGen, Inc. and the Dana-Farber Cancer Institute, Inc., effective as of March 29, 2006.	—	—	—	—
10.8*†	Amendment No. 2 to Master Supply Agreement by and among FibroGen, Inc., Shanghai SynTheAll Pharmaceutical Co., Ltd., and STA Pharmaceutical Hong Kong Limited, effective as of July 24, 2020.	—	—	—	—
10.9*†	Master Supply Agreement by and between FibroGen, Inc. and AstraZeneca UK Limited, effective as of September 10, 2020.	—	—	—	—

10.10†	Second Amended and Restated License, Development and Commercialization Agreement by and among FibroGen China Anemia Holdings, Ltd., FibroGen China Medical Technology Development Co., Ltd., FibroGen International (Hong Kong) Limited, and AstraZeneca AB, effective as of July 1, 2020.	10-Q	001-36740	10.3	08/06/2020
10.11†	Amendment No. 1 to the Amended and Restated License, Development and Commercialization Agreement by and between FibroGen, Inc. and AstraZeneca AB, effective as of July 1, 2020.	10-Q	001-36740	10.4	08/06/2020
31.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a).	—	—	—	—
31.2*	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a).	—	—	—	—
32.1*	Certification of Principal Executive Officer and Principal Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)(1)).	—	—	—	—
101.INS	Inline XBRL Instance Document: the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document	—	—	—	—
101.SCH	Inline XBRL Taxonomy Extension Schema Document	—	—	—	—
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	—	—	—	—
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	—	—	—	—
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	—	—	—	—
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	—	—	—	—
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)	—	—	—	—

* Filed herewith

† Portions of this exhibit (indicated by asterisks) have been omitted as the Company has determined that (i) the omitted information is not material and (ii) the omitted information would likely cause competitive harm if publicly disclosed

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

FibroGen, Inc.

Dated: November 5, 2020

By: /s/ Enrique Conterno
Enrique Conterno
Chief Executive Officer
(Principal Executive Officer)

Dated: November 5, 2020

By: /s/ Pat Cotroneo
Pat Cotroneo
Senior Vice President, Finance and Chief Financial Officer
(Principal Financial and Accounting Officer)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Exhibit 10.1

CONFIDENTIAL EXECUTION COPY

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COLLABORATION AGREEMENT

This COLLABORATION AGREEMENT ("Agreement"), effective as of June 1, 2005 (the "Effective Date"), is made by and between FibroGen, Inc., a Delaware corporation having offices at 225 Gateway Boulevard, South San Francisco, California 94080 ("FG" or "FibroGen"), and Astellas Pharma Inc., a Japanese corporation having offices at 3-11 Nihonbashi-Honcho, 2-Chome, Chuo-ku, Tokyo, 103-8411 Japan ("Astellas").

BACKGROUND

A. FG has a research and development program focused on the development of small molecule prolyl hydroxylase inhibitors which stabilize hypoxia inducible factor ("HIF"), for the treatment of anemia.

B. Astellas desires to collaborate with FG on the development and commercialization of, and license the rights to use as therapeutics, certain small molecule prolyl hydroxylase inhibitors on the terms and conditions set forth below for use in the Astellas Territory (as defined below).

NOW THEREFORE, for and in consideration of the covenants, conditions, and undertakings hereinafter set forth, it is agreed by and between the parties as follows:

ARTICLE 1
DEFINITIONS

1.1 "Actions" shall have the meaning as set forth in Section 14.3 below.

1.2 "Affiliate" shall mean any entity which controls, is controlled by or is under common control with Astellas or FG. For purposes of this definition only, "control" shall mean beneficial ownership (direct or indirect) of at least fifty percent (50%) of the shares of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority).

1.3 "Astellas Indemnitees" shall have the meaning as set forth in Section 17.3 below.

1.4 "Astellas Territory" shall mean the country of Japan.

1.5 "Authorized Designee" shall mean an officer of FG or Astellas, as the case may be, designated by the Chief Executive Officer of the respective corporation, that has been granted full authority to resolve a dispute arising between FG and Astellas as required under Section 2.4 or Section 19.1 hereof.

1.6 "Bridging Strategy" shall mean the decision by Astellas to file an MAA in the Astellas Territory by submitting the data from the Phase III clinical trial of FG or its Affiliate or Sublicensee.

1.7 "Bulk Product" shall mean a Lead Compound supplied by FG to Astellas as a bulk formulated drug (such as in a form, including, but not limited, to a capsule, tablet or caplet formulation) without packaging.

1.8 "Commercialize" shall mean directly or indirectly develop, manufacture, sell, market or distribute.

1.9 "Completion" shall be deemed to occur, with respect to a particular clinical trial for a Lead Compound, upon clinical database lock for such trial.

1.10 "Confidential Information" shall have the meaning as set forth in Section 16.1 below.

1.11 "Control" or "Controlled" shall mean possession of the ability to grant a license or sublicense as provided for herein without violating the terms of an agreement with a third party.

1.12 "Controlling Party" shall have the meaning as set forth in Section 14.3 below.

1.13 "Data" shall have the meaning as set forth in Section 7.1 below.

1.14 "Delivery" or "Delivered" shall mean when Lead Compound is made available by FG to Astellas at the Ex Works location.

1.15 "Development Plan" shall mean the plan for the Development Program in effect from time to time, as established in accordance with Article 3 below.

1.16 "Development Program" shall mean all Astellas activities with respect to the development and commercialization of Lead Compounds for applications within the Field in the Astellas Territory, in accordance with the Development Plan in effect at that time.

1.17 "Enforcement Action" shall have the meaning as set forth in Section 14.4 below.

1.18 "Event" shall have the meaning as set forth in Article 6 below.

1.19 "Expanded Field" shall mean the treatment of any indications in which therapeutic utility is derived from [*], including, without limitation, [*]. The Expanded Field shall not include the Field.

1.20 "Expenses" shall have the meaning as set forth in Section 14.3 below.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

1.21 "FDA" shall mean the U.S. Food and Drug Administration, or any successor agency.

1.22 "FG Acquired Patents" shall mean those FG Patents that are in-licensed or otherwise acquired by FG.

1.23 "FG Development Program" shall mean those activities by or on behalf of FG directly related to the development and commercialization of Lead Compounds for applications within the Field in the FG Territory that are directly useful or necessary for Commercialization in the Astellas Territory.

1.24 "FG Indemnitees" shall have the meaning as set forth in Section 17.2 below.

1.25 "FG Technology" shall mean FG Patents and FG Technical Information.

1.26 "FG Patents" shall mean all patents including all reissues, renewals, re-examinations and extensions thereof, and any patent applications therefor, including all divisionals or continuations, in whole or in part, thereof, which claim or otherwise cover the composition, manufacture, sale or use of a Lead Compound and that are Controlled by FG or its Affiliates during the term of this Agreement, subject to Section 14.5.1. For purposes of this definition, a patent or patent application shall be deemed to "cover" a Lead Compound if the manufacture, use or sale of such Lead Compound would, but for the license granted herein, infringe, contributorily infringe or constitute inducement to infringement of such patent or patent application, if issued or granted as pending. All patents and patent applications listed on Exhibit A, as revised from time to time to remove patents and/or patent applications by mutual agreement or to add patents and/or patent applications by FG, shall be within the scope of definition of the FG Patents, provided, however, that in the event FG designates any additional Lead Compounds, FG shall add to the list on Exhibit A patents and patent applications which claim or otherwise cover the composition, or manufacture, sale or use of the additional Lead Compounds within the Field and the Astellas Territory, and upon the cessation of the designation as any compound as Lead Compound and Astellas' cessation of development of such Lead Compound, FG shall remove at its sole discretion the related patent or patent application from Exhibit A.

1.27 "FG Technical Information" shall mean confidential information, tangible and intangible, and materials, including, but not limited to: trade secrets and know how, pharmaceutical, chemical, biological and biochemical compositions; and technical and non-technical data and information, and/or the results of tests, assays, methods and processes; and plans, specifications and/or other documents containing said information and data; in each case that is possessed by FG as of the Effective Date or discovered, developed or Controlled by FG or its Affiliates during the term of this Agreement, to the extent such relates to the development, manufacture, sale or use of a Lead Compound subject to Section 14.5.1, and such information related to a candidate for use as a Lead Compound provided by FG to Astellas in connection with the Lead Compound selection decision consultation process described in Section 4.3.

1.28 "FG Territory" shall mean all areas of the world outside of the Astellas Territory.

1.29 "Field" shall mean the treatment of anemia solely in the Indications, by means of the stabilization of HIF causing the stimulation of erythropoiesis (including an increase in endogenous erythropoietin production) and/or a subsequent increase in hematocrit through modulation of prolyl hydroxylase and/or asparaginyl hydroxylase. For purposes of clarity, FG and Astellas agree and acknowledge that the Field and the Indications exclude [*].

1.30 "First Commercial Sale" shall mean, with respect to each Lead Compound, the first bona fide commercial sale of such Lead Compound to a non-Affiliate third party by or under authority of Astellas or FG, or their Affiliates or Sublicensees, as the case may be, in the FG Territory or the Astellas Territory, respectively.

1.31 "Force Majeure Event" shall mean the occurrence of any event causing a failure to perform where failure to perform is beyond the reasonable control of the non-performing party, as described in Section 20.3.

1.32 "Fully Burdened Costs" with respect to a Lead Compound shall mean all costs to produce, package and distribute the product to Astellas or its carrier at the Ex Works location (in compliance with Section 12.6) and any royalties or other consideration (not reimbursed by Astellas) paid to third parties related to the acquisition or sale of product, with costs to produce and package the product to include the direct material, labor and indirect costs that are incurred by FG or its Affiliate(s) associated with the manufacture, filling, packaging, labeling, preparation of product for shipment and/or other preparation of such Lead Compound, as applicable, including, but not limited to taxes, fees, and customs incurred, as applicable. Costs will be determined in accordance with U.S. Generally Accepted Accounting Principles (U.S. GAAP) and will include but not be limited to the costs of facilities, labor, purchasing, depreciation of equipment, materials, payments to third parties for any necessary contract work related to the manufacture or testing of the product, the validation studies, quality assurance, quality control and other testing, storage, shipping (if requested by Astellas), costs related to distribution and a reasonable allocation of general and administrative overhead. Costs related to distribution include the labor, materials and overhead necessary to prepare and package the final product for shipment to the Ex Works location.

1.33 "Future Third Party Intellectual Property" shall mean any intellectual property rights, including without limitation all patents, trademarks, or copyrights, and any applications therefor, including any applications for registration, issuance, or grant thereof, owned or Controlled by a third party that are necessary for the practice of the license granted hereunder that were not owned or Controlled by FG as of the Effective Date and that do not qualify as Pre-existing Third Party Intellectual Property under Section 1.56.

1.34 "GMP Guidelines" shall mean then-current applicable Good Manufacturing Practices guidelines and regulations of the FDA.

1.35 "[*]" shall have the meaning as set forth in Section 1.36 below.

1.36 "[*] Percentage" shall be determined, for any Lead Compound, (i) by dividing (a) the [*], which shall be defined as the difference between (x) the [*], and (y) the [*], by (b) the [*]; and (ii) multiplying the result of (i) above by 100.

1.37 "HIF" shall mean hypoxia inducible factor.

1.38 "IND" shall mean an Investigational New Drug application, as defined in the U.S. Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, or comparable filing in a foreign jurisdiction, in each case with respect to a Lead Compound for use within the Field.

1.39 "Indemnitee" shall have the meaning as set forth in Section 17.4 below.

1.40 "Indemnitor" shall have the meaning as set forth in Section 17.4 below.

1.41 "Indications" shall mean those indications listed on Exhibit B and any other indications to be agreed upon hereafter between FG and Astellas, each of which shall be referred to as an Indication.

1.42 "Initial Development Plan" shall mean the Initial Development Plan as described in Section 3.2.1 hereof.

1.43 "Initiate" or Initiation" shall mean with respect to a particular clinical trial for a Lead Compound, the initial dosing of the first patient in such trial in accordance with the protocol therefor.

1.44 "Inspected Party" and "Inspecting Party" shall have the meanings as set forth in Section 10.5 below.

1.45 "Joint Development Committee" or "JDC" shall have the meaning as set forth in Section 2.1 below.

1.46 "Lead Compound" shall mean any compound Controlled by FG that is designated by FG as a lead compound for clinical development in an Indication in accordance with Section 4.3 for the duration of such designation. Any Lead Compound which receives a Marketing Approval in the Astellas Territory shall remain a Lead Compound for the duration of such Marketing Approval. As of the Effective Date, FG-2216 shall be deemed to be a Lead Compound.

1.47 "Listed Price" shall have the meaning as set forth in Section 9.2.

1.48 "Litigation Agreement" shall have the meaning as set forth in Section 14.4 below.

1.49 "Major Indication" shall have the meaning set forth in Section 11.3.1 below.

1.50 "Marketing Approval" shall mean, with respect to each Lead Compound, approval in the Astellas Territory by the Japanese Ministry of Health, Labour and Welfare, or in the FG Territory by U.S. or European regulatory authorities, as the case may be, to market such Lead Compound for an indication within the Field. It is understood that pricing or reimbursement approval shall constitute a part of the Marketing Approval. In any event, Marketing Approval shall be deemed to have occurred with respect to a Lead Compound no later than the date of the First Commercial Sale of such Lead Compound in the FG Territory or the Astellas Territory as the case may be, by or under authority of FG or Astellas respectively, or their Affiliate or Sublicensee, as the case may be, whether or not formal approval by the relevant health regulatory authority is required for the First Commercial Sale of such Lead Compound.

1.51 "Marketing Approval Application" or "MAA" shall mean, within the FG Territory, a New Drug Application or similar application as required under the U.S. Federal Food, Drug and Cosmetics Act and the regulations promulgated thereunder, or such similar filing in Europe, or a comparable filing for Marketing Approval in the Astellas Territory, in each case with respect to a Lead Compound for use within the Field.

1.52 "Net Sales" shall mean the gross amount billed or invoiced by Astellas, its Affiliates and its Sublicensees to unaffiliated third parties for the Lead Compound(s) in bona fide arm's length transaction, less the following deductions:

i) credits or allowances, if any, given or made on account of rejection or return of the Lead Compound(s);

ii) trade and quantity discounts actually allowed and taken in such amounts as are customary in the trade;

iii) duties, sales taxes, excise taxes, insurance and transportation charges actually paid; and

iv) charge back payments or rebates actually paid to wholesalers.

1.53 "Phase I" shall mean human clinical trials, the principal purpose of which is preliminary determination of safety in healthy individuals or patients as required in 21 C.F.R. §312.21, or similar clinical study in a country other than the United States, and for which there are no primary endpoints relating to efficacy included in the protocol.

1.54 "Phase II" shall mean human clinical trials, for which the primary endpoints include a determination of dose ranges and/or a preliminary determination of efficacy in patients with the Indication being studied as required in 21 C.F.R. §312.21, or similar clinical study in a country other than the United States.

1.55 "Phase III" shall mean human clinical trials, the principal purpose of which is to establish safety and efficacy of one or more particular doses in patients with the Indication being studied as required in 21 C.F.R. §312.21, or similar clinical study in a country other than the United States. For purposes of this Section 1.55, and Sections 1.53

and 1.54 above, a particular trial that (i) is intended to overlap two phases of trials, (ii) combines the elements of two phases of trials, or (iii) is treated by the FDA or comparable foreign agency as two phases of trials, such as a Phase I/II trial or a Phase II/III trial, shall be deemed a trial of the later, as well as the earlier, phase (*i.e.*, a Phase II and a Phase III, respectively).

1.56 "Product Specification" shall mean, with respect to a Bulk Product, the written document describing, the testing procedures and results required to determine compliance with release specifications, including, and quality control testing procedures to be determined, and be amended from time to time, by mutual agreement of both parties. The release specifications of such Product Specifications shall be determined taking into account and shall be designed to meet the shelf life requirements of the Japanese Ministry of Health, Labor and Welfare for the Lead Compound, provided, that the Product Specifications shall not require compliance with such shelf life requirements.

1.57 "Preexisting Third Party Intellectual Property" shall mean any intellectual property rights, including without limitation all patents, trademarks, copyrights, and any applications therefor, including any applications for registration, issuance, or grant thereof, owned or Controlled by a third party that are necessary for the practice of the license granted hereunder and that the existence of which was discoverable or otherwise could have been known on or prior to the Effective Date and were not owned or Controlled by FG as of the Effective Date.

1.58 "Proof of Concept" shall mean for any Indication, a demonstration of correction of anemia in relevant patients in a human clinical study.

1.59 "Prosecution and Interference Activities" shall mean the preparation, filing, prosecution and maintenance of patent applications and patents and any continuing applications thereof, and any re-examinations, reissues, renewals and requests for patent term extensions therefor, and any U.S., international or foreign counterparts of any of the foregoing, together with the conduct of any interference, opposition or other similar proceeding pertaining to patent applications or patents.

1.60 "Protected Field" shall have the meaning as set forth in Section 14.1.

1.61 "Reference Materials" shall have the meaning as set forth in Section 12.12 below.

1.62 "Relevant Standards" shall have the meaning as set forth in Section 12.8 below.

1.63 "Sales Price" shall mean the price per unit obtained by dividing the Net Sales during the relevant calendar quarter by the number of units sold during the same period.

1.64 "Standard Materials" shall have the meaning as set forth in Section 12.12 below.

1.65 "Sublicensee" shall mean a third party to whom FG or Astellas has directly or indirectly granted the right in its respective territory to make, use and sell a Lead Compound or a third party to whom FG or Astellas has directly or indirectly granted the right to distribute a Lead Compound supplied by FG or Astellas (respectively). For purposes of this Agreement, FG and Astellas shall not be deemed Sublicensees of the other.

1.66 "Technical Product Failure" shall mean as a [*], which is not attributed to Astellas' failure to fulfill its obligations hereunder.

1.67 "Third Party Agreements" shall mean collectively those agreements between FG and a third party existing as of the Effective Date, pursuant to which FG obtained rights applicable to the development, manufacture, sale or use of Lead Compounds hereunder (but excluding options or similar agreements to acquire such rights). If, after the Effective Date, FG enters into an agreement to license or acquire rights from a third party with respect to subject matter to be utilized in connection with Lead Compounds in accordance with Section 14.5 below, such agreements shall also be deemed Third Party Agreements for purposes of this Agreement.

1.68 "Third Party Licensor" shall have the meaning as set forth in Section 14.5.1 below.

ARTICLE 2
JOINT DEVELOPMENT COMMITTEE

2.1 Joint Development Committee. Astellas and FG shall establish a joint development committee to oversee, review and coordinate the research and development of Lead Compounds for applications within the Field pursuant to the Development Program ("Joint Development Committee" or "JDC"). From time to time, the JDC may establish subcommittees or project teams to oversee particular projects or activities, and such subcommittees or project teams will be constituted as the JDC agrees (*e.g.*, for oversight of the development or other day-to-day matters).

2.2 Membership. The JDC shall be comprised of an equal number of representatives from each of Astellas and FG, selected by such party. The exact number of such representatives shall be [*] for each of Astellas and FG, or such other number as the parties may agree. Subject to the foregoing provisions of this Section 2.2, FG and Astellas may replace its respective JDC representatives at any time, upon prior written notice to the other party.

2.3 JDC Meetings. The JDC shall meet no fewer than [*] times each calendar year, or as otherwise agreed by the parties, with the understanding that [*] meetings are to be held at mutually agreed locations alternating among Japan, California, Hawaii, or at such other locations as the parties agree, and the other [*] meetings are to be held by means of telecommunication, videoconference or correspondence as deemed appropriate. The parties shall conduct team meetings at the same time and location as the JDC meetings. At its meetings, the JDC will, as applicable, (i) formulate and review the Development

Program objectives, including approval of all proposed pre-clinical and clinical studies to be performed, (ii) monitor the progress of the Development Program toward those objectives, (iii) review and approve the Development Plan, pursuant to Section 3.3 of this Agreement, including review, approve and monitor the progress of the clinical and regulatory plans, (iv) resolve issues surrounding the marketing of the Lead Compounds, (v) discuss the selection of Lead Compounds, (vi) coordinate manufacturing issues, including the development of standards, scheduling of batch production, and qualification with regulatory requirements for the Astellas Territory, (vii) resolve issues arising out of the Development Program or this Agreement, and (viii) undertake and/or approve such other matters as are specifically provided for the JDC under this Agreement. One meeting each year will be focused specifically on setting Development Program goals and strategy. Other representatives of FG or Astellas may attend JDC or subcommittee meetings as non-voting observers. Astellas' lead representative shall chair the meetings and shall be responsible for preparing the agenda and minutes for such meetings, and shall provide such minutes to FG in English. Such minutes as approved by the JDC shall constitute the official record of the actions of the JDC. The JDC may also convene or be polled or consulted from time to time by means of telecommunications, videoconferences or correspondence, as deemed necessary or appropriate. Each party shall bear its own personnel, travel and lodging expenses relating to JDC meetings.

2.4 Decisions. Decisions of the JDC shall be made by unanimous agreement of the members present in person or by other means (*e.g.*, teleconference) at any meeting; provided that at least two (2) representatives of each party is present at such meeting. In the event that the JDC is unable to reach unanimous agreement on an issue, the issue shall be referred for resolution in accordance with Article 19 hereof.

ARTICLE 3
DEVELOPMENT PLANS

3.1 General. Subject to Section 3.2 below, Astellas shall prepare and propose to the JDC a detailed Development Plan pursuant to which the Development Program will be performed. The Development Plan shall specify the objectives and work plan activities by Astellas with respect to the Development Program.

3.2 Annual Review

3.2.1 Initial Development Plan. The initial Development Plan is attached hereto as Exhibit C (the "Initial Development Plan"), and shall be fixed for the period from the Effective Date through March 31, 2006, unless otherwise agreed by the JDC.

3.2.2 Other. Beginning upon the date of signing of this Agreement and by December 31 of each year thereafter until expiration or termination of this Agreement, Astellas shall submit to the JDC the proposed plan required under Section 3.1 above for the following fiscal year, including for regulatory activities within the Astellas Territory. The JDC shall review such proposals as soon as possible and shall approve the Development Plan for such following fiscal year, with such changes as the JDC may agree to the plan proposed by Astellas, no later than March 15 of the current fiscal year.

3.3 Periodic Reviews. The JDC shall review the Development Plan on an ongoing basis and may make changes thereto including variances to the Development Plan in effect.

ARTICLE 4
DEVELOPMENT PROGRAM

4.1 Development Program for the Astellas Territory. Astellas shall follow FG's development activities for the Lead Compounds, (i.e., Astellas shall develop, and shall have the right and obligation to develop, only those compounds that FG has designated as Lead Compounds, for the duration of such designation and for which FG or its Sublicensee is pursuing clinical development in the FG Territory), for those Indications being developed by FG or its sublicensee, and such Astellas development shall comply with, without limitation the procedures set forth in Section 11.3.1. In fulfillment thereof, Astellas shall conduct, directly or through third parties, the Development Program for the Astellas Territory, all in accordance with the Development Plan then in effect, and shall be responsible for all costs related to the Astellas Territory. Astellas agrees to keep the JDC informed as to the progress of its activities under the Development Program for Lead Compounds hereunder. FG shall, subject to Section 4.2.2, provide reasonable assistance to Astellas regarding Astellas' performance of its development activities within the scope of the Development Program hereunder and provide updates to Astellas as to the FG Development Program. It is understood and agreed that the Development Program for the Astellas Territory shall include all clinical trials and other development activities necessary to obtain Marketing Approvals for Lead Compounds for the Astellas Territory.

4.2 Global Harmonization

4.2.1 Reporting; Redundant Activities. FG shall provide to Astellas regular reports with respect to the FG Development Program with respect to the Lead Compounds. Such reports may be provided at the JDC meetings provided for in Section 2.3. Recognizing that the Lead Compounds may be developed on a global basis and that regulatory and budget efficiencies can be achieved through the worldwide use of appropriate data and files, the parties will seek to design pre-clinical and clinical development activities included in the Development Plan in a manner to maximize global clinical and regulatory harmonization.

4.2.2 Additional Activities. Without limiting the obligations set forth in 4.2.1, the costs of any non-clinical or clinical developmental work, whether performed by Astellas or FG, to support needs specific to the Astellas Territory and not required to be performed for the FG Territory, or at the request of Astellas, shall be borne by Astellas.

4.3 Selection of Lead Compounds. FG shall consult with Astellas with respect to Lead Compound selection, and shall provide to Astellas information as reasonably necessary to evaluate Lead Compound candidates in connection with the Lead Compound

selection process, including without limitation the information relating to patent situations in the Astellas Territory. For the avoidance of doubt, such Lead Compound candidates shall potentially include any and all compounds Controlled by FG during the term hereof for use in the Field. Notwithstanding anything contained in this Agreement, FG shall designate, at its sole discretion but in line with the basic policy that the same Lead Compound shall be Commercialized both in Astellas Territory and FG Territory for the same Indication(s), Lead Compound(s) in accordance with the terms of this Section 4.3, and shall notify the JDC of such designations. At any one time, FG may designate up to two (2) Lead Compounds for Commercialization in any Indication; provided, that in the event that FG designates two (2) Lead Compounds for Commercialization in an Indication, it shall designate one (1) as the primary Lead Compound and one (1) as the secondary Lead Compound. In the event FG determines to cease development of a primary Lead Compound in an Indication, FG may designate the secondary Lead Compound as the primary Lead Compound for such Indication. In the event, prior to Marketing Approval in the Astellas Territory, FG determines to stop development of a Lead Compound, FG shall notify the JDC, and upon such notification, such compound shall no longer be considered a Lead Compound; provided, however, that Astellas may complete those development activities on-going at the time of such notification for such Lead Compound for a reasonable period of time, unless such notification is based on safety concerns. In the event FG determines to [*], FG shall [*] within [*] days of such [*]. In the event that FG [*], Astellas may, subject to the [*], [*], provided, however, that the [*] shall apply upon the [*] set forth in such Sections, rather than the [*].

4.4 Regulatory Matters

4.4.1 Regulatory Filing. FG shall be responsible, directly or through third parties, for the preparation, filing and maintenance of all regulatory documents in the FG Territory with respect to the Lead Compound(s), which shall be filed in the name of FG or its designee. Astellas shall be responsible for all preparation, filing and maintenance of all regulatory documents in the Astellas Territory with respect to the Lead Compound(s), which shall be filed in the name of Astellas. Astellas shall select and own the trademark(s) to be used to identify any Lead Compound in the Astellas Territory.

4.4.2 Reporting Adverse Experiences

(a) With respect to adverse drug experiences relating to any Lead Compound, the parties shall promptly report such experiences to the appropriate regulatory authorities in the countries in which such Lead Compound is being developed or commercialized, in accordance with the appropriate laws and regulations of the relevant countries and authorities, and each party shall ensure that its Affiliates and Sublicensees comply with such reporting obligations. In addition, in order that each party may be fully informed of these experiences, each party shall report to the other party all “adverse events” involving such Lead Compound. “Serious adverse events” for all fatal and life-threatening adverse events shall be reported to the designated safety contact person of the other party by e-mail within five (5) calendar days of a party’s and/or its agent’s becoming aware of such an event (a “reporting party”), and all other serious adverse events shall be forwarded to the other party within seven (7) calendar days of the reporting party’s

and/or its agent's becoming aware of such an event. To the extent legally possible, FG and Astellas shall report to the other all serious adverse events with respect to a Lead Compound in the Field at least twenty-four (24) hours prior to reporting the same to a regulatory authority, and shall report adverse events which may constitute a dose limiting toxicity in a reasonably prompt time after the occurrence of such event. The reporting party shall report all non-serious adverse events on a monthly basis; provided that, non-serious adverse event data arising from a clinical trial will be included in the clinical trial report which shall be prepared and sent to the other party as soon as practicable following completion of the final clinical report.

(b) An "adverse event" is any negative symptom experienced at the time of or after the taking of a medicinal (investigational) product, whether or not considered a medicinal (investigational) product related, including any side effects, injury, toxicity or sensitivity reaction, or significant failure of expected pharmacological action. Also included are instances of symptomatic overdose, abuse or withdrawal reactions.

(c) A "serious adverse event" includes any of the following outcomes: death, a life-threatening event; that is, an adverse event that puts the patient at risk of dying, requires hospitalization, prolongs existing hospitalization or results in persistent or significant incapacity or disability, congenital anomaly/birth defect. Other important medical events that may otherwise jeopardize a patient or may require intervention to prevent one of the statuses of patients listed in the preceding sentence shall also be considered serious.

(d) The parties also agree to develop and implement such other procedures as may be necessary or appropriate to ensure that each party remains in compliance with all reporting requirements imposed by any regulatory authority in the Astellas Territory, and in the FG Territory. Upon the Initiation of Phase III, FG shall implement and be responsible for the maintenance of a complete global safety database. FG will be responsible for preparing, with Astellas' cooperation set forth below in this Section 4.4.2(d), Periodic Safety Reports for clinical studies requested by European and U.S. authorities, and Periodic Safety Update Reports (PSURs). FG shall send a draft PSUR for review to Astellas in the beginning of week 5 after database lock point. Astellas has one week for review. FG shall provide copies of the final PSURs to Astellas in the same timing as they are submitted to the authorities. Astellas will provide FG with the data needed for making the PSURs. Maintenance of Company Core Safety Information (CCSI) is under the responsibility of FG who will communicate all revisions to Astellas. FG shall prepare the periodic safety reports for clinical studies requested by European and U.S. authorities and provide Astellas with the copy of such reports at the time of submission to the regulatory authorities in the FG Territory. Astellas will provide FG with the data needed for making such periodic safety reports.

(e) Each party shall immediately inform the other party of measures taken in order not to jeopardize public health or hygiene including but not limited to, discontinuation of manufacture, import and marketing, clinical trial suspension, recall and disposal of the Lead Compound or the product or the prescription product, irrespective of whether it is due to regulatory actions or voluntary actions.

(f) Both parties hereby nominate the safety contact persons as follows:

Medical Affairs Department
FibroGen, Inc.
225 Gateway Boulevard
San Francisco, California 94080
Attn: Vice President, Medical Affairs
Tel: 1-650-866-7875
Fax: 1-650-866-7360
E-mail:dyeowell@fibrogen.com

With a copy to:
Chief Executive Officer
FibroGen, Inc.
225 Gateway Boulevard
San Francisco, California 94080
Tel: 1-650-866-7200
Fax: 1-650-866-7201
E-mail:tneff@fibrogen.com

Pharmacovigilance Department, QA, RA, and
Pharmacovigilance Division
Astellas Pharma Inc.
[*]

The safety contact persons for each party hereto may be updated from time to time as necessary upon notice to the other party.

ARTICLE 5
RECORDKEEPING; PUBLICATION

5.1 Reports and Records. Each of Astellas and FG shall use best efforts to maintain (or cause such records to be maintained) records of the Development Program and FG Development Program, respectively, in sufficient detail and in good scientific manner as will properly reflect all work done and results achieved in the performance of the Development Program or FG Development Program, as the case may be. Upon [*] days advance notice or such shorter time period as may be required in order to meet any regulatory requirements, each party shall allow the other party to have access to all records, materials and data generated by or on behalf of such party with respect to each Lead Compound for applications within the Field at reasonable times, in a reasonable manner and, upon request, to the extent required under Article 7 hereof.

5.1.1 Retention. Each of Astellas and FG shall retain its records for the minimum period of time required by applicable law in all cases, and for not less than [*] following the expiration or termination of this Agreement.

5.1.2 Reports. Not less than [*] prior to each JDC meeting under Section 2.3 above, each of Astellas and FG shall provide the JDC with a written report in English; Astellas' report summarizing the progress of the Development Program, including the developmental, clinical and other activities performed by Astellas, its Affiliates and/or Sublicensees with respect to each Lead Compound during the preceding period; and FG's report summarizing the progress of the FG Development Program.

5.1.3 Activities Outside the Field. The parties understand and acknowledge that FG is engaged in other research and development activities directed to prolyl hydroxylase inhibition and/or the stabilization of HIF, and that the focus of this collaboration and the Development Program is directed to the Field. Accordingly, it is understood that, notwithstanding any other provision of this Agreement, the obligations of FG specified herein to make available and disclose to Astellas data, technical information, scientific results and findings and other subject matter is limited in each case to subject matter directed to Lead Compounds within the Field.

5.2 Review of Publications. As soon as is practicable prior to the oral public disclosure, and prior to the submission to any outside person for publication of scientific data resulting from the Development Program, in each case to the extent the contents of the oral disclosure or publication have not been previously disclosed pursuant to this Section 5.2 before such proposed disclosure, FG or Astellas, as the case may be, shall provide to the other party a copy of the publication, or a written summary of any oral disclosure, to be made or submitted, and shall allow the other party at least [*], to determine whether such disclosure or publication contains subject matter for which patent protection should be sought prior to publication or which either party believes should be modified to avoid disclosure of Confidential Information or regulatory or other issues. With respect to publications by investigators or other third parties of scientific data resulting from the Development Program, such disclosures and publications shall also be subject to review by the reviewing party under this Section 5.2.

5.2.1 Publication Rights. Subject to the provisions of Articles 7 and 16, after the expiration of [*] from the date of receipt of such disclosure or publication, unless the authoring party has received the written notice specified below, the authoring party shall be free to submit such publication or to orally disclose or publish the disclosed research results in any manner consistent with academic standards.

5.2.2 Disapproval of Publication. Prior to the expiration of the [*] period specified in Section 5.2.1 above, the reviewing party may notify in writing the submitting party of its determination that such oral presentation or publication contains Confidential Information of the reviewing party or objectionable material or material that consists of patentable subject matter of the reviewing party for which patent protection should be sought. In such event, and unless otherwise mutually agreed, the submitting party shall withhold publication of its disclosure.

ARTICLE 6
DEVELOPMENT PROGRAM FUNDING

6.1 Payments for Reimbursement; Net Payments. FG hereby acknowledges receipt of U.S. $[*] on February 13, 2004, U.S. $[*] on January 28, 2005, and U.S. $[*] on March 22, 2005 as initial payments for reimbursement of historical research and development expenditures for the Lead Compounds. Astellas agrees to pay to FG the amounts set forth in Section 6.1.1 below. The parties hereto acknowledge that the Development Program hereunder involves a high degree of risk and uncertainty; accordingly, both parties hereto expressly disclaim any implied warranty as to the results of the Development Program.

6.1.1 Reimbursement Payments. As reimbursement and payment for FG's historical research and development expenditures with respect to pre-clinical and clinical development of Lead Compounds, Astellas agrees to make the following non-refundable, non-creditable (except as set forth in Section 14.3 below) reimbursement payments to FG upon the first occurrence of each event specified below (each, an "Event"):

	EVENT	AMOUNT
1.	Upon [*], provided, that U.S. $[*] million of such amount shall be paid no later than [*] irrespective of whether the [*] has occurred.	U.S. $[*]
2.	Upon each of [*], for a total of U.S. $[*]	U.S. $[*]
3.	Upon Initiation of the first Phase III clinical trial in the Astellas Territory or in the event that Astellas chooses to utilize the Bridging Strategy, the payment shall be made concurrent with the payment required in paragraph 4 of this Section 6.1.1 below.	U.S. $10,000,000
4.	Upon the first filing of a Marketing Approval Application in the Astellas Territory.	U.S. $15,000,000

6.1.2 Product Approval Payments. As reimbursement and payment for FG's historical and ongoing research and development expenditures with respect to pre-clinical and clinical development of Lead Compounds and as payment for the successful marketing and sales of Lead Compound(s), Astellas agrees to make the following non-refundable, non-creditable (except as set forth in Section 14.3 below) reimbursement payments to FG upon the first occurrence of each Event (other than paragraph 5 of this Section 6.1.2 below) specified below. Notwithstanding the foregoing, in the event that Astellas decides not to pursue Commercialization in [*] set forth in paragraph 3 or 4 of this Section 6.1.2, the milestone payment associated with the [*] set forth in paragraph 3 shall be due and payable upon the first [*] of either [*], and the milestone payment associated with the [*] set forth in paragraph 4 shall be due and payable upon the second [*] for a [*]; and in

the event Astellas decides to pursue only [*] set forth in paragraph 3 or 4 of this Section 6.1.2, and pursues Commercialization of either of the [*], the milestone payment for associated with the [*] for the [*] shall be due and payable upon the first [*] for a [*]; and in the event that Astellas decides to pursue [*] set forth in paragraphs 3 and 4 of this Section 6.1.2 and also does not pursue [*], the parties shall a [*] for which the milestone payments associated with the [*] set forth in paragraph(s) 3 and/or 4 of this Section 6.1.2, as the case may be, shall be due, as negotiated in good faith by the parties hereto.

	EVENT	**AMOUNT**
1.	Upon the first [*] for the [*]; provided, that in the event Astellas chooses the Bridging Strategy, such payment shall be increased by an additional U.S. $[*] for a total of U.S. $[*]	U.S. $[*]
2.	Upon the first Marketing Approval in the Astellas Territory for the "Treatment of anemia in patients with chronic kidney disease undergoing dialysis"**;** provided, that in the event Astellas chooses the Bridging Strategy, such payment shall be increased by an additional U.S. $[*] for a total of U.S. $[*].	U.S. $12,500,000
3.	Upon the first [*] in the Astellas Territory for the [*]; provided, that in the event Astellas chooses the Bridging Strategy, such payment shall be increased by an additional U.S. $[*] for a total of U.S. $[*].	U.S. $[*]
4.	Upon the first [*] in the Astellas Territory for the first indication within [*] (see Exhibit B); provided, that in the event Astellas chooses the Bridging Strategy, such payment shall be increased by an additional U.S. $[*] for a total of U.S. $[*].	U.S. $[*]
5.	Upon [*] in the Astellas Territory for each of up to [*] indications listed on Exhibit B, including separate indications within [*] up to a total of U.S. $[*].	U.S. $[*]

6.1.3 Sales Success Payments. As reimbursement and payment for FG's historical and ongoing research and development expenditures with respect to pre-clinical and clinical development of Lead Compounds and as payment for the successful marketing and sales of the Lead Compound(s), Astellas agrees to make the following non-refundable, non-creditable (except as set forth in Section 14.3 below) reimbursement payments to FG upon the first occurrence of the Event specified below.

EVENT	AMOUNT
Upon receipt of [*] aggregate annual Net Sales achieved for the first time in the Astellas Territory for all indications and Lead Compounds by Astellas and its Affiliates and Sublicensees.	U.S. [*]

If at the occurrence of an Event (except for Event 2) as set forth in Section 6.1.1 above with respect to a particular Lead Compound the payment corresponding to the occurrence of any preceding Event (except for Event 2) (*i.e.*, "previous" as contemplated by the Event number sequence specified above) has not been made, then the corresponding payment(s) for such preceding Event (except for Event 2) shall then be due.

The payments set forth in Sections 6.1.1, 6.1.2 and 6.1.3 hereof shall each be due and payable within [*] after occurrence of the corresponding Event. Astellas agrees to promptly notify FG in writing of its achievement of any Event under Sections 6.1.1, 6.1.2 and 6.1.3.

ARTICLE 7
USE OF PRECLINICAL AND CLINICAL DATA

7.1 Exchange. Subject to the provisions of this Article 7 and Article 16 below, the parties shall have access to the underlying preclinical and clinical data (including raw data thereof), analysis, reports, protocols and correspondence (collectively with such filings, "Data"), at reasonable times, upon fifteen (15) days advance notice or such shorter notice as may be required in order to meet any regulatory requirements and (upon request) in English, (it being understood and agreed that Astellas shall provide in English without cost to FG summaries of all final reports and all documents necessary to comply with regulatory and legal requirements, and shall provide all other documents in English with reasonable costs shared equally between the parties) of the other party in accordance with the following:

(a) FG shall have access to and the right to use for any purpose, any Data developed by or on behalf of Astellas or its Affiliates or Sublicensees in the course of the Development Program with respect to indications within the Field for Lead Compounds. Astellas shall obtain from such Sublicensees access to all Data prepared by or for such Sublicensee with respect to a Lead Compound, with the right to provide such Data and/or access to FG and its Sublicensees, and any sublicense failing to provide such obligation on the part of the Sublicensee shall be voidable at the option of FG.

(b) Astellas shall have access to and the right to use solely for the purpose of this Agreement, any Data developed by or on behalf of FG or its Affiliates or Sublicensees with respect to Lead Compounds in connection with the Field (i) to the extent necessary to support the application to the regulatory authority in the Astellas Territory or to fulfill other Japanese Ministry of Health, Labor and Welfare regulatory requirements, or (ii) if not necessary to support such application or to fulfill such Japanese Ministry of Health, Labor and Welfare regulatory requirements, to the extent FG is permitted subject to FG's third party

obligations; provided that FG shall [*] negotiate the availability of such Data to Astellas from such Sublicensee, and provided, further, that Astellas agrees not to use or disclose to third parties any such data for purposes outside the Field except as authorized under this Agreement.

7.2 Disclosure. Subject to the provisions of this Section 7.2, FG and Astellas may each provide copies or summaries of Data to its Affiliates and/or its permitted Sublicensees to the extent reasonably necessary for the development and commercialization of Lead Compounds in accordance with this Agreement, or in the case of FG of products other than Lead Compounds. It is understood that the foregoing shall include the right to disclose Data to third parties with whom Astellas or FG are discussing entering into agreements for such permitted purposes, subject to reasonable conditions of confidentiality, provided, that Astellas may not disclose any Data to any third party competitor of FG within the Field worldwide without the prior written consent of FG.

7.3 Regulatory Requirements. Notwithstanding the provisions of Section 7.2, in all agreements with third parties or Affiliates involving the development of Data, FG and Astellas, respectively, shall require that such third parties and Affiliates provide the other party with all such Data, to the extent such Data is required in order for each party to meet its obligations to the other party under Section 4.4.2 above.

7.4 Review of Protocols. Astellas agrees that all final protocol summaries for all clinical trials and GLP toxicology studies to be conducted by or under authority of Astellas will be subject to the review and approval of the JDC, in accordance with the following procedures set forth in this Section 7.4. Astellas shall submit to FG and the JDC the original draft protocol summary in English for any clinical trial or GLP toxicology study it proposes to conduct, and such protocol summary shall be reviewed and approved by the JDC. The protocol summary shall contain all information as may be requested by the JDC. Upon Astellas' completion of the final protocol for the proposed clinical trial or GLP toxicology study, in the event that such protocol deviates from the original protocol summary, Astellas shall resubmit to FG and the JDC for review and approval a revised, final protocol summary that indicates all changes from the original protocol summary. Notwithstanding the foregoing, FG reserves the right to request and Astellas shall provide any portion of full text of the protocols in English for review by the JDC, which portion is at issue. In the event FG requests such a full text protocol, it shall review and provide comments to the JDC as soon as practicable, and within five (5) business days of receipt.

ARTICLE 8
MARKETING RIGHTS

8.1 Astellas. Astellas shall have the exclusive right to market, sell and distribute the Lead Compounds supplied by FG for use in the Astellas Territory within the Field under the license granted in Article 13. Astellas may exercise its rights under this Section 8.1 through one or more Sublicensees; provided, that any such Sublicensee agrees to terms identical in all material respects to those contained in this Agreement, and, provided,

further, that any arrangement between Astellas and an Astellas Sublicensee with respect to a Lead Compound shall be subject to the requirements of Section 13.2.

8.2 FibroGen. FG shall have the exclusive right, including the right to authorize others, to market, sell and distribute the Lead Compounds for any use in the FG Territory. Subject to the restrictions contained in Section 8.3.4 hereof, FG retains the exclusive right, including the right to authorize others, to market, sell and distribute worldwide the Lead Compounds for use outside the Field.

8.3 Covenants

8.3.1 General. It is understood that, with respect to any particular Lead Compound, whether or not the use and sale of such Lead Compound by FG and/or Astellas in any country requires a license under intellectual property rights of the other, neither FG nor Astellas shall market, sell or distribute a Lead Compound anywhere in the world except in accordance with this Agreement, including this Article 8.

8.3.2 Independent Activities by Astellas. During the term of this Agreement, in the event Astellas seeks to Commercialize any molecules for the Field or the Expanded Field, except for actions taken within the Field in the course of the exercise of the license granted under Section 13.1 hereof and expressly authorized under this Agreement, Astellas shall notify FG immediately upon the commencement of any such activities, and provided that [*] such activities are and will be in the future conducted completely independently of any of FG Technology and/or any other FG materials, confidential information, intellectual property or other related information provided by or on behalf of FG to Astellas under this Agreement or any other agreement between FG and Astellas relating to the subject matter hereof, Astellas may proceed with such Commercialization, subject at all times to the obligations contained in this Agreement with respect to any intellectual property in connection with or related to such activities and FG's right to terminate this Agreement pursuant to Section 18.2.1 hereof.

8.3.3 Use of FG Technology by Astellas. Astellas shall use the FG Technology only to exercise the rights granted under Section 13.1 of this Agreement and as expressly authorized under the Development Program, and shall not under any circumstances use or apply any FG Technology, including without limitation any FG know-how and/or any other FG materials, confidential information, intellectual property or other related information provided by FG to Astellas under this Agreement or any other agreement between FG and Astellas relating to the subject matter hereof, for any use outside the Field at any time or within the Field after the expiration or termination of this Agreement.

8.3.4 Activities Outside Field by Astellas. Without limiting the foregoing, Astellas agrees that during the term of this Agreement it will not (and will not authorize any third party, including, without limitation, any Affiliates or Sublicensees, to) (i) Commercialize any Lead Compound within the Field in the Astellas Territory, except a Lead Compound that has been designated a Lead Compound by the JDC and that has received Marketing Approval in the Astellas Territory for use in the Field, (ii) Commercialize

any Lead Compound for use outside the Field or outside the Astellas Territory, (iii) provide any supplies of any Lead Compound to any third party, including, without limitation, any Affiliates or Sublicensees, which Astellas knows or has reason to know is being marketed, sold or distributed for use outside the Field or outside the Astellas Territory, (iv) conduct or sponsor, or provide any supplies of any Lead Compound for use in, any clinical trial designed to demonstrate that a Lead Compound can be used outside the Field, or (v) seek regulatory approval of, or use labeling for a Lead Compound stating that such Lead Compound is for use outside the Field.

8.3.5 Activities in Astellas Territory by FG

During the term of this Agreement, FG shall not Commercialize by itself or through its Sublicensee any Lead Compound or other compound, whether or not designated as a Lead Compound, within the Field in the Astellas Territory, or any Lead Compound outside the Field in the Astellas Territory, provided, however, that FG may develop a Lead Compound or other compound in the Astellas Territory in those Indications for which Astellas has determined not to pursue Commercialization or for which Astellas has lost the right to pursue Commercialization due to failure to meet diligence obligations hereunder; and provided, further, that FG may Commercialize compounds other than Lead Compounds outside the Field in the Astellas Territory, irrespective of whether such compound has the effect of stabilizing HIF causing the stimulation of erythropoiesis (including an increase in endogenous erythropoietin production) and/or a subsequent increase in hematocrit through modulation of prolyl hydroxylase and/or asparaginyl hydroxylase.

ARTICLE 9
TRANSFER PRICING

9.1 Transfer for Non-Commercial Purpose. In exchange for the transfer of any Lead Compound to Astellas for a non-commercial purpose, Astellas shall pay FG the total amount of the Fully Burdened Costs for such Lead Compound as reasonably determined by FG. Lead Compound transferred to Astellas for a non-commercial purpose shall not be used for a commercial purpose.

9.2 Transfer for Commercial Purpose. For any Lead Compound transferred to Astellas to be used for any commercial purpose, in exchange for the transfer of such Lead Compound to Astellas, Astellas shall pay FG the amounts set forth in this Section 9.2. All transfers of Lead Compound for use following Marketing Approval shall be deemed transfers for a commercial purpose, except transfers under Section 9.2(c), and transfers for the purpose of conducting clinical trials, which shall be considered transfers for a non-commercial purpose.

(a) For any quantities of Lead Compound shipped by FG to Astellas prior to the issuance of the national health insurance price as determined by the Japanese Ministry of Health, Labour and Welfare (the “Listed Price”), Astellas shall pay for such quantities at a price equal to [*] of the estimate of the Listed Price as determined in good faith by FG and Astellas, subject to adjustment upon the issuance of the actual Listed Price. Upon the issuance of such Listed Price by the Japanese Ministry of Health, Labour and Welfare, Astellas shall pay to

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

FG, or FG shall reimburse Astellas, as the case may be, the amount of any difference between the payment made for such Lead Compound at the estimated Listed Price and the payment required based upon the actual Listed Price.

(b) For all other transfers of Lead Compound, except as set forth in subparagraphs (c) or (d) below, Astellas shall pay for such quantities at a price equal to [*] of the Listed Price. In the event that a new Listed Price has been notified to Astellas by the Japanese Ministry of Health, Labour and Welfare before implementation of the new Listed Price, then such new Listed Price shall be used for calculation of the price of Lead Compound to be shipped on and after the later to occur of (i) [*] before implementation of the new Listed Price, and (ii) the date upon which Astellas has amended the price of Lead Compound to wholesalers in response to such notification by the Japanese Ministry of Health, Labour and Welfare, even before implementation of the new Listed Price.

(c) With respect to Lead Compound to be distributed as samples to medical providers and for which Astellas shall not receive any payment or other consideration, Astellas shall pay to FG the sum of its Fully Burdened Costs for amounts of Lead Compound shipped to Astellas; provided, however, that the parties shall mutually agree upon the amount of such samples for distribution without consideration in the Astellas Territory.

(d) Upon the later of (i) the initial retail sale of a generic equivalent (as defined by the Japanese Ministry of Health, Labour and Welfare) of such Lead Compound in the Territory, and (ii) and the expiration of the last to expire of the FG Patents with respect to such Lead Compound effectively precluding third parties from selling said generic equivalent, for any quantities shipped by FG to Astellas, Astellas shall pay FG for such quantities [*] of the Sales Price; provided, however, that in the event that the payment of the [*] of the Sales Price would result in FG's [*] Percentage falling below [*], FG shall have the option to initiate a renegotiation of the transfer price upon notice to Astellas, in which case the parties shall use best efforts in good faith to renegotiate reasonable terms for the transfer price; provided, further, that in the event the transfer price is not renegotiated to FG's satisfaction or FG elects not to initiate a renegotiation, FG may elect to terminate its manufacturing obligations by written notice to Astellas, and FG and Astellas shall negotiate reasonable terms for transfer of manufacturing. During such period of renegotiation, FG shall transfer the Lead Compound to Astellas at a price equal to the greater of [*] of the Sales Price and the price resulting if FG's [*] Percentage for such Lead Compound is equal to [*].

9.3 Payment. Any payments to be made with respect to the transfer of any Lead Compound in accordance with Section 9.1 or 9.2 above shall be immediately due to FG upon shipment, which shall be paid by Astellas to FG no later than [*] of the date of invoice, which invoice FG shall deliver to Astellas upon Delivery of Lead Compound to Astellas pursuant to Section 9.2(a), (b) or (c), and shall be made in U.S. dollars. For transfer of any Lead Compound in accordance with Section 9.1 or 9.2(c) above, FG shall deliver to Astellas, within ten (10) days of receipt of a firm commitment order from Astellas, an invoice for the estimated Fully Burdened Costs of the Lead Compound to be transferred to Astellas. Within [*] after the transfer of the Lead Compound to Astellas, FG shall provide a revised final invoice to Astellas that shall indicate the actual Fully Burdened Costs of the

Lead Compound. If the actual Fully Burdened Costs are less than the estimated Fully Burdened Costs, FG shall include a reimbursement payment to Astellas for the difference between the initial estimated Fully Burdened Costs and the actual Fully Burdened Costs. If the actual Fully Burdened Costs are greater than the estimated Fully Burdened Costs, Astellas shall pay such difference within [*] of receipt of an invoice from FG for such amounts. For payments for the transfer of Lead Compound under Section 9.2(d) hereof, FG's invoice to Astellas shall be calculated based on the current Listed Price as set by the Japanese Ministry of Health, Labour and Welfare. Upon calculation of the Sales Price, Astellas shall submit, for any amounts actually sold, the Sales Price to FG, and FG shall credit Astellas for the difference between the invoice cost, cost calculated based on the Listed Price and the cost calculated based on the Sales Price.

9.4 Reference Materials; Standard Materials. In exchange for the transfer by FG of any Reference Materials or Standard Materials for the purposes of conducting analytical, release, stability and other studies authorized under the Development Program, Astellas shall pay to FG, FG's Fully Burdened Costs of such materials as reasonably determined by FG.

ARTICLE 10
ADDITIONAL PAYMENTS; BOOKS AND RECORDS

10.1 Quarterly Reports. Astellas shall make quarterly reports to FG within sixty (60) days after the end of each calendar quarter (April 1 though June 30, July 1 through September 30, October 1 though December 31, January 1 through March 31), which reports shall include, (a) the Net Sales, unit shipments and other distributions, including samples, by Astellas, and its Affiliates and Sublicensees, in such calendar quarter and (b) such other information as may be reasonably requested by FG to ensure either proper payment by Astellas of amounts required under this Agreement or to calculate payments with respect to FG's Third Party Agreements. Concurrently with making such report, Astellas shall remit payment to FG for any payments due under this Agreement.

10.2 Payment Method. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the payee. All such payments made by or on behalf of Astellas hereunder shall be made by a Japanese entity. All dollar amounts specified in this Agreement, and, except as specifically authorized under Section 10.3 hereof, all payments made hereunder, are and shall be made in U.S. dollars. Any payments due under this Agreement which are not paid by the date such payments are due under this Agreement shall bear interest to the extent permitted by applicable law at the U.S. prime rate per annum quoted in the "Money Rates" column of The Wall Street Journal (U.S., Western Edition) on the first business day after such payment is due, plus an additional [*], calculated on the number of days such payment is delinquent. This Section 10.2 shall in no way limit any other remedies available to either party.

10.3 Currency Conversion. In the event that the amount of an Astellas payment obligation in U.S. dollars must be determined by the calculation of an underlying amount received by Astellas in Japanese Yen utilizing the U.S. dollar-Japanese Yen exchange rate (i.e., a transfer payment under Section 9.2(a), (b) or (d) hereof), currency conversion from Japanese Yen to U.S. dollars shall be made using the closing exchange rate reported in the Wall Street Journal (U.S. Western Edition) for the date on which the Lead Compound is Delivered to Astellas. If any such payment is not made by the due date, the exchange rate utilized for determination of such payment obligation shall be the exchange rate [*] reported in the Wall Street Journal (U.S. Western Edition) during the period from the date of invoice through the due date, not including any additional amounts owed under Section 10.2 hereof.

10.4 Taxes

10.4.1 Generally. Each party shall bear and, except as otherwise expressly provided in this Section 10.4, pay any and all taxes, duties, levies, and other similar charges (and any related interest and penalties), however designated, imposed on that party as a result of the existence or operation of this Agreement. If laws or regulations require that taxes be withheld, the paying party will (i) timely pay the taxes to the proper taxing authority, and (ii) send proof of payment to the other party within [*] following that payment.

10.4.2 Certain Payments. Notwithstanding Section 10.4.1, all payments by Astellas required under this Agreement above, including under Section 6.1.1 are expressed as net amounts and shall be made free and clear of, and without reduction for, any withholding taxes, provided, however, that in the event that any withholding taxes are due on the payments Astellas shall make to FG under Sections 6.1.2 and 6.1.3, Astellas shall make such payments directly to the Japanese Tax Authority and shall be entitled to reduce the amount paid to FG by [*] of the amount of the withholding taxes paid to Japanese Tax Authority in respect of such payment, unless the amount of such withholding taxes is reduced by a decision of the Japanese tax authority, or is subsequently adjusted downward as result of appeal, in which event the next payment due hereunder, including, without limitation, a transfer payment or a payment upon termination, shall be increased by such amount. Any such taxes which are otherwise imposed on payments to FG shall be the sole responsibility of Astellas. Astellas shall provide FG with official receipts issued by the appropriate taxing authority or such other evidence as is reasonably requested by FG to establish that such taxes have been paid. Astellas and FG shall cooperate to minimize the withholding taxes due on the amounts payable by Astellas to FG hereunder to the extent permissible under law, including, but not limited to, making appropriate application(s) to the tax authorities within the Astellas Territory. If possible, FG shall use its reasonable efforts to apply for the tax refund from U.S. tax authorities for the withholding taxes paid to the Japanese Tax Authority on the payment U.S. $[*] payment made by Astellas to FG on January 13, 2004 as set forth in Section 6.1 when such application for the tax refund becomes possible, and if FG has received any such tax refund, FG shall reimburse to Astellas for the amounts corresponding to the withholding taxes paid in Astellas' accounts as set forth above.

10.5 Records; Inspections. Astellas shall keep, and require its Affiliates and Sublicensees to keep, complete, true and accurate books of accounts and records for the purpose of determining payments due pursuant to this Agreement. Such books and records shall be kept for at least [*] following the end of the calendar quarter to which they pertain. FG shall keep, and require its Sublicensee(s) to keep, complete, true and accurate books of accounts and records for the purpose of verifying the accuracy of the [*] Percentage and Fully Burdened Costs. Such records will be open for inspection at the principal place of business of each party (the "Inspected Party") during such [*] period by an independent auditor chosen by the other party (the "Inspecting Party") and reasonably acceptable to the Inspected Party for the purpose of verifying the amounts payable by Astellas to FG hereunder or the accuracy of the [*] Percentage and/or Fully Burdened Costs. Such inspections may be made no more than once each calendar year, at reasonable times and on reasonable notice. Any books of accounts or records shall not be inspected more than once. The independent auditor retained by the Inspecting Party shall be obligated to execute a reasonable confidentiality agreement with the Inspected Party prior to commencing any such inspection, which, among other customary clauses, contains the provisions to the effect that such auditor shall not disclose to the Inspecting Party any information other than as necessary to accomplish the purpose of the inspection. Inspections conducted under this Section 10.5 shall be at the expense of the Inspecting Party. Any underpaid or overcharged amounts that are discovered will be paid by the Inspected Party, and with interest on such underpaid or overcharged amounts at the rate set forth in Section 10.2 above. The parties will endeavor to minimize disruption of the Inspected Party's normal business activities to the extent reasonably practicable.

ARTICLE 11
DUE DILIGENCE

11.1 Astellas' Due Diligence. Astellas shall use its commercially reasonable efforts (i) to conduct any development work undertaken under the Development Program, and any and all clinical trials (including without limitation Phase III) required to obtain, and thereafter to take such other actions as are necessary to obtain, Marketing Approvals for any Lead Compound in the Astellas Territory as soon as practicable, and (ii) to launch each such Lead Compound in the Astellas Territory as soon as practicable after receiving Marketing Approval in the Astellas Territory for such Lead Compound.

11.2 FG's Due Diligence. FG shall use its commercially reasonable efforts to conduct, and to the extent possible taking into account safety and other applicable issues, complete a Phase II clinical trial with FG-2216 or another Lead Compound in the FG Territory.

11.3 Development Diligence

11.3.1 Astellas shall pursue development of Indications according to the following terms: (i) Astellas shall pursue Commercialization in "Treatment of anemia in patients with chronic kidney disease undergoing dialysis" and "Treatment of anemia in

patients with chronic kidney disease not undergoing dialysis"; (ii) Astellas shall notify FG within six (6) months of the execution of this Agreement whether it shall pursue Commercialization in [*]; (iii) Astellas shall notify FG within six (6) months of the date FG notifies Astellas that it has demonstrated Proof of Concept whether it will pursue Commercialization in [*]; (iv) Astellas shall notify FG within six (6) months of the date FG notifies Astellas that it has demonstrated Proof of Concept whether it will pursue Commercialization in [*]; and (v) Astellas shall notify FG, upon Marketing Approval for any Lead Compound in each of the following Indications, whether it will pursue Commercialization of such Indication: [*], and any other indications to be added hereafter to the definition of the Indication by mutual agreement; and (vi) if FG is pursuing Commercialization of [*], Astellas shall notify FG after Marketing Approval whether it shall pursue Commercialization of such Indication. Should Astellas inform FG that it does not wish to pursue Commercialization of any Indication, or should Astellas fail to meet the due diligence obligations under Section 11.3.2 for any Indication as set forth in Section 11.3.1(iv) or under Section 11.3.3 for any Indication as set forth in Section 11.3.1(v), such Indication shall no longer be considered an Indication for the purposes of this Agreement, and Astellas shall have no right or shall lose any right with respect to such Indication under this Agreement including, without limitation, the licenses granted under Sections 8.1 and 13.1 hereof. Each Indication for which Astellas is obligated to pursue Commercialization under Section 11.3.1(i) or for which it decides to pursue Commercialization under Sections 11.3.1(ii), (iii) or (iv) shall be a "Major Indication".

11.3.2 In addition to the obligations set forth in Section 11.1 and 11.3, for each Major Indication, until such time as Astellas obtains Marketing Approval in the Astellas Territory for such Major Indication, with respect to each Lead Compound for each Major Indication, Astellas shall:

(a) If required for development of a Lead Compound in an Indication, Initiate Phase I clinical trials within [*] after the later of (i) the Effective Date, for Indications for which FG has commenced clinical trials prior to the execution of this Agreement, and (ii) FG's or its Sublicensees Initiation of a Phase I clinical trial for other such Indications.

(b) Initiate Phase II clinical trials within the later of (i) [*] after FG's, or its Sublicensee's, Initiation of Phase II, (ii) [*] after Astellas' Completion of its Phase I clinical trial(s), (iii) if Astellas' obligations under this Subsection 11.3.2(b) are triggered upon FG's notification of demonstration of Proof of Concept in an Indication, [*] after the date Astellas notifies FG that it will pursue Commercialization in such Indication, and (iv) in the event Astellas' obligations under this Section 11.3.2(b) are triggered by the designation of a secondary Lead Compound as a primary Lead Compound, [*] after such designation.

(c) Either notify FG of its intent to employ the Bridging Strategy, if applicable, or Initiate Phase III clinical trials within [*] of the later of (i) FG's, or its Sublicensee's Initiation of a Phase III clinical trial and (ii) Astellas' Completion of its Phase II clinical trial(s).

11.3.3 For each of the Indications set forth in Section 11.3.1(v), Astellas shall Initiate Phase II clinical studies within [*] of its notification to FG that it will pursue Commercialization in such Indication.

11.3.4 Astellas' diligence obligations set forth in Section 11.3.2 shall apply to all Lead Compounds designated by FG, provided, that for each Indication for which such diligence obligations apply, the diligence obligations shall only apply to the primary Lead Compound designated by FG, and for the secondary Lead Compound, Astellas' diligence obligations shall be limited to those set forth in Section 11.3.2(a) until the designation of the secondary Lead Compound as the primary Lead Compound, provided, further, upon such designation, that such diligence obligation shall be expanded to include the requirement that Astellas complete the Phase I clinical studies required to Initiate Phase II clinical studies in the Indication with such secondary Lead Compound.

ARTICLE 12
MANUFACTURING RIGHTS

12.1 Procedures. FG shall have the exclusive right to determine the methods and procedures for the manufacture of all Lead Compounds. If FG intends to make any change in the methods or procedures, including, without limitation, manufacturing process, analyzing process and/or site change for manufacture of the Lead Compounds, FG shall notify Astellas in writing of such intended change; provided, that if in Astellas' reasonable opinion, such change may lead to any amendment to the relevant Marketing Approval or Marketing Approval Application, Astellas shall use best efforts to (i) as soon as possible petition the Japanese Ministry of Health, Labor and Welfare to make the change without an amendment to the Marketing Approval or MAA and shall concurrently prepare an application for amendment to the Marketing Approval or MAA, and (ii) if the Japanese Ministry of Health, Labor and Welfare determines such an amendment is required, shall notify FG and submit the application for amendment immediately following notice of such requirement, and FG shall not make the intended change without a prior written consent from Astellas, such consent not to be unreasonably withheld or delayed, provided, further, that consent shall be deemed granted upon notice that an amendment is not required or approval of an amendment from the Japanese Ministry of Health, Labor and Welfare. FG shall provide Astellas with all the data and information necessary for Astellas to amend the Marketing Approval or MAA in Astellas Territory and shall continue to supply Astellas with the Lead Compound as manufactured with the manufacturing methods and procedures or at the manufacturing site described in Astellas' (or its Affiliate's or Sublicensee's) then current Marketing Approval or MAA until Astellas will have finished the necessary amendment to the relevant Marketing Approval or MAA or received notice that an amendment is not required.

12.2 FG Right. FG shall have the worldwide exclusive right (itself or through third party vendors) to manufacture (or have manufactured) Lead Compounds. Astellas and its Affiliates and Sublicensees shall not directly or indirectly make, produce or manufacture any Lead Compounds.

12.3 Manufacture and Supply. FG shall have the exclusive right and obligation to supply the Lead Compounds to Astellas and its Affiliates and Sublicensees for all development and commercial purposes, and Astellas and its Affiliates and Sublicensees shall purchase such Lead Compounds exclusively from FG. It is understood that FG may engage subcontractors with respect to the manufacture of such Lead Compounds to fulfill its supply obligations to Astellas hereunder. In all cases, supply by FG of Lead Compounds hereunder shall be Ex Works (Incoterms 2000) the manufacturing facility. Subject to Section 8.3.5 hereof, nothing herein is intended to preclude FG from granting rights to supply or supplying (a) any Lead Compound outside of the Astellas Territory to any third party for use within or outside the Field, or (b) any compound Controlled by FG within the Astellas Territory except for a Lead Compound for the duration of its designation in compliance with the terms and conditions of this Agreement.

12.4 Product Specifications. The Lead Compounds to be supplied by FG hereunder shall meet the Product Specifications. In addition to, but not in limitation of, the foregoing, FG and Astellas agree that upon Marketing Approval for any Lead Compound, FG's obligation to supply Astellas with Lead Compound shall be limited to, and all payment obligations set forth in Section 9.2 shall be based on, the supply of Bulk Product, unless otherwise agreed by the parties. The packaging for the Lead Compound to be distributed commercially by Astellas shall contain a clearly visible acknowledgment that the Lead Compound was manufactured by FG, and shall contain a registered trademark of the FG logo or other trademark approved by FG.

12.5 Orders Forecast

12.5.1 Orders for Non-Commercial Use. In connection with the supply of any Lead Compound for non-commercial use in the Territory, Astellas shall provide FG with a firm purchase order as early as possible prior to its requirements, and in no event less than [*] prior to the shipment or other release date(s) requested by Astellas for such Lead Compound. FG shall provide such Lead Compound to Astellas as soon as practicable within such time period, subject, prior to Marketing Approval, to the reasonable lead time requirements of third party contract manufacturers. All forecasts shall be prepared in good faith in order to facilitate FG's manufacture and shipment of the Lead Compound in compliance with this Agreement.

12.5.2 Forecast and Order for Commercial Use. In connection with the supply of any Lead Compound for commercial use in the Astellas Territory upon FG's request, Astellas and FG shall negotiate in good faith appropriate forecasting and firm purchase order lead times, taking into consideration the reasonable notice requirements of FG and its third party manufacturers. All forecasts shall be prepared in good faith in order to facilitate FG's manufacture and shipment of the Lead Compound in compliance with this Agreement.

12.6 Shipment. Astellas, or FG at Astellas' request if specified in a purchase order by Astellas, shall arrange for shipment of the Lead Compound as specified in each purchase order by Astellas, Ex Works (Incoterms 2000) the manufacturing facility. For

purposes of this Agreement, and notwithstanding anything to the contrary contained within the term “Ex Works”, it is hereby acknowledged and agreed that title and risk of loss shall transfer to Astellas from receipt by Astellas at the manufacturing facility. Astellas shall bear the costs of such carrier, including the costs of insurance of the shipment, and all customs, duties, sales taxes and other governmental charges related to the importation and sales of the Lead Compound.

12.7 Inspection of Shipment/Right to Reject. Each shipment of Lead Compound from FG to Astellas shall contain such laboratory and quality control certificate as are necessary to show that the Lead Compound is in conformity with the Product Specifications. Astellas shall promptly inspect each shipment. In the event that any portion of the shipment fails to conform to the Product Specifications, Astellas shall notify FG within [*] of Astellas’ receipt of such shipment. Such notice shall specify the manner in which the Lead Compound fails to meet the Product Specifications. In the absence of such notification, Astellas shall be deemed to have accepted the shipment. FG and Astellas agree to consult with each other to resolve any discrepancy between each other’s determinations regarding any possible nonconformity of the Lead Compound. If such consultation does not resolve the discrepancy, the parties agree to nominate a reputable independent laboratory or other independent third party, in each case acceptable to both parties, to carry out tests on representative samples taken from such shipment, and the results of such tests shall be binding on both parties. If the results of such tests demonstrate that the Lead Compound does not meet the Product Specifications, then FG shall pay the costs of such tests; otherwise, Astellas shall pay for the costs of such tests. FG shall, at its expense, promptly replace any Lead Compound to the extent that, in accordance with this Section 12.7, it is determined that it does not conform to the Product Specifications. Unless otherwise instructed by FG, all non-conforming Lead Compound shall be returned to FG at the place of manufacture at FG’s direction and at FG’s expense. If Astellas detects at any time any defect in the Lead Compound which has not been found through Astellas’ inspection, it shall notify FG to that effect within [*] of the discovery of such defect, and the procedures set forth above in this Section 12.7 shall be applied to such defective Lead Compound, provided, that FG shall only be responsible to pay for costs of defects that are the result of FG’s gross negligence or willful misconduct.

12.8 Inspection of Facilities. Astellas shall have the right, upon reasonable advance notice and during regular business hours, to inspect and audit, either by itself or through its Affiliates or consultants, the facilities (including any facilities of sub-contractors) being used by FG for production of the Lead Compound to assure compliance with applicable laws, rules and regulations, including, without limitation, Japanese regulatory standards and FG quality control procedures ("Relevant Standards"). FG shall also reasonably comply with inspection requests of the Japanese Ministry of Health, Labor & Welfare. Such inspection and audit shall be conducted at Astellas’ sole cost and expense in a manner so as to minimize disruption of FG's, or its subcontractor’s or Sublicensee’s, business operations. FG shall, within [*] after FG's receipt of written notice from Astellas detailing any deficiencies which may be noted in any such audit which relate to the Relevant Standards use good faith efforts to remedy such deficiencies, and submit a plan to the Astellas outlining steps proposed to be taken.

12.9 Recall. In the event that Astellas deems it necessary to recall any Lead Compound from the market, it may do so in its sole discretion, after notification to the FG. The costs and expenses for such recall shall be borne by Astellas unless caused by a failure for which FG is required to indemnify Astellas pursuant to Section 17.3, or by FG's gross negligence or willful misconduct, in which event it shall be borne by FG.

12.10 Warranty. FG represents and warrants that the Lead Compounds to be supplied to Astellas under this Agreement shall conform to the Product Specifications and shall, as appropriate, be manufactured in compliance with GMP Guidelines. Subject to Sections 12.9 and 17.3 hereof, FG's sole obligation and Astellas' sole remedy with respect to Lead Compound which does not meet the warranty contained herein is limited to replacement of such Lead Compound and reimbursement of Astellas' out of pocket expenses for shipping to FG at the address designated by FG.

12.11 Interruption in Supply. For any particular Lead Compound, in order to minimize any interruptions in supply hereunder, FG and Astellas agree that within [*], FG shall maintain two separate, validated manufacturing sites (which may either be its own manufacturing facilities or facilities of a contract manufacturer) for such Lead Compound.

12.12 Reference and Standard Materials. For any Lead Compound provided to Astellas hereunder, upon Astellas' request and pursuant to Section 9.4 hereof, FG shall provide to Astellas reasonable quantities of reference materials, including analogs, metabolites, impurities, degradates and radio-labeled compounds ("Reference Materials") and standard materials, i.e. defined, highly purified Lead Compound ("Standard Materials") for such Lead Compound for the purposes of conducting analytical, release, stability and other studies as may be authorized by the JDC under the Development Program.

ARTICLE 13
LICENSE GRANTS

13.1 Grant to Astellas. Subject to the terms and conditions of this Agreement including Article 12 above, FG hereby grants to Astellas an exclusive license under the FG Technology to: use, package, sell, have sold, import, market and otherwise distribute the Lead Compounds for use solely in the Field in the Astellas Territory

13.2 Sublicenses. The licenses granted under Section 13.1 above include the right to grant and authorize sublicenses, subject to the requirements of this Agreement and Section 7.2. Notwithstanding the foregoing, Astellas shall not have the right to authorize a Sublicensee to market, sell or distribute Lead Compounds without FG's prior written consent (which consent shall not be unreasonably withheld). For the purposes of the foregoing, and without limitation, it shall be deemed reasonable for FG to withhold consent for competitive concerns.

13.3 No Rights Beyond Lead Compounds. Except as expressly provided herein, nothing in this Agreement shall be deemed to grant to Astellas rights in FG Technology

other than the rights granted hereunder to the Lead Compounds, or for applications outside the Field or outside the Astellas Territory, or to manufacture Lead Compounds; nor shall any provision of this Agreement be deemed to restrict FG's right to exploit any FG Technology and/or the Lead Compounds outside the Astellas Territory.

13.4 Expanded Field Negotiation. Following the signing of this Agreement, FG agrees to negotiate in good faith with Astellas for a license to develop compounds for the Expanded Field in the Astellas Territory, exclusively for a period of [*] following such date, and non-exclusively thereafter until the execution of a license agreement with a third party to develop compounds for the Expanded Field. FG and Astellas hereby agree that FG's obligation to negotiate non-exclusively for the Expanded Field shall not constitute a right of first offer, right of first refusal, right of first negotiation or any obligation to enter into any agreement with Astellas at any time, and the failure of such negotiations to result in an agreement between FG and Astellas with respect to the Expanded Field shall not constitute a breach of this Agreement.

ARTICLE 14
INTELLECTUAL PROPERTY

14.1 Ownership of Inventions. Subject to Section 14.1.1, title to all inventions and other intellectual property made related to (i) the Development Program, (ii) the Lead Compounds, (iii) FG Technology or FG Confidential Information, (iv) the Field, or (v) the Expanded Field (subsections 14.1(i)-(v), collectively, the "Protected Field") shall be owned by or is hereby assigned to FG; provided, however that Astellas shall own inventions of general applicability relating solely to drug delivery systems created exclusively by Astellas under subsection 14.1(i), excluding inventions related to or based on subsections 14.1(ii), (iii), (iv), or (v), and provided, further, that Astellas hereby grants to FG a worldwide, fully paid non-exclusive license with the right to sublicense to practice such inventions with respect to the FG Technology. Astellas agrees to execute any and all assignments and other documents necessary to effectuate the foregoing.

14.1.1 Notwithstanding Section 14.1, in the event that Astellas develops, completely independently from any FG Technology and/or any other FG materials, confidential information, intellectual property or other related information provided by or on behalf of FG to Astellas under this Agreement or any other agreement between FG and Astellas relating to the subject matter hereof, any inventions or intellectual property rights related to the Field or the Expanded Field, [*], Astellas shall own such intellectual property and hereby grants to FG and its Sublicensees a non-exclusive, royalty-free, irrevocable license to such intellectual property for the FG Territory. Astellas agrees to execute any and all assignments and other documents necessary to effectuate the foregoing.

14.2 Patent Prosecution

14.2.1 FG Inventions. FG shall control all Prosecution and Interference Activities pertaining to FG Patents and patent applications and patents related

to its, its Affiliate's or its Sublicensee's inventions in the Protected Field worldwide using counsel of its choice and shall bear the costs of such Prosecution and Interference Activities, provided, however, that; and Astellas shall reimburse to FG, within [*] of receipt by Astellas of invoice therefor, any such costs to the extent incurred in connection with or reasonably allocable to the FG Patents registered and/or to be registered in the Astellas Territory and related to the Field and the Lead Compounds, provided, further, that, with respect to patents or patent applications excluding those covering composition of matter claims and all patents listed on Exhibit A hereto as of the Effective Date, Astellas may postpone such reimbursement until the respective FG Patent will have been registered in the Astellas Territory if [*], on condition that once the respective FG Patent has been registered in the Astellas Territory, Astellas shall pay to FG such costs, plus interest to the extent permitted by applicable law at the U.S. prime rate per annum quoted in the "Money Rates" column of The Wall Street Journal (U.S., Western Edition), calculated in each case from the date such costs were incurred, plus an additional [*] thereof.

14.2.2 Astellas Inventions. Astellas shall not file for or otherwise seek to obtain (directly or indirectly) patent or other intellectual property protection for inventions that are related to the Protected Field, without the prior written consent of FG, which may be withheld at FG's sole discretion, subject to Section 14.1.1, and provided also that Astellas may file for or otherwise seek to obtain patent protection for inventions related to drug delivery systems as described in Section 14.1. To the extent that FG consents to the filing of any patent application or other intellectual property protection related to the foregoing, such patent application or other intellectual property protection shall be subject to Section 14.1, unless otherwise agreed in writing.

14.2.3 Cooperation. Astellas shall cooperate with and assist FG in connection with Prosecution and Interference Activities and shall use best efforts to consult with FG regarding the prosecution and maintenance of the FG Patents for the FG Territory and the Astellas Territory for those FG Patents for which Astellas or its Affiliates, Sublicensees or investigators are inventors, except solely for inventions (i) of general applicability relating solely to drug delivery systems created by Astellas under subsection 14.1(i), or (ii) created in compliance with Section 14.1.1 as determined solely by FG in good faith.

14.3 Defense of Third Party Infringement Claims. If the development, manufacture, sale or use of any Lead Compound pursuant to this Agreement results in a claim, suit or proceeding (collectively, "Actions") alleging patent infringement against FG or Astellas (or their respective Affiliates or Sublicensees), such party shall promptly notify the other party hereto in writing. The party subject to such Action (for purposes of this Section 14.3, the "Controlling Party") shall have the exclusive right to defend and control the defense of any such Action using counsel of its own choice; provided, however, that if such Action is directed to the subject matter of a patent of the other party (*i.e.*, for Astellas, a FG Patent), such other party may participate in the defense and/or settlement thereof at its own expense with counsel of its choice. Except as agreed in writing by Astellas and FG, Astellas shall not enter into any settlement relating to a Lead Compound, if such settlement admits the invalidity or unenforceability, or limits any claim, of any patent within the FG

Technology. The Controlling Party agrees to keep the other party hereto reasonably informed of all material developments in connection with any such Action. Any cost, liability or expense associated with such action (including amounts paid in settlement) (together, "Expenses") shall be borne by the Controlling Party; provided, that if Astellas is the Controlling Party, and the Action is related to Future Third Party Intellectual Property, with respect to Expenses related solely to such Future Third Party Intellectual Property, it shall be entitled to deduct up to [*] of the Expenses incurred on an annual basis from [*] in such year under this Agreement, provided, however, that (i) the total amount deducted shall not exceed [*] thereunder, and (ii) notwithstanding (i) above, Astellas' right to deduct Expenses incurred shall be further limited such that in no event shall the sum of (a) the Expenses deducted by Astellas under this Section 14.3, and (b) the consideration FG contributes for the acquisition of intellectual property from Third Party Licensors for the Astellas Territory as set forth in Section 14.5, exceed [*] hereunder, and, provided further, that if FG is the Controlling Party, it shall be entitled to reimbursement by Astellas of [*] of such Expenses, as incurred. Notwithstanding the foregoing, Astellas shall be solely responsible (without right of deduction) for all Expenses related to any Action relating to Preexisting Third Party Intellectual Property.

14.4 Enforcement. Subject to the provisions of this Section 14.4, in the event that FG or Astellas reasonably believes that any FG Technology necessary for the development, manufacture, use or sale of a Lead Compound is infringed or misappropriated by a third party or is subject to a declaratory judgment action arising from such infringement, in each case with respect to the development, manufacture, sale or use of a product within the Field and within the Astellas Territory, Astellas or FG (respectively) shall promptly notify the other party hereto. Promptly after such notice the parties shall meet to discuss the course of action to be taken with respect to an Enforcement Action (as defined below) with respect to such infringement or misappropriation, including the control thereof and sharing of costs and expenses related thereto, for the purposes of entering into a litigation agreement setting forth the same ("Litigation Agreement"). If the parties do not enter such Litigation Agreement, FG shall have the initial right (but not the obligation) to enforce the intellectual property rights with respect to the FG Technology, or defend any declaratory judgment action with respect thereto (such action, for purposes of this Section 14.4, an "Enforcement Action").

14.4.1 Information. Absent a Litigation Agreement, the party initiating or defending any such Enforcement Action within the Field shall keep the other party hereto reasonably informed of the progress of any such Enforcement Action, and such other party shall have the right to participate with counsel of its own choice at its own expense.

14.4.2 Enforcement Costs; Recoveries. Absent a Litigation Agreement, FG shall have the initial right to initiate such an Enforcement Action**,** and shall notify Astellas within a reasonable time whether it elects to exercise such right. In the event that FG elects to initiate or defend such Enforcement Action, FG shall be responsible for [*] of the costs and expenses while Astellas shall be responsible for [*] of the costs and expenses, and all amounts recovered shall first be applied to reimbursement of each party's costs and

expenses with the remainder to be allocated to FG and Astellas at the ratio of [*] and [*]. In the event that FG elects not to initiate or defend such Enforcement Action, Astellas shall have the right to initiate or defend such Enforcement Action in its own name, and to the extent permitted under Third Party Agreements, in the name of FG or in the names of both FG and Astellas, in which case, Astellas shall be responsible for [*] of the costs and expenses while FG shall be responsible for [*] of the costs and expenses, and all amounts recovered shall first be applied to reimbursement of each party's costs and expenses with the remainder to be allocated to Astellas and FG at the ratio of [*] and [*].

14.4.3 Cooperation in Enforcement Action. Absent a Litigation Agreement, at the request of the party which has the right to initiate or defend an Enforcement Action, the other party shall reasonably cooperate in the Enforcement Action, such cooperation to include, without limitation, furnishing records, information and testimony, and attending conferences, discovery proceedings, hearings, trials and appeals; provided, that the requesting party shall reimburse to the cooperating party for the out-of-pocket expenses incurred for such cooperation pursuant to the reimbursement regime set forth in Section 14.4.2.

14.5 Third Party Agreements

14.5.1 Future Agreements. It is understood that FG may find it necessary to utilize in connection with a Lead Compound intellectual property that is controlled by a non-Affiliate third party (such party, a "Third Party Licensor"), in addition to or in lieu of the FG Technology existing as of the Effective Date. FG shall have the right to obtain (by purchase, license, or otherwise) rights to such intellectual property with the right to sublicense to Astellas. In the event that FG determines that it must obtain such rights, it shall provide notice and submit a description of such rights to Astellas, and shall discuss with Astellas the need to obtain such rights. Astellas shall inform FG within [*] of receipt of such notice whether it believes it is necessary to obtain such rights for the Astellas Territory and wishes to obtain such rights. In the event Astellas determines to obtain such rights, FG shall obtain a worldwide license for the rights under such terms and conditions as are [*], and such intellectual property of the Third Party Licensor shall be deemed to be the part of FG Technology, provided, however, that, notwithstanding anything contained in this Agreement (i) for Preexisting Third Party Intellectual Property, [*] shall pay [*] of all consideration due in connection with the acquisition of such rights for the Astellas Territory, and (ii) for Future Third Party Intellectual Property, [*] shall [*] pay [*] of all consideration due in connection with the acquisition of such rights for the Astellas Territory, provided, however, notwithstanding FG's obligation to contribute to the consideration due for Future Third Party Intellectual Property under (ii) above, FG's obligation to contribute shall be limited such that in no event shall the sum of (a) the consideration FG contributes for the acquisition of intellectual property from Third Party Licensors for the Astellas Territory, and (b) the Expenses for which Astellas has the right to deduct under Section 14.3 exceed [*] hereunder, and Astellas shall be responsible for all consideration related to the acquisition of rights from Third Party Licensors in excess of such amount. In the event Astellas determines not to obtain such rights for the Astellas Territory, FG shall obtain a license for the FG Territory but not the Astellas Territory, and Astellas shall be solely responsible for the

defense of any infringement Action, for all Expenses related to any such Action, and any right of Astellas to deduct Expenses under this Agreement against payments required to be made to FG hereunder shall not apply to any action brought with respect to such rights.

14.5.2 Payment; Reports. If FG is obligated to pay amounts to a Third Party Licensor, FG shall notify Astellas [*] in advance of the due date of such payment obligation (or such later date as FG may determine), and Astellas shall reimburse its share of such payments within [*] after receipt of notice therefor.

14.5.3 Limitation. To the extent that FG Patents includes any intellectual property licensed under FG's License Agreement with Imigen, Inc. relating to HIF stabilization technology dated as of October 30, 2003, and amended as from time to time of which a redacted copy shall have been provided to Astellas prior to the Effective Date, Astellas shall be considered a sublicensee and be subject to the applicable requirements thereunder.

14.5.4 Compliance with Third Party Agreements. Notwithstanding anything to the contrary contained herein, Astellas agrees to comply with the requirements (upon sublicensees or otherwise) of FG's License Agreement with Imigen, Inc. relating to HIF stabilization technology dated as of October 30, 2003. In addition, Astellas agrees to comply with the requirements (upon sublicensees or otherwise) of any future Third Party Agreements for which Astellas obtains rights through an FG license pursuant to Section 14.5.1 hereof.

ARTICLE 15
REPRESENTATIONS AND WARRANTIES

15.1 FG Warranties. FG warrants and represents to Astellas, as of the execution of this Agreement, that (i) it is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware; (ii) the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action on the part of FG; (iii) there is no pending litigation which alleges or any communication alleging that Commercialization of any Lead Compound or any compound Controlled by FG for use in the Field has infringed or misappropriated the intellectual property rights of any Third Party or has been obtained by misappropriating any Third Party's intellectual property right; and (iv) subject to the terms and conditions of the agreements for the FG Acquired Patents, FG has complete title to and ownership of the FG Patents, free and clear from any mortgages, pledges, liens, security interests, conditional and installment sale agreements, encumbrances, charges or claims of any kind.

15.2 Astellas Warranties. Astellas warrants and represents to FG, as of the execution of this Agreement, that (i) it is a corporation duly organized, validly existing and in good standing under the laws of Japan; and (ii) the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action on the part of Astellas.

15.3 Disclaimer of Warranties. EXCEPT AS OTHERWISE SET FORTH HEREIN, FG AND ASTELLAS EXPRESSLY DISCLAIM ANY WARRANTIES OR CONDITIONS, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE DEVELOPMENT PROGRAM, OR THE FG TECHNOLOGY OR LEAD COMPOUNDS, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF FG TECHNOLOGY, PATENTED OR UNPATENTED, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 16
CONFIDENTIALITY

16.1 Confidential Information. Except as expressly provided herein, the parties agree that the receiving party shall not publish or otherwise disclose and shall not use for any purpose other than this Agreement any information furnished to it by the other party hereto pursuant to this Agreement which if disclosed in tangible form is marked "Confidential" or with other similar designation to indicate its confidential or proprietary nature or if disclosed orally is indicated orally to be confidential or proprietary by the party disclosing such information at the time of such disclosure and is confirmed in writing as confidential or proprietary by the disclosing party within a reasonable time after such disclosure (collectively, "Confidential Information"). Notwithstanding the foregoing, Confidential Information shall not include information that, in each case is demonstrated by written documentation:

(a) was already known to the receiving party, other than under an obligation of confidentiality directly or indirectly to the disclosing party at the time of disclosure hereunder;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving party hereunder;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving party in breach of this Agreement; or

(d) was subsequently lawfully disclosed to the receiving party by any third party without any confidentiality obligation directly or indirectly to the disclosing party or developed by the receiving party without reference to any information or materials disclosed by the disclosing party.

It is agreed and understood that all matters discussed and presented at the meetings of the JDC shall be considered Confidential Information hereunder, subject to the terms and conditions of this Agreement.

16.2 Permitted Disclosures. Notwithstanding the provisions of Section 16.1 above, each party hereto may disclose the other party's Confidential Information to the extent such disclosure is reasonably necessary to exercise the rights granted to it, or reserved by it, under this Agreement (including, without limitation, entering into and/or performing business or scientific relationships with respect to products outside the Field as permitted hereunder), in filing or prosecuting patent applications, prosecuting or defending litigation, complying with applicable governmental regulations, submitting information to tax or other governmental authorities (including regulatory authorities), or conducting clinical trials hereunder with respect to Lead Compounds, provided that if a party is required by law to make any such disclosure of the other party's Confidential Information, to the extent it may legally do so, it will give reasonable advance notice to the latter party of such disclosure and, save to the extent inappropriate in the case of patent applications or otherwise, will use its reasonable efforts to secure confidential treatment of such Confidential Information prior to its disclosure (whether through protective orders or otherwise).

16.3 Clinical Data. Except as expressly permitted under Sections 7.2 and 16.2, and for publications or disclosures in accordance with Section 5.2, neither party shall disclose to third parties pre-clinical data, clinical data or regulatory filings, comprising Confidential Information of the other party.

16.4 Press Releases. Except as may already be, or is agreed to be, publicly disclosed, in the event that either party proposes to release a press release with respect to this Agreement or the Development Program, such party shall obtain the prior written consent of the other party, which shall not be unreasonably withheld.

ARTICLE 17
INSURANCE; INDEMNIFICATION

17.1 Insurance. Each party shall secure and maintain in effect during the term of this Agreement and for a period of five (5) years thereafter insurance policy(ies) underwritten by a reputable insurance company and in a form and having limits standard and customary for entities in the biopharmaceutical industry for exposures related to the Lead Compounds. Such insurance shall include general liability, clinical trial liability and products liability coverage with respect to such party's performance of the Development Program and commercialization of Lead Compounds hereunder. Upon request by the other party hereto, certificates of insurance evidencing the coverage required above shall be provided to the other party.

17.2 Indemnification of FG. Astellas shall indemnify each of FG and its Affiliates and the directors, officers, and employees of FG and such Affiliates and the successors and assigns of any of the foregoing (the "FG Indemnitees"), and hold each FG Indemnitee harmless from and against any and all liabilities, damages, settlements, claims, actions, suits, penalties, fines, costs or expenses (including, without limitation, reasonable attorneys' fees and other expenses of litigation) incurred by any FG Indemnitee to the

extent not otherwise covered by insurance, arising from or occurring as a result of any claim, action, suit, or other proceeding brought by third parties against a FG Indemnitee arising from or occurring as a result of any development, testing, manufacture, importation, use, offer for sale, sale or other distribution of any Lead Compound by or for the benefit of Astellas or its Affiliates or Sublicensees, distributors or agents (including, without limitation, product liability and infringement claims) except to the extent caused by failure of the Lead Compound supplied by FG to meet the Product Specifications in effect at the time of manufacture, or material deviation by FG or its sub-contractor from GMP Guidelines in manufacturing the Lead Compound, or FG's breach of this Agreement or willful misconduct.

17.3 Indemnification of Astellas. FG shall indemnify each of Astellas and its Affiliates and the directors, officers, and employees of Astellas and such Affiliates and the successors and assigns of any of the foregoing (the "Astellas Indemnitees"), and hold each Astellas Indemnitee harmless from and against any and all liabilities, damages, settlements, claims, actions, suits, penalties, fines, costs or expenses (including, without limitation, reasonable attorneys' fees and other expenses of litigation) incurred by any Astellas Indemnitee to the extent not otherwise covered by insurance, arising from or occurring as a result of any claim, action, suit, or other proceeding brought by third parties against an Astellas Indemnitee to the extent caused by failure of the Lead Compound supplied by FG to meet the Product Specifications in effect at the time of manufacture, or material deviation by FG or its sub-contractor from GMP Guidelines in manufacturing the Lead Compound, except in each case in this Section 17.3 to the extent caused by Astellas' breach of this Agreement or willful misconduct.

17.4 Procedure. A party (for purposes of this Section 17.4, the "Indemnitee") that intends to claim indemnification under any provision of this Agreement shall promptly notify the indemnifying party (the "Indemnitor") in writing of any claim, action, suit, or other proceeding brought by third parties in respect of which the Indemnitee or any of its Affiliates, or their directors, officers, employees, successors or assigns intend to claim such indemnification hereunder. As between the parties hereto the Indemnitor shall have the right to control the defense and settlement of such claim, action, suit, or other proceeding; provided, that the Indemnitee shall have the right to participate in such defense or settlement with counsel of its own choosing at its expense. The Indemnitee shall not make any settlement of any loss, claim, damage, liability or action without the consent of the Indemnitor, to the extent such consent is not withheld unreasonably or delayed. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Article 17 but the omission so to deliver written notice to the Indemnitor shall not relieve the Indemnitor of any liability that it may have to any Indemnitee otherwise than under this Article 17. Without limiting the foregoing, the Indemnitee shall keep the Indemnitor fully informed of the progress of any claim, action, suit, or other proceeding for which it intends to claim indemnification under this Article 17.

ARTICLE 18
TERM AND TERMINATION

18.1 Term. This Agreement shall become effective as of the Effective Date and, shall continue in full force and effect until terminated pursuant to this Article 18.

18.2 Termination for Cause or Technical Product Failure

18.2.1 Material Breaches. FG may forthwith terminate this Agreement in the event Astellas fails to make any payment due under Articles 6, 9 or 14, within [*] following receipt of written notice of such default, or materially breaches its obligations under Articles 8 or 14, and fails to cure such breach within [*] following receipt of written notice of such default. Astellas may forthwith terminate this Agreement in the event FG materially breaches its obligations under Article 7 or Article 12, and fails to cure such breach within [*] following receipt of written notice of such default. Any termination shall become effective at the end of such [*] or [*] period unless the defaulting or breaching party (or any other party on its behalf) has cured any such default prior to the expiration of the [*] or [*] period, as the case may be.

18.2.2 Independent Activities. Notwithstanding anything contained in Section 8.3.2 or Section 14.1.1, in the event that Astellas Commercializes any molecules for the Field or the Expanded Field, except for actions taken within the Field in the course of the exercise of the licenses granted under Sections 8.1 and 13.1 hereof and expressly authorized under this Agreement, even if FG determines that Astellas' activities are completely independent of any FG Technology and/or any other FG materials, confidential information, intellectual property or other related information provided by FG to Astellas under this Agreement or any other agreement between FG and Astellas relating to the subject matter hereof, FG shall have the right at its sole discretion to terminate this Agreement upon [*] notice to Astellas.

18.2.3 Technical Product Failure. Astellas may terminate this Agreement upon [*] notice to FG upon Technical Product Failure.

18.2.4 Development Diligence Failure. FG may terminate this Agreement upon thirty (30) days notice to Astellas in the event Astellas fails to meet any of its development diligence requirements as set forth in Article 11 hereof, provided, however, that with respect to the development diligence obligations set forth in Section 11.3.2, such termination right on behalf of FG shall be triggered only upon Astellas' failure to meet such development diligence obligations for a Major Indication (except those Major Indications set forth in Section 11.3.1(iv)), and Astellas may terminate this Agreement upon thirty (30) days notice to FG in the event FG fails to meet the development diligence requirement as set forth in Section 11.2 hereof.

18.2.5 Other Material Non-Performance/Misrepresentation. Other than a breach giving rise to a termination right as set forth in Sections 18.2.1 or 18.2.4, or a termination pursuant to a Technical Product Failure as set forth in Section 18.2.3 in the event

of (i) a party's breach or default in any other material respect in the performance or observance of any other material term, covenant or provision of this Agreement, or (ii) if any representation by a party contained in this Agreement shall prove to have been incorrect in any material respect when made, resulting in material adverse consequences for the other party, (any such default or material incorrect representation a "Material Non-Performance"), such Material Non-Performance shall be remedied only as provided in Section 18.7.4 below.

18.3 Termination in case of Generic Competition. In the event generic equivalents has captured the [*] of the quantity of Lead Compound sold by Astellas during the [*] preceding such termination calculated on a annual basis; or in the event, after the entry into the market of generic equivalents, that Astellas' annual sales fall below $[*] for all Lead Compounds, Astellas may terminate this Agreement upon [*] written notice to FG; provided, that Astellas does not Commercialize any Lead Compound after such termination until the expiration of the last to expire FG Patents applicable to such Lead Compound.

18.4 Negative Advice from Authorities. Astellas may terminate this Agreement upon [*] notice to FG in the event Astellas has commenced Phase III clinical studies in those of the following Indications that FG is developing: "Treatment of anemia in patients with chronic kidney disease undergoing dialysis", "Treatment of anemia in patients with chronic kidney disease not undergoing dialysis" and [*], and the Japanese Ministry of Health, Labor & Welfare has provided written notification that it will not approve the Lead Compounds in such Indications or the JDC determines, after the submission by Astellas of Marketing Approval Applications for such Indications, and the receipt of a response or request of the Japanese Ministry of Health, Labor & Welfare that contains development demands that are so onerous that it is not reasonable to continue with Development of the Lead Compounds in such Indications.

18.5 Admission of Invalidity or Unenforceability of FG Patent. Astellas may terminate this Agreement upon [*] notice to FG in the event that FG enters into a settlement under Section 14.3 that admits the invalidity or unenforceability of all patents within the FG Technology, including patents covering Lead Compounds.

18.6 Termination upon Notice. Subject to Section 18.7.2, Astellas may terminate this Agreement upon six (6) months notice to FG for any reason or no reason.

18.7 Effect of Termination

18.7.1 Accrued Obligations. Termination of this Agreement for any reason shall not release either party hereto from any liability which, at the time of such termination, has already accrued to the other party or which is attributable to a period prior to such termination nor preclude either party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement.

18.7.2 Termination. In the event of (a) a termination by Astellas under Section 18.6 during the period from the execution of this Agreement until the last to expire of the FG Patents, or (b) by FG under Section 18.2.1, 18.2.2, 18.2.4 or 18.2.5 hereof,

Astellas shall, upon the effective date of such termination, pay to FG (i) a termination fee of $[*] U.S. dollars and (ii) any payments to which FG is otherwise entitled to receive hereunder in the period from the date of such termination notice until the [*].

18.7.3 Survival. Articles 1, 5, 14, 16, 17, 18, 19 and 20, and Sections 8.3.3 and 10.5, shall survive any termination of this Agreement, along with FG's rights and Astellas' obligations (but not Astellas' rights or FG's obligations, except to the extent required by the Japanese Ministry of Health, Labor and Welfare) under Section 5.1.1 and Article 7. In addition, the following provisions shall survive termination of this Agreement for any reason: Astellas shall assign or cause to be assigned to FG (or if not so assignable, Astellas shall take all reasonable actions to make available to FG) all regulatory filings and registrations (including MAAs and Marketing Approvals) with respect to the Lead Compounds that have been filed or made by or under authority of Astellas, and the rights in trademark with respect to each Lead Compound as provided for in Section 4.4.1, in each case such assignment (or availability) shall be made within [*] after the notice of termination. From and after the date of a notice of termination, FG shall have no further obligations under this Agreement beyond those obligations that survive termination in such events as specified in this Section 18.7.3.

18.7.4 Material Non-Performance. In the event of any Material Non-Performance by a party, the other party shall, without reasonable delay following discovery of such Material Non-Performance notify the defaulting party in writing, and the parties shall consult with each other in good faith to endeavor to agree upon the most effective means to cure such Material Non-Performance and, if necessary, to effect a remedy in favor of the non-defaulting party for the consequences of such Material Non-Performance by the defaulting party (collectively, the "Resolution"). In the event (i) the parties are unable to agree upon Resolution, or (ii) the defaulting party, in the exercise of reasonable diligence shall have been unable to remedy such Material Non-Performance, then in either such event the remedy of the non-defaulting party with respect to the Material Non-Performance by the defaulting party shall be determined by arbitration pursuant to Section 19.2 hereof, and the arbitrators shall be authorized to fashion such remedy, including equitable relief, which may include termination of this Agreement in whole or in part, as the arbitrators shall determine appropriate, except that termination of this Agreement in whole shall only be the remedy of last resort.

18.7.5 License Upon Termination. In the event of a termination of this Agreement, FG shall have an irrevocable, exclusive, license, with the right to grant and authorize sublicenses, to any trademarks used by Astellas in association with the Lead Compounds hereunder to make, use, sell, import and otherwise exploit products within the Field in the Astellas Territory. Such license shall be royalty-free, provided, however, if such trademark is not a global trademark (i.e. materially different from the trademark used in the FG Territory) and either (i) if Astellas terminates this Agreement under Section 18.2.1 or 18.2.4, or (ii) if this Agreement is terminated in accordance with the procedure as provided for in Section 18.2.5 as a result of FG's Material Non-Performance, in which event FG and Astellas shall negotiate in good faith a reasonable fee for such license.

ARTICLE 19
DISPUTE RESOLUTION

19.1 Disputes. If the parties are unable to resolve any dispute between them regarding the breach, interpretation or enforcement of this Agreement, either party may, by written notice to the other, have such dispute referred to their Authorized Designees, provided that such individuals are not directly involved in the dispute (i.e., the dispute occurs at the JDC, such individuals shall not be members of the JDC), for good faith negotiations. If after [*] such executives are unable to resolve the issue, each of Astellas and FG shall have the right to refer the matter to mediation upon notice to the other party, and the parties shall choose a mediator within [*] of the receipt of such notice, and shall negotiate in good faith to resolve such matter through the mediator within [*] thereafter.

19.2 Full Arbitration. Any dispute, controversy or claim arising out of or relating to the breach, interpretation or enforcement of this Agreement, including disputes relating to termination of this Agreement, shall be settled by binding arbitration in the manner described in this Section 19.2. The arbitration shall be conducted pursuant to the rules of Arbitration of the International Chamber of Commerce then in effect. Notwithstanding those rules, the following provisions shall apply to the arbitration hereunder:

19.2.1 Arbitrators. The arbitration shall be conducted by a panel of three (3) arbitrators, with one (1) arbitrator chosen by each of FG and Astellas and the third appointed by the other two (2) arbitrators. If the parties are unable to agree upon a single arbitrator, or the third arbitrator in case of a panel of three (3), such third arbitrator (as the case may be) shall be appointed in accordance with the rules of the Arbitration of the International Chamber of Commerce.

19.2.2 Proceedings. Except as otherwise provided herein, the parties shall use their best efforts to complete the arbitration within [*] after the appointment of the Panel under Section 19.2.1 above, unless a party can demonstrate to the Panel that the complexity of the issues or other reasons warrant the extension of one or more of the time tables. In such case, the Panel may extend such time table as reasonably required. The Panel shall, in rendering its decision, apply the substantive law of the State of California, without regard to its conflicts of laws provisions, except that the interpretation of and enforcement of this Article 19 shall be governed by the U.S. Federal Arbitration Act. The proceeding shall be conducted in English and shall take place in the city of Vancouver, British Columbia, Canada. The judgment of the Panel shall be binding upon the parties and enforceable in any court of competent jurisdiction.

19.2.3 Interim Relief. Notwithstanding anything in this Article 19 to the contrary, FG and Astellas shall each have the right to apply to any court of competent jurisdiction for a temporary restraining order, preliminary injunction, or other similar interim or conservatory relief, as necessary, pending resolution under the above described arbitration procedures. Nothing in the preceding sentence shall be interpreted as limiting the powers of the arbitrators with respect to any dispute subject to arbitration under this Agreement.

ARTICLE 20
MISCELLANEOUS

20.1 Confidential Terms. Except as expressly provided herein, each party agrees not to disclose any terms of this Agreement to any third party without the consent of the other party, except (i) as required by securities or other applicable laws or (ii) to prospective and other investors and such party's accountants, attorneys and other professional advisors, or (iii) to others under reasonable conditions of confidentiality.

20.2 Governing Law. This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed and enforced in accordance with, the laws of the State of California, without reference to conflicts of laws principles.

20.3 Force Majeure. Nonperformance of any party (except for payment of amounts due hereunder) shall be excused to the extent that performance is rendered impossible by strike, fire, earthquake, flood, governmental acts or orders or restrictions, failure of suppliers, or any other reason where failure to perform is beyond the reasonable control of the non-performing party. In such event FG or Astellas, as the case may be, shall promptly notify the other party of such inability and of the period for which such inability is anticipated to continue. Without limiting the foregoing, the party subject to such inability shall use reasonable efforts to minimize the duration of any force majeure event.

20.4 No Implied Waivers; Rights Cumulative. No failure on the part of FG or Astellas to exercise and no delay in exercising any right under this Agreement, or provided by statute or at law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, nor shall any partial exercise of any such right preclude any other or further exercise thereof or the exercise of any other right.

20.5 Independent Contractors. Nothing contained in this Agreement is intended implicitly, or is to be construed, to constitute FG or Astellas as partners in the legal sense. No party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of any other party or to bind any other party to any contract, agreement or undertaking with any third party.

20.6 Notices. All notices, requests and other communications hereunder shall be in writing and shall be personally delivered or sent by registered or certified mail, return receipt requested, postage prepaid; facsimile transmission (receipt verified); or express courier service (signature required), in each case to the respective address specified below, or such other address or fax number as may be specified in writing to the other party hereto:

Astellas:	Astellas Pharma Inc. Attn: Director of Legal Department [*]
with copy to:	Astellas Pharma Inc. Attn: Licensing, Corporate Strategy [*]
FG:	FibroGen, Inc. Attn: Chief Executive Officer 225 Gateway Boulevard San Francisco, California 94080 Fax: 1-650-866-7202
with a copy to:	FibroGen, Inc. Attn: Legal Department 225 Gateway Boulevard San Francisco, California 94080 Fax: 1-650-866-7343

20.7 Assignment. This Agreement shall not be assignable by either party to any third party without the written consent of the other party hereto; except that either party may assign this Agreement without the other party's consent to an entity that acquires substantially all of the business or assets of the assigning party within the Field, in each case whether by merger, transfer of assets, or otherwise. Upon a permitted assignment of this Agreement, all references herein to the assigning party shall be deemed references to the party to whom the Agreement is so assigned.

20.8 Modification. No amendment or modification of any provision of this Agreement shall be effective unless in writing signed by all parties hereto. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by all parties.

20.9 Severability. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, the parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the parties and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

20.10 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which together, shall constitute one and the same instrument.

20.11 Headings. Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement.

20.12 Export Laws. Notwithstanding anything to the contrary contained herein, all obligations of FG and Astellas are subject to prior compliance with United States and foreign export regulations and such other United States and foreign laws and regulations as may be applicable, and to obtaining all necessary approvals required by the applicable agencies of the governments of the United States and foreign jurisdictions. FG and Astellas shall cooperate with each other and shall provide assistance to the other as reasonably necessary to obtain any required approvals.

20.13 Language. This Agreement is in the English language only, which language shall be controlling in all respects, and all versions hereof in any other language shall not be binding on the parties hereto. All communications and notices to be made or given pursuant to this Agreement shall be in the English language.

20.14 Entire Agreement. This Agreement (including the Exhibits hereto) constitutes the entire agreement, both written or oral, with respect to the subject matter hereof, and supersedes all prior or contemporaneous understandings or agreements, including the Binding Term Sheet, dated as of February 9, 2004 by and between FG and Astellas, as amended on January 25, 2005, whether written or oral, between FG and Astellas with respect to such subject matter.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed and delivered in duplicate originals as of the date first above written.

ASTELLAS PHARMA INC.	**FIBROGEN, INC.**
By: /s/ Toichi Takenaka	By: /s/ Thomas B. Neff
Toichi Takenaka	Thomas Neff
President and Chief Executive Officer	President and Chief Executive Officer
Date: 1.September.05	Date: 23 August 05

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

EXHIBIT A
LIST OF PATENTS

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

EXHIBIT B
INDICATIONS

Included indications:

- Treatment of anemia in patients with chronic kidney disease undergoing dialysis
- Treatment of anemia in patients with chronic kidney disease not undergoing dialysis
- [*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

EXHIBIT C
INITIAL DEVELOPMENT PLAN

[]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

COLLABORATION AGREEMENT

BY AND BETWEEN

ASTELLAS PHARMA INC.

AND

FIBROGEN, INC.

June 1, 2005

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Exhibit 10.2

AMENDED AND RESTATED

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

(for the US and Certain Other Territories)

between

FIBROGEN, INC.

and

ASTRAZENECA AB

TABLE OF CONTENTS

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

AMENDED AND RESTATED

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

THIS AMENDED AND RESTATED LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (the "***Agreement***") is entered into as of October 16, 2014 (the "***Execution Date***"), and effective as of July 30, 2013 (the "***Effective Date***") by and between **FIBROGEN, INC.**, a Delaware corporation having its principal place of business at 409 Illinois St., San Francisco, California 94158, United States ("***FibroGen***") and **ASTRAZENECA AB**, a company incorporated in Sweden under no. 556011-7482 with offices at Pepparedsleden 1, 431 83 Mölndal, Gothenburg, Sweden ("***AstraZeneca***"). FibroGen and AstraZeneca are sometimes referred to herein individually as a "***Party***" and collectively as the "***Parties***".

BACKGROUND

A. AstraZeneca is a fully-integrated, global pharmaceutical company with expertise in the research, development, manufacture and commercialization of human therapeutic products.

B. FibroGen is a biotechnology company with expertise in the discovery, research, development and manufacture of small molecule prolyl hydroxylase inhibitors that modulate hypoxia-inducible factor for the treatment of anemia.

C. FibroGen is developing certain of such compounds in collaboration with Astellas Pharma Inc. ("***Astellas***"), its exclusive licensee for Japan, Europe, the Commonwealth of Independent States (CIS), the Middle East and South Africa pursuant to certain collaboration agreements between FibroGen and Astellas (collectively, the "***Astellas Collaboration***").

D. AstraZeneca and FibroGen desire to establish as of Effective Date a collaboration for the joint continued development, including regulatory submission, and, if successful, commercialization of certain of such compounds in the U.S. and all countries of the world other than those subject to the existing Astellas Collaboration.

E. With respect to the collaboration between the Parties in China, the development and commercialization activities are governed by that certain License, Development and Commercialization Agreement (China) by and between FibroGen China Anemia Holdings, Ltd., Beijing FibroGen Medical Technology Development Co., Ltd., and FibroGen International (Hong Kong) Limited, Affiliates of FibroGen, and AstraZeneca, of even date herewith (the "***China Agreement***"), except that a portion of the governance structure for China shall be as set forth in this Agreement, and the Parties' activities with respect to all other countries not licensed to Astellas are governed by this Agreement.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

As used in this Agreement, the following initially capitalized terms, whether used in the singular or plural form, shall have the meanings set forth in this Article 1. Except where the context otherwise requires, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. In addition, the terms "includes," "including," "include" and derivative forms of them shall be deemed followed by the phrase "without limitation" (regardless of whether it is actually written there (and drawing no implication from the actual inclusion of such phrase in some instances after such terms but not others)).

1.1 "***Acquiror***" has the meaning set forth in Section 15.5.

1.2 "***Affiliate***" means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.

1.3 "***Alliance Manager***" has the meaning set forth in Section 2.7.

1.4 "***Annual Net Sales***" means the Net Sales made during any given Calendar Year.

1.5 "***Anti-Corruption Laws***" means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism.

1.6 "***Astellas***" has the meaning set forth in Section C on the first page.

1.7 "***Astellas Agreements***" means the Astellas EU Agreement and the Astellas Japan Agreement.

1.8 "***Astellas Collaboration***" has the meaning set forth in Section C on the first page.

1.9 "***Astellas EU Agreement***" means the Anemia License and Collaboration Agreement between FibroGen and Astellas with respect to the countries listed on **Exhibit A** (other than Japan) effective April 28, 2006, as amended from time to time.

1.10 "***Astellas Japan Agreement***" means the Collaboration Agreement between FibroGen and Astellas with respect to Japan effective June 1, 2005, as amended from time to time.

1.11 "***AstraZeneca Inventions***" has the meaning set forth in Section 7.8(d).

1.12 "***AstraZeneca Know-How***" means all Information Controlled as of the Effective Date or thereafter during the Term by AstraZeneca and/or its Affiliate(s) that is reasonably necessary or useful for the research, development, manufacture, use, importation or sale of Products in the Field. For clarity, the use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate due to such Third Party's acquisition of or by AstraZeneca, except as provided in Section 15.5. For additional clarity, AstraZeneca Know-How shall exclude rights under any AstraZeneca Patents and AstraZeneca's interest in the Joint Patents and Joint Inventions.

1.13 "***AstraZeneca Patents***" means all Patents that are Controlled as of the Effective Date or thereafter during the Term by AstraZeneca and/or its Affiliate(s) and that claim the composition of matter, manufacture or use of one or more Collaboration Compounds or Products or that would otherwise be infringed (or with respect to patent applications, would be infringed if issued or granted with the then-currently pending claims), absent a license, by the manufacture, use or sale of any Collaboration Compounds or Product. For clarity, the use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate due to such Third Party's acquisition of or by, AstraZeneca except as provided in Section 15.5.

1.14 "***AstraZeneca Anti-Corruption Rules and Policies***" means the key principles from AstraZeneca's ABAC and External Interactions Policies regarding anti-bribery and corruption issues, attached as **Exhibit F** to this Agreement, as the same may be amended, modified or supplemented from time to time as notified by AstraZeneca to FibroGen.

1.15 "***AstraZeneca Technology***" means the AstraZeneca Patents, AstraZeneca Know-How, and AstraZeneca's interest in Joint Patents and Joint Inventions.

1.16 "***Bankrupt Party***" has the meaning set forth in Section 13.9(b).

1.17 "***Business Day***" means a day other than a Saturday, Sunday or bank or other public holiday in San Francisco, California, the UK or Sweden.

1.18 "***Calendar Quarter***" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1.

1.19 "***Calendar Year***" means each successive period of twelve (12) calendar months commencing on January 1.

1.20 "***Carcinogenicity Studies***" means the following carcinogenicity studies in rats and mice: (1) [*].

1.21 "***China Agreement***" has the meaning set forth in Section E on the first page.

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1.22 "***China Committee***" means the governing committee established under the China Agreement, and any successor or other committee or governing body that serves the same functions under the China Agreement.

1.23 "***CKD Indications***" means (a) treatment of anemia in patients with chronic kidney disease undergoing dialysis, and (b) treatment of anemia in patients with chronic kidney disease not undergoing dialysis.

1.24 "***Clinical Trial***" means any human clinical trial of a Product.

1.25 "***Co-Commercialization Agreement***" has the meaning set forth in Section 5.10.

1.26 "***Collaboration***" has the meaning set forth in Section 2.1.

1.27 "***Collaboration Compound***" means any of the following: (a) FG-4592, (b) any HIF Compound (other than FG-4592) that is added to this Agreement pursuant to Section 3.6, and (c) any salts, esters, complexes, chelates, crystalline and amorphous morphic forms, pegylated forms, enantiomers (excluding regioisomers), prodrugs, solvates, metabolites and catabolites of any of the foregoing ((a) or (b)).

1.28 "***Collaboration Inventions***" has the meaning set forth in Section 9.2.

1.29 "***Combination Product***" means a Product that is comprised of or contains a Collaboration Compound as an active ingredient together with one (1) or more other active ingredients and is sold either as a fixed dose/unit or as separate doses/units in a single package.

1.30 "***Commercialization***" means the commercial manufacture, marketing, promotion, sale and/or distribution of Products in the Territory. Commercialization includes commercial activities conducted in preparation for Product launch in each indication. "***Commercialize***" has a correlative meaning.

1.31 "***Commercialization Costs***" means all costs incurred by or on behalf of FibroGen that are directly and reasonably allocable to the conduct of activities allocated to FibroGen under the U.S. Commercialization Plan or Co-Commercialization Agreement for the Commercialization of Products in the U.S.

1.32 "***Commercially Reasonable Efforts***" means, with respect to a Party's obligations under this Agreement to Develop or Commercialize a Product, the carrying out of such obligations or tasks with a level of efforts and resources consistent with the commercially reasonable practices of (a) in the case of AstraZeneca, a pharmaceutical company the size and geographical scope of AstraZeneca and (b) in the case of FibroGen, a biotechnology company the size and geographical scope of FibroGen, in each case (a) and (b) for the development or commercialization of similarly situated pharmaceutical products as such Product and at a similar stage of development or commercialization, taking into consideration their safety and efficacy, their cost to develop, the nature and extent of their market exclusivity (including patent coverage and regulatory exclusivity), the likelihood of Regulatory Approval, their expected profitability, including the

amounts of marketing and promotional expenditures with respect to such products and generic products, and the competitiveness of alternative compounds and products. Commercially Reasonable Efforts requires that the Party: (a) promptly assign responsibility for such obligations or tasks to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis, (b) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations, and (c) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives. For the avoidance of doubt, the commitment to use "Commercially Reasonable Efforts" shall not preclude the suspension or discontinuance by AstraZeneca of any Product, if appropriate, based on the foregoing considerations.

1.33 "***Committee***" means the Joint Steering Committee, Joint Development Committee, Joint Commercialization Committee or IP Committee, or any other subcommittee established under Article 2, as applicable.

1.34 "***Compliance Audit***" has the meaning set forth in Section 10.3(e).

1.35 "***Confidential Information***" means, with respect to a Party, all Information of such Party that is disclosed to the other Party under this Agreement, which may include, without limitation, specifications, know-how, trade secrets, technical information, models, business information, inventions, discoveries, methods, procedures, formulae, protocols, techniques, data, and unpublished patent applications, whether disclosed in oral, written, graphic, or electronic form. All confidential Information disclosed by either Party pursuant to the Existing Confidentiality Agreement shall be deemed to be Confidential Information of the disclosing Party hereunder (with the mutual understanding and agreement that any use or disclosure thereof that is authorized under Article 12 shall not be restricted by, or be deemed a violation of, such Existing Confidentiality Agreement).

1.36 "***Control***" means, with respect to any material, Information, or intellectual property right, that a Party (a) owns such material, Information, or intellectual property right, or (b) has a license or right to use to such material, Information, or intellectual property right, in each case with the ability to grant to the other Party access, a right to use, or a license, or a sublicense (as applicable) to such material, Information, or intellectual property right on the terms and conditions set forth herein, without violating the terms of any agreement or other arrangement with any Third Party.

1.37 "***Core Indication***" means any of the following: (a) treatment of anemia in patients with chronic kidney disease undergoing dialysis, (b) treatment of anemia in patients with chronic kidney disease not undergoing dialysis, (c) [*]).

1.38 "***Covenant Period 1***" has the meaning set forth in Section 7.4(a)(ii).

1.39 "***Covenant Period 2***" has the meaning set forth in Section 7.4(a)(iii).

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1.40 "***CPI-U***" means the Consumer Price Index for All Urban Consumers (All Items), or any successor to such published measure, not seasonally adjusted, as published by the U.S. Department of Labor Bureau of Labor Statistics.

1.41 "***Designated Indication***" has the meaning set forth in Section 3.5(a).

1.42 "***Designated Product***" has the meaning set forth in Section 8.4(a).

1.43 "***Development***" means all activities that relate to (a) obtaining, maintaining or expanding Regulatory Approval of a Product for one or more indications or (b) developing the process for the manufacture of clinical and commercial quantities of drug substance or drug Product. This includes: (i) preclinical testing, toxicology and Clinical Trials; (ii) preparation, submission, review, statistical analysis, report writing and development of data or information for the purpose of submission to a governmental authority to obtain, maintain and/or expand Regulatory Approval of a Product, and outside counsel regulatory legal services related thereto; and (iii) manufacturing process development and scale-up for drug substance and drug product, test method development, packaging development, stability testing, qualification and validation, production of drug substance and drug product, in bulk for preclinical and clinical studies, and related quality assurance technical support activities; provided, however, that Development shall exclude Commercialization. For clarity, Development shall include those Phase 4 Clinical Trials that are included in clause (b) of the definition of Phase 4 Clinical Trials. "***Develop***" has a correlative meaning.

1.44 "***Development Budget***" means the budget associated with the activities conducted under the Development Plan for the U.S., detailing the anticipated Development Costs.

1.45 "***Development Costs***" means all costs incurred by or on behalf of FibroGen or AstraZeneca that are reasonably allocable to the Development of Products for the U.S. in accordance with the Development Plan, which shall equal the sum of (a) Personnel Costs, (b) the Fully Burdened Cost of Collaboration Compound or Product or comparator drug, concomitant drug, placebo or other materials used in any Clinical Trial or Nonclinical Studies, and (c) all other out-of-pocket costs, in each case for activities for the U.S.

1.46 "***Development Data***" has the meaning set forth in Section 3.10(a).

1.47 "***Development Plan***" means the plan for conducting collaborative Development of Products for approval and use in the U.S. and RoW, as set forth in Section 3.2(a).

1.48 "***Development Sharing Period***" means the time period commencing on August 1, 2013 and ending on the date on which the Parties have incurred two hundred thirty-three million Dollars ($233,000,000) in Development Costs.

1.49 "***Development Strategy***" has the meaning set forth in Section 3.2(c).

1.50 "***DFCI Agreement***" means the License Agreement between FibroGen and the Dana-Farber Cancer Institute, Inc. ("***DFCI***"), dated March 29, 2006, a redacted copy of which is attached hereto as **Exhibit B**.

1.51 "***Distributor***" has the meaning set forth in Section 7.3(c).

1.52 "***Dollar***" or "***$***" means United States dollar.

1.53 "***ESA Approved Indications***" means the following indications: (a) treatment of anemia in patients with chronic kidney disease undergoing dialysis, (b) treatment of anemia in patients with chronic kidney disease not undergoing dialysis, (c) [*].

1.54 "***EU***" means all of the European Union member states as of the applicable time during the Term.

1.55 "***Executive Officer***" means, in the case of AstraZeneca, AstraZeneca's Chief Executive Officer or any senior executive designated by and who reports directly to the Chief Executive Officer of AstraZeneca, and in the case of FibroGen, FibroGen's Chief Executive Officer.

1.56 "***Existing Confidentiality Agreement***" means, collectively, the Non-Disclosure Agreement between FibroGen and AstraZeneca dated June 21, 2012, as amended February 7, 2013, and May 23, 2013, and the Non-Disclosure Agreement between FibroGen and AstraZeneca dated April 1, 2013.

1.57 "***FCPA***" means the U.S. Foreign Corrupt Practices Act of 1977, as amended, including the rules and regulations thereunder.

1.58 "***FDA***" means the United States Food and Drug Administration or its successor.

1.59 "***FD&C Act***" means the United States Federal Food, Drug and Cosmetic Act, as amended.

1.60 "***FG-4592***" means the molecule with the chemical structure set forth on **Exhibit C**.

1.61 "***FibroGen IPO***" means the initial public offering of its securities by FibroGen in any of the U.S., United Kingdom, Spain, France, Italy, Germany, Japan, China or Hong Kong.

1.62 "***FibroGen Know-How***" means all Information Controlled as of the Effective Date or thereafter during the Term by FibroGen and/or its Affiliate(s) and reasonably necessary or useful for the development, manufacture, use, importation or sale of Collaboration Compounds or Products in the Field; including, without limitation, any such Information made or generated by or on behalf of FibroGen or its Affiliate in the course of performing FibroGen's obligations or exercising FibroGen's rights under this Agreement. The use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate due to such Third Party's acquisition of FibroGen, except as provided in Section 15.5. FibroGen Know-How shall exclude (a) rights under

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any FibroGen Patents and FibroGen's interest in the Joint Patents and Joint Inventions and (b) any Third Party Information that is not included pursuant to Section 8.8(d).

1.63 "***FibroGen Patents***" means (i) the Listed Patents and (ii) all other Patents (excluding any Joint Patents) that are Controlled as of the Effective Date or thereafter during the Term by FibroGen and/or its Affiliate(s) and that claim the composition of matter, manufacture or use of one or more Collaboration Compounds or Products in the Field or that would otherwise be infringed (or with respect to patent applications, would be infringed if issued or granted with the then-currently pending claims), absent a license, by the manufacture, use or sale of any Collaboration Compound or Product in the Field. The use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate due to such Third Party's acquisition of FibroGen except as provided in Section 15.5. FibroGen Patents does not include Third Party Patents that are not included pursuant to Section 8.8(d).

1.64 "***FibroGen Technology***" means the FibroGen Patents, FibroGen Know-How, and FibroGen's interest in Joint Patents and Joint Inventions.

1.65 "***Field***" means (a) the treatment of anemia in humans and non-human animals, which means any treatment intended to increase hemoglobin levels or utilization or to increase hematocrit, as measured by acceptable clinical parameters, including unit volume concentrations of hemoglobin, red blood cell volume, or red blood cell count, and (b) any Designated Indication added to the Field pursuant to Section 3.5. For the avoidance of doubt, the Core Indications, the ESA Approved Indications as well as the indications listed on **Exhibit D** are all included in clause (a) of the preceding sentence.

1.66 "***First Commercial Sale***" means, with respect to a Product and country in the Territory, the first arm's length sale for monetary value by AstraZeneca, its Affiliates or its Sublicensees to a Third Party intended for end use or consumption by the general public (regardless of when actual consumption occurs) of such Product in such country after Regulatory Approval (and any pricing or reimbursement approvals, if reasonably necessary to commence regular commercial sales) has been obtained in such country. For the avoidance of doubt, sales prior to receipt of Regulatory Approvals necessary to commence regular commercial sales, such as so-called "treatment IND sales", "named patient sales" or "compassionate use sales", shall not be construed as a First Commercial Sale.

1.67 "***Fully Burdened Cost***" means, with respect to a Product, all costs actually incurred by FibroGen or its Affiliates attributable and fairly allocable to produce, package and distribute the Product to AstraZeneca or its carrier [*]) for the acquisition or sale of such Product, which costs to produce and package the Product will include the direct material and labor and indirect costs (fairly allocated) that are incurred by FibroGen or its Affiliates associated with the manufacture, filling, packaging, labeling, and preparation of product for shipment and/or other preparation of such Product, as applicable, including non-refundable and non-creditable Indirect Taxes, customs fees and customs duties. Fully Burdened Cost will be determined in accordance with U.S. GAAP and will include the attributable and fairly allocable costs of facilities, labor, purchasing, depreciation of equipment, materials, payments to Third Parties for any necessary

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contract work for the manufacture or testing of the Product, quality assurance, quality control and other testing (including validation studies), storage (if requested by AstraZeneca), shipping and costs for distribution, and a reasonable allocation of general and administrative overhead for the manufacturing operations attributable to Product distribution to AstraZeneca. These costs shall include capacity reservation charges paid to a Third Party, and the proportion of fixed overhead allocated to total available capacity reasonably reserved for the production of a Product, less the amount included in budgeted cost of goods (budgeted capacity); provided, that FibroGen shall use good faith efforts to utilize any such reserved but unused capacity. By way of example, if fifteen percent (15%) of the total site capacity is reasonably reserved for the production of the Product and for the same period budgeted capacity is planned for only ten percent (10%) of the site, the fixed overhead related to the remaining five percent (5%) dedicated capacity shall be included in Fully Burdened Cost as reserve capacity. Costs for distribution consist of the labor, materials and reasonably allocated overhead necessary to prepare and package the final product for shipment to AstraZeneca.

1.68 "***GCP***" means the current standards for clinical trials for pharmaceuticals, as set forth in the U.S. Code of Federal Regulations, ICH guidelines and applicable regulations, laws or rules as promulgated thereunder, as amended from time to time, and such standards of good clinical practice as are required in other countries than the U.S. in which a Product is intended to be sold to the extent such standards are not less stringent than U.S. GCP.

1.69 "***Generic Product***" means, with respect to a Product and a particular country, any pharmaceutical product (a) that is sold in such country by a Third Party that is not a Sublicensee or Distributor selling such product under authorization from AstraZeneca or its Affiliates, (b) that contains the same Collaboration Compound as the relevant Product and that is in the same dosage form as such Product and for the same route of administration as such Product and is approved by the Regulatory Authority for such country for an indication for which such Product obtained Regulatory Approval in such country and (c) that is approved in reliance on the prior approval of such Product as determined by the applicable Regulatory Authority.

1.70 "***Governmental Authority***" means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.71 "***Government Official***" means (i) any individual or entity employed by or acting on behalf of a government, government-controlled agency or entity or public international organization, (ii) any political party, party official or candidate, (iii) any individual or entity that holds or performs the duties of an appointment, office or position created by custom or convention or (iv) any individual or entity that holds himself, herself or itself out to be the authorized intermediary of any of the foregoing.

1.72 "***HICP***" means, with respect to a country, the Harmonised Index of Consumer Prices for such country published by Eurostat.

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1.73 "***HIF Compound***" means any compound that stabilizes hypoxia-inducible factor ("***HIF***") or that modulates HIF prolyl hydroxylase activity.

1.74 "***Hourly Rate***" means, as of the Effective Date, $[*], which is the blended hourly fully burdened rate for FibroGen's employees and agents conducting Development activities. The Hourly Rate will be adjusted annually as of each January 1 (commencing 2014) to reflect the percentage increase or decrease (as the case may be) from the preceding year in the average consumer price, calculated as the average of (i) the annual percentage change of US CPI-U and (ii) the average of the annual percentage changes of HICP for the 5 major EU countries (UK, France, Germany, Italy, and Spain) for such annual period, except as otherwise mutually agreed by the Parties. The Hourly Rate includes, without limitation, the following general expense categories: salaries and wages (including bonuses, moving expenses, and payroll taxes), benefits provided (including health benefits, defined contribution, defined benefit plans, vacations, etc.), direct employee costs (including recruitment costs, internal and external training costs, computer charges, automobile leases, subscriptions and reference materials, telephone, fax, cellular phone, and copy machines and related costs), and allocation of other overhead costs (including rent, insurance, and utilities).

1.75 "***IND***" means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, or (b) the equivalent application to the equivalent Regulatory Authority in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

1.76 "***Indirect Taxes***" means VAT, sales taxes, consumption taxes and other similar taxes required by law to be disclosed on the invoice.

1.77 "***Information***" means any data, results and information of any type whatsoever, in any tangible or intangible form, including, without limitation, know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, compositions of matter of any type or kind, software, algorithms, marketing reports, clinical and non-clinical study reports, regulatory submission documents and summaries, expertise, stability, technology, test data including pharmacological, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, in all cases, patentable or otherwise.

1.78 "***Initial Development Plan***" has the meaning set forth in Section 3.2(b).

1.79 "***Inventions***" has the meaning set forth in Section 9.2.

1.80 "***IP Committee***" has the meaning set forth in Section 9.1.

1.81 "***Joint Commercialization Committee***" or "***JCC***" means the committee formed by the Parties as described in Section 2.4.

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1.82 "***Joint Development Committee***" or "***JDC***" means the committee formed by the Parties as described in Section 2.3.

1.83 "***Joint Inventions***" has the meaning set forth in Section 9.2.

1.84 "***Joint Patents***" has the meaning set forth in Section 9.2.

1.85 "***Joint Project Team***" or "***JPT***" has the meaning set forth in Section 2.9.

1.86 "***Joint Steering Committee***" or "***JSC***" means the committee formed by the Parties as described in Section 2.2.

1.87 "***Large Dialysis Organization***" or "***LDO***" means (a) an organization that operates out-patient dialysis centers and that has at least twenty-five percent (25%) of the market share (measured by number of patients as determined by USRDS or any successor) of dialysis centers in the U.S. and (b) Dialysis Clinic Inc. Examples of Large Dialysis Organizations as of the Effective Date in clause (a) are Fresenius Medical Care and DaVita HealthCare Partners Inc.

1.88 "***Listed Patents***" means the Patents listed on **Exhibit E**. The Parties may update such exhibit from time to time upon mutual written agreement, e.g., to update the status of the listed Patents, to add newly filed FibroGen Patents, or to make other agreed revisions.

1.89 "***Marketing Authorization Application***" or "***MAA***" means an application for Regulatory Approval in a country, territory or possession other than the U.S.

1.90 "***Marks***" has the meaning set forth in Section 9.11.

1.91 "***Material Anti-Corruption Law Violation***" means a violation of an Anti-Corruption Law relating to the subject matter of this Agreement which [*] a material adverse effect on either Party or on the reputation of either Party because of its relationship with the other Party.

1.92 "***Medical Scientific Liaison***" or "***MSL***" means a field-based professional with scientific, medical and clinical expertise who provides medical and scientific support for marketed products, new indications and compounds in development or registration. An MSL engages in scientific exchange with medical and scientific experts including investigators, key opinion leaders, physicians and other medical professionals and customers.

1.93 "***NDA***" means a New Drug Application, as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA.

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1.94 "***Net Sales***" means the gross invoiced amount on sales of a Product by AstraZeneca, its Affiliates or its or their Sublicensees to Third Parties (including Distributors but excluding Sublicensees) in the Territory, after deduction of the following amounts:

(a) normal and customary trade, quantity or prompt settlement discounts (including chargebacks and allowances) actually allowed;

(b) amounts repaid or credited by reason of rejection, returns or recalls of goods, rebates or bona fide price reductions determined by AstraZeneca, its Affiliates or its or their Sublicensees in good faith;

(c) rebates and similar payments made with respect to sales paid for by managed care organizations, hospitals, other buying groups or any governmental or regulatory authority such as, by way of illustration and not in limitation of the Parties' rights under this Agreement, federal or state Medicaid, Medicare or similar state program in the U.S. or equivalent governmental program in any other country;

(d) any invoiced amounts that are not collected by AstraZeneca, its Affiliates or its or their Sublicensees, including bad debts (provided that such amounts will be added to Net Sales if and when recovered), up to an amount not to exceed [*]) of Net Sales;

(e) excise taxes, Indirect Taxes, customs duties, customs levies and import fees imposed on the sale, importation, use or distribution of the Products;

(f) [*]; and

(g) as an allowance for transportation costs, distribution expenses, special packaging and related insurance charges, [*].

For clarity, any deduction made pursuant to one subsection above, shall not be additionally deducted in the event that such deduction may also apply in a separate subsection (i.e., no double-counting).

In the event that a Product is sold in any country in the form of a Combination Product, Net Sales of such Combination Product shall be adjusted by multiplying actual Net Sales of such Combination Product in such country calculated pursuant to the foregoing definition of "Net Sales" by the fraction A/(A+B), where A is the average invoice price in such country of any Product that contains the same Collaboration Compound(s) as such Combination Product as its sole active ingredient(s), if sold separately in such country, and B is the average invoice price in such country of each product that contains active ingredient(s) other than the Collaboration Compound(s) contained in such Combination Product as its sole active ingredient(s), if sold separately in such country; *provided* that the invoice price in a country for each Product that contains only the Collaboration Compound(s) and each product that contains solely active ingredient(s) other than the Collaboration Compound(s) included in the Combination Product shall be for a quantity comparable to that used in such Combination Product and of substantially the same class, purity and potency or functionality, as applicable. If either such Product that contains the Collaboration

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Compound(s) as its sole active ingredient or a product that contains the active ingredient(s) (other than the Product) in the Combination Product as its sole active ingredient(s) is not sold separately in a particular country, the Parties shall negotiate in good faith a reasonable adjustment to Net Sales in such country that takes into account the medical contribution to the Combination Product of and all other factors, including patent coverage, reasonably relevant to the relative value of the Collaboration Compound(s) on the one hand and all of the other active ingredient(s), collectively, on the other hand.

In the case of pharmacy incentive programs, hospital performance incentive programs, chargebacks, disease management programs, similar programs or discounts on portfolio product offerings, all rebates, discounts and other forms of reimbursements shall be allocated among products on the basis on which such rebates, discounts and other forms of reimbursements were actually granted or, if such basis cannot be determined, in accordance with AstraZeneca's, its Affiliates' or its or their Sublicensees' existing allocation method; *provided* that any such allocation shall be done in accordance with applicable law, including any price reporting laws, rules and regulations.

Net Sales will be calculated using AstraZeneca's internal audited systems consistently applied to report such sales as adjusted for any of the deductions set forth above not taken into account in such systems. Deductions pursuant to item (d) above will be taken in the Calendar Quarter in which such sales are no longer recorded as a receivable.

Any free of charge disposition or use of reasonable quantities of a Product, up to the amount determined by the JCC, for regulatory or marketing purposes (it being understood and agreed that neither Party shall have the right to distribute the Product as samples except pursuant to Section 5.7) such as compassionate use or indigent patient programs, will not be deemed a sale or disposition for calculating Net Sales. Sales and other transfer of Product between any of AstraZeneca, its Affiliates and Sublicensees will not give rise to Net Sales except if the purchaser is an end user.

1.95 "***Nonclinical Studies***" means all *in vivo* and *in vitro* non-human studies of Collaboration Compounds and Products, including non-clinical pharmacology, toxicology, tumor and teratogenicity studies.

1.96 "***Patent***" means (i) all national, regional and international patents and patent applications, including provisional patent applications, (ii) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (iii) any and all patents that have issued or in the future issue from the foregoing patent applications ((i) and (ii)), including utility models, petty patents and design patents and certificates of invention, (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((i), (ii) and (iii)), and (v) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or

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introduction patent or registration patent or patent of additions to any such foregoing patent applications and patents.

1.97 "***Personnel Costs***" means, with respect to a reporting period, the total number of hours FibroGen employees and consultants or AstraZeneca employees and consultants, as applicable, actually spent in such reporting period conducting activities under the Development Plan multiplied by the Hourly Rate. Such activities may include, without limitation, clinical development, research activities directly in support of the Development program, management of clinical research organizations and other vendors, regulatory, supply chain, medical monitoring, biostatistics, safety data collection, monitoring and exchange, and clinical and nonclinical finance and contracting.

1.98 "***Pharmacovigilance Agreement***" has the meaning set forth in Section 4.3.

1.99 "***Phase 2 Clinical Trial***" means a Clinical Trial of a Product that would satisfy the requirements of 21 CFR 312.21(b) or its foreign equivalents.

1.100 "***Phase 3 Clinical Trial***" means a Clinical Trial of a Product that would satisfy the requirements of 21 CFR 312.21(c) or its foreign equivalents.

1.101 "***Phase 4 Clinical Trial***" means a Clinical Trial of a Product conducted after Regulatory Approval of such Product has been obtained from an appropriate Regulatory Authority, which trial is (a) conducted voluntarily by a Party to enhance marketing or scientific knowledge of the Product, or (b) conducted due to a request or requirement of a Regulatory Authority.

1.102 "***Product***" means any pharmaceutical product (including all forms, presentations, dosage strengths and formulations) containing as an active ingredient a Collaboration Compound alone or in combination with one or more other therapeutically active ingredients.

1.103 "***Product Information***" has the meaning set forth in Section 12.1.

1.104 "***Product Infringement***" has the meaning set forth in Section 9.5(a)(i).

1.105 "***Promotional Materials***" means all sales representative training materials and all written, printed, graphic, electronic, audio or video matter, including, without limitation, journal advertisements, sales visual aids, formulary binders, reprints, direct mail, direct-to-consumer advertising, internet postings and sites and broadcast advertisements intended for use or used by either Party or its Affiliates or sublicensees in connection with any promotion of a Product.

1.106 "***Publication***" has the meaning set forth in Section 12.5(b).

1.107 "***Regulatory Approval***" means all approvals necessary for the manufacture, marketing, importation and sale of a Product for one or more indications in the Field and in a country or regulatory jurisdiction, which may include, without limitation, satisfaction of all applicable regulatory and notification requirements, but which shall exclude any pricing and reimbursement approvals.

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1.108 "***Regulatory Authority***" means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval and/or, to the extent required in such country or regulatory jurisdiction, pricing or reimbursement approval of a Product in such country or regulatory jurisdiction.

1.109 "***Regulatory Materials***" means regulatory applications, submissions, notifications, registrations, Regulatory Approvals and/or other material filings or correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority), or other approvals granted by, a Regulatory Authority that are necessary or reasonably desirable in order to Develop, manufacture, market, sell or otherwise Commercialize a Product in a particular country or regulatory jurisdiction. Regulatory Materials include, without limitation, INDs, MAAs, and NDAs.

1.110 "***Representatives***" has the meaning set forth in Section 10.3(a).

1.111 "***RoW***" means all countries of the Territory other than the U.S. For clarity, except as expressly set forth in Article 2, the territories licensed under the China Agreement are not included in RoW.

1.112 "***SEC***" means the U.S. Securities and Exchange Commission.

1.113 "***Sublicense Agreement***" has the meaning set forth in Section 7.3(b).

1.114 "***Sublicensee***" means any Third Party granted a sublicense by AstraZeneca or any of its Affiliates under the rights licensed to AstraZeneca pursuant to Article 7.

1.115 "***Subsequent Agreement***" has the meaning set forth in Section 7.4(c).

1.116 "***Subsequent Licensee***" has the meaning set forth in Section 7.4(c).

1.117 "***Supply and Quality Agreement***" has the meaning set forth in Section 6.5.

1.118 "***Tax and Taxation***" means any form of tax or taxation, levy, duty, charge, social security charge, contribution, or withholding of whatever nature (including any related fine, penalty, surcharge or interest) imposed by, or payable to, a Tax Authority.

1.119 "***Tax Authority***" or "***Tax Authorities***" means any government, state or municipality, or any local, state, federal or other fiscal, revenue, customs, or excise authority, body or official anywhere in the world, authorized to levy Tax.

1.120 "***Technical Product Failure***" means (a) a [*] of a Collaboration Compound or Product under Development or Commercialization under this Agreement, as determined (including following a review of the Carcinogenicity Studies) (i) by a consensus decision by the JSC or (ii), following referral of the matter to the Executive Officers pursuant to Section 2.6(c), by a consensus decision by the Executive Officers, or (iii), in the event that a consensus decision by the Executive Officers has not been attained within twenty (20) Business Days after the JSC's

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submission of the matter to them, by expedited resolution in accordance with Section 14.8; or (b) a Regulatory Authority action or decision [*].

1.121 "***Term***" has the meaning set forth in Section 13.1.

1.122 "***Territory***" means all countries of the world other than (a) the countries listed on **Exhibit A** and (b) China (including Hong Kong SAR and Macau SAR, but excluding Taiwan region). The Territory consists of the U.S. and RoW.

1.123 "***Third Party***" means any entity other than FibroGen or AstraZeneca or an Affiliate of either of them.

1.124 "***Transatlantic Clinical Development Plan***" or "***TCDP***" has the meaning set forth in Section 3.2(b).

1.125 "***U.S.***" means the United States of America (including all possessions and territories thereof).

1.126 "***U.S. Commercialization Budget***" has the meaning set forth in Section 5.2.

1.127 "***U.S. Commercialization Plan***" has the meaning set forth in Section 5.2.

1.128 "***U.S. GAAP***" means generally accepted accounting principles in the U.S.

1.129 "***Valid Claim***" means, with respect to a Product in a particular country, any claim of a FibroGen Patent that specifically or generically claims (i) the Collaboration Compound included in such Product as a composition of matter, (ii) a method of manufacture of such Collaboration Compound, or (iii) a method of treatment or other use of such Collaboration Compound [*] and either:

(a) with respect to a granted and unexpired Patent in such country, that (i) has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal, and (ii) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or

(b) with respect to a pending Patent application, that was filed and is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application. For purposes hereof, a claim in a patent application that has not been granted within [*]) years from the priority date for such claim (or, with respect to [*]) shall not be considered to be a Valid Claim, unless and until such claim thereafter issues such that it is included in subsection (a) above.

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ARTICLE 2

COLLABORATION; GOVERNANCE

2.1 Collaboration Overview. The Parties desire and intend to collaborate with respect to the Development and Commercialization of Products in the Field in the Territory, as and to the extent set forth in this Agreement (the "***Collaboration***"). It is intended that the Collaboration utilize AstraZeneca's position as a large, fully-integrated pharmaceutical company, while recognizing FibroGen's current experience and expertise in, and aspirations to further develop its clinical development and commercialization capabilities with respect to, HIF Compounds.

2.2 Joint Steering Committee.

(a) Purpose; Formation. The Parties hereby establish a joint steering committee (the "***JSC***") that will monitor and oversee their activities under this Agreement in the Territory and under the China Agreement in China, resolve disputes within subcommittees and facilitate communications between the Parties with respect to the Development and Commercialization of Products in the Territory and in China (under the China Agreement), all in accordance with this Section 2.2.

(b) Composition. Each Party shall initially appoint five (5) representatives of such Party or its applicable Affiliates to the JSC. Each representative appointed to the JSC shall have sufficient seniority within the applicable Party or its Affiliate to make decisions arising within the scope of the JSC's responsibilities. The Parties' initial representatives to the JSC are set forth on **Exhibit G**. The JSC may change its size from time to time by mutual consent of its members, provided that the JSC shall at all times consist of an equal number of representatives of each of FibroGen and AstraZeneca. Each Party may replace its JSC representatives at any time upon written notice to the other Party. The JSC may invite non-members (including consultants and advisors of a Party who are under an obligation of confidentiality consistent with this Agreement) to participate in the discussions and meetings of the JSC, provided that such participants shall have no voting authority at the JSC. Each Party shall appoint a secretariat to the JSC who is not a member of the JSC.

(c) Specific Responsibilities. In addition to its overall responsibility for monitoring and providing a forum to discuss and coordinate the Parties' activities under this Agreement, the JSC shall in particular:

(i) oversee the collaborative activities of the Parties under this Agreement and the China Agreement, including overseeing the China Committee;

(ii) oversee and delegate responsibility for the use of any information arising under the Astellas Agreements, to the extent that (A) [*] such information; and (B) such information [*] this Agreement;

(iii) review and fully discuss the Development and Commercialization of Products and any other ongoing activities;

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(iv) receive and discuss reports from the JDC and JCC and provide guidance thereto, and approve the Development Plan (and associated Development Budget) and U.S. Commercialization Plan and amendments thereto;

(v) receive and discuss reports from the China Committee and provide guidance thereto, and approve the applicable Development and Commercialization plans and budgets;

(vi) receive and discuss reports from the IP Committee, provide guidance thereto and review strategies for obtaining, maintaining, defending and enforcing patent and trademark protection for Products within the Territory;

(vii) attempt to resolve issues presented to it by, and disputes within, the JDC, JCC and China Committee or any other subcommittee;

(viii) at least annually, discuss and determine indications for Development of Products;

(ix) review and approve the filing of an NDA for a Product in the U.S. prior to submission;

(x) establish such additional joint subcommittees as it deems necessary to achieve the objectives and intent of this Agreement;

(xi) review and approve the JPT Charter and any subsequent amendments thereto, including the composition and responsibilities of the Core JPT; and

(xii) perform such other functions as appropriate to further the purposes of this Agreement as allocated to it in writing by the Parties.

The JSC shall further – until the date when the JDC or the JCC has been formed – assume the responsibilities of the JDC and the JCC, as applicable, and delegate certain responsibilities to the Core JPT as set forth in Schedule G(a) for the JDC and Schedule G(b) for the JCC.

(d) Delegation or Assumption of Responsibilities by the JSC. The JSC may by mutual consent of its members:

(i) delegate any of its responsibilities set out in this Section 2.2 or in Schedule G(a) or G(b) to any of its subcommittees or the Core JPT; or

(ii) assume any responsibilities assigned to any of its subcommittees.

(e) Meetings. The JSC shall hold its first meeting within thirty (30) days after the Effective Date. The JSC shall meet at least one (1) time per Calendar Quarter during the Term unless the Parties mutually agree in writing to a different frequency for such meetings. Either

Party may also call a special meeting of the JSC (by videoconference or teleconference) by at least ten (10) Business Days prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, and such Party shall provide the JSC no later than ten (10) Business Days prior to the special meeting with materials reasonably adequate to enable an informed decision; provided, however, that where a special meeting is called for on shorter notice with regard to a matter that does not admit delay, such notice and such materials shall be provided as early as possible in advance of such meeting. No later than ten (10) Business Days (or such shorter period as may be necessary in the event of a special meeting called for on shorter notice in accordance with the foregoing) prior to any meeting of the JSC, the secretariats of the JSC shall jointly prepare and circulate an agenda for such meeting. The JSC may meet in person, by videoconference or by teleconference. Notwithstanding the foregoing, at least two (2) meetings per Calendar Year shall be in person unless the Parties mutually agree in writing to waive such requirement in lieu of a videoconference or teleconference. In-person JSC meetings will be held at locations alternately selected and hosted by FibroGen and by AstraZeneca. The host Party shall be responsible for the costs and expenses of the JSC meeting hosted, provided that each Party will bear the expense of its respective JSC members' and other attendees' participation in JSC meetings, including travel costs. Meetings of the JSC shall be effective only if at least one (1) representative of each Party is present or participating in such meeting. The JSC secretariat of the host Party will be responsible for keeping reasonably detailed written minutes of all JSC meetings that reflect, without limitation, material decisions made at such meetings. The JSC secretariat of the host Party shall send draft meeting minutes to the other Party's JSC secretariat, and each secretariat shall seek and obtain review and approval of such minutes from its respective Party's members of the JSC within ten (10) Business Days after each JSC meeting. Such minutes will be deemed approved unless one or more members of the JSC objects to the accuracy of such minutes within ten (10) Business Days of receipt.

(f) Decision-Making. In addition to resolving issues specifically delegated to it, the JSC shall have the authority to resolve any disputes within the Collaboration not resolved by the JDC, JCC, China Committee and any other committees that the Parties may subsequently create to assist in governance of the Collaboration, except where expressly specified elsewhere in this Agreement. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party, and all decision making shall be by consensus. Disputes at the JSC shall be handled in accordance with Section 2.6.

2.3 Joint Development Committee.

(a) Formation; Composition. At a time determined by the JSC, the Parties shall establish a committee to oversee Development of Product(s) in the Territory and in China in accordance with the Development Plan(s) for such Product(s) and to coordinate the Development activities of the Parties (the "***JDC***") and prior thereto, the JSC will be responsible for all JDC responsibilities except for the specific responsibilities it delegates to the Core JPT as set out in Schedule G(a).

Each Party shall appoint three (3) representatives of such Party or its Affiliates to the JDC at its inception. Each representative appointed to the JDC shall have knowledge and expertise in relevant

aspects of the development of small molecule pharmaceutical products, including in the area of chronic kidney disease or cardiovascular or metabolic disorders and having sufficient seniority within the applicable Party or Affiliate to make decisions arising within the scope of the JDC's responsibilities. The JDC may change its size from time to time by mutual consent of its members, provided that the JDC shall consist at all times of an equal number of representatives of each of FibroGen and AstraZeneca. Each Party may replace its JDC representatives at any time upon written notice to the other Party. The JDC may invite non-members (including consultants and advisors of a Party who are under an obligation of confidentiality consistent with this Agreement) to participate in the discussions and meetings of the JDC, provided that such participants shall have no voting authority at the JDC. The JDC shall have two (2) co-chairmen, one selected by FibroGen and one selected by AstraZeneca. The role of the co-chairmen shall be to convene and preside at meetings of the JDC, but they shall have no additional powers or rights beyond those held by the other JDC representatives. Each Party shall appoint a secretariat to the JDC.

(b) Specific Responsibilities of the JDC. In addition to its general responsibilities, the JDC (or the JSC until the JDC is formed, with certain delegations as set forth in this Section 2.3 and Schedule G(a)) shall in particular:

(i) provide regular reports to the JSC regarding the development of the Product, and discuss, prepare and submit to the JSC for approval annual and interim amendments to the Development Plan (and the Development Budget) for each Product;

(ii) discuss and manage the implementation of the Initial Development Plan;

(iii) oversee the conduct of Development;

(iv) discuss the audited final report from the Carcinogenicity Studies, including whether or not a Technical Product Failure has occurred, and provide input thereon to the JSC;

(v) propose to the JSC particular studies to be conducted;

(vi) create, implement and review the Development Strategy for Development in the Territory and the design of all Clinical Trials and Nonclinical Studies conducted under each Development Plan, including Phase 4 Clinical Trials;

(vii) oversee any CMC related development activities, e.g. stability studies or packaging development, as well as other activities to prepare for supply of drug substance and finished Product for Commercialization, including to oversee the selection process for, and select (pursuant to Section 6.4), a contract manufacturer to be used by FibroGen for commercial supplies;

(viii) decide whether and when to initiate or discontinue any Clinical Trial and any Nonclinical Study under each Development Plan, including Phase 4 Clinical Trials;

(ix) allocate budgeted resources and determine priorities for each Clinical Trial and Nonclinical Study under each Development Plan, including Phase 4 Clinical Trials;

(x) oversee the conduct of all Clinical Trials and Nonclinical Studies under each Development Plan, including Phase 4 Clinical Trials;

(xi) select Third Party contractors to conduct Clinical Trials of Products;

(xii) facilitate the flow of Information between the Parties with respect to the Development of Products, including Development Data [*] under this Agreement;

(xiii) discuss whether to Develop Products for other indications and propose any such indications to the JSC;

(xiv) allocate primary responsibility as between the Parties for tasks relating to Development of Products where not already specified in the Development Plan;

(xv) discuss the requirements for Regulatory Approval in the Territory and oversee and coordinate regulatory matters with respect to Products in the Territory, including to review and approve material regulatory filings (other than the filing of an NDA in the U.S., which shall be approved by the JSC) prior to submission thereof;

(xvi) establish a publication strategy for publications and presentations related to Products in the Territory and review and approve all such publications in accordance with Section 12.5;

(xvii) facilitate the flow of Information between the Parties with respect to obtaining Regulatory Approval for Products; and

(xviii) perform such other functions as may be appropriate to further the purposes of this Agreement, as directed by the JSC.

(c) Meetings. Following its inception, the JDC shall meet at least one (1) time per Calendar Quarter (or more frequently when necessary), spaced at regular intervals, unless the Parties mutually agree in writing to a different frequency. Either Party may also call a special meeting of the JDC (by videoconference or teleconference) by at least ten (10) Business Days prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, and such Party shall provide the JDC no later than ten (10) Business Days prior to the special meeting with materials reasonably adequate to enable an informed decision; provided, however, that where a special meeting is called for on shorter notice with regard to a matter that does not admit delay, such notice and such materials shall be provided as early as possible in advance of such meeting. No later than ten (10) Business Days (or such shorter period as may be necessary in the event of a special meeting called for on shorter notice in accordance with the foregoing) prior to any meeting of the JDC, the secretariats shall jointly prepare and circulate an agenda for such meeting; provided, however, that either Party shall be free to propose additional topics to be included on such agenda, either prior to or, subject

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to the consent of the other Party, in the course of such meeting. The JDC may meet in person, or at the request of either Party, by videoconference or teleconference. In-person JDC meetings will be held at locations alternately selected and hosted by FibroGen and by AstraZeneca. Each Party shall report to the JDC on all material issues relating to the Development of Products for and in the Territory at the JDC meeting occurring after such issues arise. The host Party shall be responsible for the costs and expenses of the JDC meeting hosted, provided that each Party will bear the expense of its respective JDC members' and other attendees' participation in JDC meetings, including travel costs. Meetings of the JDC shall be effective only if at least one (1) representative of each Party is present or participating in such meeting. The secretariat of the host Party shall be responsible for keeping reasonably detailed written minutes of all JDC meetings that reflect all decisions made at such meetings. The secretariat of the host Party shall send meeting minutes to the other Party's secretariat, and each secretariat shall seek and obtain review and approval of such minutes from its respective Party's members of the JDC within ten (10) Business Days after each JDC meeting. Minutes will be deemed approved unless one or more members of the JDC objects to the accuracy of such minutes within ten (10) Business Days of receipt.

(d) Decision-Making. The JDC shall act by consensus. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party. If the JDC cannot reach consensus on an issue that comes before the JDC and over which the JDC has oversight, then the Parties shall refer such matter to the JSC for resolution in accordance with Sections 2.2(e) and 2.6(b).

2.4 Joint Commercialization Committee.

(a) Formation; Composition. At a time determined by the JSC, but no later than the earlier of (i) eighteen (18) months prior to the date of the expected First Commercial Sale of the Product in the U.S. and (ii) six (6) months prior to the projected date of submission of the first NDA for the Product in the U.S., the Parties shall establish a committee to oversee Commercialization of Products in the Territory and in China (the "***JCC***"), and prior thereto, the JSC will be responsible for all JCC responsibilities except for the specific responsibilities it delegates to the Core JPT as set out in Schedule G(b).

Each Party shall appoint three (3) representatives of such Party or its Affiliate to the JCC at its inception. Each representative appointed to the JCC shall have knowledge and expertise in relevant aspects of the commercialization of small molecule pharmaceutical products, including in the area of chronic kidney disease or cardiovascular or metabolic disorders and having sufficient seniority within the applicable Party or its Affiliate to make decisions arising with the scope of the JCC's responsibilities. The JCC may change its size from time to time by mutual consent of its members, provided that the JCC shall consist at all times of an equal number of representatives of each of FibroGen and AstraZeneca. Each Party may replace its JCC representatives at any time upon written notice to the other Party. The JCC may invite non-members (including consultants and advisors of a Party who are under an obligation of confidentiality consistent with this Agreement) to participate in the discussions and meetings of the JCC, provided that such participants shall have no voting authority at the JCC. The JCC shall have a chairman, who shall be selected by AstraZeneca. The role of the chairman shall be to convene and preside at meetings of the JCC,

but the chairman shall have no additional powers or rights beyond those held by the other JCC representatives.

(b) Specific Responsibilities of the Joint Commercialization Committee. In addition to its general responsibilities, the Joint Commercialization Committee (or the JSC until the JCC is formed, with certain delegations as set forth in this Section 2.4 and Schedule G(b)) shall in particular:

(i) oversee Commercialization in the Territory and (as set out in more detail in the China Agreement) China;

(ii) regularly report to the JSC regarding the Commercialization of the Products, and discuss, prepare and submit for approval to the JSC the U.S. Commercialization Plan for each Product in the U.S., including any amendments thereto;

(iii) review and approve each commercialization plan for the RoW prepared by AstraZeneca;

(iv) oversee implementation of each U.S. Commercialization Plan;

(v) coordinate the Commercialization activities of FibroGen and AstraZeneca with respect to Products, including pre-launch and post-launch activities;

(vi) allocate primary responsibility as between the Parties for tasks relating to Commercialization of Products in the U.S.;

(vii) determine the amount of Product to be distributed free of charge annually for regulatory or marketing purposes or investigator-initiated trials (it being understood and agreed that neither Party shall have the right to distribute the Product as samples except pursuant to Section 5.7);

(viii) oversee global harmonization of the Product;

(ix) be responsible for publication matters as described in Section 2.3(b)(xvi) upon transition of such responsibility from the JDC to the JCC; and

(x) perform such other functions as appropriate to further the purposes of this Agreement, as directed by the JSC.

(c) Meetings. Following its inception, the JCC shall meet at least one (1) time per Calendar Quarter, spaced at regular intervals unless the Parties mutually agree in writing to a different frequency. Either Party may also call a special meeting of the JCC (by videoconference or teleconference) by at least ten (10) Business Days prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, and such Party shall provide the JCC no later than ten (10) Business Days prior to the special meeting with materials reasonably adequate to enable an informed decision; provided, however, that where a special meeting is called for on shorter notice with regard to a matter that does not admit delay, such notice and such materials shall be provided as early as

possible in advance of such meeting. No later than ten (10) Business Days (or such shorter period as may be necessary in the event of a special meeting called for on shorter notice in accordance with the foregoing) prior to any meeting of the JCC, the secretariats shall jointly prepare and circulate an agenda for such meeting; provided, however, that either Party shall be free to propose additional topics to be included on such agenda, either prior to or, subject to the consent of the other Party, in the course of such meeting. The JCC may meet in person, by videoconference, or by teleconference. In-person JCC meetings will be held at locations alternately selected and hosted by FibroGen and by AstraZeneca. Meetings of the JCC shall be effective only if at least one (1) representative of each Party is present or participating in such meeting. Each Party shall report to the JCC on all material issues relating to the Commercialization of Products promptly after such issues arise. The host Party shall be responsible for the costs and expenses of the JCC meeting hosted, provided that each Party will bear the expense of its respective JCC members' and other attendees' participation in JCC meetings, including travel costs. The secretariat of the host Party will be responsible for preparing reasonably detailed written minutes of JCC meetings that reflect all decisions made at such meetings. The secretariat of the host Party shall send meeting minutes to the other Party's secretariat, and each secretariat shall seek and obtain review and approval of such minutes from its respective Party's members of the JCC within ten (10) Business Days after each JCC meeting. Minutes will be deemed approved unless one or more members of the JCC objects to the accuracy of such minutes within ten (10) Business Days of receipt.

(d) Decision-Making. The JCC shall act by consensus. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party. If the JCC cannot reach consensus on an issue that comes before the JCC and over which the JCC has oversight, then the Parties shall refer such matter to the JSC for resolution in accordance with Sections 2.2(e) and 2.6.

2.5 Coordination with Astellas. FibroGen shall designate one of AstraZeneca's JSC representatives (as selected by AstraZeneca) to serve as a member of the steering committee under the Astellas Collaboration, who (except as described in the next sentence) shall be entitled to participate in the decision-making of such committee pursuant to the Astellas EU Agreement. The designated representative will be permitted to attend meetings of such committee; provided that such representative shall not have the right to attend portions of (or participate in decision-making with respect to) any such meeting that are not relevant to the Development or Commercialization of Products in the Territory or in China.

2.6 Resolution of Committee Disputes.

(a) Within Operating Committees. All decisions within any Committee other than the JSC shall be made by consensus, and if a dispute arises which cannot be resolved within such Committee, then the representatives of either Party may cause such matter to be referred to the JSC for resolution as provided in Section 2.2(e).

(b) Within The JSC. All decisions within the JSC (whether originating there, or referred to it by an operating Committee) shall be made by consensus. If a matter is referred by an operating Committee to the JSC, it shall use good faith efforts, in compliance with Section 2.6(d), to resolve promptly such matter. If the JSC is unable to reach consensus on any issue for which it is responsible, within ten (10) Business Days after a Party affirmatively states that a

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decision needs to be made, either Party may elect to submit such issue to the Parties' Executive Officers in accordance with Section 2.6(c).

(c) Referral to Executive Officers. If a Party makes an election under Section 2.6(b) to refer a matter to the Executive Officers, the JSC shall submit in writing the respective positions of the Parties to their respective Executive Officers. Such Executive Officers shall use good faith efforts, in compliance with Section 2.6(d), to resolve promptly such matter, which good faith efforts shall include at least one meeting (in-person, by telephone, video conference or other appropriate means) between such Executive Officers within twenty (20) Business Days after the JSC's submission of such matter to them. If the Executive Officers are unable to reach consensus on any such matter within such twenty (20) Business Day period, then either Party may invoke the dispute resolution provisions of Article 14; provided, however, that:

(i) FibroGen's Executive Officer shall have the final say with respect to: [*]

(1) [*];

(ii) AstraZeneca's Executive Officer shall have the final say with respect to:

(1) [*].

(d) Good Faith. In conducting themselves on Committees, and in exercising their rights under this Section 2.6, all representatives of both Parties shall consider diligently, reasonably and in good faith all input received from the other Party, and shall use reasonable efforts to reach consensus on all matters before them. In exercising any decision making authority granted to it under this Article 2, each Party shall act based on its good faith judgment of what is in the best interests of the Products and the Collaboration.

2.7 Alliance Managers. Each Party shall, within thirty (30) days following the Effective Date, appoint a single person who shall oversee contact between the Parties for all subject matter related to the Collaboration between meetings of the JSC, JPT, JDC and JCC, and shall have such other responsibilities as the Parties may agree in writing after the Effective Date (such person, the "***Alliance Manager***"). Each Party may replace its Alliance Manager at any time by notice in writing to the other Party. The Alliance Managers shall work together to manage and facilitate the Collaboration governance meetings and the communication between the Parties under this Agreement, including the resolution (in accordance with the terms of this Agreement) of issues between the Parties that arise in connection with this Agreement. The Alliance Managers shall not have final decision-making authority with respect to any matter under this Agreement.

2.8 General Committee Authority. Each Committee shall have solely the powers expressly assigned to it in this Article 2 and elsewhere in this Agreement. No Committee shall have any power to amend, modify, or waive compliance with this Agreement (or any agreement entered into in connection with this Agreement). It is expressly understood and agreed that the control of decision-making authority by FibroGen or AstraZeneca, as applicable, pursuant to

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Section 2.6, so as to resolve a disagreement or deadlock on a Committee for any matter will not authorize either Party to perform any function not delegated to a Committee, and that neither FibroGen nor AstraZeneca shall have any right to unilaterally modify or amend, or waive its own compliance with, the terms of this Agreement.

2.9 Joint Project Team. The Parties hereby establish a joint project team (the "***Joint Project Team***" or "***JPT***") to develop and propose plans to governing committees, manage operational activities and serve as an information resource for the Committees. The members of the JPT representing core functions relevant to the joint development and commercialization of Products (the "***Core Joint Project Team***" or "***Core JPT***") shall provide oversight to the overall JPT. Until such time as when the JDC and the JCC have been formed, the Core JPT shall have the additional responsibilities set out in Schedule G(a) and G(b), respectively. Neither the JPT nor the Core JPT will have any decision-making authority, except as set out in Schedule G(a) or G(b) or otherwise explicitly authorized by an appropriate Committee. The Parties agree to establish a JPT Charter on or prior to October 31, 2014, which contains the composition and responsibilities of the JPT and the Core JPT. Subject to the JPT Charter, the Core JPT will consist of project leaders as appointed by FibroGen and by AstraZeneca, and such additional members as the Parties deem appropriate from time to time. Each Party will appoint appropriately qualified and authorized representatives for each applicable operational area or function. The JPT members will serve as the point of contact for operational matters between the Parties. The JPT may form subteams to support the efforts of the JPT as agreed by the Parties. As appropriate, FibroGen may arrange, on its own initiative or at AstraZeneca's reasonable request from time to time, a joint meeting between the JPT and the project team under the Astellas Collaboration.

2.10 Executive Meetings. FibroGen's Chief Executive Officer and an appropriate Executive Vice President of AstraZeneca (or other appropriate representative of AstraZeneca of equivalent seniority) will meet in advance of the occurrence of key scheduled Development and Commercialization events or in connection with key decisions, to review and discuss the status and direction of the Collaboration.

2.11 Discontinuation of Participation on a Committee. Each Committee shall continue to exist until the first to occur of (a) the Parties mutually agreeing to disband the Committee, or (b) FibroGen providing to AstraZeneca written notice of its intention to disband and no longer participate in such Committee, which FibroGen retains the right to do at any time during the Term, in its sole discretion, provided, however, that doing so shall not relieve FibroGen of any of its obligations under this Agreement or the China Agreement (save from the obligation to participate at the relevant Committee meetings). Once FibroGen has provided written notice as referred to in subsection (b) above, such Committee shall have no further obligations under this Agreement and AstraZeneca shall have the right to solely decide, without consultation, any matters previously before such Committee, subject to the other terms of this Agreement.

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ARTICLE 3

DEVELOPMENT

3.1 Overview. The Parties agree to undertake a joint development program to further Develop the Collaboration Compounds and Products as provided in this Article 3 under the direction of the JDC (or, the JSC prior to the inception of the JDC), and pursuant to the Development Plan (such program, the "***Development Program***"). Prior to the JDC's inception, all references to the JDC in this Article 3 and elsewhere in this Agreement will be deemed references to the JSC (which may delegate certain responsibilities to the Core JPT in accordance with Schedule G(a)).

3.2 Development Plans.

(a) General. All Development of any given Product pursuant to this Agreement for the U.S. and RoW shall be conducted pursuant to a development plan (the "***Development Plan***") that describes (i) the proposed overall program of Development for the applicable Product and indications in the U.S. and RoW, including Clinical Trials and Nonclinical Studies, toxicology, formulation, packaging development, process and analytical development, production of registration and validation batches, regulatory plans and other elements of obtaining Regulatory Approval(s) in each applicable country; (ii) the anticipated start dates and data availability dates of such Clinical Trials, Nonclinical Studies and CMC development activities, and timelines for key Regulatory Authority meetings, filing of applications for Regulatory Approval, and the receipt of Regulatory Approvals and (iii) the respective roles and responsibilities of each Party in connection with such activities. The Development Plan will be associated with a detailed budget for all such activities conducted by the Parties for the U.S. In the event of any inconsistency between the Development Plan and this Agreement, the terms of this Agreement shall prevail.

(b) Initial Development Plan. The initial Development Plan, along with the associated Development Budget, describing (among other things) the planned development of the Product for the CKD Indications for the U.S., is attached hereto as **Exhibit H** (the "***Initial Development Plan***"). The Initial Development Plan includes and shall be integrated with those Phase 3 Clinical Trials that are currently being conducted by FibroGen or Astellas under the U.S. and EU plan for conducting Phase 3 Clinical Trials of the Product for the CKD Indications under the Astellas EU Agreement (the "***Transatlantic Clinical Development Plan***" or the "***TCDP***"). FibroGen shall notify AstraZeneca, via the JDC, of all material updates and material changes to the TCDP. The Initial Development Plan shall further outline such additional Phase 3 Clinical Trials as the Parties have agreed to conduct (i.e. in addition to those being conducted under the TCDP). Within thirty (30) days after the Effective Date, the JPT will initiate implementation of the Initial Development Plan.

(c) Development Strategy. Within one (1) year after the Effective Date or at such other time as the Parties may mutually agree, the JDC will prepare for the JSC's review and approval an overall development strategy for the Product in the Field in the Territory, including

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the CKD Indications for the RoW and any other indications (or other life cycle management) the Parties are considering to develop (or conduct) throughout the Territory, which strategy will include anticipated dates (estimated based on the date of completion of certain development events) for preparing detailed descriptions of applicable events for inclusion in an amended Development Plan (the "***Development Strategy***"). The Development Strategy will include reasonable timeframes for any additional indications (i.e., in addition to the CKD Indications) to be developed hereunder, with the understanding that not all such indications will be developed concurrently.

(d) Amendments to the Development Plan.

(i) On an annual basis (no later than October 31st of the preceding Calendar Year), or more often as the Parties deem appropriate, the JDC shall prepare amendments to the then-current Development Plan and Development Budget for approval of the JSC. Each such amended Development Plan shall specify, with a reasonable level of detail, the items described in Section 3.2(a). Such amended Development Plan shall cover the next Calendar Year (and additional periods as reasonably determined by the Parties) and shall contain a corresponding budget for U.S. activities. Such updated and amended Development Plan shall reflect any changes, re-prioritization of studies within, reallocation of resources with respect to, or additions to the then-current Development Plan. In addition, the JDC may prepare amendments for approval of the JSC to the Development Plan and corresponding Development Budget from time to time during the Calendar Year in order to reflect changes in such plan and budget for such Calendar Year, in each case, in accordance with the foregoing. At the request of either Party, but no more frequently than quarterly, the JDC shall review the Development Budget and propose any necessary amendments to the JSC for approval. Once approved by the JSC, the amended annual Development Plan and Development Budget shall become effective for the applicable period on the date approved by the JSC (or such other date as the JSC shall specify). Any JSC-approved amended Development Plan and Development Budget shall supersede the previous Development Plan and Development Budget for the applicable period.

(ii) Each Party shall notify the other Party promptly upon becoming aware that it is likely to exceed, or has exceeded, the budget for a particular activity for U.S. Development of the Product allocated to such Party in the Development Plan. Thereafter, the JDC shall promptly meet and determine whether to amend the Development Plan or Development Budget accordingly, provided that the JDC shall not unreasonably withhold its agreement to any budget amendment proposed by either Party that results from causes outside of such Party's reasonable control or that the Parties agree includes expenses reasonably incurred in the performance of the Development Plan. Any such amendment proposed by the JDC shall not be subject to the JSC's review and will be deemed automatically approved by the JSC, unless such amendment would cause the total Development Costs incurred by a Party in any Calendar Year to exceed [*] percent [*]%) of the budgeted Development Costs for such Party in such Calendar Year, in which event JSC approval will be required; provided that the JSC shall not unreasonably withhold its agreement to any budget amendment proposed by either Party that results from causes outside of such Party's reasonable control and that the Parties agree includes expenses reasonably incurred in the performance of the Development Plan.

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(e) Development Responsibilities. Unless the Parties agree in writing upon an alternate allocation of responsibility, the Parties shall have the following rights and obligations with respect to operational responsibilities under each Development Plan:

(i) U.S. Operational responsibility for all studies designed to support Regulatory Approvals in the U.S. will be shared between the Parties as allocated in the Development Plan; provided that FibroGen and Astellas (it being agreed that as between the Parties FibroGen will be responsible for all such activities conducted by Astellas; provided however, that [*] Astellas [*] Astellas [*] FibroGen [*] this Agreement [*] FibroGen [*] under the Astellas Agreements with respect to such activities) will be responsible for conducting the first Phase 3 Clinical Trials (that are included also in the TCDP) of the Product in the CKD Indications under the Initial Development Plan. For clarity, the term 'first Phase 3 Clinical Trials', as used in this section, shall be the studies identified as [*] in the Initial Development Plan.

(ii) RoW. AstraZeneca shall be solely responsible for all aspects of the Development of Collaboration Compounds and Products that are solely applicable to the RoW (which, for clarity, does not include China).

(iii) Development Sharing Period. During the Development Sharing Period, FibroGen shall conduct all Development in good faith, and using Commercially Reasonable Efforts to achieve the then-current timelines in such Development Plan.

(f) Development Decision-Making. Except as otherwise expressly provided in this Agreement, all matters regarding the Development Plan shall be decided by consensus by the JDC, subject to Section 2.6.

3.3 Coordination with Astellas.

(a) AstraZeneca understands and agrees that FibroGen's and AstraZeneca's conduct of certain Development and Commercialization activities for North America (meaning the U.S., Mexico and Canada) hereunder are subject to the terms of the Astellas EU Agreement, and that FibroGen's obligations to Astellas may require additional procedures, consents or adherence to notification obligations. Accordingly, the Parties shall, as applicable, take into consideration such obligations when formulating the plans for, and coordinate, [*], and FibroGen shall use Commercially Reasonable Efforts to obtain [*] Development in the Territory under this Agreement. [*]. Notwithstanding anything else in this Agreement to the contrary, however, FibroGen shall not be required to perform (or refrain from performing) any Development activity that would constitute a violation of its obligations under the Astellas Agreements, as disclosed to AstraZeneca prior to the Effective Date.

(b) If, [*], FibroGen shall promptly notify AstraZeneca and such matter shall be discussed at a specially convened JSC meeting. In the event that AstraZeneca, pursuant to Section 3.9, both (i) is not obligated to use Commercially Reasonable Efforts to Develop such

Product in such indication; and (ii) following notification by FibroGen, determines that it does not wish to participate in such Development in such indication, the following shall apply:

(i) FibroGen shall be free to Develop, obtain Regulatory Approval for and Commercialize such Product in such indication throughout the Territory;

(ii) As between the Parties, such Development and Commercialization shall be undertaken at FibroGen's sole cost;

(iii) FibroGen shall use Commercially Reasonable Efforts to ensure that such Development and Commercialization shall not materially impact AstraZeneca's rights under this Agreement (it being understood that such Development and Commercialization are not considered per se to materially impact AstraZeneca's rights under this Agreement);

(iv) The Parties shall, as soon as practicable, discuss in good faith an option arrangement whereby AstraZeneca may obtain rights to such Product in such indication at a future decision point. The Parties shall negotiate in good faith the terms under which AstraZeneca would obtain such rights, which terms include [*] and [*]; and

(v) The Parties shall discuss in good faith, appropriate amendments to the provisions of this Agreement to reflect such Development and Commercialization of such Product in such indication by FibroGen, including, without limitation, amendments to the pharmacovigilance provisions in Section 4.3. If the Parties fail to agree on such terms within a reasonable time period, either Party may refer the matter to the Executive Officers for discussion.

(c) The Parties shall ensure that each amended Development Plan allows for the conduct of such Clinical Trials as are included in the then current TCDP. If the JDC agrees that additional studies (i.e. in addition to those included in the TCDP) are required for the Product in the CKD Indications for the U.S., then the Parties shall, where required, [*]. FibroGen shall use Commercially Reasonable Efforts to [*], shall use Commercially Reasonable Efforts to [*].

(d) FibroGen shall use Commercially Reasonable Efforts from time to time during the Term to [*] or other rights that AstraZeneca or the Parties reasonably believe [*] in order to allow AstraZeneca to obtain the benefit of its rights and licenses pursuant to this Agreement.

3.4 Development Costs.

(a) **Allocation**. The Parties shall share equally all costs and expenses incurred by or on behalf of either Party to conduct Development of the Product for the U.S. under the Development Plan during the Development Sharing Period, according to the terms of Section 8.2, including for supply of Collaboration Compound or Product in accordance with Article 6, in each case to the extent that such Development Costs are not borne or reimbursed by Astellas under the Astellas EU Agreement, provided that FibroGen will timely inform AstraZeneca of any such costs borne or reimbursed by Astellas. AstraZeneca shall be responsible for all costs and expenses it incurs in the conduct of activities under the Development Plan for the RoW and shall reimburse

FibroGen for all costs and expenses FibroGen incurs (including Personnel Costs, the Fully Burdened Cost of Collaboration Compound or Product or comparator drug, concomitant drug, placebo or other materials used in any Clinical Trial or Nonclinical Studies, and all other out-of-pocket costs) for activities conducted by FibroGen (i) for the U.S. after the Development Sharing Period and (ii) for the RoW, in each case (i) and (ii) under the Development Plan within the applicable Development Budget (for the U.S.) or budget (for RoW) (subject to overages described in Section 3.4(b)) and according to the terms of Section 8.2, together with the reimbursement for supply of Collaboration Compound or Product in accordance with Article 6. For clarity, all Clinical Trials set out in the Initial Development Plan shall be deemed to be Development of the Product for the U.S.

(b) Overage. Notwithstanding the foregoing in Section 3.4(a), unless otherwise agreed by the JDC (subject to JSC approval to the extent set forth in Section 3.2(d)(ii)) or by the Parties, either before or after the applicable expense is incurred (which agreement shall not be unreasonably withheld for any budget overage outside the applicable Party's reasonable control and reasonably incurred in the performance of the Development Plan), for any Calendar Quarter, each Party will be solely responsible for Development Costs it incurs in excess of [*] percent [*]%) of the total amount allocated to such Party's activities in such Calendar Quarter in the Development Budget, and for any Calendar Year, each Party will be solely responsible for Development Costs it incurs in excess of [*] percent [*]%) of the total amount allocated to such Party's activities in such Calendar Year in the Development Budget, provided that Development Costs incurred in excess of [*]% for the Calendar Quarter or [*]% for the Calendar Year, as applicable, of the amounts so budgeted shall also be reimbursed if the Parties determine in good faith that such Development Costs were reasonably incurred in the performance activities under the Development Plan and that such budget overage was caused by circumstances outside of such Party's reasonable control.

3.5 Indications Outside the Field.

(a) Inclusion. If either Party desires to develop a particular Product for an indication outside the Field, it may propose such indication to the other Party in writing by providing the other Party with a high-level proposed development plan for such Product in such indication. Upon the other Party's request within sixty (60) days after receipt of such development plan, the Parties shall meet to discuss such proposed indication and shall work together in good faith to generate and gather the necessary information to support such potential development and to prepare a detailed development plan. If the Parties agree on such plan, AstraZeneca shall have the right to include the proposed indication in the Field, solely with respect to the applicable Product, by written notice to FibroGen. If AstraZeneca exercises such right, such indication will be a "***Designated Indication***", the Field will automatically be expanded to include the Designated Indication (without payment of any additional upfront fees, milestones or other consideration except those payments already provided for under this Agreement), the terms of this Agreement (including payment terms and diligence obligation) will apply to such indication and the JDC shall promptly prepare a development plan for such indication for review and approval by the JSC.

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(b) Termination. The Field will automatically be amended to remove any Designated Indication upon the occurrence of any of the following events: (a) the permanent cessation (excluding, for example, suspension, termination or completion pending further review, consideration or development planning) of all Clinical Trials by both Parties with respect to such Product for such Designated Indication prior to Regulatory Approval in any country in the Territory in such Designated Indication, (b) the termination of all Regulatory Approvals for such Designated Indication in the Territory without either Party intending or considering to restore or replace any such Regulatory Approval, or (c) the decision of the JSC to permanently cease all Commercialization of such Product in such Designated Indication.

(c) Restriction. For clarity, Designated Indications are only those indications outside the Field that AstraZeneca agrees to include in this Agreement. Except for Designated Indications pursuant to this Agreement, FibroGen shall not Develop or Commercialize (directly or indirectly, by license, supply of Product or otherwise) any Product for any indication outside the Field in the Territory during the term of this Agreement.

3.6 Additional Compounds.

(a) Added by FibroGen. At any time during the Term, FibroGen may upon written notice to AstraZeneca include any HIF Compound in the definition of Collaboration Compound (and Product). Effective upon such written notice, the identified HIF Compound shall be deemed a Collaboration Compound, provided that AstraZeneca shall not have any obligations with respect to such Collaboration Compound (or Product) under this Agreement unless and until AstraZeneca's acceptance thereof through written notice to FibroGen.

(b) Added by Agreement.

(i) If AstraZeneca wishes to include additional HIF Compounds as Collaboration Compounds (and Products), it may make such a request to FibroGen. Upon receipt of such request, FibroGen shall make good faith and diligent efforts to present to the JSC for review all reasonably relevant data and other information (excluding chemical structures) Controlled by FibroGen that is related to those HIF Compounds that it reasonably believes offer substantial clinical benefit over then-current Collaboration Compounds from its library of HIF Compounds, including results from any Phase 2 Clinical Trial conducted in the Field. For clarity, the foregoing does not impose any obligation on FibroGen to identify or generate any additional HIF Compounds.

(ii) If AstraZeneca and FibroGen, through the JDC and JSC, agree upon a development program for any such HIF Compounds, then the Parties shall negotiate in good faith to agree on any additional consideration to be payable by AstraZeneca to FibroGen for inclusion of such additional HIF Compounds as Collaboration Compounds, and upon agreement, will amend this Agreement accordingly.

(c) Subject to Section 3.3 and to FibroGen's obligations under the Astellas EU Agreement, FibroGen will use good faith in designating additional HIF Compounds as

Collaboration Compounds pursuant to this Section 3.6, and shall not nominate additional HIF Compounds for Development in the [*] without approval of the JSC.

3.7 Veterinary Applications. Following the first approval of an NDA for a Product, the Parties may agree to develop the Product for a veterinary application. No additional consideration shall be payable by AstraZeneca to FibroGen with respect to such development. Upon agreement, the Parties shall enter into a separate agreement governing such applications or amend this Agreement accordingly prior to conducting any activities with respect to veterinary applications.

3.8 Research Collaboration. Upon FibroGen's request, the Parties will discuss conducting a research program funded by AstraZeneca and directed toward franchise enhancement and lifecycle management for HIF Compounds or other topics that the Parties determine relevant to the Products and the Field. Upon agreement on the terms of such research program, the Parties will enter into a separate agreement or amend this Agreement accordingly.

3.9 Diligence; Standards of Conduct.

(a) Each Party shall use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval for the Products throughout the Territory (i) in the CKD Indications and (ii) in each [*], other indication in the Field and Designated Indication that [*] in the Development Plan. If at any time there is only one Collaboration Compound (either because no additional Collaboration Compounds have been developed or because development of all other Collaboration Compounds have been terminated), then the foregoing obligation shall be for one Product only.

(b) Each Party shall use Commercially Reasonable Efforts to carry out the tasks assigned to it under the Development Plan in a timely and effective manner. Each Party shall conduct its activities under the Development Plan in a good scientific manner and in compliance in all material respects with all applicable laws and regulations. Without prejudice to the aforesaid, the Party responsible for the conduct of any Clinical Trials hereunder shall perform such Clinical Trials in a good scientific manner, in compliance with all applicable laws and regulations, GCP, this Agreement and the Development Plan as well as the relevant protocol and investigator's brochure. Such Party shall further require the principal investigators, study sites and any contractors involved in the performance of such Clinical Trials to comply with all safety reporting procedures set forth in the Pharmacovigilance Agreement in connection with their performance of such Clinical Trials.

3.10 Development Data.

(a) Ownership and Disclosure. FibroGen shall solely own all data, records and reports generated by or on behalf of either Party in the conduct of Development activities under this Agreement (collectively, the "***Development Data***"), and AstraZeneca hereby assigns, and shall assign, to FibroGen, all of its right, title and interest in and to the Development Data. Each Party shall provide access to and, where practical, copies of the Development Data it (or its Affiliates or Sublicensees, or Third Parties acting on their behalf) generates to the other Party

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promptly upon receipt or development thereof, including nonclinical and clinical data (including raw data), analysis, reports and protocols. With respect to any data, records and reports, including nonclinical and clinical data (including raw data), analysis, reports and protocols, generated by or on behalf of FibroGen [*]"), the following shall apply. [*]. AstraZeneca shall reimburse FibroGen for any translation costs, costs for photocopying or other similar administrative expenses incurred by FibroGen in connection with providing access to the [*]. Each Party will reasonably respond to the other Party's request for access to and questions about the Development Data and Astellas Data. Such Development Data will be provided in electronic form if requested by the other Party or reasonably convertible to such electronic form.

(b) Use. Each Party shall have the right to use the Development Data, and [*], for the purpose of Developing and Commercializing Products in the Field in the Territory in accordance with the terms of this Agreement and in China in accordance with the terms of the China Agreement. [*]. AstraZeneca hereby grants [*]. AstraZeneca will take all actions reasonably requested by FibroGen to enable [*], at FibroGen's cost and expense. FibroGen hereby grants AstraZeneca, its Affiliates and Sublicensees a right of access, a right of reference and a right to use and incorporate all Development Data [*] in any regulatory filings for Products in the Territory. FibroGen will take all actions reasonably requested by AstraZeneca to enable AstraZeneca and its Affiliates and Sublicensees to practice such rights, at AstraZeneca's cost and expense.

3.11 Development Records and Reports. Each Party shall maintain or cause to be maintained complete and accurate records (in the form of technical notebooks and/or electronic files where appropriate) of all work conducted by it or on its behalf under the Development Plan and all Information resulting from such work, including in the case of FibroGen, records of whether Development Costs are borne or reimbursed by Astellas under the Astellas EU Agreement. Such records, including any electronic files where such Information may also be contained, shall fully and properly reflect all work done and results achieved in the performance of the Development Plan in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. Such records shall be retained by such Party for at least five (5) years after the term of this Agreement or such longer period as may be required by applicable laws. Each Party shall have the right to review and copy such records maintained by the other Party at reasonable times and to obtain access to originals to the extent needed for patent or regulatory purposes or for other legal proceedings. Each Party shall provide the JDC with regular reports, at least annually, detailing its Development activities under the Development Plan and the results of such activities.

3.12 Subcontracts. Each Party may perform any of its Development Program obligations under this Agreement through one or more subcontractors or consultants, provided that (a) such Party remains responsible for the work allocated to, and payment to, such subcontractors and consultants as it selects to the same extent it would if it had done such work itself; (b) the subcontractor undertakes in writing obligations of confidentiality and non-use regarding Product Information and Confidential Information, that are substantially the same as those undertaken by the Parties pursuant to Article 12 hereof, and (c) the subcontractor agrees in writing to assign all intellectual property developed in the course of performing any such work under the Development

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Program to the Party retaining such subcontractor. A Party may also subcontract work on terms other than those set forth in this Section 3.12, with the prior approval of the JDC.

ARTICLE 4

REGULATORY MATTERS

4.1 Regulatory Filings and Approvals.

(a) In General. The Parties intend that the Development Plan will set forth the regulatory strategy for seeking Regulatory Approvals (including any pricing and reimbursement approvals) throughout the Territory for all Products being Developed. All decisions regarding regulatory issues shall be made in accordance with the decision-making rules that are set forth in Article 2.

(b) Rights and Obligations.

(i) Lead Regulatory Party. The lead regulatory Party, on a jurisdiction-by-jurisdiction basis, shall be responsible for preparing and filing all Regulatory Materials, including INDs, shall be the holder of all Regulatory Approvals in such jurisdiction and will have primary operational responsibility for interactions with Regulatory Authorities, including taking the lead role at all meetings with Regulatory Authorities, subject to the right of the other Party to attend such meetings, participate in such activities and provide input, which the lead regulatory Party will consider in good faith. Without limitation, this right of participation covers all regulatory activities, including development of regulatory strategy and review of regulatory submissions, attendance at all meetings with Regulatory Authorities that may potentially impact the Development of or registration package for a particular Product, and review of outcomes of such meetings.

(ii) U.S. FibroGen shall be the lead regulatory Party in the U.S. with respect to each Product and each indication through approval of the first NDA or supplemental NDA for such Product and indication. The Parties shall cooperate in maintaining each IND and preparing and submitting each NDA and applying for Regulatory Approval in the U.S. Following such approval, FibroGen will assign and transfer each such approved NDA or supplemental NDA to AstraZeneca (but not the ownership of Development Data therein, which shall be retained by FibroGen pursuant to Section 3.10(a)), and AstraZeneca will become the lead regulatory Party for such Product and indication in the U.S.; provided that (A) FibroGen will remain the lead regulatory Party with respect to the CMC section of each NDA for so long as FibroGen is conducting manufacturing activities under this Agreement, and (B) FibroGen will continue to have access to all information in each NDA. FibroGen shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts, including the filing of such assignments, agreements, documents and instruments, as may be reasonably necessary to effectively complete such assignment and transfer of such approved NDA or supplemental NDA to AstraZeneca. Each Party shall provide reasonable cooperation, information and other support to the other Party with respect to such other Party's obligations to comply with regulatory

requirements, regardless of whether such other Party is the lead regulatory Party, including following the transfer of an NDA to AstraZeneca following Regulatory Approval.

(iii) **RoW**. AstraZeneca shall be the lead regulatory Party in the RoW for all Products and indications.

(c) **Reporting and Review.**

(i) The JPT or JDC shall develop and implement procedures for drafting and review of material Regulatory Materials for Products in the Territory, which shall provide sufficient time (at least one week) for each Party to provide substantive comments prior to the filing of such Regulatory Materials (with material regulatory filings, or regulatory filings that materially change existing regulatory filings, subject to prior approval by the JPT or, when formed, the JDC or the JSC pursuant to Section 2.2(c)(ix) or Section 2.3(b)(xv), as applicable).

(ii) Each Party shall promptly notify the other Party of all Regulatory Materials that it submits for Products anywhere in the Territory and shall promptly (and in any event within one week) provide the non-responsible Party with a copy (which may be wholly or partly in electronic form) of such Regulatory Materials. The lead regulatory Party will provide the non-responsible Party with reasonable advance notice of any scheduled meeting with any Regulatory Authority and/or any Regulatory Materials with respect to Products throughout the Territory, and the non-responsible Party shall have the right to participate in any such meeting, except to the extent prohibited under applicable law and regulations. Representatives of the Party primarily responsible for such Regulatory Materials will be the primary spokespeople at any such meeting. The Party primarily responsible for such Regulatory Materials also shall promptly furnish the non-responsible Party with copies of all material correspondence to or from, and minutes of material meetings with, any Regulatory Authority relating to Development of such Product.

4.2 **Notification of Threatened Action**. Each Party shall immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from any Third Party, including a Regulatory Authority, which may materially affect the Development, Commercialization or regulatory status of a Product, whether in or outside the Territory. Upon receipt of such information, the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

4.3 **Adverse Event Reporting and Safety Data Exchange.** At a time determined by the JSC, but in any event prior to the first to occur of (i) the commencement of any Clinical Trial to be conducted by AstraZeneca or (ii) the transfer of the first NDA in the U.S. to AstraZeneca, the Parties shall define and finalize the methods and procedures (based on and consistent where possible with those methods and procedures used by Astellas and FibroGen under the Astellas EU Agreement, unless otherwise mutually agreed) that the Parties shall employ with respect to Products to protect patient safety and promote the appropriate treatment of safety information of Products in a written pharmacovigilance agreement (the "***Pharmacovigilance Agreement***"). For clarity, the Pharmacovigilance Agreement shall include all relevant safety data regarding the Product, irrespective of territory or indication. These responsibilities shall include mutually

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acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports, pregnancy reports, and any other information concerning the safety of any Product. Such guidelines and procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under applicable laws and regulations. Furthermore, such agreed procedure shall be consistent with GCP and relevant ICH guidelines, except where such guidelines may conflict with existing local regulatory reporting or safety reporting requirements, in which case the local reporting requirements shall prevail. FibroGen shall maintain a global safety database for the Products, the expenses for which will be included in Development Costs and reimbursed by AstraZeneca, to the extent not borne or reimbursed by Astellas. Each Party hereby agrees to comply with its respective obligations under such Pharmacovigilance Agreement and to cause its Affiliates and permitted sublicensees to comply with such obligations. If and to the extent necessary, the Pharmacovigilance Agreement shall be amended by the Parties, or shall be superseded, so that an appropriate commercial-stage pharmacovigilance agreement is in place in advance of the first NDA approval for a Product.

4.4 Product Withdrawals and Recalls. If any Regulatory Authority in or outside the Territory (a) threatens, initiates or advises any action to remove any Product from the market or (b) requires or advises FibroGen, AstraZeneca, or any of their respective Affiliates or Sublicensees to distribute a "Dear Doctor" letter or its equivalent regarding use of such Product, then FibroGen or AstraZeneca, as applicable, shall notify the other Party of such event within three (3) Business Days (or sooner if required by law) after such Party becomes aware of the action, threat, advice or requirement (as applicable). The JSC will discuss and attempt to agree upon whether to recall or withdraw a Product; provided, however, that if the Parties fail to agree within an appropriate time period, the Party who is the then-holder of the NDA for the Product at issue shall decide whether to recall or withdraw such Product. AstraZeneca shall be responsible, at its sole expense, for conducting any recalls or taking such other necessary remedial action in the Territory, except that FibroGen will be responsible for such expenses to the extent (i) resulting from the failure of any Product supplied by FibroGen to conform to the applicable specifications; or (ii) such recall results from an event outside the Territory and outside the territory licensed under the China Agreement.

ARTICLE 5

COMMERCIALIZATION

5.1 Overview. The Parties agree to collaborate with respect to the Commercialization of Products in the Field in the U.S. as provided in this Article 5 under the direction of the JCC, and pursuant to the U.S. Commercialization Plan applicable to each Product. AstraZeneca shall have the sole right and responsibility for Commercializing Products in the Field in the RoW under the direction of the JCC, in accordance with this Agreement and as provided in this Article 5. Prior to the JCC's inception, all references to the JCC in this Article 5 and elsewhere in this Agreement will be deemed references to the JSC (which may delegate certain responsibilities to the Core JPT in accordance with Schedule G(b)).

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5.2 U.S. Commercialization Plan. As further described in this Section 5.2, the comprehensive strategy for the Commercialization of each Product in the U.S. shall be described in a comprehensive plan that describes the pre-launch, launch and subsequent Commercialization of such Product in the U.S. (including without limitation the high level strategies regarding messaging, branding, pricing, advertising, planning, marketing, sales force training and allocation, and reimbursement/managed care), key tactics for implementing those activities and the relative responsibilities of the Parties (each such plan, a "***U.S. Commercialization Plan***"), and the associated budget for such activities that details the anticipated Commercialization Costs (each such budget, a "***U.S. Commercialization Budget***").

(a) Promptly after the Effective Date, the JCC (or if not formed, the JSC) will determine the initial pre-commercial activities for which AstraZeneca will prepare an initial U.S. Commercialization Plan, which activities will include [*], but need not include all activities described in the first paragraph of this Section 5.2. Within ninety (90) days thereafter, AstraZeneca will present such plan to the JCC for review and approval. Within two (2) years after the Effective Date but in any event not later than two (2) years prior to the then currently anticipated NDA submission date, AstraZeneca will present to the JCC a U.S. Commercialization Plan covering all activities described in the first paragraph of this Section 5.2, for review and approval by the JCC, which plan will include the key prelaunch and launch activities, marketing and sales deployment required for the initial launch of the Product and associated budgets. The JCC shall review, revise and recommend for approval by the JSC such U.S. Commercialization Plan promptly after receipt thereof. If the JCC is not yet formed by any of the foregoing dates, the JSC will review, revise and approve the applicable U.S. Commercialization Plan.

(b) AstraZeneca will prepare a detailed U.S. Commercialization Plan and U.S. Commercialization Budget in preparation for U.S. launch of the Product for review and approval by the JCC no later than the submission of the first NDA for the Product, or at such other time determined by the JSC.

(c) All U.S. Commercialization Plans and U.S. Commercialization Budgets with respect to Products in the U.S. and subsequent revisions thereto will contain such information as the JCC believes necessary for the successful Commercialization of such Product in the U.S., both pre- and post-launch, and shall generally conform to the level of detail utilized by AstraZeneca in preparation of its own product commercialization plans. On an annual basis (no later than October 31st of the preceding Calendar Year), or more often as the Parties deem appropriate, the JCC shall prepare amendments to the then-current U.S. Commercialization Plan(s) and the corresponding U.S. Commercialization Budgets. In the event of any inconsistency between a U.S. Commercialization Plan and this Agreement, the terms of this Agreement shall prevail. Each Party shall conduct its activities under the U.S. Commercialization Plan in compliance in all material respects with all applicable laws and regulations.

5.3 RoW Commercialization Plans. AstraZeneca shall prepare Commercialization plans with respect to Products in the RoW on an annual basis, shall submit such plans to the JCC for review and approval, and shall respond in a timely fashion to any reasonable requests of FibroGen or the JCC with respect to such plans and Commercialization activities in the RoW.

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5.4 Commercialization Costs. AstraZeneca shall be solely responsible for all Commercialization Costs incurred by it or by or on behalf of FibroGen under the Co-Commercialization Agreement and in the Commercialization of Products in the U.S. and RoW. AstraZeneca will reimburse FibroGen for such costs incurred by FibroGen, plus a markup of [*]) to be applied to FibroGen's [*] costs only, all pursuant to more detailed provisions to be included in the Co-Commercialization Agreement.

5.5 Sales and Distribution; Returns; Customer Support. AstraZeneca shall be solely responsible for handling all returns, recalls, order processing, invoicing and collection, booking of sales, distribution, and inventory and receivables for Products in the Territory. FibroGen shall not accept orders for Products or make sales for its own account or for AstraZeneca's account, and if FibroGen receives any order for Products in the Territory, it shall refer such orders to AstraZeneca for acceptance or rejection. AstraZeneca shall be responsible for handling all returns of any Product. If Products are returned to FibroGen, FibroGen shall promptly ship such Products to AstraZeneca. FibroGen, if requested by AstraZeneca, shall advise the customer who made the return that the Products have been returned to AstraZeneca. AstraZeneca shall be responsible for providing customer support, handling medical queries, and responding to product and medical complaints relating to Products.

5.6 Commercialization Reports. Each Party shall keep the JCC fully informed regarding the progress and results of Commercialization activities for Products in the U.S. and RoW, including an annual review of results versus plans (as set forth in the U.S. Commercialization Plan(s)).

5.7 Samples. At a time determined by the JSC, the Parties will discuss in good faith whether, how, and under what circumstances the Parties would allow distribution of samples (i.e., Products provided free of or for a nominal charge) of Product for treatment of anemia in patients with chronic kidney disease not undergoing dialysis, or in other applicable indications outside of the CKD Indications. Neither Party will have the right to distribute Product samples without the prior written consent of the other Party, and, if such consent is granted, each Party will distribute such samples only according to the procedures and in the amounts agreed by the Parties in writing.

5.8 Commercialization Standards of Conduct.

(a) Execution of U.S. Commercialization Plan. Each Party shall use Commercially Reasonable Efforts to carry out the tasks assigned to it under the U.S. Commercialization Plan and the Co-Commercialization Agreement in a timely and effective manner and in compliance with all applicable laws and regulations.

(b) AstraZeneca Diligence Obligations. AstraZeneca shall use Commercially Reasonable Efforts to Commercialize each Product in each indication and country in the Territory for which Regulatory Approval is obtained, except for indications and countries for which FibroGen has independently obtained Regulatory Approval, without opt-in by AstraZeneca, under Section 3.3(b).

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5.9 Subcontracts. Each Party may perform any of its obligations under the U.S. Commercialization Plan through one or more subcontractors or consultants, provided that (a) AstraZeneca will not subcontract any such activities without [*]; (b) such Party remains responsible for the work allocated to, and payment to, such subcontractors and consultants as it selects to the same extent it would if it had done such work itself; (c) the subcontractor undertakes in writing obligations of confidentiality and non-use regarding Product Information and Confidential Information, that are substantially the same as those undertaken by the Parties pursuant to Article 12 hereof, and (d) the subcontractor agrees in writing to assign all intellectual property developed in the course of performing any such work under the U.S. Commercialization Plan to the Party retaining such subcontractor. A Party may also subcontract work on terms other than those set forth in this Section 5.9, with the prior approval of the JCC. AstraZeneca will have [*] (subject to compliance with clauses (b) – (d) of this Section 5.9), except that AstraZeneca will be required to reasonably [*] Third Party subcontractors for such activity.

5.10 Co-Commercialization Agreement. Following submission of the first NDA for a Product or at such earlier time as AstraZeneca may request, the Parties will negotiate and enter into an agreement (the "***Co-Commercialization Agreement***") governing the Parties' conduct of activities for Commercializing the Product in the U.S. The Co-Commercialization Agreement will be consistent with the terms of this Article 5, **Exhibit I**, other terms agreed by the Parties, and other customary terms for such an agreement.

5.11 Regulatory Compliance.

(a) Each of FibroGen and AstraZeneca shall reasonably cooperate with the other Party in its efforts toward ensuring that all government reporting (including price and gift reporting), sales, marketing and promotional practices in respect of each Product meet the standards required by (A) applicable laws and regulations; (B) applicable guidelines concerning the advertising and promotion of prescription drug products, including without limitation the Office of the Inspector General's ("***OIG***") Compliance Guidance Program issued in 2003, the American Medical Association (the "***AMA***") Guidelines on Gifts to Physicians, the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, as hereafter amended from time to time (the "***PhRMA Code***"), the PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results, and the standards set forth by the Accreditation Council for Continuing Medical Education relating to educating the medical community in the United States ("***ACCME Standards***"); (C) the Prescription Drug Marketing Act of 1987, as amended, and the rules, regulations and guidelines promulgated thereunder; (D) federal, state and local agencies and all payor "fraud and abuse", and consumer protection and false claims statutes and regulations, including the Medicare and State Health Programs Anti-Kickback Law (42 U.S.C. §1320a-7b(b)) and the Safe Harbor Regulations which are found at 42 C.F.R. §1001.952 et seq.; and (E) the FCPA. The Parties shall cooperate in good faith to update their obligations under this Section 5.11(a) from time to time to reflect any changes in any of the foregoing (A) – (E) or to resolve any conflicts in any of the foregoing standards as applied to the Parties' activities under this Agreement.

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(b) Each Party shall be responsible for tracking and reporting transfers of value initiated and controlled by its employees and/or contractors pursuant to the requirements of Section 6002 (Transparency Reports and Reporting of Physician Ownership and Investment Interest) of the Affordable Care Act, commonly referred to as the "Sunshine Act", and state marketing reporting laws. The value reported to the Centers for Medicare & Medicaid Services shall be the amount expended by the controlling Party, irrespective of the division of or reconciliation of expenses between the Parties.

(c) AstraZeneca shall provide its sales representatives appropriate training on proper marketing and sales techniques. Such training will include, among other topics, FDA requirements and other state and federal regulations and guidelines concerning the advertising of prescription drug products, the OIG Compliance Guidance Program, the AMA Guidelines on Gifts to Physicians, the PhRMA Code, and the ACCME Standards. If requested by FibroGen, AstraZeneca shall provide a written description of the training to FibroGen no less frequently than on an annual basis.

(d) Each of FibroGen and AstraZeneca shall reasonably cooperate with the other Party to provide the other Party access to any and all information, data and reports required by the other in order to comply with the relevant provisions of the Medicare Modernization Act and any other applicable laws and regulations, including without limitation reporting requirements, in a timely and appropriate manner. AstraZeneca shall ensure that its reporting to the Centers for Medicare and Medicaid Services and other federal and state healthcare programs related to the Products is true, complete and correct in all respects; provided however, that AstraZeneca shall not be held responsible for submitting erroneous reports if such deficiencies result from information provided by FibroGen which itself was not true, complete and correct.

(e) AstraZeneca shall, so far as practicable, provide to FibroGen in advance any submission containing any information provided by FibroGen pursuant to this Section 5.11 that AstraZeneca proposes to submit to any governmental entity. AstraZeneca further agrees to seek confidential treatment of any such information related to FibroGen that it submits to any governmental entity to the extent permitted under any applicable laws and regulations.

(f) FibroGen and AstraZeneca shall confer with each other on a regular basis to discuss and compare their respective procedures and methodologies relating to each Party's compliance to any applicable laws or regulations or fulfillment of any other obligation contained in this Section 5.11. In the event that the parties have different understandings or interpretations of this Section 5.11 or of the applicability of, or standards required by, any applicable laws or regulations, then the Parties shall confer and seek to reach common agreement on such matters.

(g) Each of AstraZeneca and (where applicable) FibroGen agrees that:

(i) it will instruct its sales representatives to use, and will use Commercially Reasonable Efforts to train and monitor its sales representatives to ensure that such sales representatives use, only Promotional Materials and literature approved for use under subsection (h) of **Exhibit I** for the promotion of the Products in the U.S.;

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(ii) it will instruct its sales representatives not to misbrand, change, alter or adulterate any Promotional Materials supplied to it in any way prior to or during their distribution or use; and

(iii) it will instruct its sales representatives to do, and will use Commercially Reasonable Efforts to train its sales representatives to do, and will establish appropriate internal systems, policies and procedures for the monitoring of its sales representatives with the goal of ensuring that such personnel do, the following:

(1) limit claims of efficacy and safety for the Products to those that are (A) consistent with approved promotional claims in, and not add, delete or modify claims of efficacy and safety in the promotion of such Products in any respect from those claims of efficacy and safety that are contained in, the then effective U.S. Commercialization Plan, (B) consistent with applicable laws and regulations, and (C) consistent with the Product labeling approved by the FDA;

(2) not make any changes in Promotional Materials, and use Promotional Materials within the U.S. only in a manner that is consistent with (A) the then effective U.S. Commercialization Plan, (B) applicable laws and regulations and (C) the Product labeling approved by the FDA;

(3) promote the Products in compliance with applicable legal and professional standards that are generally accepted by the pharmaceutical industry in the applicable market, including applicable laws and regulations and the applicable guidelines concerning the advertising and promotion of prescription drug products described in this Section 5.11; and

(4) not to, directly or indirectly, pay, promise to pay, or authorize the payment of any money, or give, promise to give, or authorize the giving of anything of value to any official or employee of any Governmental Authority, or to any political party, or official thereof, or to any candidate for political office (including any party, official, or candidate) for the purpose of promoting the sale or improper use of a Product.

ARTICLE 6

MANUFACTURE AND SUPPLY

6.1 Purchase and Supply Commitment. AstraZeneca hereby appoints FibroGen as its exclusive supplier of Product (drug substance and drug product) for the Territory for use in accordance with the terms of this Agreement. AstraZeneca agrees to purchase, and FibroGen agrees to supply, all of AstraZeneca's and its Affiliates' and their respective Sublicensees' requirements of Product (as bulk drug product and drug substance) for Development and Commercialization in the Territory under the terms of this Article 6. AstraZeneca shall have the exclusive right to perform (itself or through its Affiliates, Sublicensees or Distributors) and shall be solely responsible for final product labeling and secondary packaging for sale to end users in the Territory. To the extent that such labeling and packaging are relevant to FibroGen's activities

to seek and obtain Regulatory Approval for the Product, AstraZeneca will reasonably and timely cooperate with FibroGen, in a manner sufficient to enable FibroGen to receive Regulatory Approval and to provide materials and Information as requested by FibroGen. The right of FibroGen to manufacture on behalf of AstraZeneca contemplates that at a time to be determined by the JSC, and in any event before the point in time when [*] in any twelve (12) month period, AstraZeneca will have the right to select, or obligate FibroGen to select, a second supplier (which may be AstraZeneca itself), and FibroGen will have the obligation to complete activities to undertake technology transfer in order for such secondary source to establish and secure regulatory approval as a second source for drug substance for Product, which shall in any event not limit FibroGen's right to continue to ensure that a source of Product be maintained in the U.S. in order to satisfy FibroGen's obligations under the Astellas Agreements and the DFCI Agreement. For clarity, FibroGen shall have the right to manufacture Product outside the Territory to fulfill its supply obligations under this Agreement. For clarity, subject to the terms of this Agreement, FibroGen shall have the right to satisfy its obligations under this Article 6 through a Third Party contract manufacturer. In connection with FibroGen's manufacture of Products for use under this Agreement, FibroGen shall have the right to manufacture in the Territory for supply of Products under the Astellas Agreements.

6.2 Development Supply. In connection with the supply of any Product for non-commercial use, FibroGen shall supply Product in compliance with applicable law and regulations, including GMP requirements, and in accordance with forecasts set forth in the Development Plan or, if not specified therein, the forecasts developed by the JDC as necessary for the conduct of Clinical Trials set forth in the Development Plan. FibroGen shall use Commercially Reasonable Efforts to meet any applicable timelines for supplying Product, subject to the reasonable lead time requirements of Third Party contract manufacturers. AstraZeneca will pay FibroGen's Fully Burdened Cost for all Product supplied for Development, within forty-five (45) days after receipt of invoice therefor. All Products supplied for a country after Regulatory Approval in such country will be considered to be for commercial use, unless used specifically for Clinical Trials under the Development Plan. The terms of supply by FibroGen to AstraZeneca for use in any Clinical Trial conducted under the sponsorship of AstraZeneca or for other non-commercial use by or on behalf of AstraZeneca, are as set forth on **Exhibit J**.

6.3 Commercial Supply Agreement. At a time specified by AstraZeneca, but in any event in a reasonable period in advance of the anticipated launch date for the Product in the U.S., the Parties will negotiate in good faith and enter into separate supply and quality agreements governing the commercial supply of Product (in bulk and primary packaged forms) from FibroGen to AstraZeneca (together, the "***Supply and Quality Agreement***"). The Supply and Quality Agreement will include the terms and conditions set forth on **Exhibit K** and contain such further customary and commercially reasonable terms governing similar supply arrangements and other terms as the Parties may agree, including appropriate forecasting and firm purchase order lead times, taking into consideration the reasonable notice requirements of FibroGen as well as any other terms set forth in this Article 6. The initial Supply and Quality Agreement shall have a term of [*]) years for the supply of drug substance, after which AstraZeneca would have the right to extend the term for an additional [*] years or to assume responsibility for drug substance manufacture upon agreement of terms mutually agreed by the Parties, including [*] in the form

of drug substance. Under the Supply and Quality Agreement, the obligation to supply drug product shall have a term of five (5) years, which will automatically renew for succeeding five (5)-year terms and will include the price applicable pursuant to Section 6.5. In the event of any inconsistency between the Supply and Quality Agreement and Article 6 of this Agreement with regard to matters relating to supply, quality control and quality assurance, the terms of the Supply and Quality Agreement shall prevail.

6.4 Contract Manufacture Process. FibroGen is currently utilizing a contract manufacturer to fulfill its manufacturing timelines to complete drug product development in time for the expected commercial launch of the Product in the U.S. and under the Astellas Agreements. Notwithstanding the provisions of Section 6.3, upon AstraZeneca's written request to FibroGen, not to be submitted earlier than six (6) months after the Effective Date, the Parties will discuss in good faith whether to select a separate contract manufacturer mutually acceptable to the Parties to be used for formulation and bulk drug product manufacture (using drug substance supplied by FibroGen) for commercial supply under this Agreement. The Parties shall discuss in good faith the transfer, including timely technology transfer, as soon as practicable following such mutual agreement. Such selection will be conducted in accordance with the following process: As soon as reasonably practicable following AstraZeneca's request, the Parties will afford an opportunity for at least two (2) different Third Party contract manufacturers that are mutually acceptable to the Parties, consent not to be unreasonably withheld, to submit bids to conduct such manufacture. Such bids shall be based on a request for quotation, the contents of which shall be agreed by the Parties in good faith (and shall contain such specifications and forecasts as are reasonably necessary for a contract manufacturer to submit a bid with respect to such manufacture). AstraZeneca and its Affiliates shall provide a proposal on the same basis as the Third Party contract manufacturers. The Parties shall review and assess in good faith the bids submitted by the Third Party manufacturers and by AstraZeneca or its Affiliate and shall recommend to the JDC the bid that, on the whole, offers the most favorable terms for such manufacture based on a reasonable assessment of the relevant factors, including price, capital requirements, quality, capacity, capability to maintain continuity of supplies, considerations related to the supply of Product to Astellas and global supply of Product and overall timeline. FibroGen will enter into a supply and quality contract with the Third Party contract manufacturer, on terms consistent with the selected bid and otherwise reasonably acceptable to the Parties, or the responsibility to manufacture shall be transferred to AstraZeneca, as determined by the JDC. In the event FibroGen shall contract with AstraZeneca or its Affiliate in accordance with this Section 6.4, FibroGen shall – as soon as reasonably practicable after the completion of the selection process – provide the necessary technology transfer as well as all necessary assistance to obtain required regulatory approvals, all to enable AstraZeneca or its Affiliate to conduct the formulation and bulk drug product manufacture (using drug substance supplied by FibroGen) for supply of Product under this Agreement, and to Astellas under the Astellas Agreements. If AstraZeneca is not selected as the contract manufacturer, then at any time after the [*], at AstraZeneca's request, the Parties shall [*]. For clarity, to the extent that the alternative formulation and drug product manufacture is transferred to such Third Party, FibroGen shall have the right to use such source of supply to satisfy FibroGen's obligations under the Astellas Agreements.

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6.5 Transfer Price.

(a) FibroGen will supply to AstraZeneca (or its designated Affiliate or Sublicensee) Product for commercial use as drug product at a transfer price equal to [*] during the Calendar Year in which such Product is delivered. Notwithstanding the foregoing, in the event that the Parties agree that AstraZeneca shall supply drug product and FibroGen shall only supply drug substance, the transfer price for such drug substance shall be [*] during the Calendar Year in which such Product is delivered.

(i) If FibroGen supplies Product as drug product, then not less than thirty (30) days prior to the beginning of each Calendar Year during which FibroGen will be supplying product (each a "***Delivery Year***"), the Parties will calculate a preliminary transfer price per unit (the "***Preliminary Price Per Unit***"), which shall be equal to [*] multiplied by the fraction (A)/(B), where (A) shall be the estimated [*] for such Delivery Year and (B) shall be the estimated [*] in the Territory during such Delivery Year (all estimations to be made by the Parties in good faith). FibroGen will invoice AstraZeneca upon delivery of each shipment of product at the Preliminary Price Per Unit and AstraZeneca will pay for such product at such price within forty-five (45) days after its receipt of such invoice. Within forty-five (45) days following the end of each Delivery Year, the Parties will calculate the definitive transfer price per unit ("***Definitive Price Per Unit***") for such year, which shall be equal to [*] multiplied by the fraction (A)/(B), where (A) shall be the actual [*] made during the Delivery Year and (B) shall be the actual [*] in the Territory during such Delivery Year (excluding [*]). If the transfer price for the total volume of product actually delivered by FibroGen during the Delivery Year at the Definitive Price Per Unit (the "***Total Definitive Price***") exceeds the transfer price for such volume based on the Preliminary Price Per Unit (the "***Total Preliminary Price***"), then AstraZeneca shall pay the difference to FibroGen within forty-five (45) days after its receipt of an invoice from FibroGen for such amount. If the Total Preliminary Price exceeds the Total Definitive Price, FibroGen shall issue a credit note to AstraZeneca for the difference. AstraZeneca shall be entitled to set off the amount due under the credit note against any subsequent payments owed by AstraZeneca to FibroGen under this Agreement (or, in the absence of any such subsequent payments, such credit note shall be settled by FibroGen within forty-five (45) days after its receipt thereof).

(ii) If FibroGen supplies Product as drug substance, then the Parties shall calculate the price for Product according to a process similar to that described in clause (i) above, except that the multiplier shall be [*] during the Delivery Year.

(b) Potential Cost Reductions. At either Party's request during the Term, the Parties shall discuss and explore potential means of collaborating to reduce the overall costs of manufacture and supply of Products as drug substance or bulk drug product under this Agreement, with the understanding that the Parties shall share the financial benefits of any such cost reductions achieved in a reasonable manner taking into account to what extent each Party has contributed to such cost reductions.

(c) Adjustment for Generic Entry. If at any time FibroGen's net margin percentage on any Product supplied to AstraZeneca falls below [*]) after a Generic Product is

sold in any country in the Territory, FibroGen shall have the right to renegotiate the manufacturing and supply payment terms under the Supply and Quality Agreement. Upon FibroGen's request, the Parties shall renegotiate reasonable terms in good faith, taking into account also the overall profitability of such Product to AstraZeneca.

ARTICLE 7

LICENSES AND EXCLUSIVITY

7.1 License to AstraZeneca.

(a) License Grant. Subject to the terms and conditions of this Agreement, FibroGen hereby grants AstraZeneca (i) a co-exclusive (with FibroGen), royalty-bearing, sublicensable (solely as permitted in accordance with Section 7.3) license under the FibroGen Technology to Develop (solely in accordance with the Development Plan) Products in the Field in the Territory and (ii) an exclusive, royalty-bearing, sublicensable (solely as permitted in accordance with Section 7.3) license under the FibroGen Technology to Commercialize, to make and have made (solely for use in the Territory under this Agreement), and to use, sell, offer for sale, and import Products in the Field in the Territory (subject, however to a retained right for FibroGen to perform Development and Commercialization (including manufacturing) activities pursuant to this Agreement or the China Agreement or under the Astellas Agreements).

(b) DFCI Agreement.

(i) The terms and conditions of Sections [*] of the DFCI Agreement are binding on AstraZeneca in its capacity as a sublicensee of FibroGen under the DFCI Agreement.

(ii) AstraZeneca acknowledges and agrees that its rights to the FibroGen Technology that is licensed to FibroGen under the DFCI Agreement are at all times subject to the applicable terms of the DFCI Agreement. [*].

(iii) FibroGen shall use best efforts to maintain the DFCI Agreement in effect. [*].

(iv) The license granted in Section 7.1(a) is subject to certain reserved rights as set forth in Section [*] of the DFCI Agreement.

7.2 License to FibroGen. Subject to the terms and conditions of this Agreement, AstraZeneca hereby grants FibroGen a non-exclusive, worldwide, sublicensable, royalty-free, fully-paid license, under the AstraZeneca Technology during the Term, to conduct any and all activities assigned to FibroGen under the Development Plans and U.S. Commercialization Plans, and to Develop and Commercialize Products outside the Territory.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

7.3 Sublicensing.

(a) Scope of Permissible Sublicensing. The license granted by FibroGen to AstraZeneca in Section 7.1 may be sublicensed by AstraZeneca: (i) to an Affiliate of AstraZeneca without any requirement of consent, provided that such sublicense to an Affiliate of AstraZeneca shall immediately terminate if and when such party ceases to be an Affiliate of AstraZeneca, or (ii) where such sublicense is made to enable a Third Party to provide contract research or development services or contract manufacturing services for AstraZeneca, its Affiliates or Sublicensees, without such Third Party being granted the right to distribute, market or sell a Product, to such Third Party without any requirement of consent, but upon written notice to FibroGen and subject to Sections 3.12 and 5.9, and no sooner than twelve (12) days after such notice, or (iii) otherwise (i.e. other than pursuant to (i) or (ii) above) only with the prior written consent of FibroGen, not to be unreasonably withheld, and no sooner than twelve (12) days after such consent is obtained. It will not be unreasonable for FibroGen to withhold its consent to a sublicense pursuant to subsection (iii) above to (1) any entity that [*] or (2) any company engaged in the sales of tobacco or tobacco-related products. AstraZeneca shall be liable to FibroGen for the acts or omissions of its Sublicensees, and any breach of an applicable provision of this Agreement by a Sublicensee shall be deemed to be a breach by AstraZeneca.

(b) Sublicense Agreements. AstraZeneca shall, in each agreement under which it grants a sublicense under a license set forth in Section 7.1 (each, a "***Sublicense Agreement***"), require the Sublicensee to (A) comply with the obligations in Section 7.8 (as applied to such Sublicensee and its Affiliates) and (B) provide the following to FibroGen if this Agreement terminates and to AstraZeneca if only such Sublicense Agreement terminates: (i) the assignment and transfer of ownership and possession of all Regulatory Materials and Regulatory Approvals held or possessed by such Sublicensee (which assignment could also be directly to AstraZeneca prior to any such termination), and (ii) the assignment of, or a freely sublicensable exclusive license to, all intellectual property Controlled by such Sublicensee that covers or embodies a Product or Collaboration Compound or its respective use, manufacture, sale, or importation and was created by or on behalf of such Sublicensee during the exercise of its rights or fulfillment of its obligations pursuant to such Sublicense Agreement. Each Sublicense Agreement shall be subject to the applicable terms and conditions of this Agreement, the DFCI Agreement and any Third Party licenses sublicensed to the Sublicensee. AstraZeneca shall include a copy of the DFCI Agreement in all Sublicense Agreements. AstraZeneca shall forward a copy of each Sublicense Agreement (which may be redacted but shall contain all provisions relevant to this Agreement unredacted) to FibroGen within twenty (20) days after execution thereof, and FibroGen shall have the right to provide such copy to DFCI; provided that with respect to any Sublicense Agreement with an Affiliate of AstraZeneca, AstraZeneca shall only be required to provide such copy upon FibroGen's request. Annually, AstraZeneca shall forward to FibroGen a copy of the reports received by AstraZeneca from its Sublicensees during the preceding twelve (12) month period under each Sublicense Agreement as shall be pertinent to (i) the Sublicensee's operations under each Sublicense Agreement and (ii) a royalty accounting under the Sublicense Agreement, in each case solely to the extent relevant to FibroGen's rights under this Agreement or (to the extent different, as notified by FibroGen to AstraZeneca) DFCI's rights under the DFCI Agreement. FibroGen shall have the right to provide each such report to DFCI. FibroGen shall require DFCI

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to comply with confidentiality and non-use obligations in respect of information disclosed to DFCI in accordance with this Section 7.3(b), which obligations shall be substantially the same as those undertaken by the Parties pursuant to Article 12.

(c) Distributorships. AstraZeneca shall have the right, in its sole discretion, to appoint its Affiliates, and AstraZeneca, its Affiliates and its Sublicensees shall have the right, in their sole discretion, to appoint any other person or entity, in the Territory, to distribute, market and sell the Products, with or without packaging rights. In circumstances where such appointed person or entity purchases its requirements of Products from AstraZeneca, its Affiliates or its Sublicensees, but does not otherwise make any royalty or other payment to AstraZeneca, its Affiliates or its Sublicensees with respect to intellectual property rights, and where such person is not an Affiliate of AstraZeneca, then that person or entity shall be a "***Distributor***" for purposes of this Agreement. The term "packaging rights" in this Section 7.3(c) shall mean the right for the Distributor to package Products supplied in unpackaged bulk form into individual ready-for-sale packs.

(d) Co-Promotion. Subject to Section 5.9, AstraZeneca and its Affiliates shall have the right, in their sole discretion, to co-promote the Products with any other person or entity, or to appoint one or more Third Parties to promote the Products without AstraZeneca in all or any part of the Territory, provided however that the foregoing shall not adversely impact FibroGen's right to co-promote the Product as described under this Agreement.

7.4 FibroGen's Activities.

(a) Covenant by FibroGen. Except pursuant to this Agreement or the China Agreement, FibroGen and its Affiliates shall not, and shall not license or authorize any Third Party to, directly or indirectly,

(i) at any time during the Term Develop or Commercialize any Product in the Territory within or outside of the Field;

(ii) at any time during the period starting on the Effective Date and continuing until the earlier to occur of (A) the [*] this Agreement and (B) the [*] this Agreement ("***Covenant Period 1***") Develop any HIF Compound in any ESA Indication in the Territory or any indication for which AstraZeneca is Developing or Commercializing a Collaboration Compound or Product under this Agreement; and

(iii) at any time during the period starting on the Effective Date and continuing until the earlier to occur of (A) the [*] of this Agreement and (B) the [*] in the Territory ("***Covenant Period 2"***) Commercialize any HIF Compound in any ESA Indication in the Territory or any indication for which AstraZeneca is Developing or Commercializing a Collaboration Compound or Product under this Agreement.

(b) Astellas Agreements. [*].

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(c) Termination of Astellas Agreements. Effective upon the termination of either of the Astellas Agreements with respect to a particular country or countries (the "***Astellas Terminated Territory***"), FibroGen hereby grants AstraZeneca a right of first negotiation to obtain a license to develop and commercialize Products in the Astellas Terminated Territory, as detailed in this Section 7.4(c). Accordingly, prior to entering into any agreement with a Third Party for such purpose, FibroGen shall provide to AstraZeneca a written notice of FibroGen's interest in entering into an agreement with respect to the development and/or commercialization of Products in the Astellas Terminated Territory. [*]. If the Parties do not reach an agreement with respect to the grant of such rights with respect to Products in the Astellas Terminated Territory [*] FibroGen shall have no further obligation with respect to the Astellas Terminated Territory under this Section 7.4(c). Notwithstanding the foregoing sentence, if FibroGen enters into an agreement with a Third Party (a "***Subsequent Licensee***") with respect to the Products and the Astellas Terminated Territory (a "***Subsequent Agreement***"), FibroGen shall ensure that such Subsequent Agreement does not conflict with the terms of this Agreement and shall use Commercially Reasonable Efforts to ensure that AstraZeneca [*] under such Subsequent Agreement [*], and in any event shall ensure that AstraZeneca's rights with respect to the Subsequent Licensee [*].

(d) Remedy. FibroGen hereby acknowledges and agrees that in the event of any actual or threatened breach of this Section 7.4, AstraZeneca will suffer an irreparable injury, such that no remedy at law shall afford it adequate protection against, or appropriate compensation for, such injury. Accordingly, FibroGen hereby agrees that AstraZeneca shall be entitled to specific performance of FibroGen's obligations under this Section 7.4, as well as such further timely injunctive relief as may be granted by a court of competent jurisdiction.

7.5 Cross-Territorial Restriction.

(a) AstraZeneca hereby covenants and agrees that it shall not, and will ensure that its Affiliates and Sublicensees will not, either directly or indirectly, actively promote, market, distribute, import, sell or have sold Product into countries outside the Territory. As to such countries outside the Territory: (i) AstraZeneca shall not, and will ensure that its Affiliates and Sublicensees will not, engage in any advertising or promotional activities relating to the Product directed primarily to customers or other buyers or users of the Product located in such countries; and (ii) AstraZeneca shall not, and will ensure that its Affiliates and Sublicensees will not, solicit orders for Products from any prospective purchaser located in such countries. If AstraZeneca receives any order for Products from a prospective purchaser located in a country outside the Territory from which re-imports into the Territory are unlikely, AstraZeneca shall immediately refer that order to FibroGen. AstraZeneca shall not accept any such orders. AstraZeneca may not deliver or tender (or cause to be delivered or tendered) any Product into a country outside of the Territory from which re-imports into the Territory are unlikely. AstraZeneca shall not, and will ensure that its Affiliates and Sublicensees will not, restrict or impede in any manner FibroGen's exercise of its retained rights outside the Territory, provided that any such exercise of rights by FibroGen shall comply with the terms of this Agreement.

(b) FibroGen hereby covenants and agrees that it shall not and will ensure that its Affiliates and any Subsequent Licensee shall not, either directly or indirectly, actively promote,

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market, distribute, import, sell or have sold Product into countries within the Territory. As to such countries within the Territory: (i) FibroGen shall not, and will ensure that its Affiliates and Subsequent Licensees will not, engage in any advertising or promotional activities relating to the Product directed primarily to customers or other buyers or users of the Product located in such countries; and (ii) FibroGen shall not, and will ensure that its Affiliates and Subsequent Licensees will not, solicit orders for Products from any prospective purchaser located in such countries. If FibroGen receives any order for Products from a prospective purchaser located in a country within the Territory from which re-imports out from the Territory are unlikely, FibroGen shall immediately refer that order to AstraZeneca. FibroGen shall not accept any such orders. FibroGen may not deliver or tender (or cause to be delivered or tendered) any Product into a country within the Territory from which re-imports out of the Territory are unlikely. FibroGen shall not, and will ensure that its Affiliates and Subsequent Licensees will not, restrict or impede in any manner AstraZeneca's rights within the Territory, provided that any such exercise of rights by AstraZeneca shall comply with the terms of this Agreement. In addition to the foregoing, FibroGen shall use Commercially Reasonable Efforts to invoke and enforce the provisions of the Astellas Agreements with respect to restrictions on supply and commercialization in the Territory.

7.6 Negative Covenant. Each Party covenants that it will not knowingly use or practice any of the other Party's intellectual property rights licensed to it under this Article 7 except for the purposes expressly permitted in the applicable license grant.

7.7 No Implied Licenses. Except as explicitly set forth in this Agreement, neither Party grants to the other Party any license, express or implied, under its intellectual property rights. This Agreement confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents owned in whole or in part by DFCI other than the particular patents and patent applications licensed under the DFCI Agreement.

7.8 Exclusivity.

(a) Restrictive Covenant by AstraZeneca. Except pursuant to this Agreement or the China Agreement, AstraZeneca and its Affiliates shall not, and shall not license or authorize any Third Party to, directly or indirectly,

(i) at any time during Covenant Period 1, or such longer period as may follow from Section 13.6(i), research or Develop any HIF Compound in the Field; or

(ii) at any time during Covenant Period 2 and three (3) years thereafter, Commercialize any HIF Compound in the Field and in the Territory.

(b) Acquisition. Notwithstanding the foregoing in Section 7.8(a), neither AstraZeneca's nor any of its Affiliates' direct or indirect acquisition of or merger with, in whole or in part, a person or entity (or group of companies) or the business of a person or entity (or group of companies) having any activity contravening the covenants set forth in Section 7.8(a) shall constitute a breach of such covenants by AstraZeneca if AstraZeneca or its Affiliate, as the case

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may be, notifies FibroGen within forty-five (45) days following the closing of such acquisition or merger of its intent to divest itself of such assets and complies with the following:

(i) AstraZeneca shall ensure that no Development Data, Information related to Commercialization in connection with this Agreement, FibroGen Technology or Confidential Information of FibroGen is used in or for the purpose of the activities contravening such covenants.

(ii) AstraZeneca shall (or, as the case may be, cause its relevant Affiliate to) [*] the sale or transfer to a Third Party of the relevant part of the business contravening such covenants, and in any case, shall enter into (or, as the case may be, cause its relevant Affiliate to enter into) a binding definitive agreement with a Third Party for such sale or transfer no later than [*] after the closing of the acquisition or merger transaction under which the relevant business was acquired.

(iii) Neither AstraZeneca nor its Affiliates shall, during such [*] period, Commercialize a product being the subject of research or Development activities forming part of the relevant business which is to be divested, unless such product was already Commercialized prior to the closing of the acquisition or merger transaction.

(iv) AstraZeneca shall, notwithstanding anything to the contrary in this Section 7.8(b), at all times continue to be obligated to use Commercially Reasonable Efforts to Develop or Commercialize a Product in accordance with its obligations under and subject to Sections 3.9 and 5.8.

(c) **Remedy**. AstraZeneca hereby acknowledges and agrees that in the event of any actual or threatened breach of this Section 7.8, FibroGen will suffer an irreparable injury, such that no remedy at law shall afford it adequate protection against, or appropriate compensation for, such injury. Accordingly, AstraZeneca hereby agrees that FibroGen shall be entitled to specific performance of AstraZeneca's obligations under this Section 7.8, as well as such further timely injunctive relief as may be granted by a court of competent jurisdiction.

(d) **[*]**. In the event AstraZeneca or its Affiliates conducts any activities prohibited under this Section 7.8, any [*] shall be subject to the following [*]. AstraZeneca [*]. Such [*] shall be in addition to all other remedies available to FibroGen.

7.9 Additional Provisions Regarding Restrictive Covenants and Exclusivity.

(a) The Parties agree that the restrictions contained in Sections 7.4, 7.5, 7.8 and 13.6(i) are reasonable and necessary for the protection of the Parties' and their Affiliates' respective confidential information and business, that such restrictions are reasonable in all the circumstances and that the Parties would not have entered into this Agreement without the protections afforded to them under Sections 7.4, 7.5, 7.8 and 13.6(i).

(b) The words "Develop" and "Commercialize" and all variations thereof included in Sections 7.4 and 7.8 with reference to HIF Compounds shall include the activities

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described in the definitions of such words in Article 1, but with such activities being with respect to HIF Compounds rather than with respect to a Product as set forth in the relevant definition.

ARTICLE 8

FINANCIALS

8.1 License Fees. AstraZeneca shall pay to FibroGen each of the following non-refundable, non-creditable license fees on or before the applicable date set forth below; provided that with respect to payment 1, FibroGen shall provide an invoice on or before the Effective Date, and with respect to payments 2, 3 and 4, FibroGen shall provide an invoice at least forty-five (45) days before each applicable due date:

Number	Due Date	Payment
1	15th Business Day after the Effective Date	$70 million
2	June 30, 2014	$110 million
3	June 30, 2015	$120 million
4	June 30, 2016	$62 million

If this Agreement is terminated prior to the due date of payment 2 or 3, then each such payment shall remain due and payable despite such termination. If this Agreement is terminated prior to the due date of payment 4, then payment 4 will remain due and payable despite such termination; [*].

8.2 Development and Commercialization Cost Reimbursement.

(a) Prior to First NDA Approval during Development Sharing Period. The following procedure in this subsection (a) will apply prior to the first NDA approval for a Product and during the Development Sharing Period.

(i) On or before the Effective Date, FibroGen will submit an invoice to AstraZeneca for an amount of [*] in respect of certain Development Costs incurred by FibroGen under the Development Plan prior to the Effective Date. AstraZeneca shall pay such invoice within fifteen (15) Business Days of receipt of invoice.

(ii) Within twenty (20) days if reasonably possible for AstraZeneca using reasonable endeavors to meet such timeline and in no event later than twenty five (25) days after the end of each Calendar Quarter during the Development Sharing Period, and within fifteen (15) days if reasonably possible for FibroGen using reasonable endeavors to meet such timeline and in no event later than twenty (20) days after the end of each Calendar Quarter, the Party shall provide the other Party with a statement setting forth (A) the actual Development Costs incurred

by such Party in such Calendar Quarter, (B) the Development Costs budgeted for activities conducted by such Party in such Calendar Quarter under the Development Plan, (C) the amount (if any) by which the actual costs differed from the budgeted costs, subject to the provisions on budget overages in Section 3.4(b), (the "***Excess Spend***"), (D) the amount carried over from the previous Calendar Quarters for which the Development Costs incurred by AstraZeneca were greater than the Development Costs incurred by FibroGen. As soon as practicable, and not later than within thirty two (32) days of the end of the Calendar Quarter, the Parties shall discuss and resolve any issues with respect to such statements and shall use best efforts to agree the amount owed from one Party to the other for Development Costs in such Calendar Quarter, so that each Party bears fifty percent (50%) of the Development Costs incurred (subject to Section 3.4(b)), provided, however that each Party shall generate any questions and respond to any inquiries regarding the invoices as promptly as reasonably possible following receipt, including within forty-eight (48) hours for response to ordinary inquiries. Following the reconciliation process for the applicable Calendar Quarter, and not later than thirty two (32) days of the end of the Calendar Quarter, each of FibroGen and AstraZeneca shall provide an invoice to the other Party reflecting fifty percent (50%) of their respective Development Costs incurred. Within forty five (45) days after its receipt of such invoice from FibroGen, if the amount invoiced by FibroGen to AstraZeneca is greater than the amount invoiced by AstraZeneca to FibroGen, then AstraZeneca shall pay FibroGen an amount equal the difference between the invoices, subject to the offset of outstanding Development Costs as detailed below in this Section 8.2(a)(ii). If during the Development Sharing Period and following the quarterly process set out above, FibroGen owes a payment to AstraZeneca, then no payment will be made by FibroGen, to AstraZeneca. Instead such amount, in aggregate with any other such amounts, will be carried forward by AstraZeneca and set off against any subsequent Development Cost payments owed by AstraZeneca to FibroGen under this Section 8.2. For clarity, Development Costs advanced or paid under this Section 8.2(a)(ii) do not include amounts incurred prior to August 1, 2013.

(b) Prior to First NDA Approval after the Development Sharing Period. The following procedure in this subsection (b) will apply prior to the first NDA approval for a Product and after the Development Sharing Period.

(i) No earlier than forty-five (45) days prior to the beginning of each Calendar Quarter after the Development Sharing Period, FibroGen shall submit to AstraZeneca an invoice for the Development Costs budgeted to be incurred by FibroGen to conduct its activities under the Development Plan in such Calendar Quarter, as adjusted for the Cost Difference as set forth in 8.2(b)(ii) below. AstraZeneca shall pay each such invoice within forty-five (45) days after the invoice date, subject to the offset of Development Cost provisions in Section 8.2(a).

(ii) No later than twenty (20)) days after the end of each Calendar Quarter after the Development Sharing Period, FibroGen shall send to AstraZeneca a statement setting forth (i) the actual Development Costs incurred by FibroGen in such Calendar Quarter, (ii) the Development Costs budgeted for activities conducted by FibroGen in such Calendar Quarter in the Development Plan, (iii) the amount (if any) by which the actual costs differed from the budgeted costs and (iv) the difference between the amount advanced by AstraZeneca under this Section 8.2(b) and the Development Costs actually incurred, to the extent below [*] percent [*

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]%) of the budgeted amount (the "Cost Difference"). FibroGen shall adjust the invoice to be submitted to AstraZeneca under 8.2(b)(i) for the subsequent Calendar Quarter to account for the Cost Difference. Not later than within thirty two (32) days of the end of the Calendar Quarter, the Parties shall discuss and resolve any issues with respect to such statement and shall use best effort to agree the amount payable thereunder. If any items not material to FibroGen's financial statements remain outstanding at the end of the reconciliation and resolution process, the parties shall continue to work toward resolution by the end of following calendar quarter. Notwithstanding anything else set forth herein, if all amounts invoiced by FibroGen and settled under Section 8.2(a) exceed fifty per cent (50%) of the difference between the Development Costs incurred by FibroGen and the Development Costs incurred by AstraZeneca during the Development Sharing Period (subject to the provisions on budget overages in Section 3.4(b)), then any such excess may be credited by AstraZeneca against any subsequent Development Costs payments owed by AstraZeneca to FibroGen under this Section 8.2(b) and Section 8.2(c), or, in the event that the Development Costs incurred by FibroGen are no longer being incurred under this Agreement and are insufficient to make up such excess, such excess may be credited against any other payments owed by AstraZeneca to FibroGen under this Agreement, until fully used.

(c) Adjustment in Payment Schedule. At any time after January 1, 2015 and prior to the time at which ninety percent (90%) of the targeted enrollment in any CKD Indication Clinical Trials (conducted by FibroGen and for which FibroGen will be incurring Development Costs) has been achieved (the "**Increased Advance Period**"), upon request of FibroGen, the Parties shall discuss in good faith the upcoming spending plans for the Development Budget in which FibroGen reasonably anticipates that significant cost variances, such as those associated with patient enrollment rates or other reasonably unforeseen causes, may occur with respect to such CKD Indication Clinical Trials during the next Development Budget year and thereafter. The Parties shall agree upon the timing of the implementation of a further advance in any Calendar Quarter in an upcoming period during the Increased Advance Period: If FibroGen reasonably determines that anticipated spending in respect of such CKD Indication Clinical Trials such as enrollment rate is proceeding in a manner that the Development Costs for which advances have been received in a Calendar Quarter under Section 8.2(a) or (b) will likely be exceeded, then FibroGen shall notify the JSC of the basis for such anticipated overage and if such overage is anticipated to exceed by [*] percent [*]%) or more such budgeted amount, then FibroGen may invoice AstraZeneca prior to the end of the Calendar Quarter an amount it reasonably believes is necessary to cover such overage. AstraZeneca shall pay such amount within forty-five (45) days of invoice and any such amounts advanced under such invoice under this Section 8.2(c) shall be deducted from the subsequent payment under Section 8.2(a), (b) or (d).

(d) Following First NDA Approval. The following procedure in this subsection (d) will apply after the first NDA approval for a Product, unless otherwise agreed by the JDC. Within thirty (30) days after the end of each Calendar Quarter in which FibroGen conducts activities under the Development Plan, FibroGen shall send to AstraZeneca an invoice for all Development Costs incurred by FibroGen in such Calendar Quarter, up to an amount equal to [*] percent ([*]%) of the budgeted amount for the applicable activities. AstraZeneca shall pay each such invoice within forty-five (45) days after receipt thereof.

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(e) Annual Reconciliation. Within thirty (30) days after the end of each Calendar Year in which either Party conducts activities under the Development Plan, such Party shall send to the other Party a statement setting forth the Development Costs actually incurred by such Party and the budgeted amounts for all activities conducted by such Party under the Development Plan during such Calendar Year; provided that if no part of such Calendar Year was during the Development Sharing Period, or if only FibroGen is conducting Development activities, only FibroGen shall be required to provide such statement. FibroGen's statement will also include the Development Costs incurred by FibroGen and actually reimbursed by Astellas for such Calendar Year. If during the Development Sharing Period, such actual amount exceeds the budgeted amount (or amount otherwise approved by the JSC) by more than [*] percent [*]%) of the budgeted amount, then fifty percent (50%) of the excess (i.e., above [*] percent [*]%)) will be credited against or added to (depending on which Party incurred the excess) the subsequent payment from AstraZeneca to FibroGen under this Section 8.2. After the Development Sharing Period, if such actual amount incurred by FibroGen exceeds the budgeted amount (or amount otherwise approved by the JSC) by more than [*] percent [*]%) of the budgeted amount, the excess (i.e., above [*] percent ([*]%)) will be credited against the subsequent payment from AstraZeneca to FibroGen under this Section 8.2.

(f) RoW Activities. Within thirty (30) days after the end of each Calendar Quarter in which FibroGen conducts activities under the Development Plan for the RoW, FibroGen shall send to AstraZeneca an invoice for all costs incurred by FibroGen in such Calendar Quarter for such activities, including Personnel Costs, the Fully Burdened Cost of Collaboration Compound or Product or comparator drug, concomitant drug, placebo or other materials used in any Clinical Trial or Nonclinical Studies, and all other out-of-pocket costs. AstraZeneca shall pay each such invoice within forty-five (45) days after receipt thereof.

(g) Commercialization Cost. Within thirty (30) days after the end of each Calendar Quarter in which FibroGen conducts activities under the U.S. Commercialization Plan, FibroGen shall send to AstraZeneca an invoice for all Commercialization Costs incurred by FibroGen in such Calendar Quarter. AstraZeneca shall pay each such invoice within forty-five (45) days after receipt thereof.

8.3 Development Milestone Payments.

(a) Payments. AstraZeneca shall make milestone payments to FibroGen based on achievement by AstraZeneca, its Affiliate or a Sublicensee (or, if applicable, by FibroGen) of the development and regulatory milestone events set forth in this Section 8.3(a) with respect to any indication other than an indication independently developed by FibroGen pursuant to Section 3.3(b) for which AstraZeneca does not opt in.

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Number	Milestone Event	Payment
1	This milestone event will be deemed achieved on the sixtieth (60th) day after AstraZeneca's receipt from FibroGen of the audited final report from the Carcinogenicity Studies, provided that AstraZeneca has not submitted to FibroGen a notice of termination of this Agreement for Technical Product Failure within thirty (30) days after its receipt of such report.	$15 million
2	First acceptance by the FDA for filing of an NDA in the Field in the U.S.	$50 million
3	[*]	$[*] million
4	[*]	$[*] million
5	[*]	$[*] million
6	[*]	$[*] million
7	[*]	$[*] million

(b) Clarifications.

(i) With respect to the first milestone event in Section 8.3(a), if AstraZeneca [*] within such thirty (30) day period, then (A) this milestone event will be [*] and (B) this milestone event will be [*].

(ii) Each milestone payment in Section 8.3(a) shall be paid only once, without regard to whether two or more Products ultimately achieve any such milestone event. For the purposes of milestone events no. 5, 6 and 7 in Section 8.3(a), the Parties agree that the [*] shall be regarded as one and the same indication and thus not constitute [*].

(iii) The foregoing milestone events do not include events achieved by the Product for indications independently developed by FibroGen pursuant to Section 3.3(b) for which AstraZeneca does not opt in.

(c) Notice; Payment. The applicable Party shall notify the other Party upon achievement of each milestone in Section 8.3(a). AstraZeneca shall pay to FibroGen the amounts

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set forth in Section 8.3(a) within forty-five (45) days after receipt by AstraZeneca of an invoice from FibroGen for the relevant amount, following the achievement of the applicable milestone event by AstraZeneca, its Affiliate or a Sublicensee (or, if applicable, by FibroGen). Each such payment shall be made by wire transfer of immediately available funds into an account designated by FibroGen. Each such payment is nonrefundable and non-creditable against any other payments due hereunder.

8.4 [*] Milestone.

(a) Milestone. AstraZeneca shall pay a milestone to FibroGen in the amount of the discounted value of [*])], discounted using ten percent (10%) annual compounding, applied from the Trigger Date to the Discount Date (each as defined below) (such value, the [*] ***Milestone***") following the first [*] (meaning that – notwithstanding anything else set forth herein – AstraZeneca shall never be obligated to pay the Deferred Approval Milestone prior to the [*]) as of the payment date determined in accordance with Section 8.4(b); provided that and notwithstanding anything else set forth below in this Section 8.4, if any of [*]") on or before [*]") then the [*] Milestone will not be payable. The [*] Milestone is nonrefundable and non-creditable against any payments due hereunder.

(b) Payment Date. If payable pursuant to Section 8.4(a), the [*] Milestone will be due as follows:

(i) If all [*], the "***Discount Date***" will be the date of first [*], and the [*] Milestone will be payable within forty-five (45) days thereafter, provided that there is then no [*].

(ii) If [*], the "***Discount Date***" will be January 1 of the Calendar Year following the Calendar Year in which [*], and the [*] Milestone will be payable on the Discount Date, provided that there is then no [*].

(iii) If [*], but if there is no [*], then the [*] Milestone (the full undiscounted amount of [*] will be payable on the Trigger Date.

(iv) If any [*], the Discount Date will be the later to occur of (a) the date of [*] and (b) the first [*], and the [*] Milestone will be payable within forty-five (45) days after the Discount Date.

(v) At any time prior to the Trigger Date, AstraZeneca may elect to pay the [*] Milestone, and the Discount Date will be the date of payment.

(c) Trigger Date. The "***Trigger Date***" means [*], the date on which such [*]. For example, if no [*], the Trigger Date is [*]. If a [*], then the Trigger Date is [*].

8.5 Sales Milestone Payments.

(a) U.S. Events. AstraZeneca shall make each of the sales milestone payments indicated below to FibroGen when aggregate Annual Net Sales of all Products across all indications in the U.S. (other than sales by FibroGen in indications independently developed by FibroGen pursuant to Section 3.3(b) for which AstraZeneca does not opt in) first reach the Dollar values indicated below.

Aggregate Annual Net Sales in the U.S.	Payment
$[*]	$[*] million
$[*]	$[*] million
$[*]	$[*] million

Each milestone in this Section 8.5(a) shall be paid only once.

(b) Additional U.S. Milestones. AstraZeneca shall make each of the sales milestone payments indicated below to FibroGen when aggregate Annual Net Sales of Products in LDOs in the U.S. (other than sales by FibroGen in indications independently developed by FibroGen pursuant to Section 3.3(b) for which AstraZeneca does not opt in) first reach the Dollar values indicated below in any Calendar Year from 2018-2022 (inclusive).

Aggregate Annual Net Sales to LDOs in the U.S.	Payment
$[*]	$[*] million
$[*]	$[*] million
$[*]	$[*] million

(c) RoW Events. AstraZeneca shall make each of the sales milestone payments indicated below to FibroGen when aggregate Annual Net Sales of all Products across all indications in the RoW (other than sales by FibroGen in indications independently developed by

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FibroGen pursuant to Section 3.3(b) for which AstraZeneca does not opt in) first reach the Dollar values indicated below.

Aggregate Annual Net Sales in RoW	Payment
$[*]	$[*] million
$[*]	$[*] million

Each milestone in this Section 8.5(c) shall be paid only once.

(d) Notice; Payment. AstraZeneca shall notify FibroGen of achievement of each of the milestone events in this Section 8.5 within forty-five (45) days after the end of the Calendar Quarter in which achieved. AstraZeneca will pay to FibroGen the amounts set forth in Sections 8.5(a), 8.5(b) and 8.5(c) within forty-five (45) days after AstraZeneca's receipt of an invoice from FibroGen following the end of the Calendar Quarter during which the applicable milestone event has been achieved. If more than one such milestone is achieved in any Calendar Quarter, then all applicable payments will be due. Each such payment shall be made by wire transfer of immediately available funds into an account designated by FibroGen. Each such payment is nonrefundable and non-creditable against any other payments due hereunder.

8.6 Royalties

(a) Royalty Rates. AstraZeneca shall pay to FibroGen non-refundable, non-creditable royalties on the amount of aggregate Annual Net Sales of each Product in the Territory as calculated by multiplying the applicable royalty rates set forth below by the corresponding amount of incremental aggregate Annual Net Sales in the Territory of such Product in such Calendar Year. For clarity, royalties are not due on sales of Products by FibroGen solely in indications independently developed by FibroGen pursuant to Section 3.3(b) for which AstraZeneca does not opt in.

Aggregate Annual Net Sales (Per Product)	Royalty Rate
Portion less than $[*]	[*]%
Portion greater than or equal to $[*]	[*]%

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By way of example, if the aggregate Annual Net Sales of a Product in the Territory in a particular Calendar Year is two billion five hundred million Dollars ($2,500,000,000), the amount of royalties payable hereunder shall be as follows:

$ [*]

$ [*]

[*]

(b) Sales Subject to Royalties. Sales between AstraZeneca, its Affiliates and Sublicensees shall not be subject to royalties hereunder unless the purchaser is an end user. Royalties shall be calculated on AstraZeneca's, its Affiliates' and Sublicensees' sales of the Products to a Third Party, including Distributors (but excluding for the avoidance of doubt Sublicensees). Royalties shall be payable only once for any individual S.K.U. of a Product. For the purpose of determining Net Sales, the Product shall be deemed to be sold when invoiced and a "sale" shall not include, and no royalties shall be payable on, transfers by AstraZeneca, its Affiliates or Sublicensees of reasonable quantities of clinical trial materials, or other transfers or dispositions of reasonable quantities of Products for charitable, promotional, nonclinical, clinical, manufacturing, testing or qualification, regulatory or governmental purposes in compliance with this Agreement (it being understood and agreed that neither Party shall have the right to distribute the Product as samples except pursuant to Section 5.7).

(c) Generic Competition. If, in any country in the Territory, the Net Sales of any Product in any rolling four Calendar Quarter period following the first sale of a Generic Product to such Product in such country is less than [*] of the Net Sales for such Product in such country in the immediately preceding four Calendar Quarter period, then the royalty rate for such Product in such country shall be reduced to [*] that would otherwise have been applicable under Section 8.6(a) for Net Sales of such Product in such country. For clarity, if the Generic Product is barred or withdrawn from sale in such country and the Net Sales in such country in any rolling four Calendar Quarter period is greater than [*] of the value for the rolling four quarter period prior to the first sale of a Generic Product, then the foregoing reduction shall no longer apply effective as of the Calendar Quarter in which the Generic Product is barred or withdrawn from sale. The calculation of the royalty reduction under this Section 8.6(c) shall be conducted separately for each Product in each country. By way of example, if during the first Calendar Quarter of a particular Calendar Year in which the foregoing reduction applies, the Net Sales in such Calendar Quarter in a country in which the foregoing reduction applies are one billion five hundred million Dollars ($1,500,000,000), and the Net Sales in such Calendar Quarter in a country in which the foregoing royalty reduction does not apply are one billion Dollars ($1,000,000,000), the following shall apply with respect to the royalty payment owed for such Calendar Quarter: The royalty payment without regard to the reduced rate would be [*].

(d) Compulsory Licenses. If a court or a governmental agency of competent jurisdiction requires AstraZeneca or its Affiliate or Sublicensee to grant a compulsory license to a Third Party and if as a result of the compulsory license the Net Sales of such Product in any rolling

four Calendar Quarter period following the first grant of such compulsory license in such country is less than [*] of the Net Sales for such Product in such country in the immediately preceding four Calendar Quarter period, then the royalty rate for such Product in such country shall be reduced to [*] of the royalty rates (in each tier) that would otherwise have been applicable under Section 8.6(a) for Net Sales of such Product in such country. For clarity, to the extent that the compulsory licenses in the relevant country are duly terminated or expire in such country and the Net Sales in such country in any rolling four Calendar Quarter period is greater than [*] of the value for the rolling four quarter period prior to the first grant of the compulsory license in such country, then the foregoing reduction shall no longer apply effective as of the Calendar Quarter in which the compulsory license is terminated or expires. The calculation of the royalty reduction under this Section 8.6(e) shall be conducted separately for each Product in each country.

(e) Order of Royalty Reduction and Royalty Floor. Any reductions set forth in Sections 8.6(c), 8.6(d) and 8.8(c) shall be applied in the order in which the event triggering such reduction occurs, provided that in no event shall, due to the cumulative reductions set out in Sections 8.6(c) and 8.6(d), the royalty that would otherwise have been payable to FibroGen under this Section 8.6 in a particular Calendar Quarter be reduced below [*]) of the royalty set forth in Section 8.6(a).

(f) Royalty Term. AstraZeneca's obligation to pay royalties due under this Section 8.6 with respect to a particular Product in each country in the Territory will commence upon the First Commercial Sale of such Product in such country and will be payable for so long as such Product is sold in such country by AstraZeneca or its Affiliate or Sublicensee.

(g) Royalty Payments and Reports. All amounts payable to FibroGen pursuant to this Section 8.6 shall be paid in Dollars within forty-five (45) days after the end of each Calendar Quarter with respect to Net Sales in such Calendar Quarter. Each payment of royalties due to FibroGen shall be accompanied by a statement, on a country-by-country basis, of the amount of gross sales of Products in the Territory during the applicable Calendar Quarter, a calculation of Net Sales in the Territory showing the aggregate deductions from gross sales provided for in the definition of Net Sales during such Calendar Quarter, and a calculation of the amount of royalty payment due on such sales for such Calendar Quarter. For the avoidance of doubt, FibroGen acknowledges and agrees that each statement provided by AstraZeneca under this Section 8.6(g) shall constitute Confidential Information of AstraZeneca and FibroGen shall comply with its confidentiality and non-use obligations in respect of such statements as set forth in Article 12.

(h) Clarification. AstraZeneca acknowledges that it will continue to enjoy substantial benefit from its license under, and the transfer to AstraZeneca of certain elements of, the FibroGen Technology pursuant to this Agreement, as well as from AstraZeneca's own development of inventions derived from the practice of such license and AstraZeneca's use of such FibroGen Technology, even after the expiration of all FibroGen Patents claiming the Product in a particular country in which Products are sold. In addition, AstraZeneca acknowledges that the application of a uniform royalty structure during the sale of Products is more convenient to the

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Parties, facilitates payments, and reduces accounting burdens on the Parties, as compared with a payment structure dependent on the expiration of FibroGen Patents.

8.7 FibroGen IPO. AstraZeneca shall make a one-time, non-refundable, non-creditable payment of [*] to FibroGen upon a FibroGen IPO; provided that (a) if such IPO has not occurred prior to December 1, 2015, AstraZeneca will make such payment on December 15, 2015, and (b) if the Parties agree upon terms (and FibroGen undertakes, upon AstraZeneca's request, to negotiate such terms in good faith), including a lock-up and standstill agreement (subject to maximum ownership of [*]%), then in lieu of such payment, AstraZeneca will make a [*] equity investment in FibroGen at the initial public offering price simultaneous with the closing of a FibroGen IPO.

8.8 Third Party Intellectual Property.

(a) DFCI Agreement. FibroGen shall be solely responsible for all payments to DFCI under the DFCI Agreement.

(b) Right to Obtain License. If either Party desires to obtain a license under any Third Party's intellectual property in connection with the Development and Commercialization of Products, such Party will notify the other Party. FibroGen will have the first right (but not the obligation) to obtain such license. If FibroGen elects not to obtain such license, or is unsuccessful in doing so, then AstraZeneca will have the right (but not the obligation) to negotiate and obtain such license at its sole discretion and expense (but subject to Section 8.8(c)). The negotiating Party will obtain such license, with the right to sublicense, in order to permit AstraZeneca to exercise its rights and to perform its obligations under this Agreement. Subject to the foregoing, the terms and conditions involved in obtaining such license shall be determined at such negotiating Party's sole discretion.

(c) AstraZeneca Obtains License. In the event AstraZeneca obtains a license under any Third Party patents that claim the composition of matter, formulation (to the extent AstraZeneca is performing any formulation activities, which activities it may perform only with FibroGen's prior written consent), method of treatment or other use of a Collaboration Compound or Product, AstraZeneca shall provide to FibroGen a copy thereof and shall have the right to offset, against royalties payable to FibroGen under Section 8.6 for the applicable Product, [*] actually paid by AstraZeneca to such Third Party under such license for the sale of the applicable Product in the applicable country and Calendar Quarter; provided that the royalties payable to FibroGen for any Product in any Calendar Quarter under Section 8.6 may not be reduced by more than [*] of those otherwise due to FibroGen under Section 8.6(a) in any Calendar Quarter for such Product as a result of such offset and other reductions under Section 8.6. Except as provided above in this subsection (c), AstraZeneca will be solely responsible for all amounts owed by AstraZeneca or its Affiliates to Third Parties under a license to intellectual property on account of AstraZeneca's or its Affiliates' manufacture, use, sale, offer for sale, or import of Products.

(d) FibroGen Obtains License. Except as provided in subsection (a) above, the FibroGen Technology licensed to AstraZeneca in this Agreement will include patents, patent

applications and Information licensed to FibroGen by a Third Party if (i) AstraZeneca assumes [*] of all payment obligations under such license agreement to the extent arising out of the use, Development or manufacture of any Product or Commercialization of any Product by or on behalf of AstraZeneca in the Territory, as well as all other obligations of such license agreement that are applicable to AstraZeneca, and (ii) AstraZeneca acknowledges in writing that its sublicense under such license agreement is subject to the terms and conditions of such license agreement. If any such payments are not allocated among countries, the Parties shall reasonably allocate such payments to within and outside the Territory in good faith.

8.9 Taxes.

(a) Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the collaborative efforts of the Parties under this Agreement.

(b) Withholding Tax. The Party making payments under this Agreement (the "***Payor***") to the other Party (the "***Payee***") shall deduct or withhold from the payments any Taxes that it is required by applicable law to deduct or withhold. The Payee shall provide the Payor any tax forms or appropriate governmental authorization that may be reasonably necessary in order for Payor to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. The Payee shall use reasonable efforts to provide any such tax forms to the Payor at least thirty (30) days prior to the due date for any payment for which the Payee desires that Payor apply a reduced withholding rate and in any event at least fifteen (15) days prior to the time the applicable payment is due. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable laws and regulations, of withholding taxes, Indirect Taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or Indirect Taxes.

(c) Payment of Tax. To the extent the Payor is required by applicable law or regulations to deduct and withhold taxes on any payment to the Payee, the Payor shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to the Payee an official tax certificate or other evidence of such withholding sufficient to enable the Payee to claim such payment of taxes.

(d) Indirect Tax. All payments to be made by one Party to another Party, pursuant to the terms of this Agreement, are stated exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of such payments, the Party making shall payment shall pay such Indirect Taxes at the applicable rate following the receipt where applicable of an Indirect Taxes invoice in the appropriate form issued. Each Party shall issue valid invoices for all amounts payable under this Agreement consistent with all applicable laws and irrespective of whether such amounts may be netted for settlement purposes. The Parties shall cooperate in accordance with applicable law to minimize Indirect Taxes.

(e) Imports. For the avoidance of doubt, the Parties acknowledge and agree that none of the upfront payments, milestone payments or royalties payable under this Agreement

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are related to the license (or right) to import or any import of Products. The Parties shall cooperate to ensure that the Party responsible for shipping values Product in accordance with applicable laws and maximizes the full benefits of available duty free or savings programs and minimizes where permissible any such duties and any related import taxes that are not reclaimable from the relevant authorities. The receiving Party shall be responsible for any import clearance, including payment of any import duties and similar charges, in connection with any Products transferred to such Party under this Agreement.

8.10 Blocked Currency. In each country where the local currency is blocked and cannot be removed from the country, royalties accrued on Net Sales in that country shall be paid to FibroGen in the equivalent amount in Dollars.

8.11 Foreign Exchange. Conversion of sales or expenses recorded in local currencies to Dollars will be performed in a manner consistent with each Party's normal practices used to prepare its audited financial statements for external reporting purposes, provided that such practices use a widely accepted source of published exchange rates.

8.12 Late Payments. If a Party does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at a rate equal to the U.S. Prime Rate for the date payment was due as reported by the *Wall Street Journal*.

8.13 Financial Records; Audits.

(a) Records. Each Party shall maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the amount to be reimbursed, pursuant to Section 8.2, with respect to Development Costs or Commercialization Costs or other amounts to be reimbursed or shared hereunder incurred or generated (as applicable) by such Party, achievement of sales milestones, royalty payments and other compensation payable under this Agreement. Each Party shall keep or cause its Affiliates to keep such records for a period of the later of (a) six (6) years after the end of the period to which such books, records and accounts pertain and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by applicable law. Each Party shall maintain such records at its principal place of business or the principal place of business of the appropriate division of such Party to which this Agreement relates.

(b) Procedure. Upon reasonable prior notice, such records shall be open during regular business hours for a period of three (3) years from the creation of individual records, in each case, for examination at the auditing Party's expense, and not more often than once each Calendar Year, by an independent certified public accountant selected by the auditing Party and reasonably acceptable to the audited Party (or in the case of audits of AstraZeneca, by DFCI under the terms of Section 4.2.2 of the DFCI Agreement) for the sole purpose of verifying for the auditing Party the accuracy of the financial reports or sales milestone notices furnished by the audited Party pursuant to this Agreement or of any payments made, or required to be made, by or to the audited Party to the other pursuant to this Agreement. Any such auditor shall not disclose the audited

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Party's Confidential Information to the auditing Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the audited Party or the amount of payments due by the audited Party under this Agreement. Any amounts shown to be owed but unpaid, or overpaid and in need of reimbursement, shall be paid or refunded (as the case may be) within thirty (30) days after the accountant's report, plus interest (as set forth in Section 8.12) from the original due date (unless challenged in good faith by the audited Party in which case any dispute with respect thereto shall be resolved in accordance with Article 14). The auditing Party shall bear the full cost of such audit unless such audit reveals an overcharge or underpayment by the audited Party that resulted from a discrepancy in a report that the audited Party provided to the other Party during the applicable audit period, which underpayment or overcharge was more than five percent (5%) of the amount set forth in such report, in which case the audited Party shall bear the full cost of such audit.

(c) Audit Dispute. In the event of a dispute with respect to any audit under Section 8.13(b), FibroGen and AstraZeneca shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days, the dispute shall be submitted for resolution to an independent certified public accounting firm jointly selected by each Party's certified public accountants or to such other entity or individual as the Parties shall mutually agree (the "***Auditor***"). The decision of the Auditor shall be final and the costs of such resolution as well as the initial audit shall be borne between the Parties in such manner as the Auditor shall determine. Not later than ten (10) days after such decision and in accordance with such decision, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 8.12 or the auditing Party shall reimburse the excess payments, as applicable.

8.14 Manner and Place of Payment. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by FibroGen or AstraZeneca (as applicable), unless otherwise specified in writing by such Party. All payments hereunder shall be invoiced by the Payee to the Payor. Each invoice to AstraZeneca shall fulfill the requirements set forth on **Exhibit L**.

8.15 Estimated Sales and Accruals. To the extent Net Sales are based on quarterly estimates or accruals for anticipated sales of Products in the Territory, AstraZeneca shall notify FibroGen of any such estimates or accruals or adjustments or changes based on a revision in estimates and accruals within thirty (30) days of each Calendar Quarter in order to allow FibroGen to timely meet any then applicable public reporting requirements of FibroGen with respect to sales and royalties to FibroGen for Products.

ARTICLE 9

INTELLECTUAL PROPERTY

9.1 Intellectual Property Committee. The Parties shall, promptly after the Effective Date, establish an intellectual property committee (the "***IP Committee***") comprised of at least one senior patent attorney from each Party, together with other representatives of the Parties as the

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Parties may determine to be appropriate from time to time, to review and discuss, in each case with respect to FibroGen Patents and Joint Patents, the patent prosecution strategy (including whether and where to file patent applications), Orange Book Listings, applications for patent term extension and notices of infringement, as well as the selection, registration, maintenance and defense of Marks and interest in Third Party intellectual property. The IP Committee will serve solely an advisory purpose and shall not have authority to approve or disapprove any actions with respect to patent filing, prosecution and maintenance under this Agreement.

9.2 Ownership of Inventions. Ownership of Information and inventions, whether or not patentable, made during the Term in the course of conducting activities under this Agreement, including all intellectual property rights therein (collectively, "***Inventions***") shall be as follows: (a) FibroGen shall own all Inventions [*], whether made solely by employees, agents or independent contractors of either Party or its respective Affiliates, or jointly by employees, agents or independent contractors of both Parties or their respective Affiliates (collectively, "***Collaboration Inventions***"), (b) AstraZeneca shall own all Inventions that are made solely by employees, agents or independent contractors of AstraZeneca or its Affiliates that are not Collaboration Inventions, (c) FibroGen shall own all Inventions that are made solely by employees, agents or independent contractors of FibroGen or its Affiliates that are not Collaboration Inventions, and (d) the Parties shall jointly own all Inventions that are made jointly by employees, agents, or independent contractors of each Party or its Affiliates that are not Collaboration Inventions ("***Joint Inventions***"). Except to the extent either Party is restricted by the licenses granted to the other Party under this Agreement, each Party shall be entitled to practice, grant licenses to, assign and exploit the Joint Inventions and Patents claiming Joint Inventions ("***Joint Patents***") without the duty of accounting or seeking consent from the other Party. AstraZeneca hereby assigns to FibroGen all of its and its Affiliates' right, title and interest in and to the Collaboration Inventions, and agrees to take such further actions reasonably requested by FibroGen to evidence such assignment, except where such Collaboration Inventions have been made by an independent contractor retained by AstraZeneca without such contractor having agreed to assign such Collaboration Inventions to AstraZeneca, as approved by the JDC.

9.3 Disclosure of Inventions. Each Party shall promptly disclose to the other all Inventions promptly after becoming aware of them, including all invention disclosures or other similar documents submitted to such Party by its, or its Affiliates', employees, agents or independent contractors describing such Inventions. Such Party shall also respond promptly to reasonable requests from the other Party for more Information relating to such Inventions.

9.4 Prosecution of Patents.

(a) FibroGen Patents. Except as otherwise provided in this Section 9.4(a), as between the Parties, FibroGen shall have the sole right and authority to manage all FibroGen Patent prosecution activities under this Agreement, at its sole expense. This includes the right and authority to prepare, file, prosecute and maintain all FibroGen Patents in any jurisdiction in the world, including defending such FibroGen Patents in any patent office proceedings, pre- or post-grant or issuance, including reissue, reexamination, limitation or invalidation proceedings, or any opposition- or interference-type proceeding or challenge. FibroGen shall provide AstraZeneca

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reasonable opportunity to review and comment on filing and prosecution efforts regarding the FibroGen Patents in the Territory. FibroGen shall, if requested by AstraZeneca, provide AstraZeneca with copies of material communications from any patent authority in the Territory regarding any FibroGen Patents, and shall if requested provide drafts of any material filings or material responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses so that AstraZeneca may have the opportunity to review and comment thereon. FibroGen shall further take into account and may include, at FibroGen's sole discretion, any reasonable comments provided by AstraZeneca prior to submission of any such filings or responses.

(b) Requested Filings. If AstraZeneca desires FibroGen to file, in a particular jurisdiction in the Territory, a FibroGen Patent that claims priority to (or is based on the subject matter of) another FibroGen Patent, or that claims a Collaboration Invention, AstraZeneca shall provide written notice to FibroGen requesting that FibroGen file such patent application in such jurisdiction. If AstraZeneca provides such written notice to FibroGen, FibroGen shall file and prosecute such patent application and maintain any patent issuing thereon in such jurisdiction; provided that FibroGen shall not be obligated to conduct any such activities (including filing a patent application) that FibroGen reasonably believes may have an adverse effect on the FibroGen Patents anywhere in the Territory.

(c) Joint Patents. With respect to any potentially patentable Joint Invention, AstraZeneca shall have the first right, but not the obligation, to prepare patent applications based on such Joint Invention, to file and prosecute (including defense of any oppositions, interferences, reissue proceedings and reexaminations) such patent applications, and to maintain any Joint Patents issuing therefrom, in any jurisdictions throughout the Territory. FibroGen shall have the corresponding first right, but not the obligation, in any jurisdictions outside of the Territory other than China, in respect of which the China Agreement shall govern. If AstraZeneca determines in its sole discretion to abandon, cease prosecution or otherwise not file or maintain any Joint Patent anywhere in the Territory, then AstraZeneca shall provide FibroGen written notice of such determination at least thirty (30) days before any deadline for taking action to avoid abandonment (or other loss of rights) and shall provide FibroGen with the opportunity to prepare, file, prosecute and maintain such Joint Patent. The Party that is responsible for preparing, filing, prosecuting, and maintaining a particular Joint Patent (the "***Prosecuting Party***") shall provide the other Party reasonable opportunity to review and comment on such prosecution efforts regarding such Joint Patent, and such other Party shall provide the Prosecuting Party reasonable assistance in such efforts. The Prosecuting Party shall provide the other Party with a copy of all material communications from any patent authority in the applicable jurisdictions regarding the Joint Patent being prosecuted by such Party, and shall provide drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses. In particular, each Party agrees to provide the other Party with all information necessary or desirable to enable the other Party to comply with the duty of candor/duty of disclosure requirements of any patent authority. Either Party may determine that it is no longer interested in supporting the continued prosecution or maintenance of a particular Joint Patent in a country or jurisdiction, in which case: (i) the disclaiming Party shall, if requested in writing by the other Party, assign its ownership interest in such Joint Patent in such country or jurisdiction to

the other Party for no additional consideration; and (ii) if such assignment is effected, any such Joint Patent would thereafter be deemed a FibroGen Patent in the case of assignment to FibroGen, or a AstraZeneca Patent in the case of assignment to AstraZeneca; provided, however, that the disclaiming party would have an immunity from suit under such FibroGen Patent or AstraZeneca Patent, as the case may be, in the applicable country or jurisdiction. In addition, any Joint Patent that becomes a FibroGen Patent pursuant to the preceding sentence shall be excluded from the license granted to AstraZeneca in Section 7.1. Each Party shall bear its own internal costs in respect of the prosecution of Joint Patents. Out-of-pocket costs incurred in respect of the prosecution and maintenance of Joint Patents in the Territory shall be borne equally by AstraZeneca and FibroGen. In the event a Party elects to disclaim its interest in a Joint Patent, the costs incurred with respect to such Patent after the date of such disclaimer shall thereafter be borne exclusively by the other Party, without reimbursement or credit.

(d) Cooperation in Prosecution. Each Party shall, through the IP Committee, provide the other Party all reasonable assistance and cooperation in the Patent prosecution efforts provided above in this Section 9.4, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

9.5 Infringement of FibroGen Patents by Third Parties.

(a) Notification.

(i) Within five (5) Business Days from (A) a Party's or its Affiliate's receipt of any notice of any certification filed under the U.S. "Drug Price Competition and Patent Term Restoration Act" of 1984 as amended or supplemented or any successor law or (B) a Party's or its Affiliate's receipt of any notice of any certification filed under Section 505(j) of the FD&C Act or an application under Section 505(b)(2) of the FD&C Act naming a Product as a reference listed drug and including a certification under Section 505(j)(2)(A)(vii)(IV) or 505(b)(2)(A)(iv), respectively or (C) any equivalent proceeding in any country in RoW (each of (A), (B) and (C), a "***Product Infringement***") such Party shall notify the other Party thereof in writing.

(ii) If there is any infringement, threatened infringement, imminent infringement or alleged infringement of any FibroGen Patent on account of a Third Party's manufacture, use, offer for sale, or sale of a Collaboration Compound or Product in the Territory not within Section 9.5(a)(i) ("***Other Infringement***") then each Party shall promptly notify the other Party in writing of any such Other Infringement of which it becomes aware, and shall provide evidence in such Party's possession demonstrating such Other Infringement.

(b) Enforcement Rights.

(i) RoW Litigation. AstraZeneca shall have the first right, but not the obligation, to bring an appropriate suit or other action against any person or entity allegedly engaged in any Product Infringement or Other Infringement of the FibroGen Patents in the RoW (and to defend any related counterclaim), at AstraZeneca's expense. AstraZeneca shall have a period of one hundred eighty (180) days after its receipt or delivery of notice and evidence pursuant to Section 9.5(a)(i), to elect to so enforce such FibroGen Patent in the RoW (or to settle in

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accordance with Section 9.5(c) or otherwise secure the abatement of such Product Infringement or Other Infringement). In the event AstraZeneca does not so elect (or settle or otherwise secure the abatement of such Product Infringement or Other Infringement), it shall so notify FibroGen in writing as soon as practicable following the decision and in any event within such one hundred eighty (180)-day period, and FibroGen shall have the right to commence a suit or take action to enforce the applicable FibroGen Patents with respect to such Product Infringement or Other Infringement in the RoW (and to defend any related counterclaim) at FibroGen's expense. The IP Committee shall take the necessary actions to ensure that AstraZeneca has proper standing to bring suit under this Section 9.5(b)(i).

(ii) U.S. Litigation. AstraZeneca shall have the first right, but not the obligation, to bring an appropriate suit or other action against any person or entity allegedly engaged in any Product Infringement or Other Infringement of the FibroGen Patents in the U.S. (and to defend any related counterclaim), at AstraZeneca's expense. AstraZeneca shall have a period of thirty (30) days, with respect to a Product Infringement, and one hundred eighty (180) days with respect to an Other Infringement, after its receipt or delivery of notice and evidence pursuant to Section 9.5(a)(i), to elect to so enforce such FibroGen Patent in the U.S. (or to settle in accordance with Section 9.5(c) or otherwise secure the abatement of such Product Infringement or Other Infringement). The Parties shall meet periodically to discuss in good faith and determine an enforcement strategy, and AstraZeneca shall act consistently with any such agreed strategy. In the event AstraZeneca does not so elect (or settle or otherwise secure the abatement of such Product Infringement or Other Infringement), it shall so notify FibroGen in writing as soon as practicable following the decision and in any event within such thirty (30)- or one hundred eighty (180)-day period, as applicable, and FibroGen shall have the right to commence a suit or take action to enforce the applicable FibroGen Patents with respect to such Product Infringement or Other Infringement in the U.S. (and to defend any related counterclaim), at FibroGen's expense. The IP Committee shall take the necessary actions to ensure that AstraZeneca has proper standing to bring suit under this Section 9.5(b)(ii).

(iii) Cooperation. In any action, suit or proceeding instituted under this Section 9.5(b), the Parties shall cooperate with and assist each other in all reasonable respects. Upon the reasonable request of the Party instituting such action, suit or proceeding, the other Party shall join such action, suit or proceeding and shall be represented using counsel of its own choice, at the requesting Party's expense. If a Party with the right to initiate legal proceedings under this Section 9.5(b) lacks standing to do so and the other Party has standing to initiate such legal proceedings, then the Party with standing shall initiate such legal proceedings at the request and expense of the other Party (including reasonable internal personnel costs at the Hourly Rate).

(c) Settlement. Without the prior written consent of the other Party, neither Party shall settle any claim, suit or action that it brought under Section 9.5(b) involving FibroGen Patents in any manner that would negatively impact such intellectual property or that would limit or restrict the ability of either Party to sell Products anywhere in or outside the Territory.

(d) Recoveries. If either Party recovers monetary damages from a Third Party in a suit or action in respect of a Product Infringement or Other Infringement, such recovery shall

be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation and any remaining amount shall be deemed Net Sales and retained by (or paid to) AstraZeneca, subject to royalty payments on such deemed Net Sales pursuant to Section 8.6.

(e) Designated Products. Notwithstanding anything to the contrary in this Agreement:

(i) FibroGen shall have the sole right to enforce the FibroGen Patents against any of the Designated Products ("***Designated Product Infringement***"), and AstraZeneca shall be solely responsible for all expenses reasonably incurred in connection therewith and subject further to (ii) below. FibroGen will invoice AstraZeneca for its share of such expenses on a Calendar Quarter basis (including its internal personnel costs at the Hourly Rate), and AstraZeneca will pay each such invoice within forty-five (45) days after receipt thereof.

(ii) Notwithstanding (i) above, (A) in no event shall [*]; provided that in Calendar Years 2018, 2019 and 2020, AstraZeneca shall not be obligated to [*], except that if AstraZeneca reimburses [*] (the "***Deficit***"), the [*] (see example below); (B) in enforcing the FibroGen Patents against any of the Designated Products, the Parties shall unanimously select outside counsel to represent FibroGen in such enforcement proceedings (failing such unanimous agreement AstraZeneca shall be [*] (C) FibroGen shall, at all times, keep AstraZeneca reasonably informed regarding such enforcement proceedings and shall take into account any good faith comments made by AstraZeneca relating to such enforcement proceedings; and (D) FibroGen shall provide AstraZeneca with reasonably sufficient information regarding such enforcement proceedings to demonstrate that any such proceedings have a good faith basis and are brought and maintained in good faith. By way of example of clause (A), [*].

(f) Non-Product-Related Infringements. As between the Parties, FibroGen shall have the sole right to enforce the FibroGen Patents in the Territory against any infringement, imminent infringement, threatened infringement or alleged infringement that is not a Product Infringement, a Designated Product Infringement or an Other Infringement, at its expense, and to retain all associated recoveries; provided that in no event will FibroGen place an Orange Book-listed FibroGen Patent (or a FibroGen Patent listed on a Form 3542 submitted in accordance with Section 9.12 upon or after approval of the NDA as a timely filed patent) into litigation without AstraZeneca's prior written approval, which approval will not be unreasonably withheld.

(g) Joint Patents. Each Party shall promptly notify the other Party upon becoming aware of any infringement, imminent infringement, threatened infringement or alleged infringement of any Joint Patent ("***Joint Patent Infringement***"). The Parties will promptly thereafter meet to discuss in good faith how and whether to proceed to enforce the applicable Joint Patent against such Joint Patent Infringement. If the Parties fail to agree within sixty (60) days, then either Party shall have the right to take any action permitted under applicable law.

(h) Patents Licensed from Third Parties. Each Party's rights under this Section 9.5 with respect to any FibroGen Patent licensed from a Third Party shall be subject to the

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rights of such Third Party to enforce such FibroGen Patent and/or defend against any claims that such FibroGen Patent is invalid or unenforceable.

9.6 Defense of FibroGen Patents. To the extent any Party receives notice by counterclaim, or otherwise, alleging the invalidity or unenforceability of any FibroGen Patent in the Territory, it shall bring such fact to the attention of the other Party, including all relevant information related to such claim. The Parties, through the JSC, shall discuss such claim. Where such allegation is made within the context of a patent office proceeding, the provisions of Section 9.4 shall apply. Where such allegation is made in a counterclaim to or in connection with a suit or other action brought under Section 9.5, the provisions of Section 9.5 shall apply. In all other cases, (a) where such action relates to a FibroGen Patent in the U.S., FibroGen shall have the first right to defend such action, at FibroGen's expense, and AstraZeneca will cooperate with FibroGen, at FibroGen's expense, in such defense, and (b) where such action relates to a FibroGen Patent within the RoW, AstraZeneca shall have the first right but not the obligation to defend such action, at AstraZeneca's expense, and FibroGen will cooperate with AstraZeneca, at AstraZeneca's expense, in such defense. In the event a Party does not so elect to exercise its first right to defend an action under this Section 9.6, it shall so notify the other Party in writing, and such other Party shall have the right to so defend such action at its expense. Each Party shall provide to the Party defending any such rights under this Section 9.6 all reasonable assistance in such enforcement, at such defending Party's request and expense. The defending Party shall keep the other Party regularly informed of the status and progress of such efforts, and shall reasonably consider the other Party's comments on any such efforts.

9.7 Third Party Patents. FibroGen shall have the sole right and authority to initiate and/or pursue at its sole expense any patent office proceeding, pre- or post-grant or issuance, including reissue, reexamination, limitation, or invalidation proceedings, or any opposition- or interference-type proceeding or challenge against any Third Party Patent that relates or that may potentially relate to the manufacture, use, or sale of a HIF Compound, a Product, or a Designated Product.

9.8 Defense of Infringement Actions. During the Term, each Party shall bring to the attention of the other Party all information regarding potential infringement or any claim of infringement of Third Party intellectual property rights in connection with the development, manufacture, production, use, importation, offer for sale, or sale of Products in the Territory. Subject to Article 11, each Party shall be solely responsible at its sole expense for defending any action, suit, or other proceeding brought against it alleging infringement of Third Party intellectual property rights in connection with its activities under this Agreement. This Section 9.8 shall not be interpreted as placing on either Party a duty of inquiry regarding Third Party intellectual property rights.

9.9 Patent Marking. AstraZeneca shall, and shall require its Affiliates and Sublicensees to, mark Products sold by it hereunder (in a reasonable manner consistent with industry custom and practice) with appropriate patent numbers or indicia to the extent permitted by applicable law and regulations, in those countries in which such markings or such notices impact recoveries of damages or equitable remedies available with respect to infringements of

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patents. The Parties agree that listing the appropriate Patent(s) in the Orange Book shall be deemed a marking in a reasonable manner consistent with industry custom and practice under this Section 9.9, and FibroGen agrees to use good faith efforts to obtain, as soon as reasonably practicable after the Effective Date, a written confirmation from DFCI that DFCI so agrees.

9.10 Personnel Obligations. Prior to beginning work under this Agreement relating to any research, Development or Commercialization of a Collaboration Compound or a Product, to HIF or in the Field, each employee, agent or independent contractor of AstraZeneca or FibroGen or of either Party's respective Affiliates shall be bound by non-disclosure and invention assignment obligations which are consistent with the obligations of AstraZeneca or FibroGen, as appropriate, in this Article 9, including without limitation: (a) promptly reporting any invention, discovery, process or other intellectual property right; (b) assigning to AstraZeneca or FibroGen, as appropriate, all of his or her right, title and interest in and to any invention, discovery, process or other intellectual property right, such that AstraZeneca or FibroGen, as appropriate, can then comply with its obligations under this Agreement with respect to such invention, discovery, process or other intellectual property right; (c) cooperating in the preparation, filing, prosecution, maintenance and enforcement of any patent and patent application; (d) performing all acts and signing, executing, acknowledging and delivering any and all documents required for effecting the obligations and purposes of this Agreement; and (e) abiding by the obligations of confidentiality and non-use set forth in Article 12. It is understood and agreed that such non-disclosure and invention assignment agreement need not reference or be specific to this Agreement.

9.11 Trademarks. The Parties shall use Commercially Reasonable Efforts to develop a worldwide trademark, and if not possible, trademark for the Territory consistent with the trademarks for Products selected under the Astellas Collaboration. AstraZeneca, following discussion with FibroGen, shall be responsible for the selection, registration, ownership, maintenance and defense of all trademarks for use in connection with the sale or marketing of Products in the Field in the Territory (the "***Marks***"), as well as all expenses associated therewith. All uses of the Marks shall be reviewed by the JCC and shall comply with all applicable laws and regulations (including those laws and regulations particularly applying to the proper use and designation of trademarks in the applicable countries). Neither Party shall, without the other Party's prior written consent, use any trademarks or house marks of the other Party (including the other Party's corporate name), or marks confusingly similar thereto, in connection with such Party's marketing or promotion of Products under this Agreement, except as may be expressly authorized in connection with activities under Article 5 and except to the extent required to comply with applicable laws and regulations. During the Term, AstraZeneca grants to FibroGen the non-exclusive right, free of charge, to use the AstraZeneca name and logo in the U.S. solely for the purpose of Commercializing the Products in accordance with the terms of this Agreement, the U.S. Commercialization Plan and the Co-Commercialization Agreement, and FibroGen grants to AstraZeneca the non-exclusive right, free of charge, to use the FibroGen name and logo in the U.S. solely for the purpose of Commercializing the Products in accordance with the terms of this Agreement, provided that such rights shall be exercised, and all Products bearing such names and/or logos shall be manufactured, in accordance with the quality standards for such logos and trademarks established by the JSC. AstraZeneca shall remain the owner of the AstraZeneca name

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and logo and the trademarks and the goodwill pertaining thereto. FibroGen shall remain the owner of the FibroGen name and logo and the trademarks and the goodwill pertaining thereto.

9.12 Listing. Prior to the submission of the first NDA of a Product in the U.S., the Parties shall discuss in good faith in the IP Committee the Orange Book listings. FibroGen shall be responsible for the submission of documents associated with Orange Book listings in accordance with the plan set forth by the IP Committee. Upon FibroGen's receipt of a notice of allowance (or equivalent) of an applicable FibroGen Patent, FibroGen shall promptly provide AstraZeneca notification of such allowance and the Parties shall discuss in good faith in the IP Committee whether to list such FibroGen Patent in the Orange Book maintained by the FDA or similar or equivalent patent listing source, if any, in other countries in the Territory. FibroGen shall cooperate with AstraZeneca's reasonable requests in connection therewith, including meeting any submission deadlines.

9.13 Patent Term Extension. AstraZeneca shall be responsible for and control, but shall confer with FibroGen in, the selection of the appropriate FibroGen Patents as listed in the patent information section of the NDA or MAA for Products for filing to obtain a Patent Term Extension pursuant to all applicable laws, including without limitation any other extensions that are now or become available in the future wherever applicable to such patents that are applicable to the Products; provided, however, that AstraZeneca shall not have the right to make any such filing with respect to any FibroGen Patent that is not set forth on **Exhibit M** without the prior written consent of FibroGen.

ARTICLE 10

REPRESENTATIONS AND WARRANTIES

10.1 Mutual Representations and Warranties. Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows, as of the Effective Date:

(a) Corporate Existence and Power. It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including, without limitation, the right to grant the licenses granted by it hereunder.

(b) Authority and Binding Agreement. (i) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

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(c) No Conflict. It is not a party to and will not enter into any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement.

(d) No Debarment. In the course of the Development of Products, such Party has not used prior to the Effective Date and shall not use, during the Term, any employee, agent or independent contractor who has been debarred by any Regulatory Authority, or, to the best of such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

10.2 Representations and Warranties by FibroGen. FibroGen hereby represents and warrants to AstraZeneca, as of the Effective Date, as follows:

(a) Title; Encumbrances. Except for the Patents licensed to FibroGen under the DFCI Agreement and the Information licensed to FibroGen under the Astellas Agreements, FibroGen is the sole and exclusive owner of the entire right, title and interest in (a) the Listed Patents and (b) the FibroGen Know-How existing as of the Effective Date. FibroGen has all rights necessary to grant the licenses under the FibroGen Technology that it grants to AstraZeneca under this Agreement. Neither the Listed Patents nor the FibroGen Know-How is subject to any mortgage, pledge, lien, security interest, conditional and installment sale agreements, encumbrance or charges or claims of any kind.

(b) No Other Patents than those Listed. The Listed Patents represent all Patents that, as of the Effective Date, are Controlled by FibroGen and which, to FibroGen's knowledge, cover or claim any invention necessary or useful for the Development or Commercialization of Collaboration Compounds or Products in the Field in the Territory as contemplated as of the Effective Date.

(c) Prosecution of Patents etc. To FibroGen's knowledge, the Listed Patents are being diligently prosecuted before the respective patent authorities in accordance with applicable law. All applicable fees due to patent authorities with respect to the filing and prosecution of the Listed Patents existing as of the Effective Date have been paid on or before the due date for payment (as such due date may be extended in accordance with applicable laws or patent authority rules and regulations). FibroGen has not received any written notice alleging that the Listed Patents existing as of the Effective Date, if issued, would be invalid or unenforceable or that the Patent applications included in such Listed Patents will not proceed to grant. To FibroGen's knowledge, in respect of any pending U.S. patent applications included in the Listed Patents, FibroGen has submitted all material prior art of which it is aware in accordance with the requirements of the United States Patent and Trademark Office. To its knowledge, FibroGen has properly identified each and every inventor of the claims of the Listed Patents existing as of the Effective Date.

(d) No Infringement or Misappropriation. FibroGen has not received any written notice from any Third Party asserting or alleging that any research or development of Collaboration Compounds or Products by FibroGen or by Astellas prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party and FibroGen has

no reason to suspect that any such infringement or misappropriation has occurred. To FibroGen's knowledge, the conception, development and reduction to practice of the Listed Patents and FibroGen Know-How existing as of the Effective Date have not constituted or involved the misappropriation of trade secrets or other proprietary rights of any person or entity.

(e) Non-infringement of Third Party Rights. To FibroGen's knowledge, the research, development, manufacture, use and sale after the Effective Date of FG-4592 in the CKD Indications can be carried out in the manner reasonably contemplated as of the Effective Date without infringing any published patent applications or patents owned or controlled by a Third Party.

(f) No Proceedings. There are no pending actions, suits or proceedings against FibroGen or any of its Affiliates involving the FibroGen Technology, Collaboration Compounds or Products.

(g) Third Party Activities. To FibroGen's knowledge, except as disclosed in a writing of even date herewith by FibroGen to AstraZeneca, there are no activities by Third Parties that would constitute infringement or misappropriation of the FibroGen Technology (in the case of pending claims, evaluating them as if issued).

(h) DFCI Agreement. The DFCI Agreement is in full force and effect. FibroGen has no cause to believe that the DFCI Agreement is likely to be terminated prior to its expiry. To FibroGen's knowledge, neither DFCI nor FibroGen is in breach of any of its obligations under the DFCI Agreement. [*].

(i) Astellas Agreements. Nothing in the Astellas Agreements prevents FibroGen from granting the rights to AstraZeneca granted under this Agreement or prevents either FibroGen or AstraZeneca from exercising their rights or performing their obligations under this Agreement.

(j) Documentation Made Available to AstraZeneca. FibroGen has made available to AstraZeneca all material Regulatory Material, FibroGen Know-How and other Information in its possession or Control regarding or related to any Collaboration Compound and Product. All Regulatory Material, FibroGen Know-How and other Information in FibroGen's possession and Control provided to AstraZeneca regarding or related to any Collaboration Compound or Product are, to FibroGen's knowledge, true, complete and correct in all material respects. As of the Effective Date, FibroGen has prepared, maintained and retained in all material respects all material Regulatory Material that FibroGen is required to maintain or report pursuant to and in accordance with GLP, GCP, regulations and other applicable law.

(k) Patent Litigation. Neither FibroGen nor its Affiliates will initiate or maintain any patent enforcement proceeding or litigation with respect to any Designated Product unless it has a good faith basis for doing so.

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10.3 Anti-Bribery and Anti-Corruption Compliance.

(a) Each Party agrees, on behalf of itself, its officers, directors and employees and on behalf of its Affiliates, agents, representatives, consultants and subcontractors hired in connection with the subject matter of this Agreement (together with such Party, the "***Representatives***") that for the performance of its obligations hereunder:

(i) The Representatives shall not directly or indirectly pay, offer or promise to pay, authorize the payment of any money or give, offer or promise to give, or authorize the giving of anything else of value, to: (a) any Government Official in order to influence official action; (b) any individual or entity (whether or not a Government Official) (1) to influence such individual or entity to act in breach of a duty of good faith, impartiality or trust ("acting improperly"), (2) to reward such individual or entity for acting improperly or (3) where such individual or entity would be acting improperly by receiving the money or other thing of value; (c) any individual or entity (whether or not a Government Official) while knowing or having reason to know that all or any portion of the money or other thing of value will be paid, offered, promised or given to, or will otherwise benefit, a Government Official in order to influence official action for or against either Party in connection with the matters that are the subject of this Agreement; or (d) any individual or entity (whether or not a Government Official) to reward that individual or entity for acting improperly or to induce that individual or entity to act improperly.

(ii) The Representatives shall not, directly or indirectly, solicit, receive or agree to accept any payment of money or anything else of value in violation of the Anti-Corruption Laws.

(b) The Representatives shall comply with the Anti-Corruption Laws plus the AstraZeneca Anti-Corruption Rules and Policies and shall not take any action that will, or would reasonably be expected to, cause either Party or its Affiliates to be in violation of any such laws or policies.

(c) Each Party, on behalf of itself and its other Representatives, represents and warrants to the other Party that to the best of such Party's and its Affiliates' knowledge, no Representative that will participate or support its performance of its obligations hereunder has, directly or indirectly, (i) paid, offered or promised to pay or authorized the payment of any money, (ii) given, offered or promised to give or authorized the giving of anything else of value or (iii) solicited, received or agreed to accept any payment of money or anything else of value, in each case ((i), (ii) and (iii)), in violation of the Anti-Corruption Laws during the three (3) years preceding the date of this Agreement.

(d) Each Party shall promptly provide the other Party with written notice of the following events: (i) upon becoming aware of any breach or violation by such Party or its Representative of any representation, warranty or undertaking set forth in Sections 10.3(a)-(c); or (ii) upon receiving a formal notification that it is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation or upon receipt of information from any of the Representatives connected with this Agreement that any of them is

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the target of a formal investigation by a governmental authority for a Material Anti-Corruption Law Violation.

(e) Without prejudice to any auditing or inspection rights set forth elsewhere in this Agreement, each Party shall for the term of this Agreement and six (6) years thereafter, for the purpose of allowing the other Party to audit and monitor the performance of its compliance with this Agreement and particularly this Section 10.3 permit the other Party, its Affiliates, any auditors of any of them and any governmental authority to have reasonable access to any premises of such Party or other Representatives used in connection with this Agreement, together with a right to reasonably access personnel and records that relate to this Agreement ("***Compliance Audit***"). The results of any such audit shall constitute Confidential Information of the audited Party, in respect of which the other Party shall comply with the provisions contained in Article 12 (subject to the terms and exceptions set forth therein or in this Section 10.3).

(i) To the extent that any Compliance Audit by a Party requires access and review of any commercially or strategically sensitive information of the other Party or any of its other Representatives relating to the business of such Party or any other Representatives (including information about prices and pricing policies, cost structures and business strategies), such activity shall be carried out by a Third Party professional advisor appointed by the other Party and such professional advisors shall only report back to the other Party such information as is directly relevant to informing the other Party on such Party's compliance with the particular provisions of the Agreement being Compliance Audited.

(ii) Each Party shall, and shall cause its Representatives to, provide all cooperation and assistance during normal working hours as reasonably requested by the other Party for the purposes of a Compliance Audit. Such other Party shall ensure that any Third Party auditor enters into a confidentiality agreement consistent with applicable requirements of Article 12 hereof in all material respects. Such other Party shall instruct any Third Party auditor or other Person given access in respect of a Compliance Audit to cause the minimum amount of disruption to the business of the audited Party and its Affiliates and to comply with relevant building and security regulations.

(iii) The costs and fees of any Compliance Audit shall be paid by the auditing Party, except that if an inspection or Compliance Audit reveals any breach or violation by the audited Party (including through its other Representatives) of any representation, warranty or undertaking set forth in Sections 10.3(a)-(c), the costs of such inspection or Compliance Audit shall be paid by the audited Party. The audited Party shall bear its own costs of rendering assistance to the Compliance Audit.

(f) On the occurrence of any of the following events: (A) A Party becomes aware of, whether or not through a Compliance Audit, that the other Party (or any other Representative) is in breach or violation of any representation, warranty or undertaking in Sections 10.3(a)-(c) or of the Anti-Corruption Laws; or (B) notification is received under Section 10.3(d) relating to any suspected or actual Material Anti-Corruption Law Violation by a Party or its Representative, in either case ((A) or (B)), the other Party shall have the right, in addition to any

other rights or remedies under this Agreement or to which such other Party may be entitled in law or equity, to (x) take such steps as are reasonably necessary in order to avoid a potential violation or continuing violation by such other Party or any of its Affiliates of the Anti-Corruption Laws, including by requiring that the Party agrees to such additional measures, representations, warranties, undertakings and other provisions as such other Party believes in good faith are reasonably necessary ("***Provisions***") and (y) terminate any or all of the activities conducted by the Party pursuant to this Agreement or this Agreement in its entirety, immediately in the event that:

(i) A Party refuses to agree to all of the Provisions required by the other Party pursuant to this clause; *provided* that such other Party has (a) provided the Party an explanation in reasonable detail as to why such other Party considers such provisions necessary, (b) given the Party a reasonable opportunity to review and comment on the proposed Provisions and to provide its view as to the necessity or usefulness of these to address the event concerned and (c) considered such comments in good faith, or

(ii) A Party reasonably concludes that there is no Provision available that would enable such Party or its Affiliates to avoid a potential violation or continuing violation of applicable Anti-Corruption Laws.

(g) Any termination of this Agreement pursuant to Section 10.3(f) shall be treated as a termination for breach and the consequences of termination set forth in Sections 13.6 and 13.7, as applicable, shall apply and additionally: (i) subject to the accrued rights of the Parties prior to termination, the terminating Party shall have no liability to the other Party for any fees, reimbursements or other compensation or for any loss, cost, claim or damage resulting, directly or indirectly, from such termination; and (ii) any amounts that would otherwise be payable with respect to such terminated activities or pursuant to this Agreement in its entirety, as applicable, including any then outstanding and unpaid claims for payment shall be null and void to the extent permissible under applicable laws.

(h) Each Party shall be responsible for any breach of any representation, warranty or undertaking in this Section 10.3 or of the Anti-Corruption Laws by any of its Representatives.

(i) Each Party may disclose the terms of this Agreement or any action taken under this Section 10.3 to prevent a potential violation or continuing violation of applicable Anti-Corruption Laws, including the identity of the other Party and the payment terms, to any Governmental Authority if such Party determines, upon advice of counsel, that such disclosure is necessary.

(j) Each Party represents and warrants that (i) it has reviewed its internal programs in relation to the Anti-Corruption Laws and the ability of the Representatives to adhere to the AstraZeneca Anti-Corruption Rules and Policies in performance of its obligations hereunder in advance of the signing of this Agreement, (ii) it and the other Representatives can and will continue to comply with such Anti-Corruption Laws and the AstraZeneca Anti-Corruption Rules and Policies in performance of its obligations hereunder. Should either Party identify in writing

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to the other Party any measures that should be reasonably taken to improve the Representatives' compliance with such Anti-Corruption Laws and the AstraZeneca Anti-Corruption Rules and Policies for the performance of its obligations hereunder (the "***Improvement Plan***"), the other Party shall implement such Improvement Plan within an agreed reasonable timeframe (which shall in any event not be in excess of three (3) calendar months) from the date the Improvement Plan is delivered to the receiving Party or otherwise the requesting Party shall be entitled to (x) terminate this Agreement, upon written notice to the other Party with immediate effect, (y) be relieved of any obligations hereunder and (z) seek compensation from the other Party.

10.4 Disclaimer. Each Party understands that the Collaboration Compounds and Products are the subject of ongoing clinical research and development and that the other Party cannot assure the safety or usefulness of the Collaboration Compounds or Products. In addition, FibroGen makes no warranties except as set forth in this Article 10 concerning the FibroGen Technology, and AstraZeneca makes no warranties except as set forth in this Article 10 concerning the AstraZeneca Technology.

10.5 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN SECTION 5.11 AND THIS ARTICLE 10, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

ARTICLE 11

INDEMNIFICATION

11.1 Indemnification by FibroGen. FibroGen shall defend, indemnify, and hold AstraZeneca, its Affiliates, and their respective officers, directors, employees, and agents (the "***AstraZeneca Indemnitees***") harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such AstraZeneca Indemnitees (collectively, "***AstraZeneca Damages***"), all to the extent resulting from claims, suits, proceedings or causes of action brought by such Third Party ("***AstraZeneca Claims***") against such AstraZeneca Indemnitee that arise from or are based on: (a) a breach of any of FibroGen's representations, warranties, and obligations under this Agreement; (b) the willful misconduct or grossly negligent acts or omissions of FibroGen, its Affiliates, or the officers, directors, employees, or agents of FibroGen or its Affiliates in the performance of activities under this Agreement; (c) the research or Development of Collaboration Compounds or Products by FibroGen before the Effective Date; or (d) the Development, testing, manufacture, storage, handling, use, sale, offer for sale, distribution and importation of Products by FibroGen or its Affiliates or licensees (excluding, for clarity, AstraZeneca). The foregoing indemnity obligation shall not apply if the AstraZeneca Indemnitees materially fail to comply with the

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indemnification procedures set forth in Section 11.3, or to the extent that such AstraZeneca Claim is based on or alleges: (i) a breach of any of AstraZeneca's representations, warranties, and obligations under this Agreement; or (ii) the willful misconduct or grossly negligent acts or omissions of AstraZeneca or its Affiliates, or the officers, directors, employees, or agents of AstraZeneca or its Affiliates in the performance of activities under this Agreement.

11.2 Indemnification by AstraZeneca. AstraZeneca shall defend, indemnify, and hold FibroGen, its Affiliates, and each of their respective officers, directors, employees, and agents, (the "***FibroGen Indemnitees***") harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such FibroGen Indemnitees (collectively, "***FibroGen Damages***"), all to the extent resulting from any claims, suits, proceedings or causes of action brought by such Third Party (collectively, "***FibroGen Claims***") against such FibroGen Indemnitee that arise from or are based on: (a) the Development, testing, manufacture, storage, handling, use, sale, offer for sale, distribution and importation of Products by AstraZeneca or its Affiliates, Sublicensees, or distributors; (b) a breach of any of AstraZeneca's representations, warranties, and obligations under the Agreement; or (c) the willful misconduct or grossly negligent acts or omissions of AstraZeneca or its Affiliates, or the officers, directors, employees, or agents of AstraZeneca or its Affiliates in the performance of activities under this Agreement. The foregoing indemnity obligation shall not apply if the FibroGen Indemnitees materially fail to comply with the indemnification procedures set forth in Section 11.3, or to the extent that any FibroGen Claim is based on or alleges: (i) a breach of any of FibroGen's representations, warranties, and obligations under this Agreement; or (ii) the willful misconduct or grossly negligent acts or omissions of FibroGen, its Affiliates, or their officers, directors, employees, or agents in the performance of activities under this Agreement.

11.3 Indemnification Procedures. The Party claiming indemnity under this Article 11 (the "***Indemnified Party***") shall give written notice to the Party from whom indemnity is being sought (the "***Indemnifying Party***") promptly after learning of the claim, suit, proceeding or cause of action for which indemnity is being sought ("***Claim***"). The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided in this Article 11.

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11.4 Insurance. Each Party shall self-insure or procure and maintain insurance, including product liability insurance, with respect to its activities hereunder and which are consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested in human subjects or commercially distributed or sold until the expiration or termination of this Agreement or four (4) years after termination of any such clinical testing or commercial distribution, whichever is later. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 11. Each Party shall provide the other with written evidence of such insurance upon request. Each Party shall provide the other with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance or self-insurance which materially adversely affects the rights of the other Party hereunder.

11.5 DFCI Agreement. [*]

ARTICLE 12

CONFIDENTIALITY

12.1 Product Information. FibroGen recognizes that by reason of, among other things, AstraZeneca's status as licensee pursuant to the grants under Section 7.1, AstraZeneca has an interest in FibroGen's retention in confidence of information relating to the Collaboration Compounds or Products, and the Development and Commercialization thereof. Accordingly, during the Term, FibroGen shall, and shall cause its Affiliates and their respective officers, directors, employees and agents to, keep confidential, and not publish or otherwise disclose, other than under written confidentiality and non-use terms, and not use directly or indirectly for any purpose other than to perform FibroGen's obligations under this Agreement and the China Agreement, to conduct research, Development and Commercialization of Products outside the Territory pursuant to the Astellas Agreements or any Subsequent Agreement entered into pursuant to Section 7.4(c), in connection with FibroGen's research, development and commercialization of other products, and as otherwise authorized under this Agreement (including pursuant to Section 3.10), any (a) Regulatory Material (including any Regulatory Approvals) with respect to any Collaboration Compound or Product and (b) Information that is either Controlled by FibroGen or provided to FibroGen pursuant to this Agreement relating to the Development or Commercialization of Collaboration Compounds or Products, including development, sales or marketing plans therefor (collectively, (a) and (b), "***Product Information***"), except, in each case, to the extent (i) the Product Information was generally available to the public or otherwise part of the public domain, prior to the Effective Date, or thereafter became generally available to the public or otherwise part of the public domain through no fault of FibroGen, its Affiliates or any of their respective officers, directors, employees or agents or (ii) the disclosure or use of such Product Information would be expressly permitted under Section 12.3 or is otherwise expressly authorized under this Agreement. For clarification, the disclosure or transfer by FibroGen to AstraZeneca or by AstraZeneca to FibroGen of any Product Information shall not cause such information to cease to be subject to the provisions of this Section 12.1. In the event this Agreement is terminated in its entirety or in a given country for any reason, this Section 12.1 shall as from the effective date of such termination have no continuing force or effect (provided that if such termination is with

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respect to one or several specific country(ies) only, then this Section 12.1 will have no continuing force or effect as to such specific country(ies)) and all Product Information shall be deemed to be Confidential Information of FibroGen for purposes of the surviving provisions of this Agreement. For clarity, the foregoing shall not affect the Parties' respective ownership of Product Information.

12.2 Confidentiality General. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, during the Term and for ten (10) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement or the China Agreement (which includes the exercise of any rights or the performance of any obligations hereunder or thereunder) any Confidential Information furnished to it by the other Party pursuant to this Agreement except for that portion of such information or materials that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) is subsequently disclosed to the receiving Party or its Affiliate by a Third Party without obligations of confidentiality with respect thereto; or

(e) is independently discovered or developed by the receiving Party or its Affiliate without the aid, application, or use of the disclosing Party's Confidential Information.

For the avoidance of doubt, Confidential Information that is also Product Information is governed both by the terms of Section 12.1 and by the terms of this Section 12.2.

12.3 Authorized Disclosure. FibroGen may disclose Product Information and each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following situations:

(a) filing or prosecuting FibroGen Patents in accordance with Article 9;

(b) regulatory filings and other filings with Governmental Authorities (including Regulatory Authorities), including filings with the SEC or FDA, with respect to a Product;

(c) prosecuting or defending litigation;

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(d) complying with applicable laws and regulations, including regulations promulgated by securities exchanges;

(e) disclosure to its Affiliates, employees, agents, and independent contractors, and any licensees or Sublicensees, in each case only on a need-to-know basis and solely in connection with the performance of this Agreement or the China Agreement (and in the case of FibroGen, the Astellas Collaboration or any Subsequent Agreement entered into pursuant to Section 7.4(c)), provided, however, that each disclosee must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 12 prior to any such disclosure and provided, further, that the disclosing Party shall cause such disclosee to comply with confidentiality and non-use obligations at least as restrictive as those set forth in this Article 12;

(f) disclosure of the material terms of this Agreement to any bona fide potential or actual investor, investment banker, acquirer, merger partner, or other potential or actual financial partner, and in the case of FibroGen, to any licensee or sublicensee of Products (including Astellas and its sublicensees); provided that in connection with such disclosure, the disclosing Party shall inform each disclosee of the confidential nature of such Confidential Information and cause each disclosee to treat such Confidential Information as confidential; and

(g) disclosure of any Inventions or status reports (including data from any Clinical Trials) to any bona fide potential or actual investor, investment banker, acquirer, merger partner, or other potential or actual financial partner, and in the case of FibroGen, to any licensee of Products (including Astellas and its sublicensees); provided that each disclosee must be bound by obligations of confidentiality and non-use at least as restrictive as those set forth in this Article 12 prior to any such disclosure.

Notwithstanding the foregoing, in the event FibroGen is required to make a disclosure of Product Information or either Party is required to make a disclosure of the other Party's Confidential Information pursuant to Sections 12.3(a), 12.3(b), 12.3(c) or 12.3(d), it will, except where impracticable, use Commercially Reasonable Efforts to secure confidential treatment of such information. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

12.4 Publicity; Terms of Agreement.

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in Section 12.3 and this Section 12.4. The Parties have agreed to make a joint public announcement of the execution of this Agreement substantially in the form of the press release attached as **Exhibit N** on or promptly after the Effective Date.

(b) After release of such press release, if either Party desires to make a public announcement concerning the material terms of this Agreement or any activities under this Agreement, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval (except as otherwise provided

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herein), such approval not to be unreasonably withheld, except that in the case of a press release or governmental filing required by law, the disclosing Party shall provide the other Party with such advance notice as it reasonably can and shall not be required to obtain approval therefor. A Party commenting on such a proposed press release shall provide its comments, if any, within five (5) Business Days after receiving the press release for review. FibroGen shall have the right to make a press release announcing the achievement of each milestone under this Agreement as it is achieved, and the achievements of Regulatory Approvals as they occur, subject only to the review procedure set forth in the preceding sentence. In relation to AstraZeneca's review of such an announcement, AstraZeneca may make specific, reasonable comments on such proposed press release within the prescribed time for commentary, but shall not withhold its consent to disclosure of the information that the relevant milestone or Regulatory Approval has been achieved and triggered a payment hereunder. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement that have already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 12.4.

(c) The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the SEC or other Government Authorities. Each Party shall be entitled to make such a required filing, provided that it requests confidential treatment of at least the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, each Party will provide the other Party with a copy of the Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the legal requirements governing redaction of information from material agreements that must be publicly filed.

12.5 Publications.

(a) Subject to the International Committee of Medical Journal Editors ("ICMJE") Uniform Requirements for Manuscripts Submitted to Biomedical Journals and applicable legal requirements, the JDC (with approval of the JSC) will determine the overall strategy for publishing and presenting results of studies pertaining to the Products and the JDC shall approve all publications in the Territory prior to publication.

(b) Neither Party shall publicly present or publish results of studies carried out under this Agreement (each such presentation or publication a "***Publication***") without the opportunity for prior review by the other Party, except to the extent otherwise required by applicable laws or regulations, in which case Section 12.4(c) shall apply with respect to disclosures required by applicable securities laws and Section 12.3(b) shall apply with respect to disclosures required for regulatory filings. The submitting Party shall provide the other Party the opportunity to review any proposed Publication at least thirty (30) days prior to the earlier of its presentation or intended submission for publication. The submitting Party agrees, upon request by the other Party, not to submit or present any Publication until the other Party has had thirty (30) days to comment on any material in such Publication. The submitting Party shall consider the comments of the other Party in good faith, and no Publication shall be submitted for publication without the approval of the JDC or JCC. The submitting Party shall provide the other Party a copy of the

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Publication at the time of the submission or presentation. Notwithstanding the foregoing, AstraZeneca shall not have the right to publish or present FibroGen's Confidential Information without FibroGen's prior written consent, and FibroGen shall not have the right to publish or present AstraZeneca's Confidential Information without AstraZeneca's prior written consent. Each Party agrees to acknowledge the contributions of the other Party, and the employees of the other Party, in all publications as scientifically appropriate.

ARTICLE 13

TERM AND TERMINATION

13.1 Term. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 13, shall remain in effect until the date that AstraZeneca is no longer Developing or selling Products in the Territory (the "***Term***").

13.2 Termination by AstraZeneca at Will. AstraZeneca shall have the right to terminate this Agreement at any time upon one hundred eighty (180) days prior written notice to FibroGen, either (a) in its entirety or (b) with respect to one or more of the following (each a "region"): (i) the U.S., (ii) Asia, (iii) Africa or (iv) one or more of Mexico, Brazil, Canada, India or Australia and New Zealand (each considered a separate region). During such one hundred eighty (180) day period, AstraZeneca shall continue to perform all of its obligations under this Agreement and shall continue to be responsible for all costs incurred under the Agreement to be borne by AstraZeneca according to the Agreement during such one hundred eighty (180) day period.

13.3 Termination by AstraZeneca for Technical Product Failure. AstraZeneca may terminate this Agreement in its entirety at any time after the Effective Date effective upon written notice to FibroGen in the event of Technical Product Failure, such notice to describe the basis for such Technical Product Failure in reasonable detail; provided, however, that AstraZeneca shall *not* be entitled to terminate this Agreement pursuant to this Section 13.3 if such Technical Product Failure pertains only to one or several specific Collaboration Compound(s) or Product(s) but does not affect (a) FG-4592 (if FG-4592 is then still being Developed or Commercialized under this Agreement) or (b) any other Collaboration Compound or Product then in a Phase 2 Clinical Trial or later stage of Development or Commercialization under this Agreement. Disputes related to whether or not a Technical Product Failure has occurred will be resolved in accordance with Section 14.8.

13.4 Termination by Either Party for Breach.

(a) Breach. Subject to Section 13.4(b), FibroGen shall have the right to terminate this Agreement upon written notice to AstraZeneca if AstraZeneca materially breaches its obligations under this Agreement and, after receiving written notice from FibroGen identifying such material breach by AstraZeneca in reasonable detail, fails to cure such material breach within ninety (90) days from the date of such notice (or within thirty (30) days from the date of such notice in the event such material breach is solely based upon AstraZeneca's failure to pay any

material amounts due to FibroGen hereunder). Subject to Section 13.4(b), AstraZeneca shall have the right to terminate this Agreement upon written notice to FibroGen if FibroGen materially breaches its obligations under this Agreement and, after receiving written notice from AstraZeneca identifying such material breach by FibroGen in reasonable detail, fails to cure such material breach within ninety (90) days from the date of such notice (or within thirty (30) days from the date of such notice in the event such material breach is solely based upon FibroGen's failure to pay any material amounts due to AstraZeneca hereunder).

(b) Disputed Breach. If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section 13.4(a), and such alleged breaching Party provides the other Party notice of such dispute within such ninety (90) day (or thirty (30) day, as the case may be) period, then the non-breaching Party shall not have the right to terminate this Agreement under Section 13.4(a) unless and until the arbitral tribunal, in accordance with Article 14, has determined that the alleged breaching Party has materially breached the Agreement and such Party fails to cure such breach within ninety (90) days following such arbitral tribunal's decision (except to the extent such breach is solely based on the failure to make a payment when due, which breach must be cured within thirty (30) days following such arbitral tribunal's decision); provided that with respect to a failure to pay amounts due, arbitration shall be conducted in accordance with Article 14, except that it shall be conducted by only one arbitrator and shall be resolved within ninety (90) days. It is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

(c) DFCI Agreement. [*]

13.5 Termination for Patent Challenge. FibroGen may terminate this Agreement in its entirety immediately upon written notice to AstraZeneca if AstraZeneca or its Affiliates or Sublicensees (directly or indirectly, individually or in association with any other person or entity) challenges the validity, enforceability or scope of any FibroGen Patent in the Territory and such challenge is not permanently withdrawn within ninety (90) days.

13.6 Effects of Termination. Upon any termination of this Agreement other than pursuant to Section 13.3 for Technical Product Failure, the following shall apply (in addition to any other rights and obligations under Section 13.8 or otherwise under this Agreement with respect to such termination) and, in the case of termination with respect to a particular region only, shall apply only to the terminated region (it being understood that any reference below to the "terminated region" will apply to the Territory as a whole if this Agreement is terminated in its entirety):

(a) Rights and Licenses to the FibroGen Technology. As from the effective date of the termination, all licenses and rights to the FibroGen Technology granted to AstraZeneca under Article 7 shall terminate with respect to the terminated region, except to the extent and for so long as is necessary to permit AstraZeneca to comply with its obligations under this Section 13.6, to dispose of any remaining inventory of Products pursuant to Section 13.6(g) and to perform

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any activity that cannot be terminated as of such date under applicable law, including GCP, it being agreed that all such activities and responsibilities shall be discontinued and ceased (unless otherwise agreed) by transitioning such activities and responsibilities to FibroGen as soon as practicable and subject to applicable law, including GCP.

(b) AstraZeneca Technology. AstraZeneca hereby grants to FibroGen, effective only upon the effective date of such termination, a non-exclusive, fully-paid, perpetual, irrevocable, royalty-free license, with the right to grant multiple tiers of sublicenses, under the AstraZeneca Technology, to research, develop, make, have made, use, import, export, offer for sale, and sell Products in the Field in the terminated region; provided that FibroGen shall indemnify, defend and hold harmless AstraZeneca and each of the AstraZeneca Indemnitees as set forth in Section 11.1 from and against any AstraZeneca Damages arising out of or resulting from AstraZeneca Claims that arise or result from FibroGen's, its Affiliates' or licensees' activities performed under the foregoing license.

(c) Marks. AstraZeneca shall assign to FibroGen all right, title and interest in and to the Marks for the terminated regions (excluding any such Marks that include, in whole or part, any corporate name or logo of AstraZeneca or its Affiliate or Sublicensee or that relate to any other products of AstraZeneca or its Affiliates).

(d) Regulatory Materials. AstraZeneca shall transfer and assign to FibroGen all Regulatory Materials and Regulatory Approvals for Products in the terminated regions, if any, that are Controlled by AstraZeneca or its Affiliates or Sublicensees.

(e) Transition Assistance. AstraZeneca shall, at no cost to FibroGen, provide reasonable consultation and assistance for a period of no more than one hundred eighty (180) days following the effective date of termination for the purpose of transferring or transitioning to FibroGen, all AstraZeneca Know-How solely related to a Product not already in FibroGen's possession, and, at FibroGen's request, all then-existing commercial arrangements relating specifically to the terminated region and the Products to the extent reasonably necessary or useful for FibroGen to commence or continue developing, manufacturing, or commercializing Products in the terminated region, and further to the extent AstraZeneca is contractually able to do so. The foregoing consultation and assistance shall include, without limitation, assigning, upon request of FibroGen, any agreements with Third Party suppliers or vendors that specifically cover the supply or sale of Products in the Territory, to the extent such agreements are assignable by AstraZeneca. If any such contract between AstraZeneca and a Third Party is not assignable to FibroGen (whether by such contract's terms or because such contract does not relate specifically to Products) but is otherwise reasonably necessary or useful for FibroGen to commence or continue developing, manufacturing, or commercializing Products, then AstraZeneca shall reasonably cooperate with FibroGen to negotiate for the continuation of such license and/or supply from such entity. In any event, if AstraZeneca is manufacturing bulk or finished Product under an agreement entered into pursuant to Section 6.4, then AstraZeneca shall supply such bulk or finished Product, as applicable, to FibroGen and Astellas, for a reasonable transitional period (not to exceed twelve (12) months from the effective date of the termination, subject to reasonable extension by FibroGen if AstraZeneca is unable to timely effect the technology transfer required to have a Third Party

manufacturer designated by FibroGen undertake the manufacturing responsibilities) under the terms of such agreement until FibroGen either enters into a separate agreement with such Third Party supplier or vendor or establishes an alternate, validated source of supply for the Products. In consideration of such supplies, FibroGen shall pay to AstraZeneca a price equal to AstraZeneca's actual cost to manufacture or acquire such supplies, provided that where termination is by AstraZeneca pursuant to Section 13.4(a), FibroGen shall pay to AstraZeneca a price equal to AstraZeneca's actual cost to manufacture or acquire such supplies plus a mark-up [*] of such actual cost.

(f) Ongoing Clinical Trials. As soon as practicable and subject to applicable law, including GCP, AstraZeneca shall transfer to FibroGen the management and continued performance of all Clinical Trials for Products for the terminated regions ongoing as of the effective date of such termination, that are being conducted by AstraZeneca at such time.

(g) Remaining Inventories. If this Agreement is terminated in its entirety, FibroGen shall have the right to purchase from AstraZeneca any or all of the inventory of Products held by AstraZeneca as of the effective date of the termination (that are not committed to be supplied to any Third Party in the ordinary course of business as of the date of termination) at a price equal to AstraZeneca's actual cost to acquire such inventory. FibroGen shall notify AstraZeneca within sixty (60) days after the effective date of the termination whether FibroGen elects to exercise such right. In the event FibroGen does not elect to exercise such right AstraZeneca shall be entitled to dispose of such inventory as it sees fit in compliance with applicable law, subject to all applicable payments to FibroGen under Article 8.

(h) Funding of Development Costs. If AstraZeneca terminates this Agreement under Section 13.2 (but not in the event of any other termination), then AstraZeneca shall remain responsible for all (or, if during the Development Sharing Period, fifty percent (50%) of) Development Costs and all Commercialization Costs incurred by FibroGen under the respective Development Plans and Commercialization Plans [*], under the process in Section 8.2. If AstraZeneca terminates this Agreement under Section 13.2 (but not in the event of any other termination), AstraZeneca shall [*].

(i) Post-Termination Restriction. If this Agreement is terminated by AstraZeneca at will under Section 13.2 or by FibroGen under Section 13.4 for AstraZeneca's material breach or by FibroGen under Section 13.5 for patent challenge, AstraZeneca shall continue to comply with the restrictive covenant set out in Section 7.8(a) for three (3) years after the effective date of the termination.

(j) No Other Rights. For the avoidance of doubt, the rights granted to FibroGen under this Section 13.6 are restricted to Collaboration Compounds and Products and AstraZeneca does not grant any rights whatsoever to any other compounds or products or to any Patents or other intellectual property rights other than as set forth in this Section 13.6. Moreover, AstraZeneca shall not be obligated to provide FibroGen with any other intellectual property rights or other rights or services than that which are explicitly provided for under this Section 13.6.

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(k) Certain Additional Provisions for Termination for FibroGen's Breach. If this Agreement is terminated under Section 13.4 for FibroGen's material breach, FibroGen shall – in addition to any other remedies available to AstraZeneca under this Agreement or applicable law as a consequence of such breach – compensate AstraZeneca for any costs or expenses incurred by AstraZeneca or its Affiliates in connection with performing any of the activities contemplated by the applicable provisions in this Section 13.6.

13.7 Effect of Termination for Technical Product Failure. Upon termination of this Agreement pursuant to Section 13.3 for a Technical Product Failure, all licenses and rights to the FibroGen Technology granted to AstraZeneca under Article 7 shall terminate and, to the extent appropriate given the nature of the Technical Product Failure and subject to applicable law, including GCP, the other termination consequences set out in Sections 13.6(a) through 13.6(g) as well as Section 13.6(j) shall apply.

13.8 Other Remedies. Termination or expiration of this Agreement for any reason shall not release either Party from any liability or obligation that already has accrued prior to the effective date of such expiration or termination, nor affect the survival of any provision hereof to the extent it is expressly stated to survive such termination. Termination or expiration of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder or that may arise out of or in connection with such termination or expiration.

13.9 Bankruptcy.

(a) A Party shall have the right to terminate this Agreement in its entirety before the end of the Term upon the bankruptcy or insolvency of, or the filing of an action to commence insolvency proceedings against the other Party, or the making or seeking to make or arrange an assignment for the benefit of creditors of the other Party, or the initiation of proceedings in voluntary or involuntary bankruptcy, or the appointment of a receiver or trustee of such Party's property, in each case that is not discharged within sixty (60) days of the applicable filing, action or initiation of proceedings.

(b) All rights and licenses granted under or pursuant to this Agreement by FibroGen and AstraZeneca are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that each Party, as licensee of certain rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party (such Party, the "***Bankrupt Party***") under the U.S. Bankruptcy Code, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed to such other Party and all embodiments of such intellectual property, which, if not already in such other Party's possession, shall be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon such other Party's written request therefor, unless the Bankrupt Party elects to continue to perform all of its

obligations under this Agreement or (ii) if not delivered under clause (i), following the rejection of this Agreement by the Bankrupt Party upon written request therefor by the other Party.

13.10 Survival. Termination or expiration of this Agreement shall not affect rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration of this Agreement. Notwithstanding anything to the contrary, the following provisions shall survive and apply after expiration or termination of this Agreement: Sections 3.10(b), 3.11, 4.4 (last sentence only), 7.8(a)-(c) (only as and to the extent set forth in Section 13.6(i)), 7.8(d), 7.9, 8.1, 8.9-8.15, 9.2, 10.5, 12.1 (provided that all Product Information will be FibroGen's Confidential Information upon termination (but not expiration) of this Agreement), 12.2, 12.3, 12.4, 13.6, 13.7, 13.8 and 13.10 and Articles 11, 14 and 15. In addition, the other applicable provisions of Article 8 shall survive to the extent required to make final reimbursements, reconciliations or other payments with respect to Net Sales and costs and expenses incurred or accrued prior to the date of termination or expiration. For any surviving provisions requiring action or decision by a Committee or an Executive Officer, each Party will appoint representatives to act as its Committee members or Executive Officer, as applicable. All provisions not surviving in accordance with the foregoing shall terminate upon expiration or termination of this Agreement and be of no further force and effect.

ARTICLE 14

DISPUTE RESOLUTION AND GOVERNING LAW

14.1 Disputes. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. In the event of any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement (including disputes arising from the JSC that are not resolved pursuant to Section 2.6), including, without limitation, any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement (each, a "***Dispute***"), then upon the request of either Party by written notice, the dispute will be referred to the Executive Officers of each Party, who shall meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one in-person meeting. If the matter is not resolved within thirty (30) days following the written request for discussions, either Party may then invoke the provisions of Section 14.2.

14.2 Arbitration. Any dispute, controversy, difference or claim which may arise between the Parties, out of or in relation to or in connection with this Agreement (including, without limitation, arising out of or relating to the validity, construction, interpretation, enforceability, breach, performance, application or termination of this Agreement) that is not resolved pursuant to Section 14.1, except for a dispute, claim or controversy under Section 14.7 or 14.8, shall be settled by binding arbitration administered by the American Arbitration Association (the "***AAA***") in accordance with its Commercial Arbitration Rules (or the AAA International Arbitration Rules, if recommended under the AAA guidelines), as such rules may be modified by this Section 14.2 or otherwise by subsequent written agreement of the Parties. The arbitration shall

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be governed by the U.S. Federal Arbitration Act, 9 U.S.C. §§ 1-16 (the "***Federal Arbitration Act***"), to the exclusion of any inconsistent state laws. The arbitration will be conducted in New York, New York. The number of arbitrators shall be three (3), of whom the Parties shall select one (1) each. The two arbitrators so selected will select the third and final arbitrator. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the AAA shall select the third arbitrator. The language to be used in the arbitral proceedings will be English. The Parties shall have the right to be represented by counsel. The arbitration proceeding shall be confidential. Except as required by applicable law, no Party shall make (or instruct the arbitrator to make) any public announcement with respect to the proceedings or decision of the arbitrator without prior written consent of the other Party. The existence of any dispute submitted to arbitration, and the award, shall be kept in confidence by the Parties and the arbitrator, except as required in connection with the enforcement of such award or as otherwise required by applicable law. Any judgment or award rendered by the arbitrators shall be final and binding on the Parties. The Parties agree that such judgment or award may be enforced in any court of competent jurisdiction.

14.3 Governing Law. Resolution of all Disputes and any remedies relating thereto shall be governed by and construed under the substantive laws of the State of California, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

14.4 Decision. The arbitrators shall issue a reasoned opinion following a full comprehensive hearing, no later than twelve (12) months following the selection of the arbitrators.

14.5 Award. Any award shall be promptly paid in Dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by law, be charged against the Party resisting enforcement. If as to any issue the arbitrators should determine under the applicable law that the position taken by a Party is frivolous or otherwise irresponsible or that any wrongdoing it finds is in callous disregard of law and equity or the rights of the other Party, the arbitrators shall also be entitled to award an appropriate allocation of the adversary's reasonable attorney fees, costs and expenses to be paid by the offending Party, the precise sums to be determined after a bill of attorney fees, expenses and costs consistent with such award has been presented following the award on the merits. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Article 14. The award shall include interest from the date of any damages incurred for breach of the Agreement, and from the date of the award until paid in full, at a rate fixed by the arbitrators. With respect to money damages, nothing contained herein shall be construed to permit the arbitrators or any court or any other forum to award punitive or exemplary damages. By entering into this agreement to arbitrate, the Parties expressly waive any claim for punitive or exemplary damages. The only damages recoverable under this Agreement are compensatory damages.

14.6 Injunctive Relief. Provided a Party has made a sufficient showing under the rules and standards set forth in the U.S. Federal Rules of Civil Procedure and applicable case law, the arbitrator shall have the freedom to invoke, and the Parties agree to abide by, injunctive measures after either Party submits in writing for arbitration claims requiring immediate relief. Nothing in

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this Article 14 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

14.7 Patent and Trademark Disputes. Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patents or trademarks covering the manufacture, use, importation, offer for sale or sale of the Product shall be submitted to a court of competent jurisdiction in the country in which such patent or trademark rights were granted or arose.

14.8 Expedited Arbitration for Disputes Related to Technical Product Failure. Disputes with respect to a Technical Product Failure that are not resolved at the JSC or by the Executive Officers within twenty (20) Business Days after referral thereto, in the case of a Technical Product Failure as defined in Section 1.120(a), or resolved by the Parties, in the case of a Technical Product Failure as defined in Section 1.120(b), shall be finally determined as set forth in this Section 14.8. Within five (5) Business Days after the end of such twenty (20)-Business Day period, each Party shall propose a list of three (3) individuals, each of whom has at least ten (10) years of significant relevant technical experience in the pharmaceutical industry, and none of whom is or has been affiliated with either Party or with either Party's Affiliates, licensees, sublicensees or business partners, or otherwise has any interest in the resolution of the issue to be submitted by the Parties for resolution (the foregoing requirements, the "***Requirements***"). Within five (5) Business Days after the Parties exchange such lists, the Parties shall either agree upon one of such proposed individuals to resolve the disputed matter, or if the Parties do not so select one such individual within such period of time, each Party shall select one (1) such individual from the list proposed by the other Party, and the two (2) selected individuals shall select a third individual who otherwise meets the Requirements to resolve the disputed matter (the selected individual, the "***Industry Expert***"). Each Party shall submit written materials to the other Party and to the Industry Expert relating to the matters in issue within five (5) Business Days after the Industry Expert is selected. Each Party shall then have five (5) Business Days to submit a written rebuttal to the other Party's submission to the other Party and to the Industry Expert. The Industry Expert shall have the discretion to interview the Parties' officers and employees to obtain further information relating to the matters in issue and to hear oral argument. Each Party shall cooperate with the Industry Expert. The Industry Expert's determination shall be binding as to whether a Technical Product Failure has occurred, and such determination shall be given retroactive effect. Until such determination is delivered to the Parties, the Parties shall continue to perform their obligations under this Agreement in good faith and make any applicable payments accordingly. If the Industry Expert decides in AstraZeneca's favor, then the Parties shall bear all expenses incurred pursuant to this Section 14.8 equally, and if the Industry Expert decides in FibroGen's favor, then AstraZeneca shall bear all expenses incurred pursuant to this Section 14.8, including reasonable reimbursement of FibroGen's expenses for internal personnel and external advisors.

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ARTICLE 15

MISCELLANEOUS

15.1 Entire Agreement; Amendment. This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof, including, without limitation, the Existing Confidentiality Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective Date, by the other Party of its obligations pursuant to the Existing Confidentiality Agreement. In the event of any inconsistency between any plan hereunder (including the Development Plan and/or U.S. Commercialization Plan) and this Agreement or between the terms of this Agreement and the China Agreement (but solely with respect to the U.S. and RoW), the terms of this Agreement shall prevail. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

15.2 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented or delayed by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall mean conditions beyond the control of the Parties, including without limitation, an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). The non-performing Party shall within thirty (30) days after a force majeure provide the other Party a good faith estimate of the anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably necessary and the non-performing Party shall use Commercially Reasonable Efforts to remedy its inability to perform. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party.

15.3 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 15.3, and shall be deemed to have been given for all

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purposes (a) when received, if hand-delivered or sent by a reputable international expedited delivery service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered mail, postage prepaid, return receipt requested.

If to FibroGen:	FibroGen, Inc. 409 Illinois St. San Francisco, CA 94158 USA Attention: Chief Executive Officer
With a copy to:	FibroGen, Inc. 409 Illinois St. San Francisco, CA 94158 USA Attn: Michael Lowenstein, Vice President, Legal
If to AstraZeneca:	AstraZeneca AB Pepparedsleden 1, 431 83 Mölndal Gothenburg Sweden Attention: Chief Financial Officer
With a copy to:	AstraZeneca UK Limited Alderley Park Macclesfield Cheshire SK10 4TF Attention: Liam McIlveen, Deputy General Counsel

15.4 No Strict Construction; Headings. Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in the event an ambiguity or a question of intent or interpretation arises, this Agreement will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise favoring or disfavoring any Party by virtue of the authorship of any provisions of this Agreement. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

15.5 Assignment. Neither Party may assign or transfer this Agreement (either in whole or part) or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment or transfer without the other Party's consent to Affiliates or to a successor to substantially all of the business of such Party, whether in a merger, sale of stock, sale of assets or other transaction. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such

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rights and/or obligations (and in any event, any Party assigning this Agreement to an Affiliate shall remain bound by the terms and conditions hereof). In the event that a Party is acquired by a Third Party (such Third Party, hereinafter referred to as an "***Acquiror***"), then the intellectual property of such Acquiror held or developed by such Acquiror (whether prior to or after such acquisition) shall be excluded from the FibroGen Technology (in the case when the acquired Party is FibroGen) and AstraZeneca Technology (in the case when the acquired Party is AstraZeneca), and such Acquiror (and Affiliates of such Acquiror which are not controlled by the acquired Party itself) shall be excluded from "Affiliate" solely for purposes of the applicable components of the foregoing intellectual property definitions, in all such cases if and only if: (a) the acquired Party remains a wholly-owned subsidiary of the Acquiror; (b) all intellectual property of the acquired Party and all research and development assets and operations of the acquired Party with respect to the Product remain with the acquired Party and are not transferred to the Acquiror or another Affiliate of the Acquiror; (c) the scientific and development activities with respect to Product of the acquired Party and the Acquiror (if any) are maintained separate and distinct, and (d) there is no exchange of confidential Information relating to this Collaboration between the acquired Party and the Acquiror. For clarity, in the event that a Party is acquired by an Acquiror and any of the criteria described in subsections (a) through (d) is not satisfied, then the intellectual property of such Acquiror shall be included within FibroGen Technology (in the case when the acquired Party is FibroGen) and AstraZeneca Technology (in the case when the acquired Party is AstraZeneca). Any permitted assignment of the rights and obligations of a Party under this Agreement shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.5 shall be null, void and of no legal effect.

15.6 Performance by Affiliates. Subject to the limitations of Section 7.3, each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

15.7 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

15.8 Compliance with Applicable Law. Each Party shall comply with all applicable laws and regulations in the course of performing its obligations or exercising its rights pursuant to this Agreement.

15.9 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT OR ANY TORT CLAIMS ARISING HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 15.9 IS INTENDED TO OR SHALL LIMIT OR

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RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 11.1, 11.2 OR 11.3, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 12.

15.10 Severability. To the fullest extent permitted by applicable law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid or unenforceable in any respect. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by an arbitrator or by any court of competent jurisdiction from which no appeal can be or is taken (within the time period prescribed for appeal), the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one that achieves, as nearly as possible, the objectives contemplated by the Parties when entering this Agreement.

15.11 No Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

15.12 Independent Contractors. It is expressly agreed that FibroGen, on the one hand, and AstraZeneca, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither FibroGen, on the one hand, nor AstraZeneca, on the other hand, shall have the authority to make any statements, representations or commitments of any kind, or to take any action that will be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party.

15.13 English Language. This Agreement shall be written and executed in and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

15.14 Counterparts. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Signature Page Follows]

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In Witness Whereof, the Parties have executed this Agreement in duplicate originals by their duly authorized officers as of the Execution Date.

FibroGen, Inc.		**AstraZeneca AB**	
By:	/s/ Thomas B. Neff	By:	/s/ Elisabeth Bjork
Name:	Thomas B. Neff	Name:	Elisabeth Bjork
Title:	CEO	Title:	VP, GMed Head, CVMD

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EXHIBITS

Exhibit A – Territory – Excluded Countries

Exhibit B – DFCI Agreement

Exhibit C – Chemical Structure of FG-4592

Exhibit D – Field Indications

Exhibit E – Listed Patents

Exhibit F – AstraZeneca's Anti-Corruption Rules and Policies

Exhibit G – Initial Members of the JSC

Exhibit G(a) – JDC Responsibilities Delegated by the JSC to the Core JPT

Exhibit G(b) – JCC Responsibilities Delegated by the JSC to the Core JPT

Exhibit H – Initial Development Plan

Exhibit I – U.S. Co-Commercialization Terms

Exhibit J – Development Supply Terms

Exhibit K – Commercial Supply Terms

Exhibit L – Invoicing Requirements

Exhibit M – Patents that May be Extended

Exhibit N – Joint Press Release

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Exhibit A

Excluded Countries

- Albania
- Andorra
- Armenia
- Austria
- Azerbaijan
- Belarus
- Belgium
- Bosnia & Herzegovina
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Georgia
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy
- Japan
- Kazakhstan
- Kyrgyzstan
- Latvia
- Liechtenstein
- Lithuania
- Luxembourg
- Macedonia
- Malta
- Moldova
- Monaco
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Russia
- San Marino
- Serbia and Montenegro (Yugoslavia)
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Tajikistan
- Turkey
- Turkmenistan
- Ukraine
- United Kingdom
- Uzbekistan
- Vatican City
- Bahrain
- Egypt
- Iran
- Iraq
- Israel
- Jordan
- Kuwait
- Lebanon
- Oman
- Qatar
- Saudi Arabia
- Syria
- United Arab Emirates
- Yemen
- South Africa

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Exhibit B

DFCI Agreement

{*This Exhibit B is filed as Exhibit 10.24 to the Registration Statement on Form S-1 (Commission File No. 333-199069)*}

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Exhibit C

Chemical Structure of FG-4592

[*]

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Exhibit D

Field Indications

[*]

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Exhibit E

Listed Patents

[*]

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Exhibit F

AstraZeneca's Anti-Corruption Rules and Policies

ASTRAZENECA GLOBAL POLICY
ETHICAL INTERACTIONS
ANTI-BRIBERY & ANTI-CORRUPTION
EXTERNAL INTERACTIONS

This Global Policy describes what is required to meet our commitment to operate ethically and with integrity in our business and personal interactions and activities.

This Policy applies to all Employees.

The Company is committed to acting responsibly and in compliance with the requirements of the UK Bribery Act, Foreign Corrupt Practices Act and other relevant laws, regulations and adopted industry codes

CONTENTS

1. SCOPE, APPLICATION & INTERPRETATION

1.1 This Policy applies to all Employees and represents the minimum requirements that the Company has set for Interactions.

An alphabetised Glossary containing definitions for all capitalised terms used in this Policy is included at the end of this Policy.

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For certain Interactions, You must refer to more than one Section of this Policy. The relevant Sections are cross-referenced as appropriate.

Other Global Policies may also apply to Interactions. For example, the *Global Data Privacy Policy* applies to Interactions where there is a need to protect the confidentiality of Patient information.

Global Standards may also apply to Interactions. The Global Standards give additional information about what is required to ensure compliance for particular Interactions. The requirements of this Policy and of the supporting Global Standards must be considered as a whole to evaluate and support compliant Interactions. Global Standards are cross-referenced in each relevant section of this Policy.

1.2 This Policy expands on the Company's *Code of Conduct,* and aligns with (and in some cases exceeds) the requirements of applicable law and adopted industry codes.

You must follow the spirit of this Policy and not just its letter. The absence of a specific requirement relating to a particular Interaction does not mean that the Interaction is necessarily permitted; You must avoid any Interaction that breaches the Company's *Code of Conduct* or supporting Global Policies, Global Standards or Relevant Procedures.

1.3 Employees must not attempt to avoid the requirements of this Policy by requesting, allowing or enabling Third Parties (including relatives, friends or other associates) to be involved in the Interactions prohibited by this Policy on the Employee's (or the Company's) behalf.

In some cases, local law, adopted industry codes particular to a jurisdiction, or rules particular to a Business Unit (e.g., Senior Executive Team ("SET") function), may apply to Interactions, and may be more restrictive than this Policy. Where that is the case, You must follow the more restrictive rules set out in Relevant Procedures. For example, local marketing organisations must establish Relevant Procedures with respect to Interactions with Public Officials, where local law is more restrictive than this Policy.

To the extent appropriate, Business Units must establish Relevant Procedures to assure compliance with the requirements of this Policy and supporting Global Standards, including requirements for sufficient monitoring and/or audit. Employees must use reasonable judgement to create business records sufficient to demonstrate compliance with the requirements of this Policy, supporting Global Standards and these Relevant Procedures (e.g., business records of required approvals and required rationales for approvals).

For purposes of this Policy, required approvals must be obtained in advance of any Interaction.

Where the scope or interpretation of a particular provision of this Policy, supporting Global Standards or Relevant Procedures is unclear, You should seek guidance from Your line manager or Your relevant Legal and/or Compliance partner.

2. ANTI-BRIBERY & ANTI-CORRUPTION

2.1 AstraZeneca has zero tolerance for Bribery or corruption (i.e., improper influence).

The Company will support Employees and Third Parties who refuse requests to Give or Receive Bribes on the Company's behalf. Employees and Third Parties will not be subject to retaliation or other adverse consequences for such refusal, even if the Company loses business as a result.

See Section 7 for prohibitions and other requirements regarding Facilitation Payments, including payments Given under duress.

2.2 You may Give or Receive something of value in compliance with the requirements and limits of this Policy, supporting Global Standards and Relevant Procedures.

For purposes of this Policy, supporting Global Standards and Relevant Procedures, "something of value" means any financial or non-financial benefit of any kind, including, but not limited to:

a) the Giving and Receiving of Items of Value and Hospitality (See Section 3 and the *Global Standard on Items of Value and Hospitality*);

b) prices, discounts and rebates for Company Products Given to Third Parties (See Section 4);

c) Contributions Given to Third Parties (See Section 5 and the *Global Standard on Contributions*);

d) Political Support Given to Public Officials or Political Organisations and participation in Political Activities (See Section 6);

e) payments Given to Public Officials and Public Sector Organisations (See Section 7);

f) appointments, paid and volunteer work outside of the Company or other interests associated with actual, apparent or potential Conflicts of Interest (See Section 8);

g) the venue, conduct or other arrangements made for Meetings, as well as the selection and/or support of External Stakeholders to attend Meetings or independent congresses, including professional education credits and capability-building sessions (See Section 9 and the *Global Standard on Meetings*);

h) the engagement of Third Parties to provide Services, including compensation and expense reimbursement (See Section 10 and the *Global Standard on Engaging Third Parties*); and

i) support for External Stakeholders for Non-Interventional Studies and Investigator Sponsored Studies (See Sections 13 and 14).

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2.3 You must not Give or Receive something of value that is intended or could be seen as improper influence.

If you are in doubt about any Interaction, you must consult with your line manager or your relevant Legal and/or Compliance partner for appropriate guidance.

2.4 All monetary payments by the Company to Third Parties that are permitted by this Policy must be made via an approved Company financial payment system by bank transfer, cheque or company credit card, must not take the form of cash or cash equivalent (e.g., debit cards, gift cards, gift certificates), and must be accurately and appropriately recorded in the Company's books and records.

All such payments may also be made via a specifically authorised Third Party (unless otherwise noted in this Policy or supporting Global Standards), when genuine business needs require, and Relevant Procedures (with adequate controls) support such an arrangement. In such cases, the Third Party must be contractually obligated to accurately document, track and report to the Company the amounts paid on its behalf, as required by the Relevant Procedures.

This Section 2.4 prohibits cash and cash equivalent payments by Employees (or Third Parties acting on the Company's behalf), except as specifically permitted by Relevant Procedures established or approved by the Global Finance function. Also, see paragraph 1.18 of the *Global Standard on Items of Value and Hospitality* for requirements regarding exceptional Cultural Courtesy Gifts in the form of cash or cash equivalent.

2.5 You must not Give a Bribe.

Give means to directly or indirectly offer, promise or give, or to authorise such actions.

You must not Give something of value to any Third Party or any fellow Employee that is intended or could be seen to:

a) influence or reward an official action or decision (e.g., by a Public Official);

b) enable or induce a Third Party or fellow Employee to perform their function improperly, or make any decision or take any action favourable to the interests of the Company (or You) on an improper basis, or reward them for doing so;

c) provide incentive or reward to a Third Party for past, present or future willingness to prescribe, administer, recommend, purchase, pay for, reimburse, authorise, approve, supply or use any Company Product or service; or

d) obtain or retain improper business, or secure any improper professional or personal advantage.

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2.6 You must not Receive a Bribe.

Receive means to directly or indirectly solicit, agree to receive or accept, or to authorise such actions. You must not Receive something of value from any Third Party or any fellow Employee that is intended or could be seen to:

a) compromise Your independence or judgement;

b) enable or induce You to perform Your function improperly, or make any decision or take any action favourable to the interests of the Third Party (or fellow Employee) on an improper basis, or reward You for doing so; or

c) obtain or retain improper business, or secure any improper professional or personal advantage.

3. ITEMS OF VALUE & HOSPITALITY

3.1 You must not Give or Receive Items of Value or Hospitality that are intended or could be seen as improper influence.

To the extent appropriate, Business Units must establish Relevant Procedures on actual or perceived value and frequency when Giving and Receiving Items of Value and Hospitality. These Relevant Procedures must include specific limits on value (modest) and frequency (occasional) and definitions for “modest” and “occasional,” to guide Employees on appropriate value and frequency levels that would not create actual or perceived improper influence, taking into account local custom and practice (See paragraph 2.1 of the *Global Standard on Meetings*).

To the extent appropriate, Business Units must establish Relevant Procedures to enable the Company to satisfy transparency obligations, with respect to the Giving of Items of Value and Hospitality to External Stakeholders.

Items of Value and Hospitality that exceed Company limits, either separately or in total, to or from the same individual or organisation, are prohibited.

Any Giving or Receiving of Items of Value or Hospitality that is based upon a genuine personal relationship independent of the Company and that is personally funded by the individuals involved (without Company reimbursement) is permissible and is not restricted by this Policy**,** if it is not intended and could not be seen as improper influence.

3.2 See Section 2 of this Policy and the *Global Standard on Items of Value and Hospitality* for further requirements on Items of Value and Hospitality.

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4. PRICING, DISCOUNTS & REBATES

4.1 To the extent appropriate, Business Units must have an approved pricing model in place, based on objective criteria, to govern the pricing, rebates and discounts (and other commercial advantages or favourable terms) that can be Given to Third Parties.

The pricing model must be reviewed on a regular basis by the head of the relevant Business Unit or designee to ensure appropriateness and transparency.

These Business Units must document the purpose of any prices, rebates or discounts (or other commercial advantages or favourable terms) Given to Third Parties that fall outside the approved pricing model, and this documented purpose must be approved by the head of the relevant Business Unit or designee to ensure appropriateness and transparency.

4.2 See Section 2 of this Policy for further requirements on prices, discounts and rebates.

5. CONTRIBUTIONS (DONATIONS, SPONSORSHIPS & PARTNERSHIPS)

5.1 The Company is committed to making a positive impact on Our local communities and supporting the work of others in the healthcare and scientific arenas.

Contributions may be classified as Donations, Sponsorships or Partnerships, and may take the form of financial or non-financial support (e.g., funds or in-kind assistance, such as resources, facilities or employee time).

Contributions may generally only be Given for legitimate scientific, educational and/or charitable purposes to support the following: health or healthcare, medical or scientific education, advances in medical or scientific research and disaster relief. Contributions may also be Given for other purposes on an exceptional basis, only with senior management approval, as set out in Relevant Procedures.

For the avoidance of doubt, this Section does not prohibit individual Employees from supporting charities and other organisations in a purely personal capacity and without any involvement of the Company, if the support meets the requirements of Section 8 of this Policy. This Section 5 also does not prohibit Employees from organising charitable efforts on the Company premises (such as a local food drive or book drive), with line manager approval, where Employees use only their personal funds and resources to participate, if the support meets the requirements of Section 8 of this Policy.

Generally, Contributions to support a Meeting or other event must only be Given where the venue and location of the supported event are appropriate and conducive to the intended purpose, and where any Meals or other Hospitality provided by the Company or by the recipient of the Contribution are modest and incidental to the purpose of the event. See the *Global Standard on Contributions*, the *Global Standard on Items of Value and Hospitality* and the *Global Standard on Meetings* for specific requirements and exceptions.

Certain charitable Donations, Sponsorships and Partnerships that meet the relevant criteria described in the *Global Standard on Contributions* and the *Global Procedure and Guidance Community Investment* specifically qualify as Community Investment Contributions.

5.2 Contributions may only be given to reputable, recognised and independent institutions or other legitimate, established organisations, and only for legitimate purposes.

The relevant Business Unit managing the Contribution must conduct appropriate due diligence on the proposed recipient of any Contribution to establish that the proposed recipient satisfies the requirements of this Section 5.2 and to establish that Contribution will be well used. In addition, the relevant Business Unit may agree upfront with the recipient organisation to conduct appropriate post-funding review (e.g., review of a summary of the completed projects or other results of the

In addition to the requirements of Section 2, a Contribution must not be Given for any other improper purpose or use, including, but not limited to, the following:

a) to help offset an External Stakeholder's cost of purchasing or reimbursing Company Products or to influence any other decisions about listing, purchasing or reimbursing of Company Products;

b) to organisations or activities that are known to discriminate on any unlawful basis;

c) to support programming or editorial content containing gratuitous violence or sexually explicit material or any activity that does not reflect the values and/or mission of the Company, or could cause embarrassment to the Company; or d) to support any activities prohibited by Relevant Procedures.

Contributions that might be considered as excessive or inappropriate in scale and/or affiliation are not permitted.

Contributions must not be Given to avoid the restrictions on Giving Items of Value and Hospitality to Third Parties (See Section 3 and the *Global Standard on Items of Value and Hospitality*).

5.3 Contributions must not be Given to any organisation for the personal benefit of any individual or Healthcare Professional ("HCP") practice (i.e., a group of HCPs sharing premises or other resources) selected by the Company, or to disguise or conceal any such personal benefit (except as permitted in paragraph 4.5 of the *Global Standard on Contributions* regarding Fellowships and Preceptorships for scientists to support research activities).

Contributions must not be Given by the Company directly to an individual or HCP practice.

For the avoidance of doubt, direct Company support for individual External Stakeholders to attend Meetings or independent congresses is not considered to be a Contribution for purposes of this Policy and is permissible only in limited circumstances (See section 3 of the *Global Standard on Meetings*).

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For the avoidance of doubt, awards to individuals are not considered Contributions. See the *Global Standard on Items of Value and Hospitality* for requirements regarding awards and awards ceremonies.

An individual who formally represents an organisation may request a Contribution from the Company on behalf of the organisation, and such request must be considered and processed as required by Relevant Procedures. Contributions must not be Given to an organisation at the request of any other individual (e.g., to a Public Official's preferred charity), except for Sympathy Gifts Given to a designated non-profit organisation as a memorial in the event of a death, or Contributions Given at the request of an Employee as part of a Company matching fund programme.

Contributions must not be Given to financially benefit HCPs or HCP practices by replacing any assets or funding any activities that they would be expected or required to provide themselves to fulfil obligations they have under local law, contract or customary business practice. For example, Contributions must not be Given to improve business efficiencies or administrative processes of an HCP or HCP practice, such as support for billing or taxes. For the avoidance of doubt, Contributions to support HCP education are permissible, in the interest of improving Patient care and/or Patient health.

5.4 See Section 2 of this Policy and the *Global Standard on Contributions* for further requirements on Contributions.

Contributions must not be Given by Third Parties on behalf of the Company, except for Company Product Donations (See the *Global Procedure and Guidance Community Investment* and the *Global Guidance for Product Donations*).

For the avoidance of doubt, Contributions do not include Political Support or participation in Political

6. POLITICAL SUPPORT & POLITICAL ACTIVITIES

6.1 Employees must not Give Political Support on behalf of the Company unless specifically authorised to do so by the Government Affairs function or the Reviewer.

Third Parties must not Give Political Support on behalf of the Company under any circumstance. The Company will not reimburse in any way or form any Third Party or non-authorised Employee for Giving Political Support.

Political Support may only be Given where it is expressly permitted by local law and where acceptable as part of local custom and practice.

All Political Support must be Given directly to the recipient organisation or individual. The name of the organisation or individual, purpose, nature and value of the Political Support and the date of the Political Support must be properly documented and recorded in the Company's books and records, to enable public disclosure.

The Government Affairs function will establish or approve Applicable Internal Review Procedures for the Giving of Political Support.

6.2 Employees and Third Parties must not participate in Political Activities on behalf of the Company unless specifically authorised to do so by the Government Affairs function or the Reviewer.

The Government Affairs function will establish or approve Applicable Internal Review Procedures for participation in Political Activities.

6.3 The Company recognises the rights of Employees to use their own funds, time and other personal resources to Give Political Support or to participate in Political Activities.

You must ensure that you do not act or appear to act as a representative of the Company when participating in Political Activities or Giving Political Support in a personal capacity. You must make it clear that your views and actions are Your own, and that any Political Support You provide is Given on a personal basis, using Your own funds, time or other personal resources.

6.4 See Section 2 of this Policy for further requirements on Political Support and Political Activities.

7. PAYMENTS TO PUBLIC OFFICIALS & PUBLIC SECTOR ORGANISATIONS

7.1 The Company does not permit Employees or Third Parties providing Services to Give Facilitation Payments, either directly or indirectly, to Public Officials (including HCPs and other individuals employed by Public Sector Organisations), regardless of whether such payments are nominal in amount.

Employees and Third Parties must not attempt to conceal or disguise Facilitation Payments to avoid the requirements of this Section.

The nature of the Company’s business involves legitimate Interactions with a range of Public Officials. Examples include Public Officials responsible for issuing Company Product licences, making Company Product listing decisions, determining Company Product pricing and payment, providing permits and regulatory Authorisations and conducting facility inspections.

You may Give payments to individual Public Officials where they are engaged to provide legitimate Services (See Section 10). You must not Give any other payments to individual Public Officials unless such payments are required or otherwise expressly permitted by local law and not otherwise prohibited by this Policy.

You may Give legitimate and lawful payments to Public Sector Organisations with respect to taxes, permits, licences, inspections and other fees required or otherwise expressly permitted by local law and not otherwise prohibited by this Policy. Official government receipts must be obtained to support all such payments.

7.2 The Company recognises that, in exceptional circumstances, payments may be demanded under duress from Employees or Third Parties providing Services. It is permissible for Employees and Third Parties to Give payments demanded under duress, where there is reasonable fear for personal safety.

Duress describes situations of actual or threatened violence or imprisonment to force a person to act against their will. The Company is committed to ensuring the safety of its Employees and Third Parties and does not expect them to compromise their safety in such situations.

Employees and Third Parties must promptly report in writing to their line manager all incidents where:

a) Facilitation Payments are requested but not paid; or

b) payments are demanded under duress, whether paid or not.

The line manager must then promptly inform the relevant Legal partner of such incidents in writing and ensure that any payments actually made are properly documented and recorded in the Company's books and records. The line manager must also consult with the relevant Legal partner regarding the reporting of such incidents to the relevant authorities and the steps to be taken to prevent recurrence.

7.3 See Section 2 of this Policy for further requirements on payments to Public Officials and Public Sector Organisations.

8. AVOIDING CONFLICTS OF INTEREST

8.1 You must ensure that Your interests, activities and associations outside of the Company do not result in actual, apparent or potential Conflicts of Interest with Your professional duties and decisions as an Employee, by directly or indirectly compromising Your independence or professional judgement, or creating an appearance of doing so.

You must not allow, or appear to allow, a personal relationship to influence Your decision-making or judgement. You must ensure that the Company's interests are paramount when business opportunities are assessed and commercial decisions are taken.

You may make personal financial investments, pursue other business interests and maintain social relationships with people You meet through Your Employment, if all of the relevant requirements of this Section of the Policy are met. You must ensure that these Interactions do not result in actual, apparent or potential Conflicts of Interest with the Company's business activities.

You must not use Company resources or your position as an Employee for Your own personal benefit or for the benefit of Your relatives, friends or other associates.

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8.2 You must inform Your line manager in writing of any actual, apparent or potential Conflicts of Interest at the time they become known. Engagement Owners must also inform their line managers in writing of any actual, apparent or potential Conflicts of Interest of a Third Party providing Services, at the time they become known.

Line managers must provide written direction on how to resolve or avoid the Conflict of Interest after obtaining any necessary advice from the relevant Legal and/or Compliance partner.

If You, a relative or close friend has a financial or management interest in a Third Party (other than a nominal shareholding interest through a publicly-available investment), You must disclose the situation as a potential Conflict of Interest to Your line manager. You must not participate in any purchasing or other Company decisions related to that Third Party.

8.3 You must not do any volunteer or paid work outside of the Company related to Your Company work responsibilities or work product (e.g., speaking engagement, authoring or publishing) unless You obtain written approval from Your line manager, on the basis that such work is unlikely to create an actual, apparent or potential Conflict of Interest and on the basis that any payment is not intended and could not be seen as improper influence.

For all such work, You may Receive necessary and modest travel, accommodation, Meals and other directly related, incidental expenses, with written line manager approval, on the basis that such expenses are not intended and could not be seen as improper influence.

8.4 You must not accept any appointment to the Board of Directors of an external organisation in the healthcare or scientific arena, unless You obtain written approval from Your line manager.

Approval should not normally be provided for directorships of Third Parties who are conducting, or may conduct, business directly within Your scope of responsibility or where You will gain a financial benefit that could be open to question or misinterpretation if publicly disclosed.

8.5 You must not use non-public Company information for personal gain.

You must not pass such information to anyone else (either inside or outside the Company), who does not have a legitimate need for the information.

8.6 See Section 2 of this Policy for further requirements on Conflicts of Interest.

9. MEETINGS

9.1 Organising or supporting Meetings with External Stakeholders is part of Our business. Where doing so, You must follow the requirements listed in the Global Standard on Meetings.

The location, venue, conduct and other arrangements made for Meetings must be modest, conducive and appropriate to the purpose of the Meeting.

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9.2 Meetings must always have a scientific, medical education and/or other legitimate business purpose, which must be clearly stated.

The Company may Give a Contribution (See Section 5) to a Meeting organiser to support the conduct of a Meeting (e.g., a Sponsorship). Any such Contribution must meet the relevant requirements of both the *Global Standard on Contributions* and the *Global Standard on Meetings*, with respect to the substance of the Meeting as well as the conduct and arrangements made for the Meeting.

9.3 See Section 2 of the Policy and the *Global Standard on Meetings* for further requirements on Meetings.

The *Global Standard on Meetings* also includes specific requirements on Company support for External Stakeholders to attend independent congresses.

10. ENGAGING THIRD PARTIES & ENSURING COMPLIANCE

10.1 The Company is committed to engaging only those Third Parties who embrace standards of ethical behavior that are consistent with Our own.

Engagement Owners are accountable for ensuring that the Third Party's reputation and conduct are consistent with the Company's ethical standards (See Section 10.5).

For the avoidance of doubt, engagements do not include informal, routine business Interactions between Employees and Third Parties, where no Services are provided and no payment is Given (e.g., informal discussions at professional Meetings or independent congresses for scientific exchange, or routine phone calls in the normal course of business).

10.2 Engagement Owners must engage a Third Party only where there is a genuine business need for Third Party Services and must only engage the necessary and appropriate Third Parties to provide those Services.

Engagement Owners must ensure that the selected Third Party has the relevant qualifications, expertise, reputation, knowledge, experience and ability to fulfill the genuine business need, and is the most appropriate choice to provide the Services.

External Stakeholders may be engaged by the Company (either directly or through a specifically authorised Third Party on the Company's behalf) to provide Services. Such Services include, but are not limited to: providing input and information as an Advisor or consultant, speaking at Meetings (e.g., a Promotional Speaker), acting as a clinical investigator or a study site, or educating or otherwise presenting to Representatives at Representative training or business cycle sessions. Patients and Other Third Parties may also be engaged by the Company to provide Services.

Each engagement with an External Stakeholder or Patient for Services must be documented in a signed contract. If the External Stakeholder or Patient is not accepting compensation, or payment

or reimbursement of expenses, the requirement for a signed contract may be waived with documented line manager approval.

Each engagement with Other Third Parties for Services must be documented in the format required for the particular Services to be provided, such as a contract, Terms & Conditions, a Purchase Order or other required documentation of offer and acceptance of Services.

Third Parties must not provide any Service on behalf of the Company, in connection with the execution of an engagement or otherwise, unless the Service has been specifically authorised in the signed contract (or other required documentation of the engagement) between the Company and the Third Party, or has otherwise received appropriate documented approval.

You must not Give any Payments for Voluntary or Incidental Activities to any Third Party.

10.3 Our Interactions and engagements with External Stakeholders and Patients must at all times be professional exchanges, designed to enhance the practice of medicine, to benefit Patients, or to fulfill a genuine business need.

In no circumstances may the engagement of an External Stakeholder or Patient be used as a means to gain access or to disguise Promotional Activities, or create an appearance of doing so.

10.4 To the extent appropriate, Business Units must establish adequate Relevant Procedures to mitigate the risk of actual or apparent improper influence over individual External Stakeholders engaged to provide Services, and for monitoring compliance.

To the extent appropriate, Business Units must establish Relevant Procedures that include Fair Market Value guidelines, as well as limits on aggregate compensation provided to individual External Stakeholders and limits on frequency of engagement of individual External Stakeholders. The scope of such guidelines and limits ultimately established will vary, based upon locality and/or function. In developing Fair Market Value guidelines, these Business Units must consider local established compensation levels, varying levels of expertise and/or prominence of Third Parties, varying types and durations of Services to be provided, and the spirit and principles of this Policy.

Third Parties must be paid compensation consistent with and no greater than Fair Market Value, taking into account individual qualifications, experience, ability and reputation, and only for the Services actually provided, consistent with the terms of the engagement.

To the extent appropriate, Business Units must establish Relevant Procedures to enable the Company to satisfy transparency obligations, with respect to payments made to External Stakeholders.

10.5 Prior to the selection and engagement of a Third Party, Engagement Owners must conduct appropriate and proportionate risk assessments, as well as associated, due diligence procedures (if necessary), according to Relevant Procedures. Engagement Owners must take these steps to ensure that the Third Party's reputation and conduct relating to the execution of the engagement are consistent with the Company's ethical standards, with respect to all relevant areas of risk.

To the extent appropriate, Business Units must establish Relevant Procedures to guide Engagement Owners on how to assess, develop, communicate, implement and enforce required compliance expectations for Third Parties. Required compliance expectations will vary, based upon the nature of the Third Party, the Services to be provided and the nature of the associated risks. Based upon the risk assessment and outcomes for a particular Third Party, Engagement Owners may be required to implement one or more of the following actions with respect to that Third Party:

a) improvement plans or action plans;

b) monitoring or auditing requirements;

c) contractual obligations, including written assurances or commitments by the Third Party;

d) provision of Global Policies, Global Standards, Relevant Procedures or other reference materials, and/or associated training;

e) prior review of the engagement or aspects of the engagement or Services from the relevant Legal and/or Compliance partner; and/or

f) other actions to mitigate identified areas of risk, such as contractual risk mitigation clauses.

At a minimum, Engagement Owners must not engage a Third Party where it is known, or where there is a reason to believe, that the Third Party has Given or Received Bribes, unless the Engagement Owner has documented his/her satisfaction with all of the following, in consultation with the relevant Legal and/or Compliance partner:

a) the actions and improvements undertaken by the Third Party to remediate the concerns and/or behaviour;

b) the current level of compliance by the Third Party; and

c) evidence of the Third Party's ability to provide strong governance and monitoring and to prevent future occurrences of such concerns and/or behaviour.

Engagement Owners, in consultation with an appropriately senior level of management, must periodically reassess existing Third Party relationships, following the required timeframes outlined in the Relevant Procedures, and taking into account any unanticipated changes in the conduct, reputation or risks related to the particular Third Party.

10.6 See Section 2 of this Policy for further requirements on Engaging Third Parties. Engagement Owners must also refer to the *Global Standard on Engaging Third Parties* for further requirements, prior to entering into any engagement with a Third Party.

11. PROMOTIONAL & NON-PROMOTIONAL ACTIVITIES & MATERIALS

11.1 A key part of Our business is to provide information about Company Products and, where and when appropriate, to Promote their use. Promotional and Non-Promotional Activities and Materials must always be accurate, fair and balanced and not misleading in their content.

The Company has a duty to support the safe and effective use of Company Products. While the Company cannot provide medical advice to External Stakeholders or Patients, the Company may engage in Promotional and Non-Promotional Activities where this is appropriate and permitted by local law. For example, Promotional and Non-Promotional Activities directed to Patients (i.e., "direct to consumer" activities) may only be undertaken where this is permitted by local law.

Our activities must never undermine the relationship between HCPs and their Patients. All Promotional and Non-Promotional Activities and Materials directed to HCPs or Patients must therefore support HCPPatient Interactions and must allow the therapeutic value of Company Products to be assessed by HCPs in the interest of Patient care.

Promotional and Non-Promotional Materials about Company Products directed to Patients must be understandable, taking into account varying levels of education between and within populations. These Materials must be educational, scientific and balanced, and should encourage the Patient to seek further information from the appropriate HCP.

The Company may display Promotional or Non-Promotional exhibits, either in conjunction with a Meeting or as a stand-alone activity, according to the requirements included in Relevant Procedures. See the *Global Standard on Meetings* for further requirements on exhibits (with or without a Meeting).

11.2 The Company must only Promote Company Products once the time is right to do so (which will never be before the Company Product or Use has received the necessary Authorisation), and only consistent with the approved labeling.

Promotional Activities and Promotional Materials must meet all of the following requirements:

a) They must provide a fair balance between a Company Product's benefits and its risks or limitations. They must not exaggerate the benefits or downplay the risks or limitations;

b) They must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way, and must not involve false or unapproved statements about other companies' products. Company Products must only be Promoted on their own proven merits; and

c) They must be capable of substantiation by reference to the approved labeling or scientific evidence consistent with the approved labeling, and must not involve discussions of Unauthorised Company Products or Uses.

Representatives and other Employees in customer-facing roles (e.g., public relations, telemarketing, Marketing, Medical) must be trained as appropriate to their role and must do all of the following in an accurate, responsible manner:

a) They must possess sufficient Company Product and disease area knowledge to present information to External Stakeholders or Patients, as appropriate to their role; and

b) They must be able to recognise inquiries regarding Unauthorised Company Products or Uses and refer these inquiries to Scientifically Trained Personnel.

All training and educational materials must be approved through the Applicable Internal Review Procedures.

Representatives and other Employees in customer-facing roles must have available a copy of the current, approved labeling for each Company Product or Use discussion they initiate with External Stakeholders.

Any revisions to the approved labeling must be communicated to Representatives and other relevant customer-facing Employees as soon as reasonably possible.

Promotional Activities that are directed to External Stakeholders must be confined to those individuals who are recognised practitioners in the area of medicine concerning Authorised Company Products or Uses.

Promotional Activities and Promotional Materials must not be directed to External Stakeholders who have requested that they not be sent such information.

11.3 Non-Promotional Activities and Materials (including those regarding disease awareness programs) must not be used to Promote Company Products. Non-Promotional Activities and Materials must be presented in an objective, balanced manner, and must be scientific in tone, language, appearance and intent.

Where local law allows the Company to respond to Company Product-related questions from Patients, any such response may only be made by Scientifically Trained Personnel or other specifically authorised Employee or Third Party, according to Relevant Procedures. Patients communicating with the Company must not be given medical advice, but must instead be referred to their HCP.

Specifically authorised Employees are permitted to proactively issue press releases or other Non-Promotional Materials, such as those relating to financial or investor information.

Scientifically Trained Personnel are permitted to proactively present scientific data or findings regarding Authorised or Unauthorised Company Products or Uses with a view to generating further scientific insight, supporting the medical community in learning about scientific/medical progress or sharing information on current medical practice, such as at scientific congresses or similar events.

All inquiries concerning Unauthorised Company Products or Uses (whether from External Stakeholders or Patients) must be referred to Scientifically Trained Personnel. All responses to such inquiries, either oral or written, must then come directly and only from such Scientifically Trained Personnel, and must meet all of the following requirements:

a) Information must only be provided in response to unsolicited inquiries;

b) Information must be accompanied by the approved labeling, as applicable;

c) All responses must be limited to the scope of the inquiry and must provide data which are appropriate to the source of the inquiry; and

d) All responses must contain (as relevant) a statement that the information requested involves an Unauthorised Company Product or Use and that the Company does not recommend Unauthorised Uses of the Company Product.

11.4 Promotional Materials and Non-Promotional Materials must be approved through the Applicable Internal Review Procedures. Any modification to approved Promotional or Non-Promotional Materials must also be approved through the Applicable Internal Review Procedures.

You must not create, use or provide “home-made” or other unapproved Promotional or Non-Promotional Materials on any topic. You must not alter any approved Promotional or Non-Promotional Materials in any way, unless such creation or alteration is for the express purpose of submitting these Materials for review and approval.

Promotional and Non-Promotional Materials must be assigned an expiration date upon approval, must be monitored for expiration date and must not be used after the expiration date specified in the original approval, unless they are formally re-approved through the Applicable Internal Review Procedures.

Promotional and Non-Promotional Materials must be accompanied by the approved labeling where applicable, as required by Relevant Procedures.

12. PRE-AUTHORISATION ACTIVITIES & MATERIALS

12.1 It is permissible to engage in Pre-Authorisation Activities (i.e., Profiling, Market Access and Pre-Authorisation Training activities), and to use materials supporting such activities, to prepare for a successful commercial launch of a Company Product or Use. Pre-Authorisation Activities must not be used to disguise Pre-Authorisation Company Product Promotion, or create an appearance of doing so.

Materials used for Pre-Authorisation Activities must be approved through the Applicable Internal Review Procedures.

12.2 Relevant Employees (e.g., Employees in the Marketing, Medical or Sales functions) and specifically authorised Third Parties may Profile customers prior to Authorisation of a new Company Product or Use, to assist in segmentation and targeting activities.

Profiling Activities may only be conducted if all of the following requirements are met:

a) Employees engaging in Profiling must use materials (e.g., scripts) that have been approved through the Applicable Internal Review Procedures;

b) These materials must be structured to allow for a brief conversation to collect broad information about an External Stakeholder's involvement in a disease area, such as treatments and classes used (e.g., "What classes do you use to treat this disease state?"), as well as their needs and the needs of their Patients;

c) These materials must contain clear instructions on proper execution. These materials must contain a clear, prominent prohibition against engaging in Promotional Activities about the new Company Product or Use during a Profiling conversation;

d) These materials must not contain targeted questions that are specific or unique to a Company Product or Use;

e) If asked by the External Stakeholder about the purpose of the Employee's questions, Employees may objectively state that the Company has submitted a Company Product or Use for regulatory Authorisation. Employees must not proactively discuss the Company Product or Use in any further detail; and

f) In the event that the External Stakeholder asks for more details about the Company Product or Use during a Profiling discussion, Employees (other than those in the Medical function) may provide appropriate contact information for the External Stakeholder to submit his/her own request for such information (i.e., a "professional information request"), but such Employees must not directly respond to the request or submit the request on behalf of the External Stakeholder. Employees in the Medical function may directly respond to the request and may submit a professional information request on behalf of the External Stakeholder.

During, and in support of, internal Company segmentation and targeting activities, relevant Employees may share existing knowledge and review and share prescribing data and other Company-purchased or publicly available information.

For the avoidance of doubt, Profiling activities are also permitted after Authorisation of a new Company Product or Use.

12.3 Relevant Employees other than Representatives or their first line managers (e.g., Employees in the Market Access or Medical functions) and specifically authorised Third Parties may perform Market Access activities prior to Authorisation of a new Company Product or Use, by providing Company Product or relevant disease area information to Healthcare Organisations ("HCOs") (i.e., payers) or Public Officials to support regulatory Authorisation, pricing or reimbursement discussions.

For the avoidance of doubt, Market Access activities are also permitted after Authorisation of a new Company Product or Use.

12.4 Pre-Authorisation Training on Unauthorised Company Products or Uses may be initiated as necessary to allow for sufficient time to study and understand the new information presented regarding the Company Product or Use, disease area, disease management, External Stakeholder and Patient needs and/or the current market, including the current state of medical practice, competitors and existing therapies, and treatment protocols and Guidelines.

In making the determination of the timing and sequencing of Pre-Authorisation Training for a particular new Company Product or Use (as a guideline, no longer than 60 days before the expected Authorisation date), the Reviewer must seek input from Employees in the Medical, Training, Commercial, Compliance and/or Legal functions ("contributing functions"), as applicable, and must take into account all of the following considerations:

a) whether the training will involve a new or familiar disease area;

b) whether the training will involve an Unauthorised Company Product or an Unauthorised Use of an Authorised Company Product;

c) the likelihood of receiving significant changes and comments to the proposed labeling submitted to the regulatory agency responsible for Authorisation;

d) the risks of pre-Authorisation Promotion arising from providing training on Unauthorised Company Products or Uses and/or Promotional messages; and

e) other factors deemed relevant to the particular proposed training by the Reviewer and/or contributing functions, who are evaluating the training need and the associated risks.

All Pre-Authorisation Training materials must be marked with a clear, prominent, appropriate disclaimer stating that the material is strictly for internal purposes only (e.g., "For Internal Use

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Only"). These materials may include information on Unauthorised Company Products or Uses or relevant disease areas, and may include relevant reprints. These materials, or the information they contain, must not be shown, discussed, or distributed outside the Company, except where an appropriate Third Party must also be trained (e.g., a contract sales force or sales force of a co-promotional partner).

After the relevant Authorisation has been obtained, information included in Pre-Authorisation Training materials that is appropriate for discussion with External Stakeholders or Patients may be included in

Promotional and/or Non-Promotional Materials specifically designed and approved for those purposes.

13. NON-INTERVENTIONAL STUDIES

13.1 Non-Interventional Studies ("NISs") must address a scientifically and medically valid question to which the Company needs the answer.

These may include: the effectiveness and/or safety of a Company Product, medical practice and drug utilisation characterisation, disease epidemiology and clinical epidemiology, burden of disease (e.g., costs and quality of life) or other Patient-reported outcomes, and compliance/adherence to a therapeutic regimen.

13.2 The Company must not be involved in the decision to place a particular Patient on a specific Company Product. That decision is made solely by the Patient's HCP.

An NIS must not be used to induce the use or prescription of a Company Product or to train HCPs on the use of a particular therapy.

Patients must not be given a Company Product or switched to a Company Product for the purpose of taking part in the study.

13.3 NISs must be observational in nature and the collected data must undergo a formal analysis by the Company or by a Third Party on the Company's behalf.

Additional diagnostic or monitoring procedures must not be applied to the Patients, and epidemiological methods must be used for the analysis of collected data.

13.4 See Section 2 of this Policy for further requirements on NISs. Employees must also refer to the Relevant Procedures (i.e., International Procedures) for further requirements.

All NISs must be registered and their results posted according to the requirements of the Relevant Procedures.

The decision to conduct an NIS and the selection, engagement and payment of NIS investigators must meet all of the relevant requirements of Section 10 of this Policy and the *Global Standard on Engaging Third Parties.*

Support for NISs may be Given by specifically authorised Third Parties on behalf of the Company according to the Relevant Procedures.

14. INVESTIGATOR SPONSORED STUDIES

14.1 The Company recognises the importance of Investigator Sponsored Studies ("ISSs") in expanding scientific knowledge related to potential Uses of Company Products.

An ISS may be conducted with Authorised or Unauthorised Company Products or Uses.

All ISSs supported by the Company must be consistent with the research strategy for the relevant Company Product.

14.2 The Company may provide support for an ISS, but must not be considered to be the sponsor or to have any partial sponsorship role in the study in accordance with local law.

The decision to provide support for an ISS must be based on whether the study expands scientific knowledge related to potential Uses of Company Products and/or associated disease area(s) through a properly conducted independent clinical study that will result in the publication of meaningful new data.

14.3 See Section 2 of this Policy for further requirements on ISSs. Employees must also refer to the Relevant Procedures (i.e., International Procedures) for further requirements.

A contract approved through the Applicable Internal Review Procedures must be negotiated and signed by authorised representatives of the Company and the sponsor and, as applicable, the investigator, prior to study initiation.

The level of financial support that may be provided will vary among countries. It must always be consistent with Fair Market Value for the activities to be conducted as part of the clinical trial, and payments must be milestone-driven.

The Company must not provide Company Product Samples for use in ISSs.

Support for ISSs may be Given by specifically authorised Third Parties on behalf of the Company according to the Relevant Procedures.

GLOSSARY

Advisory Boards refers to internal Meetings organised by the Company where the Company engages External Stakeholders (i.e., "**Advisors**") to provide the Company with independent advice and input within their area of expertise.

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Advisors refers to the definition provided within the definition of Advisory Boards.

Applicable Internal Review Procedures refers to the review and approval requirements for Interactions and supporting materials, as set out in Relevant Procedures. These requirements include, but are not limited to, review and approval by Nominated Signatories, Scientifically Trained Personnel, the Legal Department, other specialist functions (e.g., Procurement) or line managers, as appropriate (i.e., "**Reviewers**"). Reviewers must take into account the substance, as well as the intended purpose and audience, when approving Interactions or supporting materials, and approval must be obtained in advance of any Interaction or use of supporting materials.

Authorisation or **Authorised** refers to approval of a Company Product or Use by the relevant local regulatory agency, to permit entry into the local market or to permit inclusion into the local approved labeling.

Bribe or **Bribery** refers to Giving or Receiving of something of value that is intended or could be seen as an inducement or reward for improper behaviour (i.e., behaviour that is dishonest or illegal or a breach of duty of impartiality, trust or good faith), to influence any official act or decision, or to obtain or retain business, favourable treatment or other advantage or benefit. Giving or Receiving of Bribes is a wellrecognised form of corruption (collectively referred to as "improper influence" through this Policy).

Business Unit refers to a distinct section of the Company, such as a consolidated legal entity, a local marketing organisation, a Senior Executive Team ("SET") function, a department or operating entity within a SET function, or, in some cases, a cross-functional unit comprising Employees with common responsibilities.

Community Investment Contributions refers to certain charitable Donations, Sponsorships or Partnerships Given by the Company to non-profit organisations that meet the relevant criteria described in the *Global Standard on Contributions* and the *Global Procedure and Guidance Community Investment*.

Company or **Our** refers to AstraZeneca PLC and its consolidated legal entities worldwide, including MedImmune.

Company Product refers to any pharmaceutical or biological product or medical device that is developed and/or marketed by the Company, including investigational products/devices and co-promoted products/devices. For purposes of this Policy, references to Company Products include both Authorised and Unauthorised Company Products, unless specifically noted.

Conflicts of Interest refers to situations where personal, financial or other interests, activities or associations outside of the Company may influence or compromise, or could be seen to influence or compromise, the professional duties and decisions of an Employee or Third Party providing Services.

Contributions refers to financial or non-financial support (e.g., funds or in-kind assistance, such as resources, facilities or Employee time) Given by the Company to a Third Party. Contributions may be classified as either Donations, Sponsorships or Partnerships.

Cultural Courtesy Gift refers to a personal Gift traditionally given to acknowledge a significant national, cultural or religious holiday or event.

Donations refers to the type of Contributions Given by the Company to a non-profit or Public Sector Organisation, that may or may not be for a designated pre-defined initiative.

Employee or **You(r)** refers to all Company full-time and part-time directors, officers, employees and temporary staff worldwide.

Engagement Owners refers to Employees responsible for engaging with and managing the Services provided by a Third Party.

External Stakeholders refers to the category of Third Parties who are external customers and other relevant stakeholders, including Healthcare Professionals ("HCPs") and Healthcare Organisations ("HCOs"), Scientifically Trained Personnel engaged by the Company to provide Services, Public Officials, Patient Groups and other relevant public and private organisations and groups.

A **Facilitation Payment** (or "grease" payment) is an unofficial payment or anything else of value Given to Public Officials (including HCPs and other individuals employed by Public Sector Organisations) to secure or speed up routine actions that the recipient has a duty to perform. Examples include additional payments required to issue permits or licences, speed passage through immigration controls and release goods held at port or in customs.

Fair Market Value refers to the amount that a service or item would be worth to a typical buyer who is under no duty to purchase and who receives no special advantage. Fair Market Value is determined by the home country of the relevant service provider (who receives payment for the service) or relevant buyer of the item.

Fellowships and **Preceptorships** refer to programmes conducted at host institutions and designed to provide basic training (i.e., training necessary to obtain a degree or licence) or advanced education to HCPs or scientists in a particular specialty, therapeutic area or field of research.

Gift refers to an Item of Value that is provided as a mark of appreciation, commemoration or friendship.

Give, Giving or **Given** means to directly or indirectly offer, promise or give, or to authorise such actions.

Global Policies refers to the mandatory documents that support the Company's *Code of Conduct* by setting out the compliance commitments of the Company and the key principles to be followed to meet those commitments.

Global Standards refers to the mandatory documents that support the Global Policies by describing the compliance rules to be followed to deliver the intent stated in the Global Policies or in the Company's *Code of Conduct*.

Guidelines refers to any of the following materials and may or may not relate to a specific disease state: practice guidelines, treatment guidelines, medication algorithms, disease definitions or Research & Development quality standards. Guidelines are not intended to refer to treatment guidelines or protocols developed by HCOs, where such development is essential to the business of the HCO (such as a formulary or benefit administrator), or those developed by HCP practices.

Healthcare Professionals ("HCPs") and **Healthcare Organisations ("HCOs")** refer to individuals or organisations, respectively, who may or do prescribe, administer, recommend, purchase, pay for, reimburse, authorise, approve or supply any Company Product or service, including any members of the medical, dental, pharmacy or nursing professions, and relevant associated administrative staff; and/or hospitals and other care organisations, health plans, health insurers, managed care organisations, pharmacies, formulary or benefit administrators and clinical research organisations, and relevant staff at such entities.

Hospitality refers to Meals, travel/accommodation, and other directly related, incidental expenses, as well as invitations or tickets to social or entertainment events. Entertainment events include sporting, theatre, music or recreational events.

Interactions refers to the business and personal interactions and activities described in this Policy.

Interacts refers to the conduct of an Interaction.

Investigator Sponsored Study (ISS) refers to a clinical study that is independently initiated, designed and conducted by an external investigator (who assumes both the sponsor and principal investigator role) or medical institution, collaborative research group or academic research organisation (which assumes the sponsor role and appoints principal investigator(s) for the study). For purposes of this Policy, sponsor/investigator is used as a generic term for both situations described above.

Item of Medical Utility refers to an Item of Value primarily designed to educate External Stakeholders or Patients or help External Stakeholders educate Patients about disease management in disease state areas relevant to Authorised Company Products or Uses.

Items of Value refers to Gifts, Items of Medical Utility, items used to assist in screening or diagnosis of Patients, items linked to the safe and effective administration of Company Products, logistical items, Samples (including Samples vouchers or coupons), awards and Patient Programmes.

Market Access refers to discussions with HCOs (i.e., payers) or Public Officials about regulatory Authorisation, pricing or reimbursement decisions.

Market Research refers to the systematic gathering and interpretation of quantitative or qualitative data on the market environment from External Stakeholders or Patients using statistical and analytical methods to gain insight and support decision-making. It does not include the gathering and interpretation of “real world evidence” or Company-purchased HCP-level data.

Meals refers to food and/or beverages.

Meeting refers to a planned gathering of External Stakeholders, which the Company organises or supports, either financially or non-financially. Non-financial support includes in-kind assistance, such as resources, facilities or Employee time. Meetings may be for an internal Employee audience, or for an external audience of External Stakeholders and may be held in-person or virtually.

Non-Interventional Study (NIS) refers, in general terms, to a study where the assignment of the Patient to a particular therapeutic strategy is not decided in advance by a study protocol but falls within the HCP’s current practice, and the prescription of the Company Product is clearly separated from the decision to include the Patient in the study.

Non-Promotional Activity refers to any activity that is not a Promotional Activity that is intended to provide scientific or educational information about Company Products, relevant disease areas or health and medicines generally. Non-Promotional Activities may be oral or written and may be conducted through any medium, including the Internet. Non-Promotional Activities may take a number of forms, including, but not limited to, leaflets provided with Company Products, point of sale information, information regarding disease awareness programmes, responses to queries from External Stakeholders or Patients, information provided to inform the development of Guidelines or other information contributing to scientific exchange.

Non-Promotional Materials refers to materials intended to be used during Non-Promotional Activities or to support Non-Promotional Activities.

Our or **Company** refers to AstraZeneca PLC and its consolidated legal entities worldwide, including MedImmune.

Other Third Parties refers to the category of Third Parties who are not External Stakeholders or Patients, including, but not limited to, the media, suppliers, distributors, agents and joint venture, co-promotion, research and licensing partners.

Partnerships refers to the type of Contributions Given by the Company in collaboration with a non-profit, for-profit or Public Sector Organisation for a pre-defined initiative, involving substantive, active Company participation and resulting in the delivery of specific, measurable outcomes. For purposes of this Policy, Partnerships do not include research or commercial collaborations aimed at the development or marketing of Company Products or services for the Company’s benefit.

Patient Groups refers to non-profit organisations formally representing the needs of Patients, theirfamilies and other caregivers.

Patient Programmes refers to Items of Value, specifically vouchers, rebates, coupons, co-pay assistance cards, motivational information and other programmes and materials designed to increase access and affordability of Company Products or to enhance therapy compliance.

Patients refers to the category of Third Parties who are members of the general public and who use or may use Company Products.

Payments for Voluntary or Incidental Activities refers to any compensation or expense reimbursement Given to an individual or organisation as a "thank you" for voluntary activities or for activities that are not necessary to address a genuine business need. They do not include payments made to Third Parties for contracted Services that address a genuine business need.

Policy refers to this *AstraZeneca Global Policy on Ethical Interactions*.

Political Activities refers to attendance or participation in public policy or other political activities, including participation in political conventions or fundraising events for Political Organisations or individual Public Officials and their causes.

Political Organisations refers to political parties and their employees, Political Action Committees ("PACs") and other political organisations. Political Support is distinct from Company Contributions to Public Sector Organisations (See Section 5), as well as payments to Public Officials or Public Sector Organisations (See Sections 7 and 10).

Political Support refers to financial or non-financial support (e.g., funds or in-kind assistance, such as resources, facilities or Employee time) Given to Political Organisations or individual Public Officials and their causes.

Pre-Authorisation Activities refers to Profiling, Market Access and Pre-Authorisation Training activities undertaken by Employees in preparation for Authorisation of a new Company Product or Use.

Pre-Authorisation Training refers to Company-provided education to Representatives and/or their first line managers in preparation for Authorisation of a new Company Product or Use.

Preceptorships and **Fellowships** refer to programmes conducted at host institutions and designed to provide basic training (i.e., training necessary to obtain a degree or licence) or advanced education to HCPs or scientists in a particular specialty, therapeutic area or field of research.

Presentation refers to each segment of a Meeting, where a distinct speaker is used and/or distinct topic is discussed.

Presentation Materials refers to all materials intended to be shown and/or distributed to the speaker or audience before, during or after a Presentation, including but not limited to speaker briefing documents, written summaries of Presentation objectives, slides and reference documents.

Profiling (also known as “disease insight visits”) refers to discussions with External Stakeholders to gain an understanding of their involvement in a disease area, including therapeutic options, medical gaps, External Stakeholder needs or the needs of Patients. For the avoidance of doubt, Profiling is not considered Market Research.

Promote, **Promotion** or **Promotional** refers to the conduct of Promotional Activities.

Promotional Activity refers to any activity that is intended or could be seen to Promote the prescription, administration, recommendation, purchase, payment, reimbursement, authorisation, approval, supply or use of Company Products or services. Promotional Activities may be oral or written and may be conducted through any medium, including the Internet.

Promotional Materials refers to materials intended to be used during Promotional Activities or to support Promotional Activities.

Promotional Speaker Programmes refers to Promotional Meetings organised by the Company to Promote Authorised Company Products or Uses, where the Company engages External Stakeholders

(i.e., “**Promotional Speakers**”) to speak to other External Stakeholders on behalf of the Company about such topics.

Promotional Speakers refers to the definition provided within the definition of Promotional Speaker Programmes.

Public Official refers to an individual who:

- Holds a legislative, administrative or judicial position of any kind, whether appointed or elected, or is a candidate for such a position, or
- Exercises a public function for a country or territory of a country, or for any Public Sector Organisation of a country or territory, at the national, regional or local level,
- Acts as an official or agent of an international Public Sector Organisation, or
- Is any other employee (including HCPs) of a Public Sector Organisation.

Public Sector Organisation refers to an agency, enterprise, or other entity of a government that sets or administers public policy or exercises executive, political and/or sovereign power through customs, institutions and laws within a country or territory of a country, at the national, regional or local level. It also includes state-owned and state-controlled entities, such as a state-owned or state-controlled hospital, university, energy company, telecommunications company or other similar state-owned or statecontrolled enterprises.

Receive, Receiving or **Received** means to directly or indirectly solicit, agree to receive or accept, or to authorise such actions.

Relevant Procedures refers to the written local and/or functional policies, standards, procedures and guidelines that contain details, processes and controls for compliance with this Policy and the supporting Global Standards.

Representatives refers to Employees who are members of any Commercial channel who Promote Company Products directly to External Stakeholders. Representatives may be referred to as sales representatives, service team associates, inside sales agents, medical representatives or other titles, depending upon the relevant local marketing organisation. Representatives include any Third Parties fulfilling such responsibilities on the Company's behalf (i.e., a contract sales force). Representatives do not include other Employees, such as those performing marketing or market access activities.

Reviewers refers to the definition provided within the definition of Applicable Internal Review Procedures.

Sample refers to an Item of Value, specifically a unit of pharmaceutical Company Product that is not to be sold but is provided free of charge to an HCP to allow the HCP and appropriate Patients to determine tolerability and effectiveness of the Company Product.

Scientifically Trained Personnel refers to individuals employed or engaged by the Company who are highly-trained experts, who have relevant, specialised scientific and/or medical knowledge and whose responsibilities include the provision of scientific and/or medical information. This excludes anyone in the Sales, Marketing or other non-Medical Commercial functions, even if they have scientific or medical training or backgrounds.

Section refers to Sections 1 through 14 of this Policy, listed in the Table of Contents. Each Section covers a category of Interactions.

Services refers to the activities performed by a Third Party engaged by the Company. Services include activities performed on behalf of the Company, goods, services or information provided to the Company, or the activities performed in collaboration with the Company.

Sponsorships refers to the type of Contributions Given by the Company to a non-profit, for-profit or Public Sector Organisation for a pre-defined initiative, where the Company's name is associated with the initiative and/or the Company receives other substantial recognition for the Sponsorship.

Sympathy Gift refers to a personal Gift to express sympathy for bereavement or serious illness of the recipient or immediate family member.

Third Party(ies) refers to any person or organisation who is not the Company or an Employee, with whom Employees Interact. The various types of Third Parties are categorised as either External Stakeholders, Patients, or Other Third Parties. Where a Third Party fits into more than one category, the more restrictive rules apply.

Uses refers to the indications, dosing, populations and other uses of Company Products. For purposes of this Policy, references to Uses include both Authorised and Unauthorised Uses of Company Products, unless specifically noted.

Unauthorised refers to a Company Product or Use that has not yet received Authorisation from the relevant local regulatory agency. An Unauthorised Company Product may also be referred to

as “investigational.” An Unauthorised Use (i.e., an “off-label use”) is inconsistent with the local approved labeling for a Company Product.

Voluntary or Incidental Activities refers to any voluntary activities or activities that are not necessary to address a genuine business need.

You(r) or **Employee** refers to all Company full-time and part-time directors, officers, employees and temporary staff worldwide.

REFERENCES

Global Standard on Items of Value and Hospitality
http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global_Compliance/effective/Global%20Standard/LDMS_001_00145832.pdf

Global Standard on Contributions
http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global_Compliance/effective/Global%20Standard/LDMS_001_00145831.pdf

Global Procedure and Guidance Community Investment
http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global_Compliance/effective/Procedure/LDMS_001_00146359.pdf

Global Guidance for Product Donations
http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global_Compliance/Active/Guidance%20Materials/LDMS_001_00146361.pdf

Global Standard on Meetings
http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global_Compliance/effective/Global%20Standard/LDMS_001_00145768.pdf

Global Standard on Engaging Third Parties
http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global_Compliance/effective/Global%20Standard/LDMS_001_00145830.pdf

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Exhibit G

Initial Members of the JSC

AstraZeneca

Fouzia Laghrissi Thode, Vice President, Global Product Portfolio Strategy

Elisabeth Björk, Global Product Vice President, Global Medicines Development

Howard Hutchinson, Vice President for Product Licensing, Global Medicines Development

Peter Honig, VP Global Regulatory Affairs, Global Regulatory Affairs

David Snow, President, China & Hong Kong, Global Commercial

AstraZeneca Secretariat: Joseph McCullough

FibroGen

Frank Valone

Peony Yu

Al Lin

Michael Lowenstein

Chris Chung

FibroGen Secretariat: Kirara Tsuboi

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Schedule G (a)

Until the date when the JDC has been formed, the JSC delegates the following responsibilities to the Core Joint Project Team. Unless otherwise directed by the JSC, the Core JPT shall:

(i) provide regular reports to the JSC regarding the development of the Product, and discuss, prepare and submit to the JSC for approval annual and interim amendments to the Development Plan (and the Development Budget) for each Product;

(ii) discuss and manage the implementation of the Initial Development Plan;

(iii) discuss the audited final report from the Carcinogenicity Studies, including whether or not a Technical Product Failure has occurred, and provide input thereon to the JSC;

(iv) propose to the JSC particular studies to be conducted;

(v) create, propose for JSC review and approval, and implement the Development Strategy for Development in the Territory and the design of all Clinical Trials and Nonclinical Studies conducted under each Development Plan, including Phase 4 Clinical Trials;

(vi) create and propose the CMC related development plan for JSC review and approval, and oversee any CMC related development activities according to the plan, e.g. stability studies or packaging development, as well as other activities to prepare for supply of drug substance and finished Product for Commercialization, including to oversee the selection process for, and select (pursuant to Section 6.4), a contract manufacturer to be used by FibroGen for commercial supplies;

(vii) allocate budgeted resources and determine priorities for each Clinical Trial and Nonclinical Study under each Development Plan, including Phase 4 Clinical Trials;

(viii) supervise, with regular oversight by the JSC, the conduct of all Clinical Trials and Nonclinical Studies under each Development Plan, including Phase 4 Clinical Trials;

(ix) endorse the selection of Third Party contractors to conduct Clinical Trials of Products;

(x) facilitate, with regular oversight by the JSC, the flow of Information between the Parties with respect to the Development of Products, including Development Data and Astellas Data pursuant to Section 3.10, as well as any other Information related to the Astellas Collaboration that has a material impact on AstraZeneca’s rights under this Agreement;

(xi) discuss the priority of life cycle management Development of Products for other indications and propose any such indications to the JSC;

(xii) propose to the JSC for approval allocation of primary responsibility as between the Parties for tasks relating to Development of Products where not already specified in the Development Plan;

(xiii) discuss the requirements for Regulatory Approval in the Territory and oversee and coordinate regulatory matters with respect to Products in the Territory, including to review and approve material regulatory filings (other than the filing of an NDA in the U.S., which shall be approved by the JSC) prior to submission thereof;

(xiv) propose to the JSC for approval and implement a publication strategy for publications and presentations related to Products in the Territory and review and approve all such publications in accordance with Section 12.5, provided that the responsibilities under this subsection (xvi) with respect to a certain Product shall transition from the JDC to the JCC following the first NDA approval of such Product in the U.S., the more precise timing of such transition to be mutually agreed by the Parties;

(xv) facilitate the flow of Information between the Parties with respect to obtaining Regulatory Approval for Products; and

(xvi) perform such other functions as may be appropriate to further the purposes of this Agreement, as directed by the JSC.

Schedule G (b)

Until the date when the JCC has been formed, the JSC delegates the following responsibilities to Core Joint Project Team. Unless otherwise directed by the JSC, the Core JPT shall:

(xvii) regularly report to the JSC regarding the Commercialization of the Products, and discuss, prepare and submit for approval to the JSC the U.S. Commercialization Plan for each Product in the U.S., including any amendments thereto;

(xviii) coordinate the Commercialization activities of FibroGen and AstraZeneca with respect to Products, including pre-launch and post-launch activities;

(xix) propose to the JSC for approval the allocation of primary responsibility as between the Parties for tasks relating to Commercialization of Products in the U.S.;

(xx) propose to the JSC for approval the amount of Product to be distributed free of charge annually for regulatory or marketing purposes or investigator-initiated trials (it being understood and agreed that neither Party shall have the right to distribute the Product as samples except pursuant to Section 5.7); and

(xxi) perform such other functions as appropriate to further the purposes of this Agreement, as directed by the JSC.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Exhibit H

FG-4592 Initial Development Plan

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[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

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Exhibit I

U.S. Co-Commercialization Terms

Unless the Parties agree in writing upon an alternate allocation of responsibility, the Parties shall have the following rights and obligations with respect to the operational responsibilities for the Commercialization of Products in the U.S. under each U.S. Commercialization Plan, under the direction of the JCC as specified in Section 2.4 and Article 5. [*]

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Exhibit J

Development Supply Terms

The supply from FibroGen to AstraZeneca, or to FibroGen internally where FibroGen has been assigned (either by the JDC or under the terms of the Agreement) the lead responsibility for the conduct of a Clinical Trial for which the supply is intended, shall include those GMP quantities of Product, and those development activities, in either case, approved by the JDC. As of the Effective Date, the JDC has not been convened. Therefore, the Parties have agreed that the following provisions shall govern the manufacture and delivery of the supplies necessary to conduct the Clinical Trials under the Development Plan.

FibroGen shall manufacture and supply an appropriate amount (currently estimated at up to approximately 3 million units of Product (i.e. 3 million tablets of active drug) and approximately 1.5 million tablets of placebo) for the conduct of the Phase 3 Clinical Trials sponsored by AstraZeneca as well as the amount required to support FibroGen's studies and regulatory submissions. The Parties shall agree upon more exact quantities as soon as possible. Such unit numbers shall include varying drug strengths for the Clinical Trials and shall be delivered at least four (4) months ahead of the start of the Clinical Trials, subject to Section 6.2.

FibroGen shall continue its already started development of a solid formulation, e.g. tablet, aimed at enabling attributes such as commercially viable shelf-life and use of standard primary packages, a dosage unit size to enable an attractive intake by patients as well as deemed possible to manufacture by conventional manufacturing technology in a cost effective manner and that does not reduce the clinical effectiveness or increase a hypothetical adverse event profile of the Product. FibroGen shall initiate *in vivo* testing as needed and according to timelines agreed by the JDC.

The supplies and activities set forth in this Exhibit J may be amended from time to time by the JDC or the JSC.

FibroGen shall report the progress of the items listed above to AstraZeneca's appointed Pharmaceutical Development contacts on a regular and reasonable basis. FibroGen shall also consult AstraZeneca prior to making any critical decisions with material impact on further development, e.g. choice of solid state form, particle size control methodology, choice of excipients, process technology and packaging materials, stability testing protocols, quality specifications and analytical testing methodology, choice of starting materials and sourcing.

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Exhibit K

Main Terms for Supply Agreement and Quality Agreement

The Supply Agreement ("**SA**") and Quality Agreement ("**QA**") referenced at Section 6.3 of the Agreement shall contain the following main terms and conditions. Capitalized terms used but not defined in this Exhibit K shall have the meaning ascribed to such terms in the Agreement.

Supply

- Effective Date of SA/QA: The SA and the QA will provide for an effective date which is earlier than the execution date, in case supply of Product is required prior to execution of the SA and the QA.

- Conflict: In the event of a conflict between the Agreement and the SA or the QA, the SA once executed will control with respect to supply matters, and the QA, once executed, will control with respect to quality matters.

- Forecasting, Ordering and Delivery: Terms relating to forecasting and ordering shall be set forth in the SA. The Parties shall agree and include in the SA, a mechanism for defining the lead-times for all Products ordered by AstraZeneca. Delivery of Product shall be EXW INCOTERMS 2010 to an address specified by AstraZeneca. Title shall pass to AstraZeneca on delivery to AstraZeneca or its designee.

- Failure to Supply: The SA will include remedies and other consequences for supply failure (to be defined in the SA) including: (i) rights for AstraZeneca to access relevant information in the possession of FibroGen and its affiliates relating to the manufacturing processes for the Product; and (ii) rights for AstraZeneca to contact FibroGen's suppliers (including suppliers of the active pharmaceutical ingredient for the Product), both (i) and (ii) to assess the feasibility of (including contracting with) such suppliers manufacturing and supplying the Product to AstraZeneca, solely in the event of a supply failure by FibroGen.

- Insurance and Risk: The agreement will contain provisions requiring FibroGen to maintain insurance coverage of the types and in the amounts typically carried by providers of manufacturing services in the pharmaceutical or chemical area. FibroGen shall bear the risk of loss of materials (including API) and Product while within FibroGen's or its subcontractor's control.

- Subcontractors: FibroGen may engage subcontractors ("Subcontractors") that meet the quality standards agreed by the Parties. No such subcontract shall release FibroGen from any of its obligations under the SA or the QA except to the extent such obligations are satisfactorily performed by such Subcontractor in accordance with the SA and the QA. To the extent that AstraZeneca has genuine concerns and can demonstrate with reasonable documentation to FibroGen the basis for its concern with respect to the performance of the

work for which the Subcontractor is to be engaged, the choice of such Subcontractor shall be subject to AstraZeneca's approval.

- Formulation: In the event the Parties decide that AstraZeneca will carry out formulation of the Product, such activities will be included in the SA and any applicable terms will be added to the SA to account for AstraZeneca's role in the formulation activities.

- Non-Conforming Product: The agreement will contain provisions relating to the determination and replacement of nonconforming product and the use of a Third Party testing laboratory to resolve disputes relating to nonconforming product.

- Shortfalls: The SA will include consequences relating to any failure or inability to supply full quantities of Product in compliance with the applicable product specifications ordered by AstraZeneca, including an obligation that in the event of a shortage, FibroGen will allocate an amount of its remaining manufacturing capacity in an equitable manner to be set forth in the Supply Agreement.

- Pricing and Payment: The pricing provisions set out in Section 6.5 of the Agreement shall be incorporated into the terms of the SA. AstraZeneca shall pay invoices in accordance with the terms set forth in the Agreement.

- Legal and Regulatory Requirements: Appropriate provisions shall be included in the SA to ensure that each Party complies with all relevant local, national and international legal or regulatory requirements and other relevant requirements applicable to the manufacture, handing, transport and storage of all Products at all times.

- Governance: The SA will include governance and reporting provisions specific to the manufacturing activities, which governance provisions will be designed to provide AstraZeneca transparency into the activities under such agreement, including subcontracting and CMO arrangements, and to facilitate effective management of the supply chain.

- Health and Safety: FibroGen shall be wholly accountable and liable for the safety, health and environmental aspects of all work performed on its or any of its subcontractor's premises.

- AstraZeneca Policies: The SA will include provisions required to comply with applicable AstraZeneca standard policies, including with respect to responsible procurement, product security and waste handling.

- Document Retention**:** Appropriate provisions shall be included in the SA with regard to maintaining appropriate documentation for patent and regulatory purposes and in full compliance with all applicable laws.

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- Technology Transfer: The technology transfer provisions in the Agreement will remain in effect during the term of the SA (and any post-expiration or termination supply period, as described above in Section 13.6(e) or (g)), even after the Agreement has terminated or expired.

- Liability and Indemnity: The SA will include provisions relating to liability and indemnification that are consistent with the principles of allocation of liability described in the Agreement.

- Warranties: FibroGen will be required to provide customary representations and warranties within the SA, including (but not limited to) as to the following:

  (a) that it has full power and authority, and has taken all necessary actions and has obtained all necessary authorizations, licenses, consents and approvals required, to execute and perform the SA, and

  (b) that its retention as a supplier by AstraZeneca and its performance of the SA do not, and shall not, breach any agreement with any other third party.

- Generally:

  - The SA shall include such terms as are reasonable and customary for similar supply agreements.

  - Each of the Parties agree and acknowledge that the SA will contain a number of provisions which shall be consistent with provisions in the body of the Agreement, including Confidentiality, Assignment, Governing Law and Dispute Resolution.

Quality

- General: A Quality Agreement shall be negotiated in good faith between the Parties and shall include all appropriate provisions as would normally be contained in such an agreement. Any breach of the QA shall be deemed a breach of the SA.

- The QA shall include:

  - Notice to AstraZeneca of inspections by regulatory authorities and access to such inspections

  - Notice to AstraZeneca of and access to all investigations concerning the manufacture of Products

  - Provision by FibroGen of documentation required by AstraZeneca

  - Maintenance of a change control system which allows for the pre-approval of major changes

- Rights for AstraZeneca to conduct quality audits on FibroGen or any Subcontractor
- Agreed procedures on a product recall

- Each of the Parties agrees and acknowledges that the Products must satisfy appropriate specifications and associated tests, details of which shall be set out in the QA, and a mechanism for handling any defective products shall be agreed and included in the QA.

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Exhibit L

Invoicing Requirements

Subject to any separate instructions to be agreed between the Parties regarding payments to health care professionals or health care organizations in the Territory, as required by applicable laws and regulations, invoices should be sent to:

AstraZeneca AB
AstraZeneca R&D Mölndal
Att. Christina Wågestrand
CVGI iMed Strategy
431 83 Mölndal
Sweden

Invoices shall contain the following information:

a. AstraZeneca's Agreement ID: Elisabeth Björk, Global Product Vice President, Global Medicines Development, ECHO Project ID 10007956
b. the number and date of invoice
c. the latest date of payment according to Agreement
d. description of services
e. name and address of FibroGen, Inc.
f. FibroGen, Inc. VAT registration number or EIN/TaxID,
g. AstraZeneca's VAT registration number SE556011748201 (in EC),
h. VAT rate (%), if any,
i. taxable amount per VAT rate, if any,
j. VAT amount, if any
k. legal reference or explanation when VAT is excluded,
l. invoice amount and currency,
m. bank details, preferably IBAN code, otherwise account number and bank code, and
n. SWIFT-address.

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Exhibit M

Patents that may be Extended

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Exhibit N

ASTRAZENECA AND FIBROGEN COLLABORATE TO DEVELOP AND COMMERCIALISE FG-4592, A TREATMENT FOR ANAEMIA IN CHRONIC KIDNEY DISEASE AND END-STAGE RENAL DISEASE

Collaboration to include US, China and selected other markets

31 July 2013

AstraZeneca and FibroGen today announced that they have entered into a strategic collaboration to develop and commercialise FG-4592, a first-in-class oral compound in late stage development for the treatment of anaemia associated with chronic kidney disease (CKD) and end-stage renal disease (ESRD).

This broad collaboration focuses on the US, China and all major markets excluding Japan, Europe, the Commonwealth of Independent States, the Middle East and South Africa, which are covered by an existing agreement between FibroGen and Astellas Pharma Inc. The AstraZeneca-FibroGen joint effort will be focused on the development of FG-4592 to treat anaemia in CKD and ESRD, and may be extended to other anaemia indications.

FG-4592 is a small molecule inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase. HIF is a protein that responds to oxygen changes in the cellular environment and meets the body's demands for oxygen by inducing erythropoiesis, the process by which red blood cells are produced. FG-4592 has the potential to address the considerable unmet medical need for an effective treatment for anaemia that offers the convenience of oral administration and an improved safety profile as compared to current standards of care. At present, treatment options involve a combination of injectable erythropoiesis-stimulating agents (ESAs) and iron supplements. FG-4592 works through the body's natural oxygen-sensing and response system to help produce red blood cells. This can be compared to the body's natural response to conditions at high altitude, where oxygen levels are low, which is to produce more red blood cells.

In Phase II clinical studies, FG-4592 met its primary objective of demonstrating anaemia correction in treatment-naïve CKD patients not on dialysis as well as maintenance of haemoglobin levels and anaemia correction in patients on dialysis. FG-4592 has demonstrated this efficacy combined with an acceptable safety profile in clinical trials, and has been shown to achieve anaemia correction in the absence of intravenous iron supplementation.

The companies plan to undertake an extensive FG-4592 phase III development programme for the US, and to initiate phase III trials in China, with anticipated regulatory filings in China in 2015 and in the US in 2017.

AstraZeneca will pay FibroGen committed upfront and subsequent non-contingent payments totalling $350 million, as well as potential future development related milestone payments of up to $465 million, and potential future sales related milestone payments in addition to tiered royalty

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payments on future sales on FG-4592 in the low 20% range. Additional development milestones will be payable for any subsequent indications which the companies choose to pursue. AstraZeneca will be responsible for the US commercialisation of FG-4592, with FibroGen undertaking specified promotional activities in the ESRD segment in this market. The companies will also co-commercialise FG-4592 in China where FibroGen will be responsible for clinical trials, regulatory matters, manufacturing and medical affairs, and AstraZeneca will oversee promotional activities and commercial distribution.

Pascal Soriot, Chief Executive Officer, AstraZeneca, said: “Our collaboration with FibroGen on FG-4592 is an important addition to AstraZeneca’s growing late-stage portfolio in cardiovascular and metabolic disease, one of our core therapy areas. We know from our research into complications of renal disease that anaemia continues to be a challenge for patients with chronic kidney disease, due in part to the inconvenience and complexity of existing injectable and intravenous therapies and the safety concerns associated with them. The science behind this compound is compelling. Through our collaboration with FibroGen we aim to offer a first-in-class, convenient treatment option for doctors and patients.”

Thomas B. Neff, Chief Executive Officer, FibroGen, said: “FG-4592 has the potential to offer anaemia patients an oral therapy that provides coordinated erythropoiesis, that increases natural erythropoietin within the normal physiological range, and that is effective without intravenous iron supplementation and without an increased risk for hypertension. We are especially pleased that AstraZeneca will share our commitment to making China the first-to-launch country for FG-4592 and join our effort to bring important innovation in anaemia therapy to CKD and ESRD patients in the US and other countries. This agreement secures proper development and commercialisation resources for FG-4592, and ensures US clinical trial efforts are fully funded.”

– ENDS –

NOTES TO EDITORS

About chronic kidney disease and anaemia

Diabetes, high blood pressure, and other conditions can cause significant damage to the kidneys. If left untreated, those can result in chronic kidney disease and progress to kidney failure. Such deterioration can lead to patients needing a kidney transplant or being placed on dialysis to remove excess fluid and toxins that build up in the body. The progression of CKD also increases the prevalence of anaemia, a condition associated with having fewer of the red blood cells that carry oxygen through the body, and/or lower levels of haemoglobin, the protein that enables red blood cells to carry oxygen. As haemoglobin falls, the lower oxygen-carrying capacity of an anaemic patients’ blood results in various symptoms including fatigue, loss of energy, breathlessness, and angina. Anaemia in CKD patients has been associated with increased hospitalisation rates, increased mortality, and reduced quality of life.

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CKD is a worldwide critical healthcare problem that affects millions of people and drives significant healthcare cost. In the US, prevalence of CKD has increased dramatically in the past 20 years, from 10% of the adult population (or approximately 20 million US adults) as stated in the National Health and Nutrition Evaluation Survey (NHANES) 1988-1994, to 15% (or approximately 30 million adults) in NHANES 2003-2006. In 2009, total Medicare costs for CKD patients were $34 billion. China has an estimated 125 million CKD patients, or 5 times the number of CKD patients in the US [Lancet April 2012].

About FG-4592

FG-4592 is an orally administered small molecule inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase activity, in development for the treatment of anaemia in patients with chronic kidney disease (CKD). HIF is a protein transcription factor that induces the natural physiological response to conditions of low oxygen, “turning on” erythropoiesis (the process by which red blood cells are produced) and other protective pathways. FG-4592 has been shown to correct anaemia and maintain haemoglobin levels without the need for supplementation with intravenous iron in CKD patients not yet receiving dialysis and in end-stage renal disease patients receiving dialysis. An Independent Data Monitoring Committee has found no signals or trends to date to suggest that treatment with FG-4592 is associated with increased risk of cardiovascular events, thrombosis, or increases in blood pressure requiring initiation or intensification of antihypertensive medications.

Under a licensing agreement between FibroGen, Inc. and Astellas Pharma Inc., Astellas is developing FG-4592 for the treatment of anaemia in CKD and ESRD patients in Europe, Japan, the Commonwealth of Independent States, the Middle East, and South Africa.

About FibroGen

FibroGen, Inc., is a privately-held biotechnology company focused on the discovery, development, and commercialization of therapeutic agents for treatment of fibrosis, anaemia, cancer, and other serious unmet medical needs. FibroGen’s FG-3019 monoclonal antibody is in early-stage clinical development for treatment of idiopathic pulmonary fibrosis and other proliferative diseases, including pancreatic cancer and liver fibrosis, and FG-4592 is a small molecule inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase currently in clinical development for the treatment of anaemia. FibroGen is also currently pursuing the use of proprietary recombinant human type III collagens in synthetic corneas for treatment of corneal blindness. For more information please visit: www.fibrogen.com

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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CONTACTS

Media Enquiries

Ayesha Bharmal		+44 20 7604 8034 (UK/Global)
Esra Erkal-Paler		+44 20 7604 8030 (UK/Global)
Vanessa Rhodes		+44 20 7604 8037 (UK/Global)
Michele Meixell		+1 302 885 2677 (US)
Jacob Lund		+46 8 553 260 20 (Sweden)
Investor Enquiries		
Ed Seage		+1 302 373 1361
Colleen Proctor		+1 302 357 4882

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Exhibit 10.3

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AMENDED AND RESTATED

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

(CHINA)

between

FIBROGEN CHINA ANEMIA HOLDINGS, LTD.; BEIJING FIBROGEN MEDICAL TECHNOLOGY DEVELOPMENT CO., LTD.; FIBROGEN INTERNATIONAL (HONG KONG) LIMITED

and

ASTRAZENECA AB (PUBL)

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LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (CHINA)

THIS AMENDED AND RESTATED LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (CHINA) (the **"Agreement"**) is entered into as of October 16, 2014 (the "***Execution Date***") and effective as of July 30, 2013 (the **"Effective Date"**), by and between FibroGen China Anemia Holdings, Ltd., having a registered office at c/o Ogier Fiduciary Services (Cayman) Limited, 89 Nexus Way, Camana Bay, Grand Cayman, Cayman Islands KY1-9007 ("**FibroGen Cayman**"), Beijing FibroGen Medical Technology Development Co., Ltd., a wholly foreign owned limited liability company having its principal place of business at No. 88 Building Kechuang Street 6 Building 2, Floor 4, Room 503, Beijing Economic-Technological Development Area, Beijing, 100000, the People's Republic of China ("**FibroGen WFOE**") and FibroGen International (Hong Kong) Limited, having a registered office at 18th Floor, Edinburgh Tower, The Landmark, 15 Queen's Road Central, Hong Kong ("**FibroGen HK**") (FibroGen WFOE, FibroGen Cayman and FibroGen HK, collectively, **"FibroGen China"**), on the one hand, and AstraZeneca AB, a company incorporated in Sweden under no. 556011-7482 with offices at Pepparredsleden 1, 431 83 Mölndal, Gothenburg, Sweden ("**AstraZeneca**"), on the other hand. FibroGen China and AstraZeneca are sometimes referred to herein individually as a **"Party"** and collectively as the **"Parties"**; provided that with respect to FibroGen China, the term "Party" may refer to FibroGen Cayman if the context requires.

BACKGROUND

A. FibroGen WFOE, a wholly-owned subsidiary of FibroGen Cayman, is a biotechnology company that has expertise in the discovery and development of various prolyl hydroxylase inhibitor compounds for the treatment of anemia. FibroGen WFOE is exclusively dedicated to addressing unmet medical needs of the Chinese population by introducing first-in-class, novel medicines that are affordable and accessible to the Chinese population. FibroGen WFOE is pursuing a Class 1.1 Innovative Drug pathway in China to develop, manufacture and commercialize such compounds in China, including FG-4592, to which FibroGen WFOE has certain intellectual property rights.

B. AstraZeneca is an enterprise with expertise in the commercialization of human therapeutic products in China and with significant sales and marketing resources on-the-ground in China.

C. To ensure that the cost-effective and effective therapies developed by FibroGen WFOE are made accessible to Chinese patients, FibroGen China is entering into this Agreement with AstraZeneca to commercialize the therapies developed by FibroGen WFOE. FibroGen WFOE will retain the rights to the technology, and will be responsible for registration, clinical trials, manufacturing and physician education with respect to the Products. FibroGen China will grant certain co-exclusive license rights to AstraZeneca with respect to such technology under the terms of this Agreement.

D. FibroGen, Inc. ("**FibroGen**") and AstraZeneca have entered into a License, Development and Commercialization Agreement of even date herewith, for development,

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manufacture and commercialization activities for certain of such human therapeutic compounds for certain countries outside of China (the "**U.S. and RoW Agreement**"), which agreement includes a portion of the governance structure for China related to this Agreement.

Now, Therefore, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

ARTICLE 1

Definitions

As used in this Agreement, the following initially capitalized terms, whether used in the singular or plural form, shall have the meanings set forth in this Article 1. Except where the context otherwise requires, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. In addition, the terms "includes," "including," "include" and derivative forms of them shall be deemed followed by the phrase "without limitation" (regardless of whether it is actually written there (and drawing no implication from the actual inclusion of such phrase in some instances after such terms but not others)).

1.1 **"Acquiror"** has the meaning set forth in Section 15.5.

1.2 **"Affiliate"** means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.

1.3 **"Alliance Manager"** has the meaning set forth in Section 2.4.

1.4 "**Anti-Corruption Laws**" means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, Chinese anti-corruption legislation, including the Anti-Unfair Competition Law, the Interim Provisions on Prohibition of Commercial Bribery, and Articles 164, 389 and 391 of the Criminal Law, and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism.

1.5 **"Astellas"** means Astellas Pharma, Inc.

1.6 **"Astellas Agreements"** means the Astellas EU Agreement and the Astellas Japan Agreement.

1.7 **"Astellas EU Agreement"** means the Anemia License and Collaboration Agreement between FibroGen and Astellas effective April 28, 2006, as amended from time to time.

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1.8 "Astellas Japan Agreement" means the Collaboration Agreement between FibroGen and Astellas effective June 1, 2005, as amended from time to time.

1.9 "AstraZeneca Know-How" means all Information Controlled as of the Effective Date or thereafter during the Term by AstraZeneca or its Affiliates that is reasonably necessary or useful for the research, development, manufacture, use, importation or sale of Products in the Field. For clarity, the use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate due to such Third Party's acquisition of or by, AstraZeneca, except as provided in Section 15.5. For additional clarity, AstraZeneca Know-How shall exclude rights under any AstraZeneca Patents and AstraZeneca's interest in the Joint Patents and Joint Inventions.

1.10 "AstraZeneca Patents" means all Patents that are Controlled as of the Effective Date or thereafter during the Term by AstraZeneca or its Affiliates and that claim the composition of matter, manufacture or use of one or more Collaboration Compounds or Products or that would otherwise be infringed (or with respect to patent applications, would be infringed if issued or granted with the then-currently pending claims), absent a license, by the manufacture, use or sale of any Collaboration Compounds or Product. For clarity, the use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate due to such Third Party's acquisition of or by, AstraZeneca except as provided in Section 15.5.

1.11 "**AstraZeneca Anti-Corruption Rules and Policies**" means the key principles from AstraZeneca's ABAC and External Interactions Policies regarding anti-bribery and corruption issues, attached as **Exhibit H** to this Agreement, as the same may be amended, modified or supplemented from time to time as notified by AstraZeneca to FibroGen China.

1.12 "AstraZeneca Technology" means the AstraZeneca Patents, AstraZeneca Know-How, and AstraZeneca's and its Affiliates' interest in Joint Patents and Joint Inventions.

1.13 "Audit" has the meaning set forth in Section 10.4(e).

1.14 "Auditor" has the meaning set forth in Section 8.11(c).

1.15 "Business Day" means a day other than a Saturday, Sunday or bank or other public holiday in China, the Cayman Islands or Sweden.

1.16 "Calendar Quarter" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1.

1.17 "Calendar Year" means each successive period of twelve (12) calendar months commencing on January 1.

1.18 "CFDA" means the China Food and Drug Administration or its successor.

1.19 "China Committee" means the committee formed by the Parties as described in Section 2.2.

1.20 "Clinical Trial" means any human clinical trial of a Product.

1.21 "Collaboration Compound" means any of the following: (a) FG-4592, (b) any HIF Compound (other than FG-4592) that is added to this Agreement pursuant to Section 3.5 and (c) any salts, esters, complexes, chelates, crystalline and amorphous morphic forms, pegylated forms, enantiomers (excluding regioisomers), prodrugs, solvates, metabolites and catabolites of any of the foregoing ((a) or (b)).

1.22 "Collaboration Inventions" has the meaning set forth in Section 9.2.

1.23 "Commercialization" means the commercial manufacture, marketing, promotion, sale and/or distribution of Products in the Territory. Commercialization includes Phase 4 Clinical Trials, Mandatory Post-Approval Safety Studies, and commercial activities conducted in preparation for Product launch in each indication. **"Commercialize"** has a correlative meaning.

1.24 "Commercialization Budget" has the meaning set forth in Section 5.2.

1.25 "Commercialization Costs" means (a) all Marketing and Sales Expenses, Phase 4 Clinical Costs and Mandatory Post-Approval Safety Study Costs incurred in the performance of the Parties' activities under the Commercialization Plan, in each case to be incurred by a Party as set forth in the Commercialization Plan and Commercialization Budget (or constituting a permitted overage thereto under Section 3.3), and all non-creditable and non-recoverable Indirect Taxes and duties, or (b) other costs approved by the China Committee as Commercialization Costs (i) prior to the date on which the Commercialization Plan and the initial Commercialization Budget are approved by the China Committee or (ii) as part of Commercialization Budget. Notwithstanding the foregoing, Commercialization Costs will not include Development Costs. For clarity, Third Party costs included in Commercialization Costs shall be billed directly without markup.

1.26 "Commercialization Plan" has the meaning set forth in Section 5.2.

1.27 "Commercially Reasonable Efforts" means, with respect to a Party's obligations under this Agreement to Develop or Commercialize a Product, the carrying out of such obligations or tasks with a level of efforts and resources consistent with the commercially reasonable practices of (a) in the case of AstraZeneca, a pharmaceutical company the size and geographical scope of AstraZeneca and (b) in the case of FibroGen China, a biotechnology company the size and geographical scope of FibroGen China, in each case (a) and (b) for the development or commercialization of similarly situated pharmaceutical products as such Product and at a similar stage of development or commercialization, taking into consideration their safety and efficacy, their cost to develop, the nature and extent of their market exclusivity (including patent coverage and regulatory exclusivity), the likelihood of Regulatory Approval, their expected profitability, including the amounts of marketing and promotional expenditures with respect to such products and generic products, and the competitiveness of alternative compounds and products. Commercially Reasonable Efforts requires that the Party: (a) promptly assign responsibility for such obligations or tasks to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis, (b) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations, and (c) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives. For the avoidance of doubt, the commitment to use "Commercially Reasonable Efforts" shall not

preclude the suspension or discontinuance by AstraZeneca of any Product, if appropriate, based on the foregoing considerations.

1.28 **"Committee"** means the China Committee or any subcommittee established under Article 2, as applicable.

1.29 **"Confidential Information"** means, with respect to a Party, all Information of such Party that is disclosed to the other Party under this Agreement, which may include, without limitation, specifications, know-how, trade secrets, technical information, models, business information, inventions, discoveries, methods, procedures, formulae, protocols, techniques, data, and unpublished patent applications, whether disclosed in oral, written, graphic, or electronic form. All confidential Information disclosed by either Party or its Affiliate pursuant to the Existing Confidentiality Agreement shall be deemed to be Confidential Information of the disclosing Party hereunder (with the mutual understanding and agreement that any use or disclosure thereof that is authorized under Article 12 shall not be restricted by, or be deemed a violation of, such Existing Confidentiality Agreement).

1.30 **"Control"** means, with respect to any material, Information, or intellectual property right, that a Party (a) owns such material, Information, or intellectual property right, or (b) has a license or right to use to such material, Information, or intellectual property right, in each case with the ability to grant to the other Party access, a right to use, or a license, or a sublicense (as applicable) to such material, Information, or intellectual property right on the terms and conditions set forth herein, without violating the terms of any agreement or other arrangement with any Third Party.

1.31 **"Co-Promote"** means to perform jointly those Detailing and related activities normally undertaken by a pharmaceutical company's sales force to Commercialize a product under a single trademark in the Territory.

1.32 **"Co-Promotion Agreement"** has the meaning set forth in Section 5.1.

1.33 **"Co-Promotion Fee"** has the meaning set forth in **Exhibit D**.

1.34 "**Core Commercial Provinces**" means the top ten (10) provinces that, at the applicable time, have the largest annual market share for pharmaceutical products in China. As of the Effective Date, the top six (6) Core Commercial Provinces are Beijing, Shanghai, Guangdong, Zhejiang, Jiangsu and Shandong.

1.35 "**Core Indication**" means any of the following: (a) treatment of anemia in patients with chronic kidney disease undergoing dialysis, (b) treatment of anemia in patients with chronic kidney disease not undergoing dialysis (collectively with (a), the "**CKD Indications**"), (c) [*].

1.36 **"CRO"** has the meaning set forth in Section 3.2(e)(i).

1.37 **"CTA"** means a Clinical Trial Application or other equivalent application to a Regulatory Authority in the Territory, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

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1.38 **"Detail"** has the meaning set forth in **Exhibit D**.

1.39 **"Development"** means all activities that relate to (a) obtaining, maintaining or expanding Regulatory Approval of a Product for one or more indications or (b) developing the process for the manufacture of clinical and commercial quantities of drug substance or drug Product. This includes: (i) preclinical and non-clinical testing, toxicology and Clinical Trials; (ii) preparation, submission, review, statistical analysis, report writing and development of data or information for the purpose of submission to a Governmental Authority to obtain, maintain and/or expand Regulatory Approval of a Product, and outside counsel regulatory legal services related thereto; and (iii) manufacturing process development and scale-up for drug substance and drug product, test method development, packaging development, stability testing, qualification and validation, production of drug substance and drug product, in bulk for preclinical and clinical studies, and related quality assurance technical support activities; provided, however, that Development shall exclude Commercialization. **"Develop"** has a correlative meaning.

1.40 **"Development Budget"** means the budget associated with the activities conducted under a Development Plan for the Territory, detailing the anticipated Development Costs.

1.41 **"Development Costs"** means all costs incurred by or on behalf of a Party that are reasonably allocable to the Development of Products in the Territory in accordance with the Development Plan or are otherwise incurred or accrued under the Development Budget (including costs incurred prior to the Effective Date and paid under Section 8.2). For clarity, Third Party costs included in Development Costs shall be billed directly without markup.

1.42 **"Development Plan"** has the meaning set forth in Section 3.2(a).

1.43 **"Distribution Agreement"** means the distribution agreement to be entered into between FibroGen China and AstraZeneca or AstraZeneca's designated Affiliate, as set forth in Section 5.3.

1.44 **"Dollar"** or **"$"** means United States dollar.

1.45 "**Drug Administration Law"** means the Drug Administration Law of the PRC and its implementing regulations, as amended from time to time.

1.46 **"ESA Approved Indications"** means the following indications: (a) treatment of anemia in patients with chronic kidney disease undergoing dialysis, (b) treatment of anemia in patients with chronic kidney disease not undergoing dialysis, (c) [*].

1.47 **"Executive Officer"** means, in the case of AstraZeneca, AstraZeneca's Chief Executive Officer or any senior executive designated by and who reports directly to the Chief Executive Officer of AstraZeneca, and in the case of FibroGen China, FibroGen Cayman's Chief Executive Officer.

1.48 **"Existing Confidentiality Agreement"** means, collectively, the Non-Disclosure Agreement between FibroGen and AstraZeneca dated June 21, 2012, as amended February 7,

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2013, and May 23, 2013, and the Non-Disclosure Agreement between FibroGen and AstraZeneca dated April 1, 2013.

1.49 **"FG-4592"** means the molecule with the chemical structure set forth on **Exhibit A**.

1.50 **"FG-6874"** means the molecule in Development by FibroGen currently identified by FibroGen as "FG-6874".

1.51 **"FibroGen Contracting Parties"** means FibroGen HK, FibroGen Cayman, and FibroGen WFOE.

1.52 **"FibroGen China Know-How"** means all Information Controlled as of the Effective Date or thereafter during the Term by FibroGen China and/or its Affiliate(s) and reasonably necessary or useful for the development, manufacture, use, importation or sale of Collaboration Compounds or Products in the Field; including, without limitation, any such Information made or generated by or on behalf of FibroGen China or its Affiliate in the course of performing FibroGen China's obligations or exercising FibroGen China's rights under this Agreement. The use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate due to such Third Party's acquisition of FibroGen China, except as provided in Section 15.5. FibroGen China Know-How shall exclude (a) rights under any FibroGen China Patents and (b) FibroGen's interest in the Joint Patents and Joint Inventions.

1.53 **"FibroGen China Patents"** means (i) the Listed Patents and (ii) all other Patents (excluding any Joint Patents) that are Controlled as of the Effective Date or thereafter during the Term by FibroGen China and/or its Affiliate(s) and that claim the composition of matter, manufacture or use of one or more Collaboration Compounds or Products in the Field or that would otherwise be infringed (or with respect to patent applications, would be infringed if issued or granted with the then-currently pending claims), absent a license, by the manufacture, use or sale of any Collaboration Compound or Product in the Field. The use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate due to such Third Party's acquisition of FibroGen China except as provided in Section 15.5.

1.54 **"FibroGen China Technology"** means the FibroGen China Patents, FibroGen China Know-How, and FibroGen China's interest in Joint Patents and Joint Inventions.

1.55 **"Field"** means the treatment of anemia in humans and non-human animals, which means any treatment intended to increase hemoglobin levels or utilization or to increase hematocrit, as measured by acceptable clinical parameters, including unit volume concentrations of hemoglobin, red blood cell volume, or red blood cell count. For the avoidance of doubt, the Core Indications and the ESA Approved Indications are included in the Field.

1.56 **"Finance Subcommitee"** has the meaning set forth in **Exhibit D**.

1.57 "**First Commercial Sale**" means, with respect to a Product, the first arm's length sale for monetary value by AstraZeneca, its Affiliates or its Sublicensees to a Third Party intended

for end use or consumption by the general public (regardless of when actual consumption occurs) of such Product after Regulatory Approval (and any pricing or reimbursement approvals, if reasonably necessary to commence regular commercial sales) has been obtained.

1.58 **"FTE Rate"** has the meaning set forth in **Exhibit D**.

1.59 **"Governmental Authority"** means any multi-national, national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.60 "**Government Official**" means (i) any individual or entity employed by or acting on behalf of a government, government-controlled agency or entity or public international organization, (ii) any political party, party official or candidate, (iii) any individual or entity that holds or performs the duties of an appointment, office or position created by custom or convention or (iv) any individual or entity that holds himself, herself or itself out to be the authorized intermediary of any of the foregoing.

1.61 **"HIF Compound"** means any compound that stabilizes hypoxia-inducible factor ("**HIF**") or that modulates HIF prolyl hydroxylase activity.

1.62 "**Indirect Taxes**" means VAT, sales taxes, consumption taxes and other similar taxes required by law to be disclosed on the invoice.

1.63 **"Information"** means any data, results and information of any type whatsoever, in any tangible or intangible form, including, without limitation, know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, compositions of matter of any type or kind, software, algorithms, marketing reports, clinical and non-clinical study reports, regulatory submission documents and summaries, expertise, stability, technology, test data including pharmacological, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, in all cases, patentable or otherwise.

1.64 **"Initial Development Plan"** has the meaning set forth in Section 3.2(b).

1.65 "**Innovation Indication**" has the meaning set forth in Section 3.4(a)(i).

1.66 **"Inventions"** has the meaning set forth in Section 9.2.

1.67 **"IP Committee"** has the meaning set forth in Section 9.1.

1.68 **"Joint Inventions"** has the meaning set forth in Section 9.2.

1.69 **"Joint Operating Subcommittee"** or **"JOS"** has the meaning set forth in Section 6.8.

1.70 **"Joint Patent"** has the meaning set forth in Section 9.2.

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1.71 **[**Deliberately left blank**]**

1.72 **"Listed Patents"** means the Patents listed on **Exhibit G**. The Parties may update such exhibit from time to time upon mutual written agreement, e.g., to update the status of the Listed Patents, to add newly filed FibroGen China Patents, or to make other agreed revisions.

1.73 **"Mandatory Post-Approval Safety Study"** means a Clinical Trial of a Product conducted after Regulatory Approval of such Product has been obtained from an appropriate Regulatory Authority, which trial is conducted due to a requirement of a Regulatory Authority.

1.74 **"Mandatory Post-Approval Safety Study Costs"** has the meaning set forth in **Exhibit D**.

1.75 "**Manufacturing Approval**" means a Product License (yao pin sheng chan xu ke zheng □□□□□□□) or any other license issued by a Governmental Authority in the Territory that authorizes a party to conduct manufacturing of the Product for commercial sale.

1.76 "**Marketing and Sales Expenses**" has the meaning set forth in **Exhibit D**.

1.77 **"Marks"** has the meaning set forth in Section 9.11.

1.78 "**Material Anti-Corruption Law Violation**" means a violation of an Anti-Corruption Law relating to the subject matter of this Agreement which [*] a material adverse effect on either Party or on the reputation of either Party because of its relationship with the other Party.

1.79 **"Medical Scientific Liaison"** or **"MSL"** means a field-based professional with scientific, medical and clinical expertise who provides medical and scientific support for marketed products, new indications and compounds in development. A MSL engages in scientific exchange with medical and scientific experts including investigators, key opinion leaders, physicians and other medical professionals and customers.

1.80 **"NDA"** means an application to the CFDA for Regulatory Approval in the Territory.

1.81 **"Net Loss"** has the meaning set forth in **Exhibit D.**

1.82 **"Net Profit"** has the meaning set forth in **Exhibit D.**

1.83 "**Net Sales**" means (solely for use in Section 8.4, it being understood that Net Sales are different from Product Revenue) the gross invoiced amount on sales of a Product by AstraZeneca or Sublicensees to Third Parties (including sub-distributors) in the Territory, after deduction of the following amounts:

(a) normal and customary trade, quantity or prompt settlement discounts (including chargebacks and allowances) actually allowed;

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(b) amounts repaid or credited by reason of rejection, returns or recalls of goods, rebates or bona fide price reductions determined by AstraZeneca in good faith;

(c) rebates and similar payments made with respect to sales paid for by managed care organizations, hospitals, other buying groups or any governmental or regulatory authority;

(d) any invoiced amounts that are not collected by AstraZeneca or its Affiliates, including bad debts (provided that such amounts will be added to Net Sales if and when recovered), up to an amount not to exceed [*] of Net Sales;

(e) excise taxes, Indirect Taxes, customs duties, customs levies and import fees imposed on the sale, importation, use or distribution of the Products; and

(f) as an allowance for transportation costs, distribution expenses, special packaging and related insurance charges, [*].

For clarity, any deduction made pursuant to one subsection above, shall not be additionally deducted in the event that such deduction may also apply in a separate subsection (i.e., no double-counting).

In the event that a Product is sold in any country in the form of a Combination Product (as defined below), Net Sales of such Combination Product shall be adjusted by multiplying actual Net Sales of such Combination Product in such country calculated pursuant to the foregoing definition of "Net Sales" by the fraction A/(A+B), where A is the average invoice price in such country of any Product that contains the same Collaboration Compound(s) as such Combination Product as its sole active ingredient(s), if sold separately in such country, and B is the average invoice price in such country of each product that contains active ingredient(s) other than the Collaboration Compound(s) contained in such Combination Product as its sole active ingredient(s), if sold separately in such country; *provided* that the invoice price in a country for each Product that contains only the Collaboration Compound(s) and each product that contains solely active ingredient(s) other than the Collaboration Compound(s) included in the Combination Product shall be for a quantity comparable to that used in such Combination Product and of substantially the same class, purity and potency or functionality, as applicable. If either such Product that contains the Collaboration Compound(s) as its sole active ingredient or a product that contains the active ingredient(s) (other than the Product) in the Combination Product as its sole active ingredient(s) is not sold separately in a particular country, the Parties shall negotiate in good faith a reasonable adjustment to Net Sales in such country that takes into account the medical contribution to the Combination Product of and all other factors, including patent coverage, reasonably relevant to the relative value of the Collaboration Compound(s) on the one hand and all of the other active ingredient(s), collectively, on the other hand. As used above, "**Combination Product**" means a Product that is comprised of or contains a Collaboration Compound as an active ingredient together with one (1) or more other active ingredients and is sold either as a fixed dose/unit or as separate doses/units in a single package.

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Net Sales will be calculated using AstraZeneca's internal audited systems consistently applied to report such sales as adjusted for any of the deductions set forth above not taken into account in such systems. Deductions pursuant to item (d) above will be taken in the Calendar Quarter in which such sales are no longer recorded as a receivable.

1.84 "**Nonclinical Studies**" means all *in vivo* and *in vitro* non-human studies of Collaboration Compounds and Products including non-clinical pharmacology, toxicology, tumor and teratogenicity studies.

1.85 "**NRDL**" means National Reimbursement Drug List or its equivalent.

1.86 **"Patent"** means (i) all national, regional and international patents and patent applications, including provisional patent applications, (ii) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (iii) any and all patents that have issued or in the future issue from the foregoing patent applications ((i) and (ii)), including utility models, petty patents and design patents and certificates of invention, (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((i), (ii) and (iii)), and (v) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent applications and patents.

1.87 **"Pharmacovigilance Agreement"** has the meaning set forth in Section 4.3.

1.88 **"Phase 4 Clinical Trial"** means a Clinical Trial of a Product conducted after Regulatory Approval of such Product has been obtained from an appropriate Regulatory Authority in the Territory, which trial is conducted voluntarily by a Party to enhance marketing or scientific knowledge of the Product. For clarity, Phase 4 Clinical Trials do not include Mandatory Post-Approval Safety Studies.

1.89 **"Phase 4 Clinical Costs"** has the meaning set forth in **Exhibit D**.

1.90 [Deliberately left blank]

1.91 **"Probe Compound"** means (a) FG-6874 and (b) any HIF Compound other than FG-4592 that is designated by FibroGen China from time to time.

1.92 **"Product"** means any pharmaceutical product (including all forms, presentations, dosage strengths and formulations) containing as an active ingredient a Collaboration Compound alone or in combination with one or more other therapeutically active ingredients.

1.93 **"Product Infringement"** has the meaning set forth in Section 9.6(a).

1.94 **"Product Liability Losses"** has the meaning set forth in **Exhibit D**

1.95 "**Product Reimbursement**" means first inclusion of a Product into the NRDL or any Provincial Reimbursement Drug List in the Territory.

1.96 "**Product Revenues**" has the meaning set forth in **Exhibit D**.

1.97 **"Promotional Materials"** means all sales representative training materials and all written, printed, graphic, electronic, audio or video matter, including, without limitation, journal advertisements, sales visual aids, formulary binders, reprints, direct mail, direct-to-consumer advertising, internet postings and sites and broadcast advertisements intended for use or used by either Party or its Affiliates or sublicensees in connection with any promotion of a Product.

1.98 **"Publication"** has the meaning set forth in Section 12.4(b).

1.99 **"Regulatory Approval"** means all approvals necessary for the manufacture, marketing, importation and sale of a Product for one or more indications in the Field and in a country or regulatory jurisdiction, which may include, without limitation, satisfaction of all applicable regulatory and notification requirements, but which shall exclude any pricing and reimbursement approvals.

1.100 **"Regulatory Authority"** means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval and/or, to the extent required in such country or regulatory jurisdiction, pricing or reimbursement approval of a Product in such country or regulatory jurisdiction.

1.101 **"Regulatory Materials"** means regulatory applications, submissions, notifications, registrations, Regulatory Approvals and/or other material filings or correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority), or other approvals granted by, a Regulatory Authority that are necessary or reasonably desirable in order to Develop, manufacture, market, sell or otherwise Commercialize a Product in a particular country or regulatory jurisdiction. Regulatory Materials include, without limitation, CTAs and NDAs.

1.102 **"Royalty Fees"** has the meaning set forth in **Exhibit D**.

1.103 **"Royalty Withholding Tax"** has the meaning set forth in **Exhibit D**.

1.104 **"Sublicensee"** means any Third Party granted a sublicense by AstraZeneca or any of its Affiliates under the rights licensed to AstraZeneca pursuant to Article 7.

1.105 "**Technical Product Failure**" means (a) a [*] of a Collaboration Compound or Product under Development or Commercialization under this Agreement, as determined (i) by a consensus decision by the China Committee or the JSC (if the China Committee cannot reach consensus) or (ii) following referral of the matter to the Executive Officers pursuant to Section 2.2(e) and Section 2.6(c) of the U.S. and RoW Agreement, by a consensus decision by the Executive Officers, or (iii) in the event that a consensus decision by the Executive Officers has not been attained within twenty (20) Business Days after the JSC's submission of the matter to them,

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by expedited resolution in accordance with Section 14.8; or (b) a Regulatory Authority action or decision [*].

1.106 **"Term"** has the meaning set forth in Section 13.1.

1.107 **"Territory"** or "**China**" or "**PRC**" means the People's Republic of China (including Hong Kong SAR.

1.108 **"Third Party"** means any entity other than FibroGen China or AstraZeneca or an Affiliate of either of them.

1.109 **"Tier 1 Cities"** means those cities designated, at the applicable time, as tier 1 cities by the applicable Governmental Authority in the Territory based on gross domestic product and population. As of the Effective Date, the Tier 1 Cities are Beijing, Shanghai and Guangzhou.

1.110 **"U.S."** means the United States of America (including all possessions and territories thereof).

ARTICLE 2

COLLABORATION; GOVERNANCE

2.1 **Collaboration Overview.** The Parties desire and intend to collaborate with respect to the Development and Commercialization of Products in the Field in the Territory, including, without limitation, as described in the Co-Promotion Agreement, and as and to the extent set forth in this Agreement (the **"Collaboration"**). It is intended that the Collaboration utilize AstraZeneca's Development and Commercialization capabilities, while recognizing FibroGen China's current experience and expertise in and aspirations to further develop its clinical development, manufacturing and commercialization capabilities with respect to HIF Compounds. In addition, it is a goal of the Collaboration to facilitate innovation with HIF Compounds in the Field in the Territory.

2.2 **China Committee**

(a) **Purpose; Formation.** The Parties hereby establish the China Committee (the **"China Committee"**) to oversee Development and Commercialization of Product(s) in the Territory in accordance with the Development Plan(s) and Commercialization Plans for such Product(s) and to coordinate the Development and Commercialization activities of the Parties. Each Party shall initially appoint three (3) representatives of such Party or its Affiliates to the China Committee, with each representative having knowledge and expertise in the development and/or commercialization of pharmaceutical products in the Territory and having sufficient seniority within the applicable Party or Affiliate to make decisions arising with the scope of the China Committee's responsibilities. The China Committee may change its size from time to time by mutual consent of its members, provided that the China Committee shall consist at all times of an equal number of representatives of each of FibroGen China and AstraZeneca. Each Party may replace its China Committee representatives at any time upon written notice to the other Party.

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The China Committee may invite non-members (including consultants and advisors of a Party who are under an obligation of confidentiality consistent with this Agreement) to participate in the discussions and meetings of the China Committee, provided that such participants shall have no voting authority at the China Committee. Each Party shall appoint one co-chairperson to the China Committee. The role of the co-chairpersons shall be to convene and preside at meetings of the China Committee, but the co-chairpersons shall have no additional powers or rights beyond those held by the other China Committee representatives.

(b) Meetings. The China Committee shall meet at least once per Calendar Quarter during the Term unless the Parties mutually agree in writing to a different frequency for such meetings as reasonably necessary. The meetings shall be scheduled in advance of any meeting of the Joint Steering Committee established under the U.S. and RoW Agreement (the "**JSC**") scheduled during the same Calendar Quarter as much as practicable. Notwithstanding the foregoing, at least two (2) meetings per Calendar Year shall be in person unless the Parties mutually agree in writing to waive such requirement in lieu of a videoconference or teleconference. In-person China Committee meetings will be held at locations alternately selected and hosted by FibroGen and by AstraZeneca. The host Party shall be responsible for the costs and expenses of the China Committee meeting hosted, provided that each Party will bear the expense of its respective members' and other attendees' participation in meetings. The secretariat of the host Party shall be responsible for keeping reasonably detailed written minutes of all China Committee meetings that reflect all decisions made at such meetings. The secretariat of the host Party shall send meeting minutes to the other Party's secretariat, and each secretariat shall seek and obtain review and approval of such minutes from its respective Party's members of the China Committee within ten (10) Business Days after each China Committee meeting. Minutes will be deemed approved unless one or more members of the China Committee objects to the accuracy of such minutes within ten (10) Business Days of receipt.

(c) Relationship to U.S. and RoW Agreement Joint Steering Committee. The China Committee shall at all times be subject to oversight by the JSC on all matters (unless expressly indicated otherwise in this Agreement). The JSC shall be responsible for (i) reviewing and finally approving the Development Plans and Commercialization Plans for the Products, including any amendments thereto; (ii) resolving any disputes within the China Committee; and (iii) providing strategic guidance with respect to the Development and Commercialization of Products in the Territory.

(d) Specific Responsibilities of the China Committee. In addition to its general responsibilities, the China Committee shall have the following responsibilities in particular for the Territory, certain of which shall be subject to approval by the JSC:

(i) The following responsibilities of the China Committee shall require submission to the JSC for approval:

(1) discuss, prepare and approve for submission to the JSC for approval annual and interim amendments to the Development Plan for each Product;

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(2) propose indications for Development of Products to the JSC for approval;

(3) prepare the Development Strategy for submission to the JSC for approval;

(4) propose to the JSC for approval particular studies to be conducted;

(5) design all Clinical Trials and Nonclinical Studies recommended to the JSC to be conducted under each Development Plan, for approval by the JSC, including Phase 4 Clinical Trials and Mandatory Post-Approval Safety Studies;

(6) recommend to the JSC whether and when to initiate or discontinue any Clinical Trial and any Nonclinical Study under each Development Plan, for approval by the JSC;

(7) discuss proposals to Develop Products for other indications and submit such proposals to the JSC for approval;

(8) recommend to the JSC a publication strategy for publications and presentations related to the Product in the Territory;

(9) discuss, review and approve for submission to the JSC for approval the Commercialization Plan for each Product in the Territory, including any amendments thereto;

(10) discuss and prepare, for approval by the JSC, the calculation of Net Profit as prepared by the Finance Subcommittee, as set forth in **Exhibit D**; and

(11) subject to JSC approval, determine the amount of Product to be distributed free of charge in the Territory annually for regulatory or marketing purposes or investigator-initiated trials.

(ii) The following responsibilities of the China Committee shall be conducted and approved at the China Committee level and not subject to JSC approval (but may, for clarity, be submitted to the JSC for resolution of disputes pursuant to Section 2.2(e)):

(1) implement the Development Plan;

(2) oversee the conduct of Development according to the Development Plan;

(3) allocate budgeted resources and determine priorities for each Clinical Trial and Nonclinical Study under each Development Plan, including Phase 4 Clinical Trials;

(4) oversee the conduct of (A) all Clinical Trials and Nonclinical Studies under each Development Plan, including Phase 4 Clinical Trials, and (B) Mandatory Post-Approval Safety Studies;

(5) review the qualifications of Third Party contractors selected by FibroGen China to conduct Clinical Trials of Products (provided that such review does not include an approval right);

(6) facilitate the flow of Information between the Parties with respect to the Development of Products;

(7) allocate primary responsibility as between the Parties for tasks relating to Development of Products where not already specified in the Development Plan;

(8) discuss the requirements for Regulatory Approval in the Territory and oversee and coordinate regulatory matters with respect to Products in the Territory pursuant to the Development Plan;

(9) facilitate the flow of Information between the Parties with respect to obtaining Regulatory Approval for Products;

(10) form subcommittees and task forces for Development and Commercialization as required to facilitate implementation of Development and Commercialization Plans;

(11) oversee implementation of each Commercialization Plan;

(12) coordinate the Commercialization activities of FibroGen China and AstraZeneca with respect to Products, including pre-launch and post-launch activities and all activities set forth in the Co-Promotion Agreement;

(13) allocate primary responsibility as between the Parties for tasks relating to Commercialization of Products in the Territory pursuant to the Commercialization Plan;

(14) coordinate global harmonization of the Product with respect to the Territory; and

(15) attempt to resolve issues presented to it by, and disputes within, the Joint Operations Subcommittee.

(iii) In addition, the China Committee will perform such other functions as appropriate to further the purposes of this Agreement, as directed by the JSC.

(e) **Decision-Making.** The China Committee shall act by consensus. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party. If the China Committee cannot reach consensus on an issue that comes before the China Committee and

over which the China Committee has oversight, then the Parties shall refer such matter to (A) during the term of the U.S. and RoW Agreement, the JSC for resolution in accordance with the U.S. and RoW Agreement (including escalation to the Executive Officers pursuant to Section 2.6(c) thereof) and (B) after the expiration or termination of the U.S. and RoW Agreement, the Executive Officers; provided that:

(i) the Executive Officer of FibroGen will have final say with respect to (1) Development of Products in China (including the Development Budget) and (2) conduct of the Mandatory Post-Approval Safety Studies, including the Mandatory Post-Approval Safety Study Costs included in the Commercialization Budget and (3) governmental pricing negotiations to establish the maximum allowable retail price; and

(ii) the Executive Officer of AstraZeneca will have final say with respect to Commercialization of Products in China (including the Commercialization Budget and management of commercial discounting process), subject to Article 6, other than the Mandatory Post-Approval Safety Studies and Mandatory Post-Approval Safety Study Costs; and

(iii) disputes with respect to whether a Technical Product Failure as defined in Section 1.106(a) has occurred will be resolved pursuant to Section 14.8 if the Executive Officers fail to reach consensus.

(f) Good Faith. In conducting themselves on the China Committee, and in exercising their rights under this Section 2.2, all representatives of both Parties shall consider diligently, reasonably and in good faith all input received from the other Party, and shall use reasonable efforts to reach consensus on all matters before them.

2.3 Finance Subcommittee. Through the Finance Subcommittee, FibroGen China shall provide AstraZeneca with regular updates of the financial condition of FibroGen WFOE in accordance with **Exhibit D**.

2.4 Appointment of Alliance Managers. Each Party shall appoint a single person(s) who shall oversee contact between the Parties for all matters between meetings of the China Committee and shall have such other responsibilities as the Parties may agree in writing after the Effective Date (such person, the "**Alliance Manager**"). Each Party may replace its Alliance Manager at any time by notice in writing to the other Party. The Alliance Managers shall work together to manage and facilitate the communication between the Parties under this Agreement, including the resolution (in accordance with the terms of this Agreement) of issues between the Parties that arise in connection with this Agreement. The Alliance Managers shall not have final decision-making authority with respect to any matter under this Agreement.

2.5 General Committee Authority. Each Committee shall have solely the powers expressly assigned to it in this Article 2 (or as delegated to it by the JSC or China Committee) and elsewhere in this Agreement. No Committee shall have any power to amend, modify, or waive compliance with this Agreement (or any agreement entered into in connection with this Agreement). It is expressly understood and agreed that the control of decision-making authority pursuant to Section 2.2(e), so as to resolve a disagreement or deadlock on the China Committee

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for any matter will not authorize either Party to perform any function not delegated to the China Committee, and that neither FibroGen China nor AstraZeneca shall have any right to unilaterally modify or amend, or waive its own compliance with, the terms of this Agreement or the approval requirements of the JSC.

2.6 Executive Meetings. No less than once per Calendar Year, FibroGen Cayman's Chief Executive Officer and AstraZeneca's Marketing Company President will meet in advance of the occurrence of key scheduled Development and Commercialization events or in connection with key decisions, to review and discuss the status and direction of the collaboration in the Territory.

2.7 Discontinuation of Participation on a Committee. Each Committee shall continue to exist until the first to occur of (a) the Parties mutually agreeing to disband the Committee, or (b) FibroGen China providing to AstraZeneca written notice of its intention to disband and no longer participate in such Committee, which FibroGen China retains the right to do at any time during the Term, in its sole discretion; provided, however, that doing so shall not relieve FibroGen China of any of its obligations under this Agreement (save from the obligation to participate at the relevant Committee meetings). Once FibroGen China has provided written notice as referred to in subsection (b) above, such Committee shall have no further obligations under this Agreement and AstraZeneca shall have the right to solely decide, without consultation, any matters previously before such Committee, subject to the other terms of this Agreement.

ARTICLE 3

DEVELOPMENT

3.1 Overview. The Parties agree to undertake a development program to further Develop the Collaboration Compounds and Products in the Territory as provided in this Article 3 under plans and budgets approved by the JSC and implemented under the direction of the China Committee.

3.2 Development Plans.

(a) General. All Development of any given Product pursuant to this Agreement for the Territory shall be conducted pursuant to a development plan (the **"Development Plan"**) that describes (i) the proposed overall program of Development for the applicable Product and indications in the Territory, including Clinical Trials and Nonclinical Studies, toxicology, formulation, and packaging development, process and analytical development, regulatory plans and other elements of obtaining Regulatory Approval(s); (ii) the anticipated start dates and data availability dates of such Clinical Trials and Nonclinical Studies and chemistry, manufacturing and controls development activities, and timelines for key Regulatory Authority meetings, filing of applications for Regulatory Approval, and the receipt of Regulatory Approvals; and (iii) the respective roles and responsibilities of each Party in connection with such activities. The Development Plan will be associated with a detailed budget for all such activities proposed to be conducted by FibroGen China and AstraZeneca. In the event of any

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inconsistency between the Development Plan and this Agreement, the terms of this Agreement shall prevail.

(b) Initial Development Plan. The initial Development Plan, along with the associated Development Budget (which includes amounts reimbursed under Section 8.2), describing the Development of the Product for the CKD Indications for the Territory, is attached hereto as **Exhibit E** (the **"Initial Development Plan"**). The Parties acknowledge and agree that they will not withhold approval to any amendments to the Initial Development Plan resulting from requirements or recommendations of the CFDA or any other Governmental Authority in the Territory.

(c) Development Strategy. Within one (1) year after the Effective Date or at such other time as the Parties may mutually agree, the China Committee will prepare an overall development strategy for the Product in the Field in the Territory including the indications (or other life cycle management) the Parties are considering to develop (or conduct) throughout the Territory, which strategy will include the anticipated dates (estimated based on the date of completion of certain development events) for preparing detailed descriptions of applicable events for inclusion in an amended Development Plan (the **"Development Strategy**"). The Development Strategy will include reasonable timelines for any additional indications to be developed hereunder, with the understanding that not all such indications will be developed concurrently.

(d) Amendments to the Development Plan.

(i) On an annual basis (no later than September 30th of the preceding Calendar Year), or more often as the Parties deem appropriate, the China Committee shall prepare amendments to the then-current Development Plan and budget for approval of the JSC as appropriate. Each such amended Development Plan shall specify, with a reasonable level of detail, the items described in Section 3.2(a). Such amended Development Plan shall cover the next Calendar Year (and additional periods as reasonably determined by the Parties) and shall contain a corresponding budget. Such updated and amended Development Plan shall reflect any changes, re-prioritization of studies within, reallocation of resources with respect to, or additions to the then-current Development Plan. In addition, the China Committee may prepare amendments for approval of the JSC to the Development Plan and corresponding Development Budget from time to time during the Calendar Year in order to reflect changes in such plan and budget for such Calendar Year, in each case, in accordance with the foregoing. At the request of either Party, but no more frequently than quarterly, the China Committee shall review the Development Budget and propose any necessary amendments to the JSC for approval. Once approved by the JSC, the amended annual Development Plan and Development Budget shall become effective for the applicable period on the date approved by the JSC (or such other date as the JSC shall specify). Any JSC-approved amended Development Plan and Development Budget shall supersede the previous Development Plan and Development Budget for the applicable period.

(ii) Each Party shall notify the other Party promptly upon becoming aware that it is likely to exceed, or has exceeded, the budget for a particular Calendar Year or Calendar Quarter in the Development Budget. Thereafter, the China Committee shall promptly meet and determine whether to submit to the JSC an amendment to the Development Plan or

Development Budget accordingly, provided that the China Committee and the JSC shall not unreasonably withhold agreement to any budget amendment proposed by either Party that results from causes outside of such Party's reasonable control or that the Parties agree includes expenses reasonably incurred in the performance of the Development Plan.

(iii) The Parties agree that the total amount of the Development Budget in the Initial Development Plan from January 1, 2013 through expected launch in the second half of 2016 (including those amounts reimbursed under Section 8.2), may not be increased without the approval of the Parties or by the JSC.

(e) Development Responsibilities. Unless the Parties agree in writing upon an alternate allocation of responsibility, FibroGen China shall be responsible for conducting the Clinical Trials under the Development Plan in accordance with GCP and all applicable laws and regulations. The Development Plan shall specify success criteria and a timetable for the completion of such Clinical Trials.

(i) CROs. FibroGen China shall ensure any such Clinical Trials are conducted through a FibroGen China Affiliate incorporated in the Territory. In the event that FibroGen China engages a Third Party contract research organization ("**CRO**") to undertake any Clinical Trial (or any portion of any Clinical Trial), FibroGen China shall ensure that such CRO is qualified in the Territory and capable of producing data acceptable to the CFDA and other applicable Regulatory Authorities in the Territory. FibroGen China shall discuss any possible engagement of a CRO with the China Committee. FibroGen China shall ensure that any Clinical Trials conducted in China shall be conducted only at hospitals that are accredited by the CFDA.

(ii) Medical Scientific Liaisons. FibroGen China shall be responsible for conducting activities related to the education of physicians regarding the Field and the Products in the Territory in accordance with the Development Plan and, following Regulatory Approval, Commercialization Plan. The costs associated with such activities shall be deemed Development Costs or Commercialization Costs, as applicable.

(iii) Decision Making. Except as otherwise expressly provided in this Agreement, all matters regarding the Development Plan shall be decided by consensus by the China Committee.

(f) Additional Indications in the Field. If either Party desires to develop a Product in an indication in the Field not then included in the Development Plan or Development Strategy, such Party shall propose such indication to the other Party. The Parties shall thereafter discuss such indication in good faith and, if so agreed, prepare a proposed development plan and budget for development in such indication for submission to the JSC. Upon approval by the JSC, such plan and budget shall be included in the Development Plan and Development Budget. For clarity, the Parties shall not have the right to develop a Product for the Territory in any indication outside the Field.

3.3 Development Costs. The Parties shall share equally all Development Costs the Parties incur in the conduct of the Development Plan (to the extent that such Development Costs

are not reimbursed by Astellas under the Astellas Agreements) as provided in Section 8.5, including costs for supply of Collaboration Compound or Product as provided in Section 6.6. Notwithstanding the foregoing, unless otherwise agreed by the China Committee or by the Parties, either before or after the applicable expense is incurred (which agreement shall not be unreasonably withheld for any budget overage outside of a Party's reasonable control and reasonably incurred in the performance of the Development Plan), for any Calendar Quarter, each Party will be solely responsible for Development Costs in excess of one hundred [*] percent ([*]%) of the total amount allocated to such Party's activities in such Calendar Quarter in the Development Budget, and for any Calendar Year, each Party will be solely responsible for Development Costs in excess of one hundred [*] percent ([*]%) of the total amount allocated to such Party's activities in such Calendar Year in the Development Budget; provided that Development Costs incurred in excess of one hundred [*] percent ([*]%) for the Calendar Quarter or one hundred [*] percent ([*]%) for the Calendar Year, as applicable, of the amounts so budgeted shall also be included in Development Costs and shared by the Parties if the Parties determine in good faith that such development costs were reasonably incurred in the performance of activities under the Development Plan and that such budget overage was caused by circumstances outside of such Party's reasonable control.

3.4 Probe Compounds.

(a) Subject to AstraZeneca's option as described below in this Section 3.4, FibroGen China shall have the sole right and responsibility for Development and Commercialization of all Probe Compounds in the Field, subject to the remainder of this Section 3.4; provided that FibroGen China shall have the right to Develop and Commercialize Probe Compounds as set forth below notwithstanding Section 7.5:

(i) With respect to the first two indications in the Field that are neither (1) Core Indications nor (2) any other indications being developed under the U.S. and RoW Agreement, but including [*] (the "**Innovation Indications**"), FibroGen China shall notify AstraZeneca in writing before conducting the first Clinical Trial of a Probe Compound in such Innovation Indication, including providing data and information in support of such Clinical Trial. AstraZeneca may elect within thirty (30) days after such notice either (y) to have the [*] such Probe Compound shall become a Collaboration Compound under this Agreement; or (z) [*], AstraZeneca may elect to have such Probe Compound become a Collaboration Compound hereunder (the "**Probe Compound Option**") by providing FibroGen Cayman a notice of exercise and [*] such Probe Compound shall become a Collaboration Compound under this Agreement. Any such Probe Compound in the Innovation Indications that becomes a Collaboration Compound shall thereafter be subject to (A) sharing of Development Costs and Commercialization Costs under Sections 8.5 and 8.6 and (B) [*]. In addition, AstraZeneca shall reimburse FibroGen China for its development costs that are reasonably allocable to the development of the Probe Compound in the applicable indication and incurred prior to the date of amendment of this Agreement adding the Probe Compound as a Collaboration Compound plus [*] of such Development Costs. If AstraZeneca does not timely exercise the Probe Compound Option for a Probe Compound in an Innovation Indication, then FibroGen China shall be free to further Develop and Commercialize such Probe Compound alone or with or through a Third Party licensee in the Territory; provided however that if FibroGen China has not licensed such Probe Compound to a Third Party within

[*] after expiration of the Probe Compound Option, then the Probe Compound Option shall be reinstated for such Probe Compound with respect to any subsequent Clinical Trials then being conducted or planned to be conducted at the time of reinstatement of the Probe Compound Option.

(b) With respect to Probe Compounds (including, for clarity, a Probe Compound that has become Collaboration Compound as a result of AstraZeneca's exercise of the Probe Compound Option) being developed for indications other than the two (2) Innovation Indications (the "**Remaining Innovation Indications**"), following completion and delivery to AstraZeneca from FibroGen China of a reasonably detailed data and information package regarding either: (A) a proof of concept study or (B) a dose-defining Clinical Trial, for a Probe Compound in any Remaining Innovation Indication, AstraZeneca shall have ninety (90) days following delivery of such data and information package to review, request additional information regarding such Clinical Trial results and negotiate and agree with FibroGen China upon a proposed Development Plan and Development Budget for such Probe Compound, as well as milestones for further Development and Commercialization of such Probe Compound as a Product. If the Parties reach agreement upon the Development Plan and Development Budget and such additional milestones within such ninety (90)-day period, then the Parties shall amend this Agreement accordingly, and AstraZeneca shall reimburse FibroGen China for its development costs that are reasonably allocable to the development of the Probe Compound in the applicable indication and incurred prior to the date of amendment of this Agreement adding the Probe Compound as a Collaboration Compound plus [*] of such Development Costs. If the Parties are unable to reach agreement in the ninety (90) days following the triggering of the Probe Compound Option, then FibroGen China shall be free to further Develop and Commercialize such Probe Compound alone or with or through a Third Party Sublicensee in the Territory; provided however that such Probe Compound shall not in any event be further Developed or Commercialized in any indication prohibited under Section 7.5(a)(ii).

3.5 Additional HIF Compounds. If AstraZeneca wishes to include additional HIF Compounds that are not Probe Compounds as Collaboration Compounds under this Agreement, it may make such a request to FibroGen China. Upon receipt of such request, FibroGen China shall make good faith and diligent efforts to present to the JSC for review all reasonably relevant data and other information (excluding chemical structures) Controlled by FibroGen China that is related to those HIF Compounds from its library of HIF Compounds, including results from any Clinical Trial conducted in the Field. For clarity, the foregoing does not impose any obligation on FibroGen China to identify or generate any additional HIF Compounds. If AstraZeneca and FibroGen China, through the China Committee and JSC, agree upon a development program for any such HIF Compounds, then the Parties shall negotiate upfront and milestone payment terms for inclusion of such additional HIF Compounds as Collaboration Compounds, and upon agreement, will amend this Agreement accordingly.

3.6 Diligence; Standards of Conduct. Each Party shall use Commercially Reasonable Efforts to carry out the tasks assigned to it under the Development Plan in a timely and effective manner. Each Party shall conduct its activities under the Development Plan in a good scientific manner and in compliance in all material respects with all applicable laws and regulations. Without prejudice to the aforesaid, the Party responsible for the conduct of any Clinical Trials hereunder shall perform such Clinical Trials in a good scientific manner, in compliance with all applicable

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laws and regulations, GCP, this Agreement, the Development Plan as well as the relevant protocol and investigator's brochure. Such Party shall further require the principal investigators, study sites and any contractors involved in the performance of such Clinical Trials to comply with all safety reporting procedures set forth in the Pharmacovigilance Agreement in connection with their performance of such Clinical Trials.

3.7 Development Data.

(a) Ownership and Disclosure. FibroGen Cayman shall solely own all data, records and reports generated by or on behalf of either Party in the conduct of Development activities under this Agreement (collectively, the "**Development Data**"), and AstraZeneca hereby assigns, and shall assign, to FibroGen Cayman, all of its right, title and interest in and to the Development Data. Each Party shall provide access to and, where practical, copies of the Development Data it (or its Affiliates or Sublicensees, or Third Parties acting on their behalf) generates to the other Party promptly upon receipt or development thereof, including nonclinical and clinical data (including raw data), analysis, reports and protocols. Each Party will reasonably respond to the other Party's request for access to and questions about the Development Data. Such Development Data will be provided in electronic form if requested by the other Party or reasonably convertible to such electronic form.

(b) Use. Each Party shall have the right to use the Development Data for the purpose of Developing and Commercializing Products in the Field in the Territory in accordance with the terms of this Agreement. In addition, FibroGen China will have the right to use the Development Data for the purpose of developing and commercializing Products outside the Territory, and to transfer such Development Data to its licensees outside the Territory, and to grant such licensees the right to use the Development Data for such purpose outside the Territory. AstraZeneca hereby grants FibroGen China and its Affiliates and licensees a right of access, a right of reference and a right to use and incorporate all Development Data and relevant Regulatory Materials in any regulatory filings for Products outside the Territory. AstraZeneca will take all actions reasonably requested by FibroGen China, at FibroGen China's cost, to enable FibroGen China and its licensees to practice such rights.

3.8 Development Records and Reports. Each Party shall maintain or cause to be maintained complete and accurate records (in the form of technical notebooks and/or electronic files where appropriate) of all work conducted by it or on its behalf under the Development Plan and all Information resulting from such work. Such records, including any electronic files where such Information may also be contained, shall fully and properly reflect all work done and results achieved in the performance of the Development Plan in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. Such records shall be retained by such Party for at least five (5) years after the term of this Agreement or such longer period as may be required by applicable laws. Each Party shall have the right to review and copy such records maintained by the other Party at reasonable times and to obtain access to originals to the extent needed for patent or regulatory purposes or for other legal proceedings. Each Party shall provide the China Committee with quarterly reports detailing its Development activities under the Development Plan and the results of such activities.

3.9 Subcontracts. Each Party may perform any of its Development Program obligations under this Agreement through one or more subcontractors or consultants, including CROs in accordance with Section 3.2(e)(i), provided that (a) such Party remains responsible for the work allocated to, and payment to, such subcontractors and consultants as it selects to the same extent it would if it had done such work itself; (b) the subcontractor undertakes in writing obligations of confidentiality and non-use regarding Confidential Information, that are substantially the same as those undertaken by the Parties pursuant to Article 12 hereof, and (c) the subcontractor agrees in writing to assign all intellectual property developed in the course of performing any such work under the Development Program to the Party retaining such subcontractor. A Party may also subcontract work on terms other than those set forth in this Section 3.9, with the prior approval of the China Committee.

ARTICLE 4

REGULATORY MATTERS

4.1 Regulatory Filings and Approvals.

(a) In General. The Parties intend that the Development Plan will set forth the regulatory strategy for seeking Regulatory Approvals (including any pricing and reimbursement approvals) in the Territory for all Products being Developed.

(b) Responsibilities. FibroGen China shall be responsible for preparing and filing all Regulatory Materials, including CTAs, shall be the holder of all Regulatory Approvals in the Territory and will have primary operational responsibility for interactions with Regulatory Authorities, including taking the lead role at all meetings with Regulatory Authorities, subject to the right of AstraZeneca to participate as an observer in such activities and provide input, which FibroGen China will consider in good faith. Without limitation, this observer right includes participation in all regulatory activities, including development of regulatory strategy and review of regulatory submissions, observer status at all meetings with Regulatory Authorities that may potentially impact the Development Plan or registration package for a particular Product, and review of outcomes of such meetings.

(c) Reporting and Review.

(i) The China Committee shall develop and implement procedures for drafting and review of Regulatory Materials for Products in the Territory, which shall provide sufficient time (at least one week) for each Party to provide substantive comments prior to the filing of such Regulatory Materials.

(ii) Each Party shall promptly notify the other Party of all Regulatory Materials that it submits for Products in the Territory and shall promptly (and in any event within one week) provide the non-responsible Party with a copy (which may be wholly or partly in electronic form) of such Regulatory Materials throughout the Territory. The Party primarily responsible for such Regulatory Materials will provide the non-responsible Party with reasonable advance notice of any scheduled meeting with any Regulatory Authority and/or any Regulatory

Materials with respect to Products throughout the Territory, and the non-responsible Party shall have the right to participate as an observer in any such meeting, except to the extent prohibited under applicable law and regulations. Representatives of the Party primarily responsible for such Regulatory Materials will be the primary spokespeople at any such meeting. The Party primarily responsible for such Regulatory Materials also shall promptly furnish the non-responsible Party with copies of all material correspondence to or from, and minutes of material meetings with, any Regulatory Authority relating to Development of such Product.

4.2 Notification of Threatened Action. Each Party shall immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from any Third Party, including a Regulatory Authority, which may materially affect the Development, Commercialization or regulatory status of a Product in the Territory. Upon receipt of such information, the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

4.3 Adverse Event Reporting and Safety Data Exchange. At a time determined by the JSC, but in any event prior to the commencement of any Clinical Trial or any other activities that would generate safety data required to be reported to Regulatory Authorities that are conducted by AstraZeneca, the Parties shall define and finalize the methods and procedures (based on and consistent with those methods and procedures used by Astellas and FibroGen under the Astellas Agreements) that the Parties shall employ with respect to Products and to Probe Compounds independently Developed and Commercialized by FibroGen China to protect patient safety and promote the appropriate treatment of safety information of such products in a written pharmacovigilance agreement (the "**Pharmacovigilance Agreement**"). For clarity, the Pharmacovigilance Agreement shall include all relevant safety data regarding the Product, irrespective of territory or indication. These responsibilities shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports, pregnancy reports, and any other information concerning the safety of any such product in the Territory. Such guidelines and procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under applicable laws and regulations. Furthermore, such agreed procedure shall be consistent with GCP and relevant ICH guidelines, except where such guidelines may conflict with existing local regulatory reporting or safety reporting requirements, in which case the local reporting requirements shall prevail. FibroGen China shall maintain a safety database for the Products in the Territory, the expenses for which will be included in Development Costs. FibroGen China shall be responsible for reporting quality complaints, adverse events and safety data related to Products to applicable Regulatory Authorities in the Territory, as well as responding to safety issues and to all requests of Regulatory Authorities relating to Products in the Territory. Each Party hereby agrees to comply with its respective obligations under such Pharmacovigilance Agreement and to cause its Affiliates and permitted Sublicensees to comply with such obligations.

4.4 Product Withdrawals and Recalls. If any Regulatory Authority in the Territory (a) threatens, initiates or advises any action to remove any Product from the market or (b) requires or advises FibroGen China, AstraZeneca, or any of their respective Affiliates or Sublicensees to distribute a "Dear Doctor" letter or its equivalent regarding use of such Product, then FibroGen

China or AstraZeneca, as applicable, shall notify the other Party of such event within three (3) Business Days (or sooner if required by law) after such Party becomes aware of the action, threat, advice or requirement (as applicable). The JSC will discuss and attempt to agree upon whether to recall or withdraw a Product in the Territory; provided, however, that if the Parties fail to agree within an appropriate time period, the Party who is the then-holder of the Regulatory Approval for the Product at issue shall decide whether to recall or withdraw such Product and shall be responsible for such recall or withdrawal, with the associated costs being deemed Development Costs.

ARTICLE 5

COMMERCIALIZATION

5.1 Overview. The Parties agree to Co-Promote the Products in the Field in the Territory as provided in this Article 5 under the direction of the China Committee, and pursuant to the Commercialization Plan applicable to each Product. Within twelve (12) months after the Effective Date or at such other time as the Parties may mutually agree, the Parties or their designated Affiliates in the Territory will negotiate and enter into an agreement (the "**Co-Promotion Agreement**") governing the Parties' conduct of activities for Commercializing the Product in the Territory, including the terms set forth on **Exhibit C** hereto.

5.2 Commercialization Plans and Budget. As further described in this Section 5.2, the strategy for the Commercialization of each Product in the Territory shall be described in a comprehensive plan that describes the pre-launch, launch and subsequent Commercialization of such Product in the Territory (including without limitation messaging, branding, pricing, advertising, planning, marketing, sales force training and allocation, and reimbursement/managed care), key tactics for implementing those activities and the relative responsibilities of the Parties (each such plan, a **"Commercialization Plan"**), and the associated budget for such activities (each such budget, a **"Commercialization Budget"**). The Mandatory Post-Approval Safety Study Costs in the Commercialization Budget shall be reasonably determined by FibroGen WFOE in light of the applicable requirements for the Mandatory Post-Approval Safety Studies. All Commercialization Plans and Commercialization Budgets with respect to Products in the Territory and subsequent revisions thereto will contain such information as the China Committee believes necessary for the successful Commercialization of such Product in the Territory. Within thirty (30) days after the Effective Date, the Parties shall prepare an initial high-level Commercialization Plan for review and approval by the China Committee and JSC. Within twelve (12) months after the Effective Date (or at another time as soon as reasonably practicable thereafter as the Parties may mutually agree), the Parties shall prepare a detailed Commercialization Plan for review and approval by the China Committee and JSC.

5.3 Responsibilities. Except as otherwise described in the Commercialization Plan or the Co-Promotion Agreement, AstraZeneca or its designated Affiliate shall have the sole right and responsibility for distribution of Products in the Territory on behalf of FibroGen China pursuant to the terms of the Distribution Agreement to be entered into by the Parties as soon as practicable after the Effective Date. The key terms of the Distribution Agreement are described in **Exhibit F**. In addition, the Distribution Agreement will contain representations, warranties and covenants by

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AstraZeneca and its applicable Affiliates that are equivalent to the representations, warranties and covenants in Section 10.4. FibroGen China shall have the right to conduct commercial activities related to Product containing FG-4592 to the extent sufficient to demonstrate substance in Hong Kong in order to benefit from preferential tax treatment on withholding taxes under the applicable China–Hong Kong tax treaties; provided that such activities shall not include Product distribution.

5.4 Commercialization Reports. Each Party shall keep the China Committee fully informed regarding the progress and results of Commercialization activities for Products in the Territory, including an annual review of results versus plans (as set forth in the Commercialization Plan(s)).

5.5 Samples. Neither Party shall distribute any samples of Products without the prior written consent of the other Party.

5.6 Diligence; Subcontracts. Each Party shall use Commercially Reasonable Efforts to carry out the tasks assigned to it under the Commercialization Plan and the Co-Promotion Agreement in a timely and effective manner and in compliance with all applicable laws and regulations. Each Party may perform any of its obligations under the Commercialization Plan through one or more subcontractors or consultants, provided that (a) such Party remains responsible for the work allocated to, and payment to, such subcontractors and consultants as it selects to the same extent it would if it had done such work itself; (b) the subcontractor undertakes in writing obligations of confidentiality and non-use regarding Confidential Information, that are substantially the same as those undertaken by the Parties pursuant to Article 12 hereof, and (c) the subcontractor agrees in writing to assign all intellectual property developed in the course of performing any such work under the Commercialization Plan to the Party retaining such subcontractor.

5.7 Regulatory Compliance.

(a) Each of FibroGen China and AstraZeneca shall reasonably cooperate with the other Party in its efforts toward ensuring that all government reporting (including price and gift reporting), sales, marketing and promotional practices in respect of each Product meet the standards required by (A) the Drug Administration Law, (B) the Anti-unfair Competition Law of the PRC, (C) the Advertising Law of the PRC, the Standards for the Review and Publication of Drug Advertisement issued by the CFDA and the State Administration of Industry and Commerce, (D) the Code of Practice of the China Association of Enterprise with Foreign Investment R&D-Based Pharmaceutical Association Committee, (E) the Anti-Corruption Laws, and (F) other applicable laws and regulations.

(b) In accordance with Section 5.7(a), each Party shall provide its sales representatives appropriate training on proper marketing and sales techniques. Such training will include, among other topics, CFDA requirements and other national and local regulations and industry guidelines, including those set forth in clause (a) above. If requested by a Party, the other Party shall provide a written description of the training to the requesting Party no less frequently than on an annual basis.

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(c) Each of FibroGen China and AstraZeneca shall reasonably cooperate with the other Party to provide the other Party access to any and all information, data and reports required by the other in order to comply with the relevant provisions of any applicable laws and regulations, including without limitation reporting requirements, in a timely and appropriate manner. Each Party shall ensure that its reporting to the state and local healthcare programs related to the Products is true, complete and correct in all respects; provided however, that a Party shall not be held responsible for submitting erroneous reports if such deficiencies result from information provided by the other Party which itself was not true, complete and correct.

(d) AstraZeneca shall, so far as practicable, provide to FibroGen China in advance any submission containing any information provided by FibroGen China pursuant to this Section 5.7 that AstraZeneca proposes to submit to any Regulatory Authority. AstraZeneca further agrees to seek confidential treatment of any such information related to FibroGen China that it submits to any governmental entity to the extent permitted under any applicable laws and regulations.

(e) FibroGen China and AstraZeneca shall confer with each other on a regular basis to discuss and compare their respective procedures and methodologies relating to each Party's compliance to any applicable laws or regulations or fulfillment of any other obligation contained in this Section 5.7. In the event that the Parties have different understandings or interpretations of this Section 5.7 or of the applicability of, or standards required by, any applicable laws or regulations, then the Parties shall confer and seek to reach common agreement on such matters.

(f) Each Party agrees that:

(i) it will instruct its sales representatives to use, and will use Commercially Reasonable Efforts to train and monitor its sales representatives to ensure that such sales representatives use, only Promotional Materials and literature approved for use under Section 5.7 for the promotion of the Products in the Territory;

(ii) it will instruct its sales representatives not to misbrand, change, alter or adulterate any Promotional Materials supplied to it in any way prior to or during their distribution or use; and

(iii) it will instruct its sales representatives to do, and will use Commercially Reasonable Efforts to train its sales representatives to do, and will establish appropriate internal systems, policies and procedures for the monitoring of its sales representatives with the goal of ensuring that such personnel do, the following:

(1) limit claims of efficacy and safety for the Products to those that are (A) consistent with approved promotional claims in, and not add, delete or modify claims of efficacy and safety in the promotion of such Products in any respect from those claims of efficacy and safety that are contained in, the then effective Commercialization Plan, (B) consistent with applicable laws and regulations, and (C) consistent with the Product labeling approved by the Regulatory Authorities;

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(2) not make any changes in Promotional Materials, and use Promotional Materials within the Territory only in a manner that is consistent with (A) the then effective Commercialization Plan, (B) applicable laws and regulations and (C) the Product labeling approved by the Regulatory Authorities;

(3) promote the Products in compliance with applicable legal and professional standards that are generally accepted by the pharmaceutical industry in the applicable market, including applicable laws and regulations and the applicable guidelines concerning the advertising and promotion of prescription drug products described in Section 5.7; and

(4) not to, directly or indirectly, pay, promise to pay, or authorize the payment of any money, or give, promise to give, or authorize the giving of anything of value to any healthcare professional, official or employee of any Governmental Authority, or to any political party, or official thereof, or to any candidate for political office (including any party, official, or candidate) for the purpose of promoting the sale or improper use of a Product.

ARTICLE 6

MANUFACTURE AND SUPPLY

6.1 Supply Commitment. AstraZeneca agrees to purchase, and FibroGen WFOE agrees to supply, all of AstraZeneca's and its Sublicensees' requirements of Product for Development and Commercialization in the Territory under the terms of this Article 6 and in accordance with this Agreement. All Product supplied to AstraZeneca by or on behalf of FibroGen WFOE under this Agreement will be supplied as finished product.

6.2 Covenant. Except as expressly set forth in this Article 6 or the Supply and Quality Agreement or the U.S. and RoW Agreement, AstraZeneca shall not have the right to manufacture any Product anywhere in the world.

6.3 Second Source for Drug Substance. At a time to be determined by the JSC, FibroGen WFOE will complete activities to establish and secure Regulatory Approval for a second source for drug substance for Product using a Third Party supplier reasonably acceptable to AstraZeneca, and will thereafter maintain two separate, validated manufacturing sites for such drug substance, one of which will be FibroGen WFOE's Beijing plant.

6.4 Selection of Contract Manufacturer for Drug Product. Upon AstraZeneca's written request to FibroGen WFOE, which request shall not be submitted earlier than six (6) months after the Effective Date, the Parties will discuss in good faith the selection of a contract manufacturer to be used by FibroGen WFOE to conduct formulation and packaging (using drug substance supplied by FibroGen WFOE) for supply under this Agreement. The Parties shall discuss in good faith the introduction of such contract manufacturer into the supply chain when capacity at FibroGen WFOE's Beijing plant becomes fully occupied. Such selection will be conducted in accordance with the following process: As soon as reasonably practicable following AstraZeneca's request, the Parties will afford an opportunity for at least two (2) different Third

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Party contract manufacturers that are mutually acceptable to the Parties, consent not to be unreasonably withheld, to submit bids to conduct such manufacture. Such bids shall be based on a request for quotation, the contents of which shall be agreed by the Parties in good faith (and shall contain such specifications and forecasts as are reasonably necessary for a contract manufacturer to submit a bid with respect to such manufacture). AstraZeneca shall be afforded an opportunity to submit a bid on the same basis as the Third Party contract manufacturers. The Parties shall review and assess in good faith the bids submitted by the Third Party manufacturers and by AstraZeneca and shall recommend to the China Committee the bid that, on the whole, offers the most favorable terms for such manufacture of Product for supply to AstraZeneca under this Agreement, based on a reasonable assessment of the relevant factors, including price, capital requirements, quality, capacity and capability to maintain continuity of supplies. FibroGen WFOE will enter into a supply and quality contract with the Third Party contract manufacturer or (as the case may be) with AstraZeneca, whichever submitted the bid selected by the China Committee, on terms consistent with the selected bid and otherwise reasonably acceptable to FibroGen WFOE. In the event FibroGen WFOE shall contract with AstraZeneca in accordance with this Section 6.4, FibroGen WFOE shall, as soon as reasonably practicable after the completion of the selection process, provide the necessary technology transfer and royalty free licenses (if any) as well as all necessary assistance to obtain required Regulatory Approvals, all to enable AstraZeneca to conduct the formulation and packaging (using drug substance supplied by FibroGen WFOE) for supply of Product under this Agreement. If AstraZeneca is not selected as the contract manufacturer, then at any time after the [*], then AstraZeneca may request that the selection process set out above in this Section 6.4 shall be repeated. If AstraZeneca so requests, the Parties shall repeat such process, but only after the end of the then-current term of the then-current supply agreement with the Third Party manufacturer.

6.5 Supply and Quality Agreement. At a time agreed by the Parties that is reasonably sufficiently early enough to meet the objectives under this Section 6.5, the Parties will negotiate in good faith and enter into separate supply and quality agreements governing the commercial supply of finished product from FibroGen WFOE to AstraZeneca (the "**Supply and Quality Agreement**"). Such agreements will reflect the terms and conditions set forth on **Exhibit K** of the U.S. and RoW Agreement and contain such further commercially reasonable terms governing similar supply arrangements and other terms as the Parties may agree, including appropriate forecasting and firm purchase order lead times, taking into consideration the reasonable notice requirements of FibroGen WFOE and its Third Party manufacturers as well as any other terms set forth in this Article 6. In the event of any inconsistency between the Supply and Quality Agreement and Article 6 of this Agreement with regard to matters relating to supply, quality control and quality assurance, the terms of the Supply and Quality Agreement shall prevail.

6.6 Product Price. As further described in the Supply and Quality Agreement, prior to establishment of a Product price as approved by the applicable Regulatory Authority, the Parties will determine in good faith an estimated price per unit of Product for the supply of Product to AstraZeneca based on the then-current Commercialization Plan. Once such price is established, the price approved by the applicable Regulatory Authority will be used for such supply, and the Parties shall reconcile the estimated price with the actual price by means of a credit or additional payment, as applicable. Thereafter, COGS will be calculated based on [*] as set forth in the Supply and Quality Agreement.

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6.7 Potential Cost Reductions. At either Party's request during the Term (without prejudice to AstraZeneca's right to participate in the contract manufacturer selection process pursuant to Section 6.4), the Parties shall discuss and explore potential means of collaborating to reduce the overall costs of manufacture and supply of Products as drug substance or bulk drug product under this Agreement, with the understanding that the Parties shall share the financial benefits of any such cost reductions achieved in a reasonable manner taking into account to what extent each Party has contributed to such cost reductions.

6.8 Joint Operations Subcommittee. The Parties shall, within thirty (30) days following the Effective Date, establish a Joint Operations Subcommittee ("the **JOS"**) with equal representation from each Party to oversee the establishment and operation of the commercial supply chain for the Products in the Territory. The JOS shall meet each Calendar Quarter, or as otherwise agreed between the Parties. Decision making shall be by consensus and the team members from each Party shall jointly have one (1) vote. Disputes at the JOS shall be handled by the China Committee. The JOS shall have a chair selected by FibroGen China. The role of the chair shall be to convene and preside at meetings of the JOS, to prepare and circulate agendas and to ensure the preparation of minutes. The JOS' responsibilities shall include:

(i) Overseeing the construction and qualification of the FibroGen WFOE Beijing plant;
(ii) Identifying any additional resource or capabilities needed to deliver the plant;
(iii) Defining a China supply strategy for the Products in the Territory;
(iv) Carrying out the supplier selection process and recommending suitable CMOs to the China Committee;
(v) Overseeing supply chain performance for the Products in the Territory; and
(vi) Identifying, where practicable, performance improvement opportunities and agreeing, in good faith, an appropriate and equitable allocation of any financial benefits arising from such performance improvement opportunities.

ARTICLE 7

LICENSES AND EXCLUSIVITY

7.1 License to AstraZeneca. Subject to the terms and conditions of this Agreement, FibroGen Cayman hereby grants AstraZeneca a co-exclusive (with FibroGen Cayman, who retains a licensable right to develop, use, sell, offer for sale, import and Commercialize Products in the Field in the Territory), royalty-bearing, sublicensable (solely as permitted in accordance with Section 7.3) license under the FibroGen China Technology and the Marks to Develop (solely in accordance with the applicable Development Plan), use, sell, offer for sale, import and Commercialize, but not manufacture, Products in the Field in the Territory. With respect to any Product hereunder, notwithstanding the foregoing, AstraZeneca shall (a) not exercise any of the co-exclusive rights to Develop granted hereunder until FibroGen WFOE has sole ownership of and is the sole named party for the regulatory licenses in the Territory, which shall include without limitation the (i) New Drug License, (ii) Product Approval Code, (iii) Manufacturing License, and (iv) GMP License, and for such licenses any other necessary, related or successor licenses, and (b) take all actions and execute all documents reasonably necessary to ensure that FibroGen WFOE

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shall solely hold such licenses. FibroGen shall promptly notify AstraZeneca upon the issuance of such licenses.

7.2 Licenses to FibroGen China. Subject to the terms and conditions of this Agreement, AstraZeneca hereby grants FibroGen Cayman a non-exclusive, sublicensable, royalty-free, fully-paid license, under the AstraZeneca Technology during the Term, to conduct any and all activities assigned to FibroGen China under the Development Plans and Commercialization Plans, and to Develop and Commercialize Products outside of the Territory.

7.3 Sublicensing. For clarity, the license granted by FibroGen Cayman to AstraZeneca in Section 7.1 may be sublicensed by AstraZeneca to: (i) an Affiliate of AstraZeneca without any requirement of consent, provided that such sublicense to an Affiliate of AstraZeneca shall immediately terminate if and when such party ceases to be an Affiliate of AstraZeneca or (ii) a Third Party only with the prior written consent of FibroGen Cayman, except where such sublicensing is permitted under an applicable Development Plan or Commercialization Plan, in which case consent shall not be required.

7.4 Co-Promotion. Except for the co-promotion rights expressly granted to the Parties under this Agreement and except as otherwise permitted under an applicable Commercialization Plan or Co-Promotion Agreement, neither Party shall be permitted to Co-Promote the Products in the Territory with any Third Party.

7.5 Covenants by FibroGen China.

(a) Except as provided in this Agreement, including the right to Develop and Commercialize Probe Compounds in accordance with Section 3.4, during the Term, FibroGen China and its Affiliates shall not, and shall not license or authorize any Third Party to, (i) Commercialize any Product in the Territory outside the Field or (ii) develop or commercialize any HIF Compound in any ESA Approved Indication in the Territory or any indication for which a "Product" is being Developed or Commercialized under the U.S. and RoW Agreement.

(b) During the Term, the applicable Affiliate of FibroGen China shall not make any amendment to any of the Astellas Agreements that has a material adverse impact on AstraZeneca's rights under this Agreement without the prior written consent of AstraZeneca.

7.6 Cross-Territorial Restriction.

(a) Except as permitted under the U.S. and RoW Agreement, AstraZeneca hereby covenants and agrees that it shall not, and will ensure that its Sublicensees will not, either directly or indirectly, actively promote, market, distribute, import, sell or have sold Product into countries outside the Territory. As to such countries outside the Territory: (i) AstraZeneca shall not, and will ensure that its Sublicensees will not, engage in any advertising or promotional activities relating to the Product directed primarily to customers or other buyers or users of the Product located in such countries; and (ii) AstraZeneca shall not, and will ensure that its Sublicensees will not, solicit orders for Products from any prospective purchaser located in such countries. If AstraZeneca receives any order for Products from a prospective purchaser located in

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a country outside the Territory from which re-imports into the Territory are unlikely, AstraZeneca shall immediately refer that order to FibroGen Cayman. AstraZeneca shall not accept any such orders. AstraZeneca may not deliver or tender (or cause to be delivered or tendered) any Product into a country outside of the Territory from which re-imports into the Territory are unlikely. AstraZeneca shall not, and will ensure that its Affiliates and Sublicensees will not, restrict or impede in any manner FibroGen Cayman's exercise of its retained rights outside the Territory, provided that any such exercise of rights by FibroGen Cayman shall comply with the terms of this Agreement. For clarity, nothing in this Section 7.6(a) restricts or limits AstraZeneca's rights under the U.S. and RoW Agreement.

(b) Except as permitted under the U.S. and RoW Agreement, FibroGen China hereby covenants and agrees that it shall not, and will ensure that its Affiliates and Sublicensees will not, either directly or indirectly, actively promote, market, distribute, import, sell or have sold Product into countries outside the Territory. As to such countries outside the Territory: (i) FibroGen China shall not, and will ensure that its Affiliates and Sublicensees will not, engage in any advertising or promotional activities relating to the Product directed primarily to customers or other buyers or users of the Product located in such countries; and (ii) FibroGen China shall not, and will ensure that its Affiliates and Sublicensees will not, solicit orders for Products from any prospective purchaser located in such countries. If FibroGen China receives any order for Products from a prospective purchaser located in a country outside the Territory from which re-imports into the Territory are unlikely, FibroGen China shall immediately refer that order to AstraZeneca. FibroGen China shall not accept any such orders. FibroGen China may not deliver or tender (or cause to be delivered or tendered) any Product into a country outside of the Territory from which re-imports into the Territory are unlikely. FibroGen China shall not, and will ensure that its Affiliates and Sublicensees will not, restrict or impede in any manner AstraZeneca's rights within the Territory, provided that any such exercise of rights by AstraZeneca shall comply with the terms of this Agreement. For clarity, nothing in this Section 7.6(b) restricts or limits FibroGen China's rights under the U.S. and RoW Agreement.

7.7 Negative Covenant. Each Party covenants that it will not knowingly use or practice any of the other Party's intellectual property rights licensed to it under this Article 7 except for the purposes expressly permitted in the applicable license grant.

7.8 No Implied Licenses. Except as explicitly set forth in this Agreement, neither Party grants to the other Party any license, express or implied, under its intellectual property rights.

7.9 Exclusivity. AstraZeneca hereby covenants that during the Term and the term of the U.S. and RoW Agreement, except pursuant to this Agreement or the U.S. and RoW Agreement, neither it nor its Affiliates will, directly or indirectly, by itself or with a Third Party, research, manufacture, develop, sell, market or otherwise commercialize any HIF Compound in the Territory, and neither it nor its Affiliates will license or authorize a Third Party to conduct any such activity in the Territory. Notwithstanding the foregoing, AstraZeneca shall not be in breach of this Section 7.9 solely as a result of its conduct of preclinical research on HIF Compounds if such research is not part of a research program conducted by AstraZeneca.

ARTICLE 8

FINANCIALS

8.1 License Fees. AstraZeneca shall pay to FibroGen Cayman each of the following non-refundable, non-creditable license fees on or before the applicable date set forth below, provided that with respect to payment 1, FibroGen Cayman has provided an invoice on the Effective Date, and with respect to payment 2, FibroGen Cayman has provided an invoice at least forty-five (45) days before the applicable due date:

License Fees. Number	**Due Date**	**Payment**
1	15th Business Day after the Effective Date	$[*] million
2	[*]	$[*] million

If this Agreement is terminated prior to the due date of payment 2, then payment 2 shall remain due and payable. Each such payment shall be made by wire transfer of immediately available funds into an account designated by FibroGen China. Each such payment is nonrefundable and non-creditable against any other payments due hereunder.

8.2 Upfront Development Reimbursement. Within fifteen (15) Business Days after the Effective Date, AstraZeneca will pay FibroGen Cayman a one-time, non-refundable, non-creditable payment of [*] to reimburse the expenses incurred by FibroGen China to develop the Product from January 1, 2013 until the Effective Date. The applicable FibroGen China entity shall provide an invoice for such payment on the Effective Date.

8.3 Development Milestone Payments.

(a) Development Milestone Payments. AstraZeneca shall make milestone payments to FibroGen Cayman based on achievement by AstraZeneca or a Sublicensee (or, if

applicable, by FibroGen China) of the substantive development and regulatory milestones in the Territory as set forth in this Section 8.3.

Number	Milestone	Payment
1	NDA submission for a Product in the Field in the Territory	$15 million
2	First Regulatory Approval for a Product in the Field in the Territory	$6 million
3	First Manufacturing Approval for a Product in the Field in the Territory	$6 million
4	Upon Product Reimbursement in 3 Tier 1 Cities	$5 million
5	Upon Product Reimbursement in 6 Core Commercial Provinces	$7 million
6	Upon the earlier of (a) inclusion of a Product in the NRDL and (b) Product Reimbursement in 15 Provinces	$10 million
[*]	**[*]**	**[*]**

Each milestone in Section 8.3(a) shall be paid only once, without regard to whether two or more Products ultimately achieve any such milestone event.

[*].

(b) Notice; Payment. FibroGen Cayman or AstraZeneca, as applicable, will notify the other Party of the achievement of the applicable milestone event by such Party or its Affiliate or Sublicensee within forty-five days after achievement thereof. Thereafter, FibroGen Cayman shall submit an invoice to AstraZeneca, and within forty five (45) days after receipt of invoice, AstraZeneca shall pay the amounts set forth in Section 8.3(a). Each such payment shall be made by wire transfer of immediately available funds into an account designated by FibroGen Cayman. Each such payment is nonrefundable and noncreditable against any other payments due hereunder.

8.4 Sales Milestone Payments.

(a) Milestones. AstraZeneca shall make each of the substantive sales milestone payments indicated below to FibroGen Cayman when aggregate annual Net Sales of all

Products across all indications in the Field in the Territory first reach the Dollar values indicated below.

Aggregate Annual Net Sales	Payment
[*]	[*]

Each milestone in this Section 8.4(a) shall be paid only once on the first achievement of such milestone without regard to whether two or more Products ultimately achieve any such milestone event or how many times such milestone may be achieved once paid.

(b) Notice; Payment. AstraZeneca shall notify FibroGen Cayman of the achievement of each of the milestone events in Section 8.4(a) within forty-five (45) days after the end of the Calendar Quarter in which achieved. Thereafter, FibroGen Cayman shall invoice AstraZeneca, and AstraZeneca will pay to FibroGen Cayman the applicable amount within forty-five (45) days after AstraZeneca's receipt of an invoice from FibroGen Cayman. Each such payment shall be made by wire transfer of immediately available funds into an account designated by FibroGen Cayman. Each such payment is nonrefundable and non-creditable against any other payments due hereunder.

8.5 Development Reimbursement Payments.

(a) Reimbursement for Development. With respect to Development Costs for the Products in the Territory not already reimbursed under Section 8.2, FibroGen China and AstraZeneca shall share equally (fifty percent (50%) each) the costs and expenses of the Development efforts of the Parties under the Development Plan and Development Budget, as well as the capital and equipment costs for the manufacturing plant in the Territory for the Products (including [*] for such capital and equipment costs).

(b) Payments and Reports. All amounts payable to FibroGen China or AstraZeneca pursuant to this Section 8.5 shall be paid in Dollars on a Calendar Quarter basis, unless FibroGen China requests that any such payment to FibroGen China be made in RMB, in which case such payments will be made in RMB. Within twenty (20) days if reasonably possible for AstraZeneca using reasonable endeavors to meet such timeline and in no event later than twenty five (25) days after the end of each Calendar Quarter after the Effective Date, AstraZeneca shall submit to FibroGen Cayman and FibroGen Cayman or FibroGen WFOE, as applicable, shall within fifteen (15) days if reasonably possible for FibroGen Cayman or FibroGen WFOE, as applicable, using reasonable endeavors to meet such timeline and in no event later than twenty (20) days after the end of each Calendar Quarter submit to AstraZeneca a statement setting forth the Development Costs incurred by it during such Calendar Quarter. As soon as practicable, and not later than within thirty two (32) days of the end of the Calendar Quarter, the Parties shall discuss and shall use best efforts to resolve any issues with respect to such statements, provided, however that each Party shall generate any questions and respond to any inquiries regarding the invoices as promptly as reasonably possible following receipt, including within forty-eight (48) hours for response to ordinary inquiries. Following the reconciliation process for the applicable

Calendar Quarter, each of FibroGen and AstraZeneca shall provide an invoice to the other Party reflecting fifty percent (50%) of their respective Development Costs incurred. Within forty five (45) days after its receipt of such invoices, the Party who incurred less Development Costs in the Calendar Quarter shall pay to the other Party an amount equal to fifty percent (50%) of the difference between the invoices so that each Party bears fifty percent (50%) of the total Development Costs incurred by the Parties in such Calendar Quarter (subject to the provisions on budget overages in Section 3.3), except as set forth on Exhibit D.

8.6 Net Profit and Net Loss Share.

(a) General. AstraZeneca and FibroGen Cayman shall receive fifty percent (50%) of any Net Profit and Royalty Payments, and bear fifty percent (50%) of any Net Loss, as applicable, for the Products in the Territory as set forth in **Exhibit D**.

(b) Profits Payments and Reports. Details with respect to Net Profit and Royalties and related payments are as set forth in **Exhibit D**.

8.7 Taxes.

(a) Taxes on Income. Subject to **Exhibit D**, each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the collaborative efforts of the Parties under this Agreement.

(b) Withholding Tax. The Party making payments under this Agreement (the "**Payor**") to the other Party (the "**Payee**") shall deduct or withhold from the payments any Taxes that it is required by applicable law to deduct or withhold. The Payee shall provide the Payor any tax forms or appropriate governmental authorization that may be reasonably necessary in order for Payor to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. The Payee shall use Commercially Reasonable Efforts to provide any such tax forms to the Payor at least thirty (30) days prior to the due date for any payment for which the Payee desires that Payor apply a reduced withholding rate and in any event at least fifteen (15) days prior to the time the applicable payment is due. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable laws and regulations, of withholding taxes, Indirect Taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or Indirect Taxes.

(c) Payment of Tax. To the extent the Payor is required by applicable law or regulations to deduct and withhold taxes on any payment to the Payee, the Payor shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to the Payee an official tax certificate or other evidence of such withholding sufficient to enable the Payee to claim such payment of taxes.

(d) Indirect Tax. All payments to be made by one Party to another Party, pursuant to the terms of this Agreement, are stated exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of such payments, the Party making shall payment shall pay such Indirect Taxes at the applicable rate following the receipt where applicable of an Indirect Taxes

invoice in the appropriate form issued. Each Party shall issue valid invoices for all amounts payable under this Agreement consistent with all applicable Laws and irrespective of whether such amounts may be netted for settlement purposes. The Parties shall cooperate in accordance with applicable law to minimize Indirect Taxes

8.8 Blocked Currency. In each country where the local currency is blocked and cannot be removed from the country, reimbursements or other payments in that country that are to be under this Agreement in RMB shall instead be paid to FibroGen China or AstraZeneca, as the case may be, in the equivalent amount in Dollars.

8.9 Foreign Exchange. With the exception of Co-Promotion Fees and payments from Product purchases which shall be paid in RMB, all amounts payable and all calculations under this Agreement shall be made in Dollars. Sales or costs and expenses recorded in any foreign currency shall be converted into Dollars in a manner consistent with FibroGen China's and AstraZeneca's customary and usual conversion procedures used to prepare such Party's audited financial statement for external reporting purposes, provided always that such practices use a widely accepted source of published exchange rates.

8.10 Late Payments. Except as set forth in **Exhibit D**, if a Party does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at a rate equal to the U.S. Prime Rate for the date payment was due as reported by the *Wall Street Journal*.

8.11 Financial Records; Audits.

(a) Records. Each Party shall maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the amount to be reimbursed, pursuant to Section 8.5 or 8.6, with respect to Development Costs or Commercialization Costs and in relation to the calculation of Net Profit and Net Loss and related payments as described in Section 8.6 above and **Exhibit D**, or other amounts to be reimbursed or shared hereunder incurred or generated (as applicable) by such Party, achievement of sales milestones and other compensation payable under this Agreement. Each Party shall keep or cause its Affiliates to keep such records for a period of the later of (i) six (6) years after the end of the period to which such books, records and accounts pertain and (ii) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by applicable law.

(b) Procedure. Upon reasonable prior notice, such records shall be open during regular business hours for a period of three (3) years from the creation of individual records, in each case, for examination at the auditing Party's expense, and not more often than once each Calendar Year, by an independent certified public accountant selected by the auditing Party and reasonably acceptable to the audited Party for the sole purpose of verifying for the auditing Party the accuracy of the financial reports or sales milestone notices furnished by the audited Party pursuant to this Agreement or of any payments made, or required to be made, by or to the audited Party to the other pursuant to this Agreement. Any such auditor shall not disclose the audited Party's Confidential Information to the auditing Party, except to the extent such disclosure is

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necessary to verify the accuracy of the financial reports furnished by the audited Party or the amount of payments due by the audited Party under this Agreement. Any amounts shown to be owed but unpaid, or overpaid and in need of reimbursement, shall be paid or refunded (as the case may be) within thirty (30) days after the accountant's report, plus interest (as set forth in Section 8.10) from the original due date (unless challenged in good faith by the audited Party in which case any dispute with respect thereto shall be resolved in accordance with Article 14). The auditing Party shall bear the full cost of such audit unless such audit reveals an overcharge or underpayment by the audited Party that resulted from a discrepancy in a report that the audited Party provided to the other Party during the applicable audit period, which underpayment or overcharge was more than five percent (5%) of the amount set forth in such report, in which case the audited Party shall bear the full cost of such audit.

(c) Audit Dispute. In the event of a dispute with respect to any audit under Section 8.11(b), FibroGen China and AstraZeneca shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days, the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other entity or individual as the Parties shall mutually agree (the "**Auditor**"). The decision of the Auditor shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in such manner as the Auditor shall determine. Not later than ten (10) days after such decision and in accordance with such decision, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 8.10 or the auditing Party shall reimburse the excess payments, as applicable.

8.12 Manner and Place of Payment. Except as otherwise expressly provided under this Agreement, all payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by FibroGen WFOE, FibroGen Cayman or AstraZeneca (as applicable), unless otherwise specified in writing by such Party. All payments hereunder shall be invoiced by the Payee to the Payor. Each invoice to AstraZeneca shall fulfill the requirements set forth on **Exhibit I**.

8.13 Estimated Sales and Accruals. To the extent that any amounts used in the calculation of Development Costs or Commercialization Costs are based on estimates or accruals with respect to the Products in the Territory, FibroGen China shall notify AstraZeneca of any such estimates or accruals or adjustments or changes based on a revision in estimates and accruals or true-up of such amounts within thirty (30) days of any such adjustment or reconciliation by FibroGen China.

ARTICLE 9

INTELLECTUAL PROPERTY

9.1 Intellectual Property Committee. The Parties shall, promptly after the Effective Date, establish an intellectual property committee (the "**IP Committee**") comprised of at least one senior patent attorney from each Party, together with such representatives of the Parties as the Parties may determine to be appropriate from time to time, to review and discuss, in each case with

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respect to FibroGen China Patents and Joint Patents, the patent prosecution strategy (including whether and where to file patent applications), applications for patent term extension and notices of infringement, as well as the selection, registration, maintenance and defense of Marks and interest in Third Party intellectual property. The IP Committee will serve solely an advisory purpose and shall not have authority to approve or disapprove any actions with respect to patent filing, prosecution and maintenance under this Agreement.

9.2 Ownership of Inventions. Ownership of Information and inventions, whether or not patentable, made during the Term in the course of conducting activities under this Agreement, including all intellectual property rights therein (collectively, "**Inventions**") shall be as follows: (a) FibroGen Cayman shall own all Inventions [*], whether made solely by employees, agents or independent contractors of either Party or its respective Affiliates, or jointly by employees, agents or independent contractors of both Parties or their respective Affiliates, (collectively, "**Collaboration Inventions**"), (b) AstraZeneca shall own all Inventions that are made solely by employees, agents or independent contractors of AstraZeneca or its Affiliates that are not Collaboration Inventions, (c) FibroGen Cayman shall own all Inventions that are made solely by employees, agents or independent contractors of FibroGen China or its Affiliates that are not Collaboration Inventions, and (d) AstraZeneca and FibroGen Cayman shall jointly own all Inventions that are made jointly by employees, agents, or independent contractors of each Party or its Affiliates that are not Collaboration Inventions ("**Joint Inventions**"). Except to the extent either Party is restricted by the licenses granted to the other Party under this Agreement, each of AstraZeneca and FibroGen Cayman shall be entitled to practice, grant licenses to, assign and exploit the Joint Inventions and Patents claiming Joint Inventions ("**Joint Patents**") without the duty of accounting or seeking consent from the other Party. AstraZeneca hereby assigns to FibroGen Cayman all of its and its Affiliates' right, title and interest in and to the Collaboration Inventions, and agrees to take such further actions reasonably requested by FibroGen Cayman to evidence such assignment, except where such Collaboration Inventions have been made by an independent contractor retained by AstraZeneca without such contractor having agreed to assign such Collaboration Inventions to AstraZeneca, as approved by the China Committee.

9.3 Disclosure of Inventions. Each Party shall promptly disclose to the other all Inventions promptly after becoming aware of them, including all invention disclosures or other similar documents submitted to such Party by its, or its Affiliates', employees, agents or independent contractors describing such Inventions. Such Party shall also respond promptly to reasonable requests from the other Party for more Information relating to such Inventions.

9.4 AstraZeneca Independent Inventions. In the event that AstraZeneca develops, during the Term, independently of its activities under this Agreement, any inventions or intellectual property rights that [*], AstraZeneca [*] with respect to HIF Compounds.

9.5 Prosecution of Patents.

(a) FibroGen China Patents. Except as otherwise provided in this Section 9.5(a), as between the Parties, FibroGen Cayman shall have the sole right and authority to manage all FibroGen China Patent prosecution activities under this Agreement. This includes the right and authority to prepare, file, prosecute and maintain all FibroGen China Patents in any jurisdiction

in the world, including defending such FibroGen China Patents in any patent office proceedings, pre- or post-grant or issuance, including reissue, reexamination, limitation or invalidation proceedings, or any opposition- or interference-type proceeding or challenge. FibroGen Cayman shall provide AstraZeneca reasonable opportunity to review and comment on filing and prosecution efforts regarding the FibroGen China Patents in the Territory. FibroGen Cayman shall, if requested by AstraZeneca, provide AstraZeneca with copies of material communications from any patent authority in the Territory regarding any FibroGen China Patents so designated by the IP Committee, and shall, if requested, provide drafts of any material filings or material responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses so that AstraZeneca may have the opportunity to review and comment thereon. FibroGen Cayman shall further take into account and may include, at FibroGen Cayman's sole discretion, any reasonable comments provided by AstraZeneca prior to submission of any such filings or responses. Each Party shall bear its own internal and out-of-pocket costs in respect of the prosecution of FibroGen China Patents.

(b) Joint Patents. With respect to any potentially patentable Joint Invention, AstraZeneca shall have the first right, but not the obligation, to prepare patent applications based on such Joint Invention, to file and prosecute (including defense of any oppositions, interferences, reissue proceedings and reexaminations) such patent applications, and to maintain any Joint Patents in any jurisdictions throughout the Territory. If AstraZeneca determines in its sole discretion to abandon, cease prosecution or otherwise not file or maintain any Joint Patent anywhere in the Territory, then AstraZeneca shall provide FibroGen Cayman written notice of such determination at least thirty (30) days before any deadline for taking action to avoid abandonment (or other loss of rights) and shall provide FibroGen Cayman with the opportunity to prepare, file, prosecute and maintain such Joint Patent. The Party that is responsible for preparing, filing, prosecuting, and maintaining a particular Joint Patent (the **"Prosecuting Party"**) shall provide the other Party reasonable opportunity to review and comment on such prosecution efforts regarding such Joint Patent, and such other Party shall provide the Prosecuting Party reasonable assistance in such efforts. The Prosecuting Party shall provide the other Party with a copy of all material communications from any patent authority in the applicable jurisdictions regarding the Joint Patent being prosecuted by such Party, and shall provide drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses. In particular, each Party agrees to provide the other Party with all information necessary or desirable to enable the other Party to comply with the duty of candor/duty of disclosure requirements of any patent authority. Either Party may determine that it is no longer interested in supporting the continued prosecution or maintenance of a particular Joint Patent in a country or jurisdiction, in which case: (i) the disclaiming Party shall, if requested in writing by the other Party, assign its ownership interest in such Joint Patent in such country or jurisdiction to the other Party for no additional consideration; and (ii) if such assignment is effected, any such Joint Patent would thereafter be deemed a FibroGen China Patent in the case of assignment to FibroGen Cayman, or a AstraZeneca Patent in the case of assignment to AstraZeneca; provided, however, that the disclaiming party would have an immunity from suit under such FibroGen China Patent or AstraZeneca Patent, as the case may be, in the applicable country or jurisdiction. In addition, any Joint Patent that becomes a FibroGen China Patent pursuant to the preceding sentence shall be excluded from the license granted to AstraZeneca in

Section 7.1. Each Party shall bear its own internal costs in respect of the prosecution of Joint Patents. Out-of-pocket costs incurred in respect of the prosecution and maintenance of Joint Patents in the Territory shall be borne equally by AstraZeneca and FibroGen Cayman. In the event a Party elects to disclaim its interest in a Joint Patent, the costs incurred with respect to such Patent after the date of such disclaimer shall thereafter be borne exclusively by the other Party, without reimbursement or credit.

(c) Cooperation in Prosecution and Extensions. Each Party shall through the IP Committee provide the other Party all reasonable assistance and cooperation in the Patent prosecution efforts provided above in this Section 9.5, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

9.6 Infringement of FibroGen China Patents by Third Parties.

(a) Notification. If there is any infringement, threatened infringement, imminent infringement or alleged infringement of any of the FibroGen China Patents on account of a Third Party's manufacture, use, offer for sale, or sale of a Collaboration Compound or Product in the Field in the Territory (in each case, a **"Product Infringement"**), then each Party shall promptly notify the other Party in writing of any such Product Infringement of which it becomes aware, and shall provide evidence in such Party's possession demonstrating such Product Infringement.

(b) Enforcement Rights. FibroGen China shall have the first right, but not the obligation, to bring an appropriate suit or other action against any person or entity allegedly engaged in any Product Infringement of the FibroGen China Patents in the Territory (and to defend any related counterclaim) and the costs and expenses shall be shared equally by the Parties. FibroGen China shall have a period of one hundred eighty (180) days after its receipt or delivery of notice and evidence pursuant to Section 9.6(a) above, to elect to enforce such FibroGen China Patent in the Territory (or to settle or otherwise secure the abatement of such Product Infringement). In the event that FibroGen China does not so elect (or settle or otherwise secure the abatement of such Product Infringement), it shall so notify AstraZeneca in writing, and AstraZeneca shall have the right to commence a suit or take action to enforce the applicable FibroGen China Patent with respect to a Product Infringement in the Field in the Territory (and to defend any related counterclaim) at AstraZeneca's expense. The IP Committee shall take the necessary actions to ensure that AstraZeneca has proper standing to bring suit under this Section 9.6(b).

(c) Cooperation. In any action, suit or proceeding instituted under this Section 9.6, the Parties shall cooperate with and assist each other in all reasonable respects. Upon the reasonable request of the Party instituting such action, suit or proceeding, the other Party shall join such action, suit or proceedings and shall be represented using counsel of its own choice, at the requesting Party's expense. If a Party with the right to initiate legal proceedings under this Section 9.6 lacks standing to do so and the other Party has standing to initiate such legal proceedings, then the Party with standing shall initiate such legal proceedings at the request and expense of the other Party (including reasonable internal personnel costs).

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

(d) Settlement. Without the prior written consent of the other Party, neither Party shall settle any claim, suit or action that it brought under this Section 9.6 involving FibroGen China Patents in any manner that would negatively impact such intellectual property or that would limit or restrict the ability of either Party to sell Products anywhere in or outside the Territory.

(e) Expenses and Recoveries. Any expenses incurred by such Party as a result of any claim, suit or action under Section 9.6(b) against any person or entity engaged in Product Infringement or any other infringement of the FibroGen China Patents shall be treated as a shared expense of the Parties under this Agreement. If such Party recovers monetary damages from such Third Party in such suit or action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel) and any remaining amount shall be designated as Product Revenue at the FibroGen Cayman level and subject to restrictions on payments to FibroGen as dividends under **Exhibit D**.

(f) Other Infringements. For clarity, as between the Parties, FibroGen China shall have the sole right to enforce the FibroGen China Patents in the Territory against any infringement, imminent infringement, threatened infringement or alleged infringement that is not a Product Infringement in the Field.

(g) Patents Licensed from Third Parties. Each Party's rights under this Section 9.6 with respect to any FibroGen China Patent licensed from a Third Party shall be subject to the rights of such Third Party to enforce such FibroGen China Patent and/or defend against any claims that such FibroGen China Patent is invalid or unenforceable.

(h) Joint Patents. Each Party shall promptly notify the other Party upon becoming aware of any infringement, imminent infringement, threatened infringement or alleged infringement of any Joint Patent ("**Joint Patent Infringement**"). The Parties will promptly thereafter meet to discuss in good faith how and whether to proceed to enforce the applicable Joint Patent against such Joint Patent Infringement. If the Parties fail to agree within sixty (60) days, then either Party shall have the right to take any action permitted under applicable law.

(i) Defense of FibroGen China Patents. To the extent any Party receives notice by counterclaim, or otherwise, alleging the invalidity or unenforceability of any FibroGen China Patent in the Territory, it shall bring such fact to the attention of the other Party, including all relevant information related to such claim. FibroGen China shall have the sole right to defend such action, at FibroGen China's expense, and AstraZeneca will cooperate with FibroGen China in such defense. All costs and expenses incurred in such activities shall be a shared expense of the Parties and reconciled as part of the FibroGen Cayman reconciliation in accordance with **Exhibit D**. FibroGen China shall keep AstraZeneca regularly informed of the status and progress of such efforts, and shall reasonably consider AstraZeneca's comments on any such efforts.

9.7 Third Party Patents. FibroGen China shall have the sole right and authority to initiate and/or pursue at its sole expense any patent office proceedings, pre- or post-grant or issuance, including reissue, reexamination, limitation, or invalidation proceedings, or any

opposition- or interference-type proceeding or challenge against any Third Party Patent that relates or that may potentially relate to the manufacture, use, or sale of a HIF Compound or a Product.

9.8 Defense of Infringement Actions. During the Term, each Party shall bring to the attention of the other Party all information regarding potential infringement or any claim of infringement of Third Party intellectual property rights in the Territory in connection with the development, manufacture, production, use, importation, offer for sale, or sale of Products in the Territory. Subject to Article 11, each Party shall be solely responsible for defending any action, suit, or other proceeding brought against it alleging infringement of Third Party intellectual property rights in connection with its activities under this Agreement, provided that if both Parties are named in such action, then FibroGen China shall have the first right to defend such action and the costs and expenses shall be a shared expense of the Parties and reconciled as part of the FibroGen Cayman reconciliation in accordance with **Exhibit D**. This Section 9.8 shall not be interpreted as placing on either Party a duty of inquiry regarding Third Party intellectual property rights.

9.9 Patent Marking. FibroGen China shall, and shall require its Affiliates and Sublicensees, to mark Products sold by it hereunder (in a reasonable manner consistent with industry custom and practice) with appropriate patent numbers or indicia to the extent permitted by applicable law and regulations, in those countries in which such markings or such notices impact recoveries of damages or equitable remedies available with respect to infringements of patents.

9.10 Personnel Obligations. Prior to beginning work under this Agreement relating to any research, Development or Commercialization of a Collaboration Compound or a Product, to HIF or in the Field, each employee, agent or independent contractor of AstraZeneca or FibroGen China or of either Party's respective Affiliates shall be bound by non-disclosure and invention assignment obligations which are consistent with the obligations of AstraZeneca or FibroGen China, as appropriate, in this Article 9, including without limitation: (a) promptly reporting any invention, discovery, process or other intellectual property right; (b) assigning to AstraZeneca or FibroGen China, as appropriate, all of his or her right, title and interest in and to any invention, discovery, process or other intellectual property right, such that AstraZeneca or FibroGen China, as appropriate, can then comply with its obligations under this Agreement with respect to such invention, discovery, process or other intellectual property right; (c) cooperating in the preparation, filing, prosecution, maintenance and enforcement of any patent and patent application; (d) performing all acts and signing, executing, acknowledging and delivering any and all documents required for effecting the obligations and purposes of this Agreement; and (e) abiding by the obligations of confidentiality and non-use set forth in Article 13. It is understood and agreed that such non-disclosure and invention assignment agreement need not reference or be specific to this Agreement.

9.11 Trademarks. The Parties shall use Commercially Reasonable Efforts to develop a trademark consistent with the worldwide trademarks for Products selected under the U.S. and RoW Agreement. FibroGen China shall be responsible for the selection, registration, maintenance and defense of, and FibroGen Cayman (or its Affiliate designated by FibroGen Cayman) will own, all trademarks for use in connection with the sale or marketing of Products in the Field in the

Territory (the **"Marks"**) and such costs shall be a shared expense of the Parties and reconciled as part of the FibroGen WFOE reconciliation in accordance with **Exhibit D**. All uses of the Marks shall be reviewed by the China Committee and shall comply with all applicable laws and regulations (including those laws and regulations particularly applying to the proper use and designation of trademarks in the applicable countries). Neither Party shall, without the other Party's prior written consent, use any trademarks or house marks of the other Party (including the other Party's corporate name), or marks confusingly similar thereto, in connection with such Party's marketing or promotion of Products under this Agreement, except as may be expressly authorized in connection with activities under Article 6 and except to the extent required to comply with applicable laws and regulations. FibroGen Cayman grants (and shall cause any of its Affiliates owning any such Marks or names to grant) to AstraZeneca a non-exclusive, sub-licensable license, free of charge, to use the Marks and the FibroGen China names and logos in the Territory pursuant to the Commercialization Plan solely for the purpose of Commercializing the Products in accordance with the terms of this Agreement, provided that such rights shall be exercised, and all Products bearing such names and/or logos shall be manufactured, in accordance with the quality standards for such logos and trademarks established by the JSC. AstraZeneca shall remain the owner of the AstraZeneca name and logo and the trademarks and the goodwill pertaining thereto. FibroGen Cayman shall remain the owner of the FibroGen China names and logos and the trademarks and the goodwill pertaining thereto.

9.12 Patent Term Extension. The Parties shall discuss via the IP Committee responsibility for the selection of the appropriate FibroGen China Patents to obtain any patent term extensions that are now or become available in the future in the Territory.

ARTICLE 10

REPRESENTATIONS AND WARRANTIES

10.1 Mutual Representations and Warranties. Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows, as of the Effective Date:

(a) Corporate Existence and Power. It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including, without limitation, the right to grant the licenses granted by it hereunder.

(b) Authority and Binding Agreement. (i) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

(c) No Conflict. It is not a party to and will not enter into any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement.

(d) No Debarment. In the course of the Development of Products, such Party has not used prior to the Effective Date and shall not use, during the Term, any employee, agent or independent contractor who has been debarred by any Regulatory Authority, or, to the best of such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

10.2 Representations and Warranties by FibroGen China. FibroGen China hereby represents and warrants to AstraZeneca, as of the Effective Date, as follows:

(a) Title; Encumbrances. Except for the Information licensed to FibroGen under the Astellas Agreements, FibroGen Cayman is the sole and exclusive owner of the entire right, title and interest in (a) the Listed Patents and (b) the FibroGen China Know-How existing as of the Effective Date. Neither the Listed Patents nor the FibroGen China Know-How owned by FibroGen Cayman is subject to any mortgage, pledge, lien, security interest, conditional and installment sale agreement, encumbrance or charge or claim of any kind.

(b) No Other Patents other than those listed. The Listed Patents represent all Patents that, as of the Effective Date, are Controlled by FibroGen China and which, to FibroGen China's knowledge, cover or claim any invention necessary or useful for the Development or Commercialization of Collaboration Compounds or Products in the Territory as contemplated as of the Effective Date.

(c) Prosecution of Patents etc. To FibroGen China's knowledge, the Listed Patents are being diligently prosecuted before the respective patent authorities in accordance with applicable law. All applicable fees due to patent authorities with respect to the filing and prosecution of the Listed Patents existing as of the Effective Date have been paid on or before the due date for payment (as such due date may be extended in accordance with applicable laws or patent authority rules and regulations). FibroGen China has not received any written notice alleging that the Listed Patents existing as of the Effective Date, if issued, would be invalid or unenforceable or that the Patent applications included in such Listed Patents will not proceed to grant. To FibroGen China's knowledge, in respect of any pending patent applications included in the Listed Patents, FibroGen China has submitted all material prior art of which it is aware in accordance with the requirements of the State Intellectual Property Office. To its knowledge, FibroGen China has properly identified each and every inventor of the claims of the Listed Patents existing as of the Effective Date.

(d) Notice of Infringement or Misappropriation. FibroGen China has not received any written notice from any Third Party asserting or alleging that any research or development of Collaboration Compounds or Products by FibroGen China or by Astellas prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party and FibroGen China has no reason to suspect that any such infringement or misappropriation has occurred. To FibroGen China's knowledge, the conception, development and reduction to practice of the Listed Patents and the FibroGen China Know-How existing as of the Effective Date have

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not constituted or involved the misappropriation of trade secrets or other proprietary rights of any person or entity.

(e) Non-infringement of Third Party Rights. To FibroGen China's knowledge, the research, development, manufacture, use and sale after the Effective Date of FG-4592 in the CKD Indications can be carried out in the manner reasonably contemplated as of the Effective Date without infringing any published Patents owned or controlled by a Third Party.

(f) No Proceedings. There are no pending actions, suits or proceedings against FibroGen China or any of its Affiliates involving the FibroGen China Technology, Collaboration Compounds or Products.

(g) Third-Party Activities. To FibroGen China's knowledge, except as disclosed in a writing of even date herewith by FibroGen China to AstraZeneca, there are no activities by Third Parties that would constitute infringement or misappropriation of the FibroGen China Technology (in the case of pending claims, evaluating them as if issued).

(h) Astellas Agreements. Nothing in the Astellas Agreements prevents FibroGen Cayman from granting the rights to AstraZeneca granted under this Agreement or prevents either FibroGen China or AstraZeneca from performing their rights under this Agreement.

(i) Documentation Made Available to AstraZeneca. FibroGen China has made available to AstraZeneca all material Regulatory Material, FibroGen China Know-How and other Information in its possession or Control regarding or related to any Collaboration Compound and Product. All Regulatory Material, FibroGen China Know-How and other Information in FibroGen China's possession and Control provided to AstraZeneca regarding or related to any Collaboration Compound or Product are, to FibroGen China's knowledge, true, complete and correct in all material respects. As of the Effective Date, FibroGen China has prepared, maintained and retained in all material respects all material Regulatory Material that FibroGen China is required to maintain or report pursuant to and in accordance with GLP, GCP, regulations and other applicable law.

10.3 Additional Covenants of FibroGen HK, FibroGen Cayman and FibroGen WFOE. FibroGen HK, FibroGen Cayman and FibroGen WFOE each separately covenants to AstraZeneca, as of the Effective Date and during the Term that:

(a) Calculation of Net Profit and Net Loss. In calculating Net Profit and Net Loss for the Product, no account shall be taken of any costs, expenses or activities conducted outside the scope of this Agreement, including with respect to the development and commercialization of other products, in or outside the Territory.

(b) No material harm. During the Term, it shall not, and its Affiliates shall not, engage in any activities or practices or prioritization of cash flows that would materially harm the Collaboration, including any activities or practices or prioritization of cash flows that would deprive or artificially reduce the calculation of any Net Profit or increase the Royalty Payments above the level approved by the tax authorities in the Territory under this Agreement.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

10.4 Anti-Bribery and Anti-Corruption Compliance.

(a) Each Party agrees, on behalf of itself, its officers, directors and employees and on behalf of its Affiliates, agents, representatives, consultants and subcontractors hired in connection with the subject matter of this Agreement (together with such Party, the "**Representatives**") that for the performance of its obligations hereunder:

(i) The Representatives shall not directly or indirectly pay, offer or promise to pay, authorize the payment of any money or give, offer or promise to give, or authorize the giving of anything else of value, to: (a) any Government Official in order to influence official action; (b) any individual or entity (whether or not a Government Official) (1) to influence such individual or entity to act in breach of a duty of good faith, impartiality or trust ("acting improperly"), (2) to reward such individual or entity for acting improperly or (3) where such individual or entity would be acting improperly by receiving the money or other thing of value; (c) any individual or entity (whether or not a Government Official) while knowing or having reason to know that all or any portion of the money or other thing of value will be paid, offered, promised or given to, or will otherwise benefit, the individuals or entities for the purposes listed in clauses (a) and (b) above.

(ii) The Representatives shall not, directly or indirectly, solicit, receive or agree to accept any payment of money or anything else of value in violation of the Anti-Corruption Laws.

(b) The Representatives shall comply with the Anti-Corruption Laws plus the AstraZeneca Anti-Corruption Rules and Policies and shall not take any action that will, or would reasonably be expected to, cause either Party or its Affiliates to be in violation of any such laws or policies.

(c) Each Party, on behalf of itself and its other Representatives, represents and warrants to the other Party that to the best of such Party's and its Affiliates' knowledge, no Representative that will participate or support its performance of its obligations hereunder has, directly or indirectly, (i) paid, offered or promised to pay or authorized the payment of any money, (ii) given, offered or promised to give or authorized the giving of anything else of value or (iii) solicited, received or agreed to accept any payment of money or anything else of value, in each case ((i), (ii) and (iii)), in violation of the Anti-Corruption Laws during the three (3) years preceding the date of this Agreement.

(d) Each Party shall promptly provide the other Party with written notice of the following events: (i) upon becoming aware of any breach or violation by such Party or its Representative of any representation, warranty or undertaking set forth in Sections 10.4(a)-(c); or (ii) upon receiving a formal notification that it is the target of an investigation by a Governmental Authority for a Material Anti-Corruption Law Violation or upon receipt of information from any of the Representatives connected with this Agreement that any of them is the target of an investigation by a Governmental Authority for a Material Anti-Corruption Law Violation.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

(e) Without prejudice to any auditing or inspection rights set forth elsewhere in this Agreement, each Party shall for the term of this Agreement and six (6) years thereafter, for the purpose of allowing the other Party to audit and monitor the performance of its compliance with this Agreement and particularly this Section 10.4 permit the other Party, its Affiliates, any auditors of any of them and any Governmental Authority to have access to any premises of such Party or other Representatives used in connection with this Agreement, together with a right to access personnel and records that relate to this Agreement ("**Audit**").The results of any such audit shall constitute Confidential Information of the audited Party, in respect of which the other Party shall comply with the provisions contained in Article 12 (subject to the terms and exceptions set forth therein or in this Section 10.4).

(i) To the extent that any Audit by a Party requires access and review of any commercially or strategically sensitive information of the other Party or any of its other Representatives relating to the business of such Party or any other Representatives (including information about prices and pricing policies, cost structures and business strategies), such activity shall be carried out by a Third Party professional advisor appointed by the other Party and such professional advisors shall only report back to the other Party such information as is directly relevant to informing the other Party on such Party's compliance with the particular provisions of the Agreement being Audited.

(ii) Each Party shall, and shall cause its Representatives to, provide all cooperation and assistance during normal working hours as reasonably requested by the other Party for the purposes of an Audit. Such other Party shall ensure that any Third Party auditor enters into a confidentiality agreement consistent with applicable requirements of Article 12 hereof in all material respects. Such other Party shall instruct any Third Party auditor or other Person given access in respect of an Audit to cause the minimum amount of disruption to the business of the audited Party and its Affiliates and to comply with relevant building and security regulations.

(iii) The costs and fees of any Audit shall be paid by the auditing Party, except that if an inspection or Audit reveals any breach or violation by the audited Party (including through its other Representatives) of any representation, warranty or undertaking set forth in Sections 10.4(a)-(c), the costs of such inspection or Audit shall be paid by the audited Party. The audited Party shall bear its own costs of rendering assistance to the Audit.

(f) On the occurrence of any of the following events: (A) A Party becomes aware of, whether or not through an Audit, that the other Party (or any other Representative) is in breach or violation of any representation, warranty or undertaking in Sections 10.4(a)-(c) or of the Anti-Corruption Laws; or (B) notification is received under Section 10.4(d) relating to any suspected or actual Material Anti-Corruption Law Violation by a Party or its Representative, in either case ((A) or (B)), the other Party shall have the right, in addition to any other rights or remedies under this Agreement or to which such other Party may be entitled in law or equity, to (x) take such steps as are reasonably necessary in order to avoid a potential violation or continuing violation by such other Party or any of its Affiliates of the Anti-Corruption Laws, including by requiring that the Party agrees to such additional measures, representations, warranties, undertakings and other provisions as such other Party believes in good faith are reasonably

necessary ("**Provisions**") and (y) terminate any or all of the activities conducted by the Party pursuant to this Agreement or this Agreement in its entirety, immediately in the event that:

(i) A Party refuses to agree to all of the Provisions required by the other Party pursuant to this clause; *provided* that such other Party has (a) provided the Party an explanation in reasonable detail as to why such other Party considers such provisions necessary, (b) given the Party a reasonable opportunity to review and comment on the proposed Provisions and to provide its view as to the necessity or usefulness of these to address the event concerned and (c) considered such comments in good faith, or

(ii) A Party reasonably concludes that there is no Provision available that would enable such Party or its Affiliates to avoid a potential violation or continuing violation of applicable Anti-Corruption Laws.

(g) Any termination of this Agreement pursuant to Section 10.4(f) shall be treated as a termination for breach and the consequences of termination set forth in Sections 13.6 and 13.7, as applicable, shall apply and additionally: (i) subject to the accrued rights of the Parties prior to termination, the terminating Party shall have no liability to the other Party for any fees, reimbursements or other compensation or for any loss, cost, claim or damage resulting, directly or indirectly, from such termination; and (ii) any amounts that would otherwise be payable with respect to such terminated activities or pursuant to this Agreement in its entirety, as applicable, including any then outstanding and unpaid claims for payment shall be null and void to the extent permissible under applicable laws or the payment of which will subject the terminating Party to liabilities under the Anti-Corruption Laws.

(h) Each Party shall be responsible for any breach of any representation, warranty or undertaking in this Section 10.4 or of the Anti-Corruption Laws by any of its Representatives.

(i) Each Party may disclose the terms of this Agreement or any action taken under this Section 10.4 to prevent a potential violation or continuing violation of applicable Anti-Corruption Laws, including the identity of the other Party and the payment terms, to any Governmental Authority if such Party determines, upon advice of counsel, that such disclosure is necessary.

(j) Each Party represents and warrants that (i) it has reviewed its internal programs in relation to the Anti-Corruption Laws and the ability of the Representatives to adhere to the AstraZeneca Anti-Corruption Rules and Policies in performance of its obligations hereunder in advance of the signing of this Agreement, (ii) it and the other Representatives can and will continue to comply with such Anti-Corruption Laws and the AstraZeneca Anti-Corruption Rules and Policies in performance of its obligations hereunder. Should either Party identify in writing to the other Party any measures that should be reasonably taken to improve the Representatives' compliance with such Anti-Corruption Laws and the AstraZeneca Anti-Corruption Rules and Policies for the performance of its obligations hereunder (the "**Improvement Plan**"), the other Party shall implement such Improvement Plan within an agreed reasonable timeframe (which shall in any event not be in excess of three (3) calendar months) from the date the Improvement Plan is

delivered to the receiving Party or otherwise the requesting Party shall be entitled to (x) terminate this Agreement, upon written notice to the other Party with immediate effect, (y) be relieved of any obligations hereunder and (z) seek compensation from the other Party.

10.5 Disclaimer. Each Party understands that the Collaboration Compounds and Products are the subject of ongoing clinical research and development and that the other Party cannot assure the safety or usefulness of the Collaboration Compounds or Products. In addition, FibroGen China makes no warranties except as set forth in this Article 10 concerning the FibroGen China Technology, and AstraZeneca makes no warranties except as set forth in this Article 10 concerning the AstraZeneca Technology.

10.6 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

ARTICLE 11

INDEMNIFICATION

11.1 Indemnification by FibroGen China. FibroGen China shall defend, indemnify, and hold AstraZeneca, its Affiliates, and their respective officers, directors, employees, and agents (the **"AstraZeneca Indemnitees"**) harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such AstraZeneca Indemnitees (collectively, "**AstraZeneca Damages**"), all to the extent resulting from claims, suits, proceedings or causes of action brought by such Third Party ("**AstraZeneca Claims**") against such AstraZeneca Indemnitee that arise from or are based on: (a) a breach of any FibroGen Contracting Party's representations, warranties, and obligations under this Agreement; (b) the willful misconduct or grossly negligent acts or omissions of FibroGen China, its Affiliates, or the officers, directors, employees, or agents of FibroGen China or its Affiliates in the performance of activities under this Agreement; (c) the research or Development of Collaboration Compounds or Products by FibroGen China before the Effective Date; or (d) the Development, testing, manufacture, storage, handling, use, sale, offer for sale, distribution and importation of Products by FibroGen China or its Affiliates or licensees (excluding, for clarity AstraZeneca). The foregoing indemnity obligation shall not apply if the AstraZeneca Indemnitees materially fail to comply with the indemnification procedures set forth in Section 11.3, or to the extent that such AstraZeneca Claim is based on or alleges: (i) a breach of any of AstraZeneca's representations, warranties, and obligations under this Agreement or the U.S. and RoW Agreement; or (ii) the willful misconduct or grossly negligent acts or omissions of AstraZeneca or its Affiliates, or the officers, directors, employees, or agents of AstraZeneca or its Affiliates in the performance of activities under this Agreement or the U.S. and RoW Agreement.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

11.2 Indemnification by AstraZeneca. AstraZeneca shall defend, indemnify, and hold each FibroGen Contracting party, their Affiliates, and each of their respective officers, directors, employees, and agents, (the **"FibroGen China Indemnitees"**) harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such FibroGen China Indemnitees (collectively, **"FibroGen China Damages"**), all to the extent resulting from any claims, suits, proceedings or causes of action brought by such Third Party (collectively, **"FibroGen China Claims"**) against such FibroGen China Indemnitee that arise from or are based on: (a) the Development, testing, manufacture, storage, handling, use, sale, offer for sale, distribution and importation of Products by AstraZeneca or its Affiliates, Sublicensees, or distributors; (b) a breach of any of AstraZeneca's representations, warranties, and obligations under the Agreement; or (c) the willful misconduct or grossly negligent acts or omissions of AstraZeneca or its Affiliates, or the officers, directors, employees, or agents of AstraZeneca or its Affiliates in the performance of activities under this Agreement. The foregoing indemnity obligation shall not apply if the FibroGen China Indemnitees materially fail to comply with the indemnification procedures set forth in Section 11.3, or to the extent that any FibroGen China Claim is based on or alleges: (i) a breach of any FibroGen Contracting Party's representations, warranties, and obligations under this Agreement or FibroGen's breach of the U.S. and RoW Agreement; or (ii) the willful misconduct or grossly negligent acts or omissions of FibroGen China, its Affiliates, or their officers, directors, employees, or agents in the performance of activities under this Agreement or the U.S. and RoW Agreement.

11.3 Indemnification Procedures. The Party claiming indemnity under this Article 11 (the **"Indemnified Party"**) shall give written notice to the Party from whom indemnity is being sought (the **"Indemnifying Party"**) promptly after learning of the claim, suit, proceeding or cause of action for which indemnity is being sought ("**Claim**"). The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided in this Article 11.

11.4 Insurance. Each Party shall self insure or procure and maintain insurance, including product liability insurance, with respect to its activities hereunder and which are consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested in human subjects or commercially distributed

or sold, and for four (4) years after the expiration or termination of this Agreement. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 11. Each Party shall provide the other with written evidence of such insurance upon request. Each Party shall provide the other with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance or self-insurance which materially adversely affects the rights of the other Party hereunder.

ARTICLE 12

CONFIDENTIALITY

12.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, during the Term and for ten (10) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement or the U.S. and RoW Agreement (which includes the exercise of any rights or the performance of any obligations hereunder or thereunder) any Confidential Information furnished to it by the other Party pursuant to this Agreement except for that portion of such information or materials that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) is subsequently disclosed to the receiving Party or its Affiliate by a Third Party without obligations of confidentiality with respect thereto; or

(e) is independently discovered or developed by the receiving Party or its Affiliate without the aid, application, or use of the disclosing Party's Confidential Information;

Notwithstanding the definition of "Confidential Information" in Article 1, all Information generated under this Agreement or the U.S. and RoW Agreement, whether generated by one or both Parties, shall be deemed the Confidential Information of FibroGen China.

12.2 Authorized Disclosure. Each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following situations:

(a) filing or prosecuting FibroGen China Patents in accordance with Article 9;

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

(b) regulatory filings and other filings with Governmental Authorities (including Regulatory Authorities), including filings with the U.S. SEC or CFDA, with respect to a Product;

(c) prosecuting or defending litigation;

(d) complying with applicable laws and regulations, including regulations promulgated by securities exchanges;

(e) disclosure to its Affiliates, employees, agents, and independent contractors, and any licensees or Sublicensees, in each case only on a need-to-know basis and solely in connection with the performance of this Agreement (and in the case of FibroGen China, the Astellas Agreements or other agreements with licensees of Products), provided that each disclosee must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 12 prior to any such disclosure;

(f) disclosure of the material terms of this Agreement to any bona fide potential or actual investor, investment banker, acquirer, merger partner, or other potential or actual financial partner, and in the case of FibroGen China, to any licensee of Products; provided that in connection with such disclosure, the disclosing Party shall inform each disclosee of the confidential nature of such Confidential Information and cause each disclosee to treat such Confidential Information as confidential; and

(g) disclosure of any Collaboration Inventions or status reports (including data from any Clinical Trials) to any bona fide potential or actual investor, investment banker, acquirer, merger partner, or other potential or actual financial partner, and in the case of FibroGen China, to any licensee of Products; provided that each disclosee must be bound by obligations of confidentiality and non-use at least as restrictive as those set forth in this Article 12 prior to any such disclosure.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Sections 12.2(a), 12.2(b), 12.2(c) or 12.2(d), it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use Commercially Reasonable Efforts to secure confidential treatment of such information. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

12.3 Publicity; Terms of Agreement.

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in Section 12.2 and this Section 12.3. The Parties have agreed to make a joint public announcement of the execution of this Agreement and the U.S. and RoW Agreement on or promptly after the Effective Date.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

(b) After release of such press release, if either Party desires to make a public announcement concerning the material terms of this Agreement or any activities under this Agreement, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval (except as otherwise provided herein), such approval not to be unreasonably withheld, except that in the case of a press release or governmental filing required by law, the disclosing Party shall provide the other Party with such advance notice as it reasonably can and shall not be required to obtain approval therefor. A Party commenting on such a proposed press release shall provide its comments, if any, within five (5) Business Days after receiving the press release for review. FibroGen China shall have the right to make a press release announcing the achievement of each material milestone under this Agreement as it is achieved, and the achievements of Regulatory Approvals as they occur, subject only to the review procedure set forth in the preceding sentence. In relation to AstraZeneca's review of such an announcement, AstraZeneca may make specific, reasonable comments on such proposed press release within the prescribed time for commentary, but shall not withhold its consent to disclosure of the information that the relevant milestone or Regulatory Approval has been achieved and triggered a payment hereunder. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement that have already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 12.3.

(c) The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with Government Authorities. Each Party shall be entitled to make such a required filing, provided that it requests confidential treatment of at least the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, each Party will provide the other Party with a copy of the Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the legal requirements governing redaction of information from material agreements that must be publicly filed.

12.4 Publications.

(a) Subject to the International Committee of Medical Journal Editors ("ICMJE") Uniform Requirements for Manuscripts Submitted to Biomedical Journals and applicable legal requirements, the China Committee (with approval of the JSC or its designee for such responsibility) will determine the overall strategy for publishing and presenting results of studies pertaining to the Products and the JSC or its designee shall approve all publications in the Territory prior to publication.

(b) Neither Party shall publicly present or publish results of studies carried out under this Agreement (each such presentation or publication a "**Publication**") without the opportunity for prior review by the other Party, except to the extent otherwise required by applicable laws or regulations, in which case Section 12.3(c) shall apply with respect to disclosures required by applicable securities laws and Section 12.2(b) shall apply with respect to disclosures required for regulatory filings. The submitting Party shall provide the other Party the opportunity to review any proposed Publication at least thirty (30) days prior to the earlier of its presentation or intended submission for publication. The submitting Party agrees, upon request by the other

Party, not to submit or present any Publication until the other Party has had thirty (30) days to comment on any material in such Publication. The submitting Party shall consider the comments of the other Party in good faith and no Publication shall be submitted for publication without the approval of the JSC. The submitting Party shall provide the other Party a copy of the Publication at the time of the submission or presentation. Notwithstanding the foregoing, AstraZeneca shall not have the right to publish or present FibroGen China's Confidential Information without FibroGen China's prior written consent, and FibroGen China shall not have the right to publish or present AstraZeneca's Confidential Information without AstraZeneca's prior written consent. Each Party agrees to acknowledge the contributions of the other Party, and the employees of the other Party, in all publications as scientifically appropriate.

ARTICLE 13

TERM AND TERMINATION

13.1 Term. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 13, shall remain in effect until the date that AstraZeneca is no longer Developing or selling Products in the Territory (the **"Term"**).

13.2 Termination by AstraZeneca at Will. AstraZeneca shall have the right to terminate this Agreement upon one hundred eighty (180) days prior written notice to FibroGen China. During such one hundred eighty (180) day period, AstraZeneca shall continue to perform all of its obligations under this Agreement and shall continue to be responsible for all costs incurred under the Agreement during such one hundred eighty (180) day period. In addition, AstraZeneca shall not take any action that would reasonably be expected to materially adversely affect or impair the further development and commercialization of the Products during such one hundred eighty (180) day period.

13.3 Termination by AstraZeneca for Technical Product Failure. AstraZeneca may terminate this Agreement in its entirety at any time after the Effective Date upon written notice to FibroGen China in the event of Technical Product Failure; provided, however, that AstraZeneca shall not be entitled to terminate this Agreement pursuant to this Section 13.3 if such Technical Product Failure pertains only to one or several specific Collaboration Compound(s) or Product(s) but does not affect (a) FG-4592 (if FG-4592 is then still being Developed or Commercialized under this Agreement) or (b) any other Collaboration Compound or Product then in a Phase 2 Clinical Trial or later stage of Development or Commercialization under this Agreement.

13.4 Termination by Either Party for Breach.

(a) Breach. Subject to Section 13.4(b), FibroGen China shall have the right to terminate this Agreement upon written notice to AstraZeneca if AstraZeneca materially breaches its obligations under this Agreement and, after receiving written notice from FibroGen China identifying such material breach by AstraZeneca in reasonable detail, fails to cure such material breach within ninety (90) days from the date of such notice (or within thirty (30) days from the date of such notice in the event such material breach is solely based upon AstraZeneca's failure to pay any material amounts due to FibroGen China hereunder). Subject to Section 13.4(b),

AstraZeneca shall have the right to terminate this Agreement upon written notice to FibroGen China if FibroGen China materially breaches its obligations under this Agreement and, after receiving written notice from AstraZeneca identifying such material breach by FibroGen China in reasonable detail, fails to cure such material breach within ninety (90) days from the date of such notice (or within thirty (30) days from the date of such notice in the event such material breach is solely based upon FibroGen China's failure to pay any material amounts due to AstraZeneca hereunder).

(b) Disputed Breach. If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section 13.4(a), and such alleged breaching Party provides the other Party notice of such dispute within such ninety (90) day (or thirty (30) day, as the case may be) period, then the non-breaching Party shall not have the right to terminate this Agreement under Section 13.4(a) unless and until the arbitral tribunal, in accordance with Article 14, has determined that the alleged breaching Party has materially breached the Agreement and such Party fails to cure such breach within ninety (90) days following such arbitral tribunal's decision (except to the extent such breach is solely based on the failure to make a payment when due, which breach must be cured within thirty (30) days following such arbitral tribunal's decision); provided that with respect to a failure to pay amounts due, arbitration shall be conducted in accordance with Article 14, except that it shall be conducted by only one arbitrator and shall be resolved within ninety (90) days. It is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

13.5 Termination for Patent Challenge. FibroGen China may terminate this Agreement in its entirety immediately upon written notice to AstraZeneca if AstraZeneca or its Affiliates or sublicensees (directly or indirectly, individually or in association with any other person or entity) challenges the validity, enforceability or scope of any FibroGen China Patent in the Territory and such challenge is not permanently withdrawn within ninety (90) days.

13.6 Effects of Termination of the Agreement. Upon any termination of this Agreement, the following shall apply (in addition to any other rights and obligations under Section 13.8 or otherwise under this Agreement with respect to such termination):

(a) Licenses. The licenses granted in Article 7 shall terminate. Notwithstanding the foregoing, AstraZeneca hereby grants to FibroGen Cayman, effective only upon such termination, a non-exclusive, worldwide, fully-paid, perpetual, irrevocable, royalty-free license, with the right to grant multiple tiers of sublicenses, under the AstraZeneca Technology, to research, develop, make, have made, use, import, export, offer for sale, and sell Products as in existence as of the termination date in the Territory; provided that FibroGen Cayman shall indemnify, defend and hold harmless AstraZeneca and each of the AstraZeneca Indemnitees as set forth in Section 11.1 from and against any AstraZeneca Damages arising out of or resulting from AstraZeneca Claims that arise or result from FibroGen Cayman's, its Affiliates' or licensees' activities performed under the foregoing license

(b) Regulatory Materials. AstraZeneca shall transfer and assign to the FibroGen Contracting Party(ies) as directed by FibroGen China all Regulatory Materials and Regulatory Approvals for Products in the Territory, if any, that are Controlled by AstraZeneca or its Affiliates or Sublicensees.

(c) Transition Assistance. AstraZeneca shall, at no cost to FibroGen China, provide reasonable consultation and assistance for a period of no more than one hundred eighty (180) days following the effective date of termination for the purpose of transferring or transitioning to FibroGen China, all AstraZeneca Know-How related to a Product not already in FibroGen China's possession, and, at FibroGen China's request, all then-existing commercial arrangements relating specifically to Products in the Territory to the extent reasonably necessary or useful for FibroGen China to commence or continue developing, manufacturing, or commercializing Products, and further to the extent AstraZeneca is contractually able to do so. The foregoing consultation and assistance shall include, without limitation, assigning, upon request of FibroGen China, any agreements with Third Party suppliers or vendors that specifically cover the supply or sale of Products in the Territory, to the extent such agreements are assignable by AstraZeneca. If any such contract between AstraZeneca and a Third Party is not assignable to FibroGen China (whether by such contract's terms or because such contract does not relate specifically to Products) but is otherwise reasonably necessary or useful for FibroGen China to commence or continue developing, manufacturing, or commercializing Products, then AstraZeneca shall reasonably cooperate with FibroGen China to negotiate for the continuation of such license and/or supply from such entity. In any event, if AstraZeneca is manufacturing bulk or finished Product under an agreement entered into pursuant to Section 6.4, then AstraZeneca shall supply such bulk or finished Product, as applicable, to FibroGen China and Astellas, for a reasonable transitional period (not to exceed twelve (12) months) from the effective date of the termination, subject to reasonable extension by FibroGen China if AstraZeneca is unable to timely effect the technology transfer required to have a Third Party manufacturer designated by FibroGen China undertake the manufacturing responsibilities) under the terms of such agreement until FibroGen China either enters into a separate agreement with such Third Party supplier or vendor or establishes an alternate, validated source of supply for the Products. FibroGen China shall pay to AstraZeneca a price equal to AstraZeneca's actual cost to manufacture or acquire such supplies, provided that where termination is by AstraZeneca pursuant to Section 13.4(a), FibroGen China shall pay to AstraZeneca a price equal to AstraZeneca's actual cost to manufacture or acquire such supplies plus a mark-up of [*] of such actual cost.

(d) Ongoing Clinical Trials. As soon as practicable and subject to applicable law, including GCP, AstraZeneca shall transfer to FibroGen China the management and continued performance of all Clinical Trials for Products for the Territory ongoing as of the effective date of such termination that are being conducted by AstraZeneca at such time.

(e) Remaining Inventories. FibroGen China shall have the right to purchase from AstraZeneca any or all of the inventory of Products held by AstraZeneca as of the effective date of termination (that are not committed to be supplied to any Third Party in the ordinary course of business as of the date of termination) at a price equal to AstraZeneca's actual cost to acquire such inventory. FibroGen China shall notify AstraZeneca within sixty (60) days after the date of termination whether FibroGen China elects to exercise such right. In the event FibroGen China

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

does not elect to exercise such right AstraZeneca shall be entitled to dispose of such inventory as it sees fit in compliance with applicable law, subject to all applicable payments under Article 8.

(f) Effect of Termination by AstraZeneca at Will. If AstraZeneca terminates this Agreement under Section 13.2 (but not in the event of any other termination), AstraZeneca shall remain responsible for all Development Costs and all Commercialization Costs incurred by FibroGen China under the respective Development Plans and Commercialization Plans during the [*]. If AstraZeneca terminates this Agreement under Section 13.2 (but not in the event of any other termination), then AstraZeneca shall additionally pay (i) to FibroGen Cayman or FibroGen WFOE, as applicable, all reasonable costs to transition any then-ongoing Clinical Trials of Products in the Territory and (ii) to FibroGen Cayman a payment of ten million Dollars ($10,000,000).

(g) Post-Termination Restriction. If this Agreement is terminated by AstraZeneca at will under Section 13.2 or by FibroGen China under Section 13.4 for AstraZeneca's material breach or by FibroGen China under Section 13.5 for patent challenge, for three (3) years after the effective date of termination, AstraZeneca will not develop, manufacture or commercialize (directly or indirectly), nor license or authorize a Third Party to commercialize, any HIF Compound in the Territory for use in the Field, or knowingly sell or supply HIF Compounds to a Third Party for such purpose.

(h) No Other Rights. For the avoidance of doubt, the rights granted to FibroGen China under this Section 13.6 are restricted to Collaboration Compounds and Products and AstraZeneca does not grant any rights whatsoever to any other compounds or products or to any Patents or other intellectual property rights other than as set forth in this Section 13.6. Moreover, AstraZeneca shall not be obligated to provide FibroGen China with any other intellectual property rights or other rights or services than that which is explicitly provided for under this Section 13.6.

13.7 Certain Additional Provisions for Termination for FibroGen China's Breach.

(a) If this Agreement is terminated by AstraZeneca under Section 13.4 for FibroGen China's material breach, FibroGen China shall, in addition to any other remedies available to AstraZeneca under this Agreement or applicable law as a consequence of such breach, compensate AstraZeneca for any costs or expenses incurred by AstraZeneca or its Affiliates in connection with performing any of the activities contemplated by the applicable provisions in Section 13.6.

(b) If FibroGen China's material breach is a material breach of Section 5.7 (Regulatory Compliance), in addition to the rights and remedies set forth in this Agreement, AstraZeneca may, at its option, elect to continue the Agreement, in which case the rights and obligations of the Parties shall continue in full force and effect as described herein, except that (i) at AstraZeneca's option, FibroGen China's co-promotion rights shall terminate; and (ii) AstraZeneca shall, as an exception to the decision making principles set forth in Section 2.2(e), have final say over any and all future decision and issues relating to regulatory compliance pursuant to Section 5.7.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

13.8 Other Remedies. Termination or expiration of this Agreement for any reason shall not release either Party from any liability or obligation that already has accrued prior to the effective date of such expiration or termination, nor affect the survival of any provision hereof to the extent it is expressly stated to survive such termination. Termination or expiration of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder or that may arise out of or in connection with such termination or expiration.

13.9 Bankruptcy. In addition to the termination rights set forth in Sections 13.1 – 13.8 above, a Party shall have the right to terminate this Agreement in its entirety before the end of the Term upon the bankruptcy or insolvency of, or the filing of an action to commence insolvency proceedings against the other Party, or the making or seeking to make or arrange an assignment for the benefit of creditors of the other Party, or the initiation of proceedings in voluntary or involuntary bankruptcy, or the appointment of a receiver or trustee of such Party's property, in each case that is not discharged within sixty (60) days of the applicable filing, action or initiation of proceedings. In the case of AstraZeneca's rights under this Section 13.9, such rights shall extend to any of the aforementioned bankruptcy or insolvency events described above occurring in relation to any of the FibroGen Contracting Parties. In addition, if in the Territory an equivalent law to Section 365(n) of the U.S. Bankruptcy Code comes into effect, the Parties shall amend this Agreement as necessary to ensure that each Party as licensee of intellectual property is able to enjoy the full benefits of such law.

13.10 Survival. Termination or expiration of this Agreement shall not affect rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration of this Agreement. Notwithstanding anything to the contrary, the following provisions shall survive and apply after expiration or termination of this Agreement: Sections 3.7(b), 3.8, 8.1, 8.7-8.13, 9.2, 10.6, 12.1, 12.2, 12.3, 13.6, 13.8 and 13.10 and Articles 11, 14 and 15. In addition, the other applicable provisions of Article 8 shall survive to the extent required to make final reimbursements, reconciliations or other payments with respect to Net Sales and costs and expenses incurred or accrued prior to the date of termination or expiration. For any surviving provisions requiring action or decision by a Committee or an Executive Officer, each Party will appoint representatives to act as its Committee members or Executive Officer, as applicable. All provisions not surviving in accordance with the foregoing shall terminate upon expiration or termination of this Agreement and be of no further force and effect.

ARTICLE 14

DISPUTE RESOLUTION AND GOVERNING LAW

14.1 Disputes. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. In the event of any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement (including disputes arising from the JSC that are not resolved pursuant to Section 2.2(e)), including, without limitation, any alleged failure to perform, or breach, of this Agreement, or any

issue relating to the interpretation or application of this Agreement (each, a "**Dispute**"), then upon the request of either Party by written notice, the dispute will be referred to the Executive Officers of each Party, who shall meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one in-person meeting. If the matter is not resolved within thirty (30) days following the written request for discussions, either Party may then invoke the provisions of Section 14.2.

14.2 Arbitration. Any dispute, controversy, difference or claim which may arise between the Parties, out of or in relation to or in connection with this Agreement (including, without limitation, arising out of or relating to the validity, construction, interpretation, enforceability, breach, performance, application or termination of this Agreement) that is not resolved pursuant to Section 14.1, except for a dispute, claim or controversy under Section 14.7 or 14.8, shall be settled by binding arbitration administered by the American Arbitration Association (the "**AAA**") in accordance with its Commercial Arbitration Rules (or the AAA International Arbitration Rules, if recommended under the AAA guidelines), as such rules may be modified by this Section 14.2 or otherwise by subsequent written agreement of the Parties. The arbitration shall be governed by the U.S. Federal Arbitration Act, 9 U.S.C. §§ 1-16 (the "**Federal Arbitration Act**"), to the exclusion of any inconsistent state laws. The arbitration will be conducted in New York, New York. The number of arbitrators shall be three (3), of whom the Parties shall select one (1) each. The two arbitrators so selected will select the third and final arbitrator. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the AAA shall select the third arbitrator. The language to be used in the arbitral proceedings will be English. The Parties shall have the right to be represented by counsel. The arbitration proceeding shall be confidential. Except as required by applicable law, no Party shall make (or instruct the arbitrator to make) any public announcement with respect to the proceedings or decision of the arbitrator without the prior written consent of the other Party. The existence of any dispute submitted to arbitration, and the award, shall be kept in confidence by the Parties and the arbitrator, except as required in connection with the enforcement of such award or as otherwise required by applicable law. Any judgment or award rendered by the arbitrators shall be final and binding on the Parties. The Parties agree that such judgment or award may be enforced in any court of competent jurisdiction.

14.3 Governing Law. Resolution of all Disputes and any remedies relating thereto shall be governed by and construed under the substantive laws of the State of California, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

14.4 Decision. The arbitrators shall issue a reasoned opinion following a full comprehensive hearing, no later than twelve (12) months following the selection of the arbitrators.

14.5 Award. Any award shall be promptly paid in Dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by law, be charged against the Party resisting enforcement. If as to any issue the arbitrators should determine under the applicable law that the position taken by a Party is frivolous or otherwise irresponsible or that any wrongdoing it finds is in callous disregard of law and equity or the rights of the other Party, the arbitrators shall also be entitled to award an appropriate

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allocation of the adversary's reasonable attorney fees, costs and expenses to be paid by the offending Party, the precise sums to be determined after a bill of attorney fees, expenses and costs consistent with such award has been presented following the award on the merits. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Article 14. The award shall include interest from the date of any damages incurred for breach of the Agreement, and from the date of the award until paid in full, at a rate fixed by the arbitrators. With respect to money damages, nothing contained herein shall be construed to permit the arbitrators or any court or any other forum to award punitive or exemplary damages. By entering into this agreement to arbitrate, the Parties expressly waive any claim for punitive or exemplary damages. The only damages recoverable under this Agreement are compensatory damages.

14.6 Injunctive Relief. Provided a Party has made a sufficient showing under the rules and standards set forth in the U.S. Federal Rules of Civil Procedure and applicable case law, the arbitrator shall have the freedom to invoke, and the Parties agree to abide by, injunctive measures after either Party submits in writing for arbitration claims requiring immediate relief. Nothing in this Article 14 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

14.7 Patent and Trademark Disputes. Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patents or trademarks covering the manufacture, use, importation, offer for sale or sale of the Product shall be submitted to a court of competent jurisdiction in the country in which such patent or trademark rights were granted or arose.

14.8 Expedited Arbitration for Disputes Related to Technical Product Failure. Disputes with respect to a Technical Product Failure that are not resolved at the JSC or by the Executive Officers within twenty (20) Business Days after referral thereto, in the case of a Technical Product Failure as defined in Section 1.105(a), or resolved by the Parties, in the case of a Technical Product Failure as defined in Section 1.105(b), shall be finally determined as set forth in this Section 14.8. Within five (5) Business Days after the end of such twenty (20)-Business Day period, each Party shall propose a list of three (3) individuals, each of whom has at least ten (10) years of significant relevant technical experience in the pharmaceutical industry, and none of whom is or has been affiliated with either Party or with either Party's Affiliates, licensees, sublicensees or business partners, or otherwise has any interest in the resolution of the issue to be submitted by the Parties for resolution (the foregoing requirements, the "**Requirements**"). Within five (5) Business Days after the Parties exchange such lists, the Parties shall either agree upon one of such proposed individuals to resolve the disputed matter, or if the Parties do not so select one such individual within such period of time, each Party shall select one (1) such individual from the list proposed by the other Party, and the two (2) selected individuals shall select a third individual who otherwise meets the Requirements to resolve the disputed matter (the selected individual, the "**Industry Expert**"). Each Party shall submit written materials to the other Party and to the Industry Expert relating to the matters in issue within five (5) Business Days after the Industry Expert is selected. Each Party shall then have five (5) Business Days to submit a written rebuttal

to the other Party's submission to the other Party and to the Industry Expert. The Industry Expert shall have the discretion to interview the Parties' officers and employees to obtain further information relating to the matters in issue and to hear oral argument. Each Party shall cooperate with the Industry Expert. The Industry Expert's determination shall be binding, and such determination shall be given retroactive effect. Until such determination is delivered to the Parties, the Parties shall continue to perform their obligations under this Agreement in good faith and make any applicable payments accordingly. If the Industry Expert decides in AstraZeneca's favor, then the Parties shall bear all expenses incurred pursuant to this Section 14.8 equally, and if the Industry Expert decides in FibroGen's favor, then AstraZeneca shall bear all expenses incurred pursuant to this Section 14.8, including reasonable reimbursement of FibroGen's expenses for internal personnel and external advisors.

ARTICLE 15

MISCELLANEOUS

15.1 Entire Agreement; Amendment. This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof, including, without limitation, the Existing Confidentiality Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective Date, by the other Party of its obligations pursuant to the Existing Confidentiality Agreement. In the event of any inconsistency between any plan hereunder (including the Development Plan and/or Commercialization Plan) and this Agreement or between the terms of this Agreement and the U.S. and RoW Agreement, the terms of this Agreement shall prevail (but solely with respect to the Territory). There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

15.2 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented or delayed by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall mean conditions beyond the control of the Parties, including without limitation, an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). The non-performing Party shall within thirty (30) days after a force majeure

provide the other Party a good faith estimate of the anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably necessary and the non-performing Party shall use Commercially Reasonable Efforts to remedy its inability to perform. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party.

15.3 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 15.3, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by a reputable international expedited delivery service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered mail, postage prepaid, return receipt requested.

If to FibroGen:	FibroGen China Anemia Holdings, Ltd. FibroGen Medical Technology Development Co., Ltd. FibroGen International (Hong Kong Limited) c/o FibroGen, Inc. San Francisco, CA 94158 USA Attn: Chief Executive Officer
With a copy to:	FibroGen, Inc. 409 Illinois St. San Francisco, CA 94158 USA Attn: Michael Lowenstein, Vice President, Legal Affairs
If to AstraZeneca:	AstraZeneca AB Pepparedsleden 1, 431 83 Mölndal Gothenburg Sweden Attention: Chief Financial Officer
With a copy to:	AstraZeneca UK Limited Alderley Park Macclesfield Cheshire SK10 4TF Attention: Liam McIlveen, Deputy General Counsel

15.4 No Strict Construction; Headings. Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the

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joint efforts of the Parties hereto and their counsel. Accordingly, in the event an ambiguity or a question of intent or interpretation arises, this Agreement will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise favoring or disfavoring any Party by virtue of the authorship of any provisions of this Agreement. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

15.5 Assignment. Neither Party may assign or transfer this Agreement (either in whole or part) or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment or transfer without the other Party's consent to Affiliates or to a successor to substantially all of the business of such Party, whether in a merger, sale of stock, sale of assets or other transaction. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations (and in any event, any Party assigning this Agreement to an Affiliate shall remain bound by the terms and conditions hereof). In the event that a Party is acquired by a Third Party (such Third Party, hereinafter referred to as an **"Acquiror"**), then the intellectual property of such Acquiror held or developed by such Acquiror (whether prior to or after such acquisition) shall be excluded from the FibroGen China Technology (in the case when the acquired Party is FibroGen China) and AstraZeneca Technology (in the case when the acquired Party is AstraZeneca), and such Acquiror (and Affiliates of such Acquiror which are not controlled by the acquired Party itself) shall be excluded from "Affiliate" solely for purposes of the applicable components of the foregoing intellectual property definitions, in all such cases if and only if: (a) the acquired Party remains a wholly-owned subsidiary of the Acquiror; (b) all intellectual property of the acquired Party and all research and development assets and operations of the acquired Party with respect to the Product remain with the acquired Party and are not transferred to the Acquiror or another Affiliate of the Acquiror; (c) the scientific and development activities with respect to Product of the acquired Party and the Acquiror (if any) are maintained separate and distinct, and (d) there is no exchange of confidential Information relating to Product between the acquired Party and the Acquiror. For clarity, in the event that a Party is acquired by an Acquiror and any of the criteria described in subsections (a) through (d) is not satisfied, then the intellectual property of such Acquiror shall be included within FibroGen China Technology (in the case when the acquired Party is FibroGen China) and AstraZeneca Technology (in the case when the acquired Party is AstraZeneca). Any permitted assignment of the rights and obligations of a Party under this Agreement shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.5 shall be null, void and of no legal effect.

15.6 Performance by Affiliates. Subject to the limitations of Section 7.3, each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

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15.7 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

15.8 Compliance with Applicable Law. Each Party shall comply with all applicable laws and regulations in the course of performing its obligations or exercising its rights pursuant to this Agreement.

15.9 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT OR ANY TORT CLAIMS ARISING HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 15.9 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 11.1, 11.2 OR 11.3, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 12.

15.10 Severability. To the fullest extent permitted by applicable law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid or unenforceable in any respect. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by an arbitrator or by any court of competent jurisdiction from which no appeal can be or is taken (within the time period prescribed for appeal), the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one that achieves, as nearly as possible, the objectives contemplated by the Parties when entering this Agreement.

15.11 No Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

15.12 Independent Contractors. It is expressly agreed that each of the FibroGen Contracting Parties, on the one hand, and AstraZeneca, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency, except as provided in this Section 15.12. Notwithstanding the foregoing, the Parties acknowledge and agree that the Collaboration between them established by this Agreement (i) will be treated as a partnership for United States federal, state, and local income tax purposes and that the provisions set forth in **Exhibit B** shall be incorporated into this document, solely for United States federal income tax purposes and (ii) will not be treated as a partnership for Swedish tax purposes. Neither FibroGen China, on the one hand, nor AstraZeneca, on the other hand, shall have the authority to make any statements, representations or commitments of any kind, or to take any action that will be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party

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and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party.

15.13 English Language. This Agreement shall be written and executed in and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

15.14 Counterparts. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Signature Page Follows]

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In Witness Whereof, the Parties have executed this Agreement in duplicate originals by their duly authorized officers as of the Execution Date.

FibroGen China Anemia Holdings, Ltd.

By: /s/ Martin S. Zolnai
Name: Martin S. Zolnai
Title: General Manager

AstraZeneca AB

By: /s/ Elisabeth Bjork
Name: Elisabeth Bjork
Title: VP, GMed Head, CVMD

Beijing FibroGen Medical Technology Development Co., Ltd.

Chop: {Seal dated 20 Oct 2014}

FibroGen International (Hong Kong) Limited

By: /s/ Martin S. Zolnai
Name: Martin S. Zolnai
Title:

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EXHIBITS

Exhibit A – Structure of FG-4592

Exhibit B – United States Federal Income Tax Matters

Exhibit C – Certain Co-Promotion Agreement Terms

Exhibit D – Net Profit and Net Loss Calculations

Exhibit E – Initial Development Plan

Exhibit F – Distribution Agreement Key Terms

Exhibit G – Listed Patents

Exhibit H – AstraZeneca's Anti-Corruption Rules and Policies

Exhibit I – Invoicing Requirements

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Exhibit A
Structure of FG-4592

[*]

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Exhibit B

United States Federal Income Tax Matters

1. Purpose and Scope

(a) **Purpose**. The Parties hereby acknowledge and agree that the Collaboration between them established by this Agreement will be viewed as a partnership for United States federal, state, and local income tax purposes (the **"Partnership"**). Pursuant to the status of the Collaboration as a partnership for such purposes, this Exhibit B provides for the manner in which FibroGen Cayman will cause Capital Accounts to be maintained for each Party and the manner in which the Partnership's items of income, gain, loss, deduction or credit will be allocated among the Parties, in each case solely for United States federal, state, and local income tax purposes. This Exhibit B shall not alter or affect the Parties' obligations to make any payments or to receive any payments under the Agreement. Furthermore the Parties acknowledge and agree that this Exhibit B has no bearing on the Parties' treatment of the Collaboration for non-US tax purposes, and each Party will be free to take any position or any action with respect to taxes for non-US purposes, whether or not consistent with this Exhibit B.

(b) **Scope**. The Parties acknowledge and agree that this Exhibit B is intended to govern the allocations and reporting of FibroGen Cayman's items of income, gain, loss, deduction or credit for United States federal, state, and local income tax purposes only, and that consistent with such intention and the purpose stated in Section 1(a) of this Exhibit B, if the provisions of this Exhibit B conflict with any other provisions of the Agreement, the other provisions of the Agreement shall prevail.

2. Definitions

For purposes of this Exhibit B, the following words and expressions shall have the following meanings respectively given to them:

"Adjusted Capital Account Deficit" means, with respect to any Party, the deficit balance in such Party's Capital Account as of the end of the relevant taxable period, after giving effect to the following adjustments: (i) credit to such Capital Account any amounts which such Party is deemed to be obligated to restore pursuant to Treasury Regulations Section 1.704-1(b)(2)(c) and pursuant to the penultimate sentences in Treasury Regulations Sections 1.704-2(g)(1) and 1.704-2(i)(5); and (ii) debit from such Capital Account the items described in Treasury Regulations Sections 1.704-1(b)(2)(ii)(*d*)(4), (5) and (6). The foregoing definition of Adjusted Capital Account Deficit is intended to comply with the provisions of Treasury Regulations Section 1.704-1(b)(2)(ii)(*d*) and shall be interpreted consistently therewith.

"Capital Account" means a capital account established and maintained on behalf of the Partnership for a Party and adjusted in accordance with the provisions of this Exhibit B.

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"Code" means the United States Internal Revenue Code of 1986, as amended. Any reference to a section of the Code shall include a reference to any successor provision thereto.

"IRS" means the United States Internal Revenue Service.

"Treasury Regulations" means the United States federal income tax regulations promulgated under the Code, as such regulations may be amended from time to time (including corresponding provisions of succeeding regulations).

3. Partnership Accounting Matters

(a) Except as otherwise provided in this Section 3(a) of Exhibit B, (i) the amount of any cash payment made by a Party under this Agreement shall be treated as the contribution of an equivalent amount of cash by such Party to the Partnership, and (ii) the amount of any cash payment received by a Party under this Agreement shall be treated as the distribution of an equivalent amount of cash to such Party by the Partnership. Notwithstanding the foregoing clause (ii), the sales milestone payments made by AstraZeneca to FibroGen Cayman pursuant to Section 8.4(a) of this Agreement and the Co-Promotion Profit paid to AstraZeneca under the Co-Promotion Agreement shall be treated as guaranteed payments within the meaning of Code Section 707(c) that are made to FibroGen Cayman or AstraZeneca, respectively, not in their capacity as a partners of the Partnership. For the avoidance of doubt, sales milestones payments made by AstraZeneca to FibroGen Cayman pursuant to Section 8.4(a) of this Agreement and the Co-Promotion Profit paid to AstraZeneca under the Co-Promotion Agreement shall not reduce the Capital Accounts of FibroGen Cayman and AstraZeneca, respectively, and shall result in a corresponding item of Partnership deduction.

(b) FibroGen Cayman shall calculate the Partnership's items of income, gain, loss, deduction and credit for each taxable period of the Partnership, using the same methodologies used to calculate Net Profit and Net Loss and Development Costs.

4. Capital Accounts

(a) FibroGen Cayman will cause a separate Capital Account to be established for each Party. The Capital Account of each Party will be adjusted and maintained in accordance with Code Section 704 and Treasury Regulations Section 1.704-1(b)(2)(iv).

(b) If the Capital Account of any Party has a deficit balance (after giving effect to all contributions, distributions, and allocations for all periods), such Party will not be obligated to make any payments as contributions to the capital of the Partnership with respect to such deficit, and such deficit will not be considered a debt owed to the Partnership or to any other person for any purpose whatsoever.

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5. Allocations

(a) **General**. In accordance with the Parties' intention to share Development Costs, Net Profits and Net Losses equally, after giving effect to the allocation set forth in Section 5(b) of this Exhibit B and subject to the application of Section 5(c) of this Exhibit B, all items of Partnership income, gain, loss, deduction and credit for any taxable period shall be allocated fifty percent (50%) to AstraZeneca and fifty percent (50%) to FibroGen Cayman.

(b) **Qualified Income Offset**. In the event any Party unexpectedly receives any adjustments, allocations or distributions described in Treasury Regulations Sections 1.704-1(b)(2)(ii)(d)(4), (5) or (6), items of Partnership income and gain shall be specially allocated to such Party in an amount and manner sufficient to eliminate, to the extent required by Treasury Regulations, the Adjusted Capital Account Deficit of the Party as quickly as possible; provided that an allocation pursuant to this Section 5(b) of Exhibit B shall be made only if and to the extent that such Party would have an Adjusted Capital Account Deficit after all other allocations provided for in this Section 5 of this Exhibit B have been tentatively made as if this Section 5(b) of Exhibit B were not in this Agreement.

(c) **Loss Limitation**. Any items of Partnership loss or deduction allocated pursuant to Section 5(a) of this Exhibit B shall not exceed the maximum amount of items of Partnership loss or deduction that can be allocated without causing any Party to have an Adjusted Capital Account Deficit at the end of any taxable period. In the event one but not both Parties would have an Adjusted Capital Account Deficit as a consequence of an allocation of any items of Partnership loss or deduction allocated pursuant to Section 5(a) of this Exhibit B, the limitation set forth in the immediately preceding sentence of this Section 5(c) of Exhibit B shall be applied and items of Partnership loss or deduction not allocable to a Party as a result of such limitation shall be allocated to the other Party to the extent such items of Partnership loss or deduction can be allocated without causing such other Party to have an Adjusted Capital Account Deficit.

(d) **Other Allocation Rules**.

(i) Items of Partnership income, gain, loss or deduction shall be allocated to the Parties pursuant to this Section 5 of Exhibit B as of the last day of each taxable period.

(ii) **Creditable Foreign Tax Expenditures**. The Partnership's “creditable foreign tax expenditures,” within the meaning of Treasury Regulations Section 1.704-1(b)(4)(viii)(*b*), shall be allocated in proportion to the Parties’ share of the corresponding item of Partnership income, gain, loss and deduction to which such creditable foreign tax expenditure relates.

(e) **Tax Allocations; Code Section 704(c)**. Each item of Partnership income, gain, loss, deduction and credit, as determined for United States federal income tax

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purposes, shall be allocated among the Parties in the same manner as such items are allocated for book purposes to the Parties' Capital Accounts. In accordance with Code Section 704(c) and the Treasury Regulations thereunder, income, gain, loss, and deduction with respect to any property deemed contributed to the Partnership shall, solely for United States federal income tax purposes, be allocated among the Parties so as to take account of any variation between the adjusted basis of such property to the Partnership for United States federal income tax purposes and its fair market value at the time of contribution, using any method that FibroGen Cayman, in its sole discretion, determines is necessary or appropriate to reflect the purpose and intentions of this Agreement. Allocations pursuant to this Section 5(e) of Exhibit B are solely for purposes of United States federal, state and local income taxes and shall not affect, or in any way be taken into account in computing, any Party's Capital Account.

6. Other Tax Matters

(a) **Tax Filings and Elections**. FibroGen Cayman will be responsible for timely causing the Partnership to make the following tax elections and filings:

(i) An Internal Revenue Service Form SS-4 (Application for Employer Identification Number) for the Partnership using any name for the Partnership as FibroGen Cayman deems appropriate;

(ii) An election under Code Section 6231(a)(1)(B)(ii) to have the TEFRA audit provisions of subchapter C of chapter 23 of the Code apply to the Partnership; and

(iii) Any other election for United States federal, state, and local tax purposes that FibroGen Cayman, in its sole discretion, deems necessary or appropriate.

In each case, where any filing identifies AstraZeneca or any Affiliate thereof as partner of the Partnership, FibroGen Cayman will provide a written notice of such filing and a copy of the relevant portion thereof to AstraZeneca at least ten (10) Business Days prior to the proposed submission date for AstraZeneca's review and approval, such approval not to be unreasonably withheld.

(b) **Tax Matters Partner**. FibroGen Cayman shall serve as the "tax matters partner" of the Partnership for purposes of Code Section 6231 (and any similar provisions under any state, or local tax law). FibroGen Cayman shall promptly notify AstraZeneca if any tax return of the Partnership is audited or if any adjustments to any such return are proposed in writing and shall promptly furnish AstraZeneca with all copies of material documents and notices received in connection with an administrative or judicial proceeding relating to United States income tax matters of the Partnership. FibroGen Cayman will provide a final draft of any tax document to AstraZeneca at least ten (10) Business Days before the date on which such document is to be submitted to the relevant tax authority and will ensure that

reasonable comments made by AstraZeneca in relation to such final drafts are considered. FibroGen Cayman shall ensure that AstraZeneca is kept informed in reasonable detail of the progress of, and is consulted in relation to, all tax matters. FibroGen Cayman is authorized to take the following actions, but shall not take any such action without first obtaining the prior written consent of AstraZeneca, which consent shall not be unreasonably withheld.

(i) To enter into any settlement with the IRS with respect to any administrative or judicial proceedings for the adjustment of Partnership items (within the meaning of Code Section 6231) required to be taken into account by any Party for United States federal, state or local income tax purposes (such administrative proceedings being referred to as a "tax audit" and such judicial proceedings being referred to as "judicial review"); and in the settlement agreement FibroGen Cayman may expressly state that such agreement shall bind all Parties, except that such settlement agreement shall not bind any Party (A) who (within the time prescribed pursuant to the Code and Treasury Regulations) files a statement with the IRS providing that FibroGen Cayman shall not have the authority to enter into a settlement agreement on behalf of such Party or (B) who is a "notice partner" (as defined in Code Section 6231(a)(8)) or a member of a "notice group" (as defined in Code Section 6223(b)(2));

(ii) In the event that a notice of a final administrative adjustment at the Partnership level of any item required to be taken into account by a Party for United States federal income tax purposes (a "final adjustment") is mailed to FibroGen Cayman, to seek judicial review of such final adjustment, including the filing of a petition for readjustment with the United States Tax Court or the applicable District Court of the United States;

(iii) To file a request for an administrative adjustment with the IRS at any time and, if part of such request is not allowed by the IRS, to file an appropriate pleading (petition or complaint) for judicial review with respect to such request;

(iv) To enter into an agreement with the IRS to extend the period for assessing any United States federal income tax which is attributable to any item required to be taken into account by a Party for tax purposes, or an item affected by such item; and

(v) To take any other action on behalf of the Parties in connection with any tax audit or judicial review proceeding to the extent permitted by applicable law or regulations.

(c) **Tax Information**. If required by applicable law, FibroGen Cayman shall cause the necessary United States federal income tax information to be delivered to AstraZeneca as soon as practicable after the end of each taxable period of the

Partnership, and in any event within fifteen (15) Business Days after any such information has been determined.

(d) **Consistent Treatment**. The Parties are aware of the United States federal income tax consequences of the allocations made by this Exhibit B and hereby agree to be bound by the provisions of this Exhibit B in reporting their shares of Partnership income and loss for United States federal income tax purposes.

(e) **Treatment as Partnership**. It is the intent of the Parties that the Collaboration between them established by this Agreement be taxed as a partnership for United States federal income tax purposes. Accordingly, the Parties hereby agree not to take any position or any action or to make any election in a U.S. tax return inconsistent therewith. Notwithstanding the foregoing, the Parties acknowledge and agree that this Exhibit B has no bearing on the Parties' tax treatment or filing in relation to the Collaboration for non-U.S. tax purposes or any activities outside the scope of the Collaboration.

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Exhibit C

Certain Co-Promotion Terms

Commercialization	The Commercialization Plan will include (a) a multi-year marketing strategy, (b) a multi-year communications strategy, (c) a multi-year detailing strategy (including, without limitation, a call plan which shall consist of a high-level geographic distribution of details, a target range of the aggregate number of details to be performed and the position of such details (i.e., primary or secondary)), and (d) a high-level operating plan and budget for Commercialization of the Product. The numbers in contemplating the initial Commercialization Plan are as follows: 12-month period prior to launch --$[*] First 12-month period after launch --$[*] (such 12-month period and each successive 12-month period thereafter, a “launch year”) 2nd launch year--$[*] 3rd launch year--$[*] 4th launch year--$[*]

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Teams and responsibilities	1. AstraZeneca will hire, train, and manage the marketing team in accordance with budget and activities set forth in the Commercialization Plan. 2. AstraZeneca will hire, train, and manage the national sales team to cover all target hospitals, affiliated or independent dialysis centers, and physicians according to the Commercialization Plan. If AstraZeneca desires to utilize an external sales force to detail the Products, then it shall discuss such utilization with the China Committee. AstraZeneca shall not utilize any such external sales force without the approval of FibroGen China, and FibroGen China shall not utilize any external sales force without the approval of AstraZeneca, in either case, such approval not to be unreasonably withheld. Any such sales force will be required to agree in writing to meet all of the quality, ethical and compliance standards undertaken by AstraZeneca or FibroGen China (as the case may be, including, but not limited to, all of AstraZeneca's policies regarding engagement of health care professionals), and shall not have been found to have committed a material violation of any rule or regulation of the CFDA. 3. FibroGen China will hire, train, and manage brand physicians and the Medical Science Liaison (MSL) team to conduct medical affairs activities according to the Development Plan and to provide scientific support for the Sales and Marketing teams in the Territory according to the Commercialization Plan. 4. AstraZeneca will provide commercial and key account services through its existing infrastructure and hire, train, and manage additional full-time equivalents according to the Commercialization Plan. 5. AstraZeneca's Government affairs and Market Access teams will work jointly with FibroGen China's team on key market access activities such as Provincial and National RDL according to the Commercialization Plan.
Launch Pricing.	The Parties are committed to making first-in-class novel therapies available to Chinese patients on a cost-effective basis. FibroGen WFOE as the manufacturer will have responsibility for pricing. Pricing decisions will be subject to approval by the China Committee. AstraZeneca shall conduct Market research to help establish the optimal pricing level in accordance with the Commercialization Plan.
Pharmacy Channel.	There may be opportunity for separate channels to serve patients in the stage 5 non-dialysis population who are currently not being treated due to logistical constraints at the hospitals, e.g., retail pharmacies outside of hospitals.
Co-Promotion Fee	The Co-Promotion Agreement shall provide for the payment to AstraZeneca or AstraZeneca's designated Affiliate in the Territory of a service fee (the "**Co-Promotion Fee**") in RMB consisting of [*]. Notwithstanding the foregoing, no such [*] as set forth in this Agreement.

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Exhibit D

Net Profit and Net Loss Calculations (Product containing FG-4592)

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

EXHIBIT D-1

FINANCE SUBCOMMITTEE

Formation and Purpose. FibroGen China and AstraZeneca (either itself or via its designated Affiliate) shall, as soon as practicable after the Effective Date, establish a Finance Subcommittee (the "FSC"), which shall consist of up to four (4) representatives from each Party (or such other number as may be mutually agreed by the Parties, *provided*, that each Party at all times has an equal number of representatives on the FSC). Each Party may replace its FSC representatives at any time upon written notice to the other Party. Each Party shall appoint a secretariat to the FSC who is not a member of the FSC.

The FSC shall report to the China Committee with respect to all tax, accounting and financial matters relating to the Products in the Territory, including the Net Profit and Net Loss calculations described in this Exhibit D.

Authority and Decision Making. The FSC shall act by consensus. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party. If the FSC cannot reach consensus on an issue that comes before the FSC and over which the FSC has oversight, then the Parties shall refer such matter to the China Committee for resolution in accordance with Section 2.2(e).

The FSC shall have no power to amend, modify, or waive compliance with Exhibit D or this Agreement.

Meetings. The FSC shall meet at least once per Calendar Quarter during the Term unless the Parties mutually agree in writing to a different frequency for such meetings as reasonably necessary. The meeting shall be scheduled in advance of any meeting of the China Committee scheduled during the same Calendar Quarter. Not later than ten (10) Business Days, or such shorter period as may be necessary in the event of any meeting convened on an ad hoc basis, the secretariats of the FSC shall jointly prepare and circulate an agenda for such meeting. The FSC may meet in person, by videoconference or by teleconference. In person FSC meetings will be held at locations alternately selected and hosted by FibroGen China and by AstraZeneca. The host Party shall be responsible for the costs and expenses of the FSC meetings hosted, provided that each Party will bear the expense of its respective members' participation in FSC meetings, including travel costs. Meetings of the FSC shall be effective only if at least one (1) representative of each Party is present or participating in such meeting. The FSC secretariat of the host Party will be responsible for keeping reasonably detailed written minutes of all FSC meetings that reflect, without limitation, material decision made at such meetings. The FSC secretariat of the host Party shall send draft meeting minutes to the other Party's FSC secretariat, and each secretariat shall seek and obtain review and approval of such minutes from its respective Party's members of the FSC within ten (10) Business Days after each FSC meeting. Such minutes will be deemed approved unless one or more members of the FSC objects to the accuracy of such minutes within ten (10) Business Days of receipt.

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Specific Responsibilities. In addition to its general responsibilities, the FSC shall have the following responsibilities. For clarity, certain decisions of the China Committee are subject to approval by the JSC:

- review, discuss and agree the proposed calculation of Net Profit which for clarity shall be initially prepared by FibroGen China, including the calculation of any amounts to be paid by the Parties hereunder; the FSC shall prepare for the China Committee a mutually agreed calculation of Net Profit for final approval by the JSC.
- review the statement to be prepared by FibroGen China setting forth Product Revenues, COGS, Marketing and Sales Expenses, Royalty Payments, Royalty Withholding Tax, Taxes and Net Profit for the applicable Calendar Quarter as well as the anticipated cash balance (net of payables) projected for the end of the applicable Calendar Year.
- review and discuss the Minimum Cash Level for FibroGen WFOE for the applicable Calendar Quarter.
- review and discuss the payment of Co-Promotion Fees or Deferred Co-Promotion Fees, as applicable.
- review and discuss the prioritisation of payments as described in this Exhibit D.
- review and discuss the distribution of available cash as described in this Exhibit D.
- review and discuss an appropriate adjustment to the payment flow process described in this Exhibit D, if necessary in relation to the funding of Mandatory Post-Approval Safety Studies and maintaining of a reasonable level of working capital for the ongoing and planned operations of FibroGen WFOE, as further described in this Exhibit D. Any adjustments mutually agreed by the FSC shall be prepared for the China Committee for approval, for final approval by the JSC; no such adjustments shall be implemented unless and until finally approved by the JSC.
- recommend any amendments to Exhibit D, for review by the China Committee and final approval, if any, by the JSC. Such proposed amendments may comprise amendments to the payment methodology described in this Exhibit D, taking into account a Party's then current transfer pricing policies, manufacturing plant locations, and inter-Affiliate licensing practices and policies. Any amendments mutually agreed by the FSC shall be prepared for the China Committee for approval, for final approval by the JSC; no such amendments shall be implemented unless and until finally approved by the JSC. For clarity, no Party shall be required to make any material changes to its internal accounting and reporting systems and standards to implement any such amendments.
- review significant cost and expense reconciliation questions raised between the Parties.
- review the reconciliation of payment flows at the FibroGen Cayman level.
- establish the process for financial detail discussions between the Parties regarding the costs and expenses charged to the profit and loss calculations for FG-4592.

In addition, the FSC will perform such other functions as are appropriate to further the purposes of this Agreement, as directed by the China Committee or the JSC.

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Exhibit E

Initial Development Plan

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Exhibit F

Distribution Agreement Key Terms

FibroGen China to deliver all Products to AstraZeneca or its designated Affiliate according to a rolling demand forecast mechanism.

AstraZeneca or its designated Affiliate will take transfer of title and assume full and unconditional credit risk on acceptance of delivery EXW (Incoterms 2010) FibroGen China's or its CMO's manufacturing warehouse, and pay FibroGen China within ninety (90) days.

AstraZeneca or its designated Affiliate shall sell to its sub-distributors [*].

AstraZeneca or its designated Affiliate will pay a transfer price to FibroGen China equal to [*] for the national distribution service in the Territory. The Parties agree such price may be revised by AstraZeneca or its designated Affiliate following any change in applicable law, regulations and prevailing practice required by the tax authority.

AstraZeneca and FibroGen China will jointly select the next level distributors for AstraZeneca or its designated Affiliate under the China Committee.

AstraZeneca or its designated Affiliate will allow FibroGen China full access to all distribution data including all hospital sales data related to the Product to the extent that AstraZeneca or its designated Affiliate has access to such data.

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Exhibit G

Listed Patents

DOCKET NO.	COUNTRY	STATUS	APPLICATION NO.	FILING DATE	PATENT NO.	GRANT DATE
[*]	[*]	[*]	[*]	[*]	[*]	[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Exhibit H

AstraZeneca's Anti-Corruption Rules and Policies

ASTRAZENECA GLOBAL POLICY
ETHICAL INTERACTIONS
ANTI-BRIBERY & ANTI-CORRUPTION
EXTERNAL INTERACTIONS

This Global Policy describes what is required to meet our commitment to operate ethically and with integrity in our business and personal interactions and activities.

This Policy applies to all Employees.

The Company is committed to acting responsibly and in compliance with the requirements of the UK Bribery Act, Foreign Corrupt Practices Act and other relevant laws, regulations and adopted industry codes

CONTENTS

1. SCOPE, APPLICATION & INTERPRETATION

1.1 This Policy applies to all Employees and represents the minimum requirements that the Company has set for Interactions.

An alphabetised Glossary containing definitions for all capitalised terms used in this Policy is included at the end of this Policy.

For certain Interactions, You must refer to more than one Section of this Policy. The relevant Sections are cross-referenced as appropriate.

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Other Global Policies may also apply to Interactions. For example, the *Global Data Privacy Policy* applies to Interactions where there is a need to protect the confidentiality of Patient information.

Global Standards may also apply to Interactions. The Global Standards give additional information about what is required to ensure compliance for particular Interactions. The requirements of this Policy and of the supporting Global Standards must be considered as a whole to evaluate and support compliant Interactions. Global Standards are cross-referenced in each relevant section of this Policy.

1.2 This Policy expands on the Company's *Code of Conduct,* and aligns with (and in some cases exceeds) the requirements of applicable law and adopted industry codes.

You must follow the spirit of this Policy and not just its letter. The absence of a specific requirement relating to a particular Interaction does not mean that the Interaction is necessarily permitted; You must avoid any Interaction that breaches the Company's *Code of Conduct* or supporting Global Policies, Global Standards or Relevant Procedures.

1.3 Employees must not attempt to avoid the requirements of this Policy by requesting, allowing or enabling Third Parties (including relatives, friends or other associates) to be involved in the Interactions prohibited by this Policy on the Employee's (or the Company's) behalf.

In some cases, local law, adopted industry codes particular to a jurisdiction, or rules particular to a Business Unit (e.g., Senior Executive Team ("SET") function), may apply to Interactions, and may be more restrictive than this Policy. Where that is the case, You must follow the more restrictive rules set out in Relevant Procedures. For example, local marketing organisations must establish Relevant Procedures with respect to Interactions with Public Officials, where local law is more restrictive than this Policy.

To the extent appropriate, Business Units must establish Relevant Procedures to assure compliance with the requirements of this Policy and supporting Global Standards, including requirements for sufficient monitoring and/or audit. Employees must use reasonable judgement to create business records sufficient to demonstrate compliance with the requirements of this Policy, supporting Global Standards and these Relevant Procedures (e.g., business records of required approvals and required rationales for approvals).

For purposes of this Policy, required approvals must be obtained in advance of any Interaction.

Where the scope or interpretation of a particular provision of this Policy, supporting Global Standards or Relevant Procedures is unclear, You should seek guidance from Your line manager or Your relevant Legal and/or Compliance partner.

2. ANTI-BRIBERY & ANTI-CORRUPTION

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

2.1 AstraZeneca has zero tolerance for Bribery or corruption (i.e., improper influence).

The Company will support Employees and Third Parties who refuse requests to Give or Receive Bribes on the Company's behalf. Employees and Third Parties will not be subject to retaliation or other adverse consequences for such refusal, even if the Company loses business as a result.

See Section 7 for prohibitions and other requirements regarding Facilitation Payments, including payments Given under duress.

2.2 You may Give or Receive something of value in compliance with the requirements and limits of this Policy, supporting Global Standards and Relevant Procedures.

For purposes of this Policy, supporting Global Standards and Relevant Procedures, "something of value" means any financial or non-financial benefit of any kind, including, but not limited to:

a) the Giving and Receiving of Items of Value and Hospitality (See Section 3 and the *Global Standard on Items of Value and Hospitality*);

b) prices, discounts and rebates for Company Products Given to Third Parties (See Section 4);

c) Contributions Given to Third Parties (See Section 5 and the *Global Standard on Contributions*);

d) Political Support Given to Public Officials or Political Organisations and participation in Political Activities (See Section 6);

e) payments Given to Public Officials and Public Sector Organisations (See Section 7);

f) appointments, paid and volunteer work outside of the Company or other interests associated with actual, apparent or potential Conflicts of Interest (See Section 8);

g) the venue, conduct or other arrangements made for Meetings, as well as the selection and/or support of External Stakeholders to attend Meetings or independent congresses, including professional education credits and capability-building sessions (See Section 9 and the *Global Standard on Meetings*);

h) the engagement of Third Parties to provide Services, including compensation and expense reimbursement (See Section 10 and the *Global Standard on Engaging Third Parties*); and

i) support for External Stakeholders for Non-Interventional Studies and Investigator Sponsored Studies (See Sections 13 and 14).

2.3 You must not Give or Receive something of value that is intended or could be seen as improper influence.

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If you are in doubt about any Interaction, you must consult with your line manager or your relevant Legal and/or Compliance partner for appropriate guidance.

2.4 All monetary payments by the Company to Third Parties that are permitted by this Policy must be made via an approved Company financial payment system by bank transfer, cheque or company credit card, must not take the form of cash or cash equivalent (e.g., debit cards, gift cards, gift certificates), and must be accurately and appropriately recorded in the Company's books and records.

All such payments may also be made via a specifically authorised Third Party (unless otherwise noted in this Policy or supporting Global Standards), when genuine business needs require, and Relevant Procedures (with adequate controls) support such an arrangement. In such cases, the Third Party must be contractually obligated to accurately document, track and report to the Company the amounts paid on its behalf, as required by the Relevant Procedures.

This Section 2.4 prohibits cash and cash equivalent payments by Employees (or Third Parties acting on the Company's behalf), except as specifically permitted by Relevant Procedures established or approved by the Global Finance function. Also, see paragraph 1.18 of the *Global Standard on Items of Value and Hospitality* for requirements regarding exceptional Cultural Courtesy Gifts in the form of cash or cash equivalent.

2.5 You must not Give a Bribe.

Give means to directly or indirectly offer, promise or give, or to authorise such actions.

You must not Give something of value to any Third Party or any fellow Employee that is intended or could be seen to:

a) influence or reward an official action or decision (e.g., by a Public Official);

b) enable or induce a Third Party or fellow Employee to perform their function improperly, or make any decision or take any action favourable to the interests of the Company (or You) on an improper basis, or reward them for doing so;

c) provide incentive or reward to a Third Party for past, present or future willingness to prescribe, administer, recommend, purchase, pay for, reimburse, authorise, approve, supply or use any Company Product or service; or

d) obtain or retain improper business, or secure any improper professional or personal advantage.

2.6 You must not Receive a Bribe.

Receive means to directly or indirectly solicit, agree to receive or accept, or to authorise such actions. You must not Receive something of value from any Third Party or any fellow Employee that is intended or could be seen to:

a) compromise Your independence or judgement;

b) enable or induce You to perform Your function improperly, or make any decision or take any action favourable to the interests of the Third Party (or fellow Employee) on an improper basis, or reward You for doing so; or

c) obtain or retain improper business, or secure any improper professional or personal advantage.

3. ITEMS OF VALUE & HOSPITALITY

3.1 You must not Give or Receive Items of Value or Hospitality that are intended or could be seen as improper influence.

To the extent appropriate, Business Units must establish Relevant Procedures on actual or perceived value and frequency when Giving and Receiving Items of Value and Hospitality. These Relevant Procedures must include specific limits on value (modest) and frequency (occasional) and definitions for “modest” and “occasional,” to guide Employees on appropriate value and frequency levels that would not create actual or perceived improper influence, taking into account local custom and practice (See paragraph 2.1 of the *Global Standard on Meetings*).

To the extent appropriate, Business Units must establish Relevant Procedures to enable the Company to satisfy transparency obligations, with respect to the Giving of Items of Value and Hospitality to External Stakeholders.

Items of Value and Hospitality that exceed Company limits, either separately or in total, to or from the same individual or organisation, are prohibited.

Any Giving or Receiving of Items of Value or Hospitality that is based upon a genuine personal relationship independent of the Company and that is personally funded by the individuals involved (without Company reimbursement) is permissible and is not restricted by this Policy**,** if it is not intended and could not be seen as improper influence.

3.2 See Section 2 of this Policy and the *Global Standard on Items of Value and Hospitality* for further requirements on Items of Value and Hospitality.

4. PRICING, DISCOUNTS & REBATES

4.1 To the extent appropriate, Business Units must have an approved pricing model in place, based on objective criteria, to govern the pricing, rebates and discounts (and other commercial advantages or favourable terms) that can be Given to Third Parties.

The pricing model must be reviewed on a regular basis by the head of the relevant Business Unit or designee to ensure appropriateness and transparency.

These Business Units must document the purpose of any prices, rebates or discounts (or other commercial advantages or favourable terms) Given to Third Parties that fall outside the approved

pricing model, and this documented purpose must be approved by the head of the relevant Business Unit or designee to ensure appropriateness and transparency.

4.2 See Section 2 of this Policy for further requirements on prices, discounts and rebates.

5. CONTRIBUTIONS (DONATIONS, SPONSORSHIPS & PARTNERSHIPS)

5.1 The Company is committed to making a positive impact on Our local communities and supporting the work of others in the healthcare and scientific arenas.

Contributions may be classified as Donations, Sponsorships or Partnerships, and may take the form of financial or non-financial support (e.g., funds or in-kind assistance, such as resources, facilities or employee time).

Contributions may generally only be Given for legitimate scientific, educational and/or charitable purposes to support the following: health or healthcare, medical or scientific education, advances in medical or scientific research and disaster relief. Contributions may also be Given for other purposes on an exceptional basis, only with senior management approval, as set out in Relevant Procedures.

For the avoidance of doubt, this Section does not prohibit individual Employees from supporting charities and other organisations in a purely personal capacity and without any involvement of the Company, if the support meets the requirements of Section 8 of this Policy. This Section 5 also does not prohibit Employees from organising charitable efforts on the Company premises (such as a local food drive or book drive), with line manager approval, where Employees use only their personal funds and resources to participate, if the support meets the requirements of Section 8 of this Policy.

Generally, Contributions to support a Meeting or other event must only be Given where the venue and location of the supported event are appropriate and conducive to the intended purpose, and where any Meals or other Hospitality provided by the Company or by the recipient of the Contribution are modest and incidental to the purpose of the event. See the *Global Standard on Contributions*, the *Global Standard on Items of Value and Hospitality* and the *Global Standard on Meetings* for specific requirements and exceptions.

Certain charitable Donations, Sponsorships and Partnerships that meet the relevant criteria described in the *Global Standard on Contributions* and the *Global Procedure and Guidance Community Investment* specifically qualify as Community Investment Contributions.

5.2 Contributions may only be given to reputable, recognised and independent institutions or other legitimate, established organisations, and only for legitimate purposes.

The relevant Business Unit managing the Contribution must conduct appropriate due diligence on the proposed recipient of any Contribution to establish that the proposed recipient satisfies the requirements of this Section 5.2 and to establish that Contribution will be well used. In addition,

the relevant Business Unit may agree upfront with the recipient organisation to conduct appropriate post-funding review (e.g., review of a summary of the completed projects or other results of the

In addition to the requirements of Section 2, a Contribution must not be Given for any other improper purpose or use, including, but not limited to, the following:

a) to help offset an External Stakeholder's cost of purchasing or reimbursing Company Products or to influence any other decisions about listing, purchasing or reimbursing of Company Products;

b) to organisations or activities that are known to discriminate on any unlawful basis;

c) to support programming or editorial content containing gratuitous violence or sexually explicit material or any activity that does not reflect the values and/or mission of the Company, or could cause embarrassment to the Company; or d) to support any activities prohibited by Relevant Procedures.

Contributions that might be considered as excessive or inappropriate in scale and/or affiliation are not permitted.

Contributions must not be Given to avoid the restrictions on Giving Items of Value and Hospitality to Third Parties (See Section 3 and the *Global Standard on Items of Value and Hospitality*).

5.3 Contributions must not be Given to any organisation for the personal benefit of any individual or Healthcare Professional ("HCP") practice (i.e., a group of HCPs sharing premises or other resources) selected by the Company, or to disguise or conceal any such personal benefit (except as permitted in paragraph 4.5 of the *Global Standard on Contributions* regarding Fellowships and Preceptorships for scientists to support research activities).

Contributions must not be Given by the Company directly to an individual or HCP practice.

For the avoidance of doubt, direct Company support for individual External Stakeholders to attend Meetings or independent congresses is not considered to be a Contribution for purposes of this Policy and is permissible only in limited circumstances (See section 3 of the *Global Standard on Meetings*).

For the avoidance of doubt, awards to individuals are not considered Contributions. See the *Global Standard on Items of Value and Hospitality* for requirements regarding awards and awards ceremonies.

An individual who formally represents an organisation may request a Contribution from the Company on behalf of the organisation, and such request must be considered and processed as

required by Relevant Procedures. Contributions must not be Given to an organisation at the request of any other individual (e.g., to a Public Official's preferred charity), except for Sympathy Gifts Given to a designated non-profit organisation as a memorial in the event of a death, or Contributions Given at the request of an Employee as part of a Company matching fund programme.

Contributions must not be Given to financially benefit HCPs or HCP practices by replacing any assets or funding any activities that they would be expected or required to provide themselves to fulfil obligations they have under local law, contract or customary business practice. For example, Contributions must not be Given to improve business efficiencies or administrative processes of an HCP or HCP practice, such as support for billing or taxes. For the avoidance of doubt, Contributions to support HCP education are permissible, in the interest of improving Patient care and/or Patient health.

5.4 See Section 2 of this Policy and the *Global Standard on Contributions* for further requirements on Contributions.

Contributions must not be Given by Third Parties on behalf of the Company, except for Company Product Donations (See the *Global Procedure and Guidance Community Investment* and the *Global Guidance for Product Donations*).

For the avoidance of doubt, Contributions do not include Political Support or participation in Political

6. POLITICAL SUPPORT & POLITICAL ACTIVITIES

6.1 Employees must not Give Political Support on behalf of the Company unless specifically authorised to do so by the Government Affairs function or the Reviewer.

Third Parties must not Give Political Support on behalf of the Company under any circumstance. The Company will not reimburse in any way or form any Third Party or non-authorised Employee for Giving Political Support.

Political Support may only be Given where it is expressly permitted by local law and where acceptable as part of local custom and practice.

All Political Support must be Given directly to the recipient organisation or individual. The name of the organisation or individual, purpose, nature and value of the Political Support and the date of the Political Support must be properly documented and recorded in the Company's books and records, to enable public disclosure.

The Government Affairs function will establish or approve Applicable Internal Review Procedures for the Giving of Political Support.

6.2 Employees and Third Parties must not participate in Political Activities on behalf of the Company unless specifically authorised to do so by the Government Affairs function or the Reviewer.

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The Government Affairs function will establish or approve Applicable Internal Review Procedures for participation in Political Activities.

6.3 The Company recognises the rights of Employees to use their own funds, time and other personal resources to Give Political Support or to participate in Political Activities.

You must ensure that you do not act or appear to act as a representative of the Company when participating in Political Activities or Giving Political Support in a personal capacity. You must make it clear that your views and actions are Your own, and that any Political Support You provide is Given on a personal basis, using Your own funds, time or other personal resources.

6.4 See Section 2 of this Policy for further requirements on Political Support and Political Activities.

7. PAYMENTS TO PUBLIC OFFICIALS & PUBLIC SECTOR ORGANISATIONS

7.1 The Company does not permit Employees or Third Parties providing Services to Give Facilitation Payments, either directly or indirectly, to Public Officials (including HCPs and other individuals employed by Public Sector Organisations), regardless of whether such payments are nominal in amount.

Employees and Third Parties must not attempt to conceal or disguise Facilitation Payments to avoid the requirements of this Section.

The nature of the Company's business involves legitimate Interactions with a range of Public Officials. Examples include Public Officials responsible for issuing Company Product licences, making Company Product listing decisions, determining Company Product pricing and payment, providing permits and regulatory Authorisations and conducting facility inspections.

You may Give payments to individual Public Officials where they are engaged to provide legitimate Services (See Section 10). You must not Give any other payments to individual Public Officials unless such payments are required or otherwise expressly permitted by local law and not otherwise prohibited by this Policy.

You may Give legitimate and lawful payments to Public Sector Organisations with respect to taxes, permits, licences, inspections and other fees required or otherwise expressly permitted by local law and not otherwise prohibited by this Policy. Official government receipts must be obtained to support all such payments.

7.2 The Company recognises that, in exceptional circumstances, payments may be demanded under duress from Employees or Third Parties providing Services. It is permissible for Employees and Third Parties to Give payments demanded under duress, where there is reasonable fear for personal safety.

Duress describes situations of actual or threatened violence or imprisonment to force a person to act against their will. The Company is committed to ensuring the safety of its Employees and Third Parties and does not expect them to compromise their safety in such situations.

Employees and Third Parties must promptly report in writing to their line manager all incidents where:

a) Facilitation Payments are requested but not paid; or

b) payments are demanded under duress, whether paid or not.

The line manager must then promptly inform the relevant Legal partner of such incidents in writing and ensure that any payments actually made are properly documented and recorded in the Company's books and records. The line manager must also consult with the relevant Legal partner regarding the reporting of such incidents to the relevant authorities and the steps to be taken to prevent recurrence.

7.3 See Section 2 of this Policy for further requirements on payments to Public Officials and Public Sector Organisations.

8. AVOIDING CONFLICTS OF INTEREST

8.1 You must ensure that Your interests, activities and associations outside of the Company do not result in actual, apparent or potential Conflicts of Interest with Your professional duties and decisions as an Employee, by directly or indirectly compromising Your independence or professional judgement, or creating an appearance of doing so.

You must not allow, or appear to allow, a personal relationship to influence Your decision-making or judgement. You must ensure that the Company's interests are paramount when business opportunities are assessed and commercial decisions are taken.

You may make personal financial investments, pursue other business interests and maintain social relationships with people You meet through Your Employment, if all of the relevant requirements of this Section of the Policy are met. You must ensure that these Interactions do not result in actual, apparent or potential Conflicts of Interest with the Company's business activities.

You must not use Company resources or your position as an Employee for Your own personal benefit or for the benefit of Your relatives, friends or other associates.

8.2 You must inform Your line manager in writing of any actual, apparent or potential Conflicts of Interest at the time they become known. Engagement Owners must also inform their line managers in writing of any actual, apparent or potential Conflicts of Interest of a Third Party providing Services, at the time they become known.

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Line managers must provide written direction on how to resolve or avoid the Conflict of Interest after obtaining any necessary advice from the relevant Legal and/or Compliance partner.

If You, a relative or close friend has a financial or management interest in a Third Party (other than a nominal shareholding interest through a publicly-available investment), You must disclose the situation as a potential Conflict of Interest to Your line manager. You must not participate in any purchasing or other Company decisions related to that Third Party.

8.3 You must not do any volunteer or paid work outside of the Company related to Your Company work responsibilities or work product (e.g., speaking engagement, authoring or publishing) unless You obtain written approval from Your line manager, on the basis that such work is unlikely to create an actual, apparent or potential Conflict of Interest and on the basis that any payment is not intended and could not be seen as improper influence.

For all such work, You may Receive necessary and modest travel, accommodation, Meals and other directly related, incidental expenses, with written line manager approval, on the basis that such expenses are not intended and could not be seen as improper influence.

8.4 You must not accept any appointment to the Board of Directors of an external organisation in the healthcare or scientific arena, unless You obtain written approval from Your line manager.
Approval should not normally be provided for directorships of Third Parties who are conducting, or may conduct, business directly within Your scope of responsibility or where You will gain a financial benefit that could be open to question or misinterpretation if publicly disclosed.

8.5 You must not use non-public Company information for personal gain.
You must not pass such information to anyone else (either inside or outside the Company), who does not have a legitimate need for the information.

8.6 See Section 2 of this Policy for further requirements on Conflicts of Interest.

9. MEETINGS

9.1 Organising or supporting Meetings with External Stakeholders is part of Our business. Where doing so, You must follow the requirements listed in the Global Standard on Meetings.

The location, venue, conduct and other arrangements made for Meetings must be modest, conducive and appropriate to the purpose of the Meeting.

9.2 Meetings must always have a scientific, medical education and/or other legitimate business purpose, which must be clearly stated.

The Company may Give a Contribution (See Section 5) to a Meeting organiser to support the conduct of a Meeting (e.g., a Sponsorship). Any such Contribution must meet the relevant requirements of both the *Global Standard on Contributions* and the *Global Standard on*

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Meetings, with respect to the substance of the Meeting as well as the conduct and arrangements made for the Meeting.

9.3 See Section 2 of the Policy and the *Global Standard on Meetings* for further requirements on Meetings.

The *Global Standard on Meetings* also includes specific requirements on Company support for External Stakeholders to attend independent congresses.

10. ENGAGING THIRD PARTIES & ENSURING COMPLIANCE

10.1 The Company is committed to engaging only those Third Parties who embrace standards of ethical behavior that are consistent with Our own.

Engagement Owners are accountable for ensuring that the Third Party's reputation and conduct are consistent with the Company's ethical standards (See Section 10.5).

For the avoidance of doubt, engagements do not include informal, routine business Interactions between Employees and Third Parties, where no Services are provided and no payment is Given (e.g., informal discussions at professional Meetings or independent congresses for scientific exchange, or routine phone calls in the normal course of business).

10.2 Engagement Owners must engage a Third Party only where there is a genuine business need for Third Party Services and must only engage the necessary and appropriate Third Parties to provide those Services.

Engagement Owners must ensure that the selected Third Party has the relevant qualifications, expertise, reputation, knowledge, experience and ability to fulfill the genuine business need, and is the most appropriate choice to provide the Services.

External Stakeholders may be engaged by the Company (either directly or through a specifically authorised Third Party on the Company's behalf) to provide Services. Such Services include, but are not limited to: providing input and information as an Advisor or consultant, speaking at Meetings (e.g., a Promotional Speaker), acting as a clinical investigator or a study site, or educating or otherwise presenting to Representatives at Representative training or business cycle sessions. Patients and Other Third Parties may also be engaged by the Company to provide Services.

Each engagement with an External Stakeholder or Patient for Services must be documented in a signed contract. If the External Stakeholder or Patient is not accepting compensation, or payment or reimbursement of expenses, the requirement for a signed contract may be waived with documented line manager approval.

Each engagement with Other Third Parties for Services must be documented in the format required for the particular Services to be provided, such as a contract, Terms & Conditions, a Purchase Order or other required documentation of offer and acceptance of Services.

Third Parties must not provide any Service on behalf of the Company, in connection with the execution of an engagement or otherwise, unless the Service has been specifically authorised in the signed contract (or other required documentation of the engagement) between the Company and the Third Party, or has otherwise received appropriate documented approval.

You must not Give any Payments for Voluntary or Incidental Activities to any Third Party.

10.3 Our Interactions and engagements with External Stakeholders and Patients must at all times be professional exchanges, designed to enhance the practice of medicine, to benefit Patients, or to fulfill a genuine business need.

In no circumstances may the engagement of an External Stakeholder or Patient be used as a means to gain access or to disguise Promotional Activities, or create an appearance of doing so.

10.4 To the extent appropriate, Business Units must establish adequate Relevant Procedures to mitigate the risk of actual or apparent improper influence over individual External Stakeholders engaged to provide Services, and for monitoring compliance.

To the extent appropriate, Business Units must establish Relevant Procedures that include Fair Market Value guidelines, as well as limits on aggregate compensation provided to individual External Stakeholders and limits on frequency of engagement of individual External Stakeholders. The scope of such guidelines and limits ultimately established will vary, based upon locality and/or function. In developing Fair Market Value guidelines, these Business Units must consider local established compensation levels, varying levels of expertise and/or prominence of Third Parties, varying types and durations of Services to be provided, and the spirit and principles of this Policy.

Third Parties must be paid compensation consistent with and no greater than Fair Market Value, taking into account individual qualifications, experience, ability and reputation, and only for the Services actually provided, consistent with the terms of the engagement.

To the extent appropriate, Business Units must establish Relevant Procedures to enable the Company to satisfy transparency obligations, with respect to payments made to External Stakeholders.

10.5 Prior to the selection and engagement of a Third Party, Engagement Owners must conduct appropriate and proportionate risk assessments, as well as associated, due diligence procedures (if necessary), according to Relevant Procedures. Engagement Owners must take these steps to ensure that the Third Party's reputation and conduct relating to the execution of the engagement are consistent with the Company's ethical standards, with respect to all relevant areas of risk.

To the extent appropriate, Business Units must establish Relevant Procedures to guide Engagement Owners on how to assess, develop, communicate, implement and enforce required compliance expectations for Third Parties. Required compliance expectations will vary, based upon the nature of the Third Party, the Services to be provided and the nature of the associated risks. Based upon the risk assessment and outcomes for a particular Third Party, Engagement

Owners may be required to implement one or more of the following actions with respect to that Third Party:

a) improvement plans or action plans;

b) monitoring or auditing requirements;

c) contractual obligations, including written assurances or commitments by the Third Party;

d) provision of Global Policies, Global Standards, Relevant Procedures or other reference materials, and/or associated training;

e) prior review of the engagement or aspects of the engagement or Services from the relevant Legal and/or Compliance partner; and/or

f) other actions to mitigate identified areas of risk, such as contractual risk mitigation clauses.

At a minimum, Engagement Owners must not engage a Third Party where it is known, or where there is a reason to believe, that the Third Party has Given or Received Bribes, unless the Engagement Owner has documented his/her satisfaction with all of the following, in consultation with the relevant Legal and/or Compliance partner:

a) the actions and improvements undertaken by the Third Party to remediate the concerns and/or behaviour;

b) the current level of compliance by the Third Party; and

c) evidence of the Third Party's ability to provide strong governance and monitoring and to prevent future occurrences of such concerns and/or behaviour.

Engagement Owners, in consultation with an appropriately senior level of management, must periodically reassess existing Third Party relationships, following the required timeframes outlined in the Relevant Procedures, and taking into account any unanticipated changes in the conduct, reputation or risks related to the particular Third Party.

10.6 See Section 2 of this Policy for further requirements on Engaging Third Parties. Engagement Owners must also refer to the *Global Standard on Engaging Third Parties* for further requirements, prior to entering into any engagement with a Third Party.

11. PROMOTIONAL & NON-PROMOTIONAL ACTIVITIES & MATERIALS

11.1 A key part of Our business is to provide information about Company Products and, where and when appropriate, to Promote their use. Promotional and Non-Promotional

Activities and Materials must always be accurate, fair and balanced and not misleading in their content.

The Company has a duty to support the safe and effective use of Company Products. While the Company cannot provide medical advice to External Stakeholders or Patients, the Company may engage in Promotional and Non-Promotional Activities where this is appropriate and permitted by local law. For example, Promotional and Non-Promotional Activities directed to Patients (i.e., "direct to consumer" activities) may only be undertaken where this is permitted by local law.

Our activities must never undermine the relationship between HCPs and their Patients. All Promotional and Non-Promotional Activities and Materials directed to HCPs or Patients must therefore support HCPPatient Interactions and must allow the therapeutic value of Company Products to be assessed by HCPs in the interest of Patient care.

Promotional and Non-Promotional Materials about Company Products directed to Patients must be understandable, taking into account varying levels of education between and within populations. These Materials must be educational, scientific and balanced, and should encourage the Patient to seek further information from the appropriate HCP.

The Company may display Promotional or Non-Promotional exhibits, either in conjunction with a Meeting or as a stand-alone activity, according to the requirements included in Relevant Procedures. See the *Global Standard on Meetings* for further requirements on exhibits (with or without a Meeting).

11.2 The Company must only Promote Company Products once the time is right to do so (which will never be before the Company Product or Use has received the necessary Authorisation), and only consistent with the approved labeling.

Promotional Activities and Promotional Materials must meet all of the following requirements:

a) They must provide a fair balance between a Company Product's benefits and its risks or limitations. They must not exaggerate the benefits or downplay the risks or limitations;

b) They must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way, and must not involve false or unapproved statements about other companies' products. Company Products must only be Promoted on their own proven merits; and

c) They must be capable of substantiation by reference to the approved labeling or scientific evidence consistent with the approved labeling, and must not involve discussions of Unauthorised Company Products or Uses.

Representatives and other Employees in customer-facing roles (e.g., public relations, telemarketing, Marketing, Medical) must be trained as appropriate to their role and must do all of the following in an accurate, responsible manner:

a) They must possess sufficient Company Product and disease area knowledge to present information

to External Stakeholders or Patients, as appropriate to their role; and

b) They must be able to recognise inquiries regarding Unauthorised Company Products or Uses and refer these inquiries to Scientifically Trained Personnel.

All training and educational materials must be approved through the Applicable Internal Review Procedures.

Representatives and other Employees in customer-facing roles must have available a copy of the current, approved labeling for each Company Product or Use discussion they initiate with External Stakeholders.

Any revisions to the approved labeling must be communicated to Representatives and other relevant customer-facing Employees as soon as reasonably possible.

Promotional Activities that are directed to External Stakeholders must be confined to those individuals who are recognised practitioners in the area of medicine concerning Authorised Company Products or
Uses.

Promotional Activities and Promotional Materials must not be directed to External Stakeholders who have requested that they not be sent such information.

11.3 Non-Promotional Activities and Materials (including those regarding disease awareness programs) must not be used to Promote Company Products. Non-Promotional Activities and Materials must be presented in an objective, balanced manner, and must be scientific in tone, language, appearance and intent.

Where local law allows the Company to respond to Company Product-related questions from Patients, any such response may only be made by Scientifically Trained Personnel or other specifically authorised Employee or Third Party, according to Relevant Procedures. Patients communicating with the Company must not be given medical advice, but must instead be referred to their HCP.

Specifically authorised Employees are permitted to proactively issue press releases or other Non-Promotional Materials, such as those relating to financial or investor information.

Scientifically Trained Personnel are permitted to proactively present scientific data or findings regarding Authorised or Unauthorised Company Products or Uses with a view to generating further scientific insight, supporting the medical community in learning about scientific/medical progress or sharing information on current medical practice, such as at scientific congresses or similar events.

All inquiries concerning Unauthorised Company Products or Uses (whether from External Stakeholders or Patients) must be referred to Scientifically Trained Personnel. All responses to such inquiries, either oral or written, must then come directly and only from such Scientifically Trained Personnel, and must meet all of the following requirements:

a) Information must only be provided in response to unsolicited inquiries;

b) Information must be accompanied by the approved labeling, as applicable;

c) All responses must be limited to the scope of the inquiry and must provide data which are appropriate to the source of the inquiry; and

d) All responses must contain (as relevant) a statement that the information requested involves an Unauthorised Company Product or Use and that the Company does not recommend Unauthorised Uses of the Company Product.

11.4 Promotional Materials and Non-Promotional Materials must be approved through the Applicable Internal Review Procedures. Any modification to approved Promotional or Non-Promotional Materials must also be approved through the Applicable Internal Review Procedures.

You must not create, use or provide “home-made” or other unapproved Promotional or Non-Promotional Materials on any topic. You must not alter any approved Promotional or Non-Promotional Materials in any way, unless such creation or alteration is for the express purpose of submitting these Materials for review and approval.

Promotional and Non-Promotional Materials must be assigned an expiration date upon approval, must be monitored for expiration date and must not be used after the expiration date specified in the original approval, unless they are formally re-approved through the Applicable Internal Review Procedures.

Promotional and Non-Promotional Materials must be accompanied by the approved labeling where applicable, as required by Relevant Procedures.

12. PRE-AUTHORISATION ACTIVITIES & MATERIALS

12.1 It is permissible to engage in Pre-Authorisation Activities (i.e., Profiling, Market Access and Pre-Authorisation Training activities), and to use materials supporting such activities, to prepare for a successful commercial launch of a Company Product or Use. Pre-Authorisation Activities must not be used to disguise Pre-Authorisation Company Product Promotion, or create an appearance of doing so.

Materials used for Pre-Authorisation Activities must be approved through the Applicable Internal Review Procedures.

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12.2 Relevant Employees (e.g., Employees in the Marketing, Medical or Sales functions) and specifically authorised Third Parties may Profile customers prior to Authorisation of a new Company Product or Use, to assist in segmentation and targeting activities.

Profiling Activities may only be conducted if all of the following requirements are met:

a) Employees engaging in Profiling must use materials (e.g., scripts) that have been approved through the Applicable Internal Review Procedures;

b) These materials must be structured to allow for a brief conversation to collect broad information about an External Stakeholder's involvement in a disease area, such as treatments and classes used (e.g., "What classes do you use to treat this disease state?"), as well as their needs and the needs of their Patients;

c) These materials must contain clear instructions on proper execution. These materials must contain a clear, prominent prohibition against engaging in Promotional Activities about the new Company Product or Use during a Profiling conversation;

d) These materials must not contain targeted questions that are specific or unique to a Company Product or Use;

e) If asked by the External Stakeholder about the purpose of the Employee's questions, Employees may objectively state that the Company has submitted a Company Product or Use for regulatory Authorisation. Employees must not proactively discuss the Company Product or Use in any further detail; and

f) In the event that the External Stakeholder asks for more details about the Company Product or Use during a Profiling discussion, Employees (other than those in the Medical function) may provide appropriate contact information for the External Stakeholder to submit his/her own request for such information (i.e., a "professional information request"), but such Employees must not directly respond to the request or submit the request on behalf of the External Stakeholder. Employees in the Medical function may directly respond to the request and may submit a professional information request on behalf of the External Stakeholder.

During, and in support of, internal Company segmentation and targeting activities, relevant Employees may share existing knowledge and review and share prescribing data and other Company-purchased or publicly available information.

For the avoidance of doubt, Profiling activities are also permitted after Authorisation of a new Company Product or Use.

12.3 Relevant Employees other than Representatives or their first line managers (e.g., Employees in the Market Access or Medical functions) and specifically authorised Third Parties may perform Market Access activities prior to Authorisation of a new Company Product or Use, by providing Company Product or relevant disease area information to

Healthcare Organisations (“HCOs”) (i.e., payers) or Public Officials to support regulatory Authorisation, pricing or reimbursement discussions.

For the avoidance of doubt, Market Access activities are also permitted after Authorisation of a new Company Product or Use.

12.4 Pre-Authorisation Training on Unauthorised Company Products or Uses may be initiated as necessary to allow for sufficient time to study and understand the new information presented regarding the Company Product or Use, disease area, disease management, External Stakeholder and Patient needs and/or the current market, including the current state of medical practice, competitors and existing therapies, and treatment protocols and Guidelines.

In making the determination of the timing and sequencing of Pre-Authorisation Training for a particular new Company Product or Use (as a guideline, no longer than 60 days before the expected Authorisation date), the Reviewer must seek input from Employees in the Medical, Training, Commercial, Compliance and/or Legal functions (“contributing functions”), as applicable, and must take into account all of the following considerations:

a) whether the training will involve a new or familiar disease area;

b) whether the training will involve an Unauthorised Company Product or an Unauthorised Use of an Authorised Company Product;

c) the likelihood of receiving significant changes and comments to the proposed labeling submitted to the regulatory agency responsible for Authorisation;

d) the risks of pre-Authorisation Promotion arising from providing training on Unauthorised Company Products or Uses and/or Promotional messages; and

e) other factors deemed relevant to the particular proposed training by the Reviewer and/or contributing functions, who are evaluating the training need and the associated risks.

All Pre-Authorisation Training materials must be marked with a clear, prominent, appropriate disclaimer stating that the material is strictly for internal purposes only (e.g., “For Internal Use Only”). These materials may include information on Unauthorised Company Products or Uses or relevant disease areas, and may include relevant reprints. These materials, or the information they contain, must not be shown, discussed, or distributed outside the Company, except where an appropriate Third Party must also be trained (e.g., a contract sales force or sales force of a co-promotional partner).

After the relevant Authorisation has been obtained, information included in Pre-Authorisation Training materials that is appropriate for discussion with External Stakeholders or Patients may be included in
Promotional and/or Non-Promotional Materials specifically designed and approved for those purposes.

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13. NON-INTERVENTIONAL STUDIES

13.1 Non-Interventional Studies ("NISs") must address a scientifically and medically valid question to which the Company needs the answer.

These may include: the effectiveness and/or safety of a Company Product, medical practice and drug utilisation characterisation, disease epidemiology and clinical epidemiology, burden of disease (e.g., costs and quality of life) or other Patient-reported outcomes, and compliance/adherence to a therapeutic regimen.

13.2 The Company must not be involved in the decision to place a particular Patient on a specific Company Product. That decision is made solely by the Patient's HCP.

An NIS must not be used to induce the use or prescription of a Company Product or to train HCPs on the use of a particular therapy.

Patients must not be given a Company Product or switched to a Company Product for the purpose of taking part in the study.

13.3 NISs must be observational in nature and the collected data must undergo a formal analysis by the Company or by a Third Party on the Company's behalf.

Additional diagnostic or monitoring procedures must not be applied to the Patients, and epidemiological methods must be used for the analysis of collected data.

13.4 See Section 2 of this Policy for further requirements on NISs. Employees must also refer to the Relevant Procedures (i.e., International Procedures) for further requirements.

All NISs must be registered and their results posted according to the requirements of the Relevant Procedures.

The decision to conduct an NIS and the selection, engagement and payment of NIS investigators must meet all of the relevant requirements of Section 10 of this Policy and the *Global Standard on Engaging Third Parties.*

Support for NISs may be Given by specifically authorised Third Parties on behalf of the Company according to the Relevant Procedures.

14. INVESTIGATOR SPONSORED STUDIES

14.1 The Company recognises the importance of Investigator Sponsored Studies ("ISSs") in expanding scientific knowledge related to potential Uses of Company Products.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

An ISS may be conducted with Authorised or Unauthorised Company Products or Uses.

All ISSs supported by the Company must be consistent with the research strategy for the relevant Company Product.

14.2 The Company may provide support for an ISS, but must not be considered to be the sponsor or to have any partial sponsorship role in the study in accordance with local law.

The decision to provide support for an ISS must be based on whether the study expands scientific knowledge related to potential Uses of Company Products and/or associated disease area(s) through a properly conducted independent clinical study that will result in the publication of meaningful new data.

14.3 See Section 2 of this Policy for further requirements on ISSs. Employees must also refer to the Relevant Procedures (i.e., International Procedures) for further requirements.

A contract approved through the Applicable Internal Review Procedures must be negotiated and signed by authorised representatives of the Company and the sponsor and, as applicable, the investigator, prior to study initiation.

The level of financial support that may be provided will vary among countries. It must always be consistent with Fair Market Value for the activities to be conducted as part of the clinical trial, and payments must be milestone-driven.

The Company must not provide Company Product Samples for use in ISSs.

Support for ISSs may be Given by specifically authorised Third Parties on behalf of the Company according to the Relevant Procedures.

GLOSSARY

Advisory Boards refers to internal Meetings organised by the Company where the Company engages External Stakeholders (i.e., "**Advisors**") to provide the Company with independent advice and input within their area of expertise.

Advisors refers to the definition provided within the definition of Advisory Boards.

Applicable Internal Review Procedures refers to the review and approval requirements for Interactions and supporting materials, as set out in Relevant Procedures. These requirements include, but are not limited to, review and approval by Nominated Signatories, Scientifically Trained Personnel, the Legal Department, other specialist functions (e.g., Procurement) or line managers, as appropriate (i.e., "**Reviewers**"). Reviewers must take into account the substance, as well as the intended purpose and audience, when approving Interactions or supporting materials, and approval must be obtained in advance of any Interaction or use of supporting materials.

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Authorisation or **Authorised** refers to approval of a Company Product or Use by the relevant local regulatory agency, to permit entry into the local market or to permit inclusion into the local approved labeling.

Bribe or **Bribery** refers to Giving or Receiving of something of value that is intended or could be seen as an inducement or reward for improper behaviour (i.e., behaviour that is dishonest or illegal or a breach of duty of impartiality, trust or good faith), to influence any official act or decision, or to obtain or retain business, favourable treatment or other advantage or benefit. Giving or Receiving of Bribes is a wellrecognised form of corruption (collectively referred to as “improper influence” through this Policy).

Business Unit refers to a distinct section of the Company, such as a consolidated legal entity, a local marketing organisation, a Senior Executive Team (“SET”) function, a department or operating entity within a SET function, or, in some cases, a cross-functional unit comprising Employees with common responsibilities.

Community Investment Contributions refers to certain charitable Donations, Sponsorships or Partnerships Given by the Company to non-profit organisations that meet the relevant criteria described in the *Global Standard on Contributions* and the *Global Procedure and Guidance Community Investment*.

Company or **Our** refers to AstraZeneca PLC and its consolidated legal entities worldwide, including MedImmune.

Company Product refers to any pharmaceutical or biological product or medical device that is developed and/or marketed by the Company, including investigational products/devices and co-promoted products/devices. For purposes of this Policy, references to Company Products include both Authorised and Unauthorised Company Products, unless specifically noted.

Conflicts of Interest refers to situations where personal, financial or other interests, activities or associations outside of the Company may influence or compromise, or could be seen to influence or compromise, the professional duties and decisions of an Employee or Third Party providing Services.

Contributions refers to financial or non-financial support (e.g., funds or in-kind assistance, such as resources, facilities or Employee time) Given by the Company to a Third Party. Contributions may be classified as either Donations, Sponsorships or Partnerships.

Cultural Courtesy Gift refers to a personal Gift traditionally given to acknowledge a significant national, cultural or religious holiday or event.

Donations refers to the type of Contributions Given by the Company to a non-profit or Public Sector Organisation, that may or may not be for a designated pre-defined initiative.

Employee or **You(r)** refers to all Company full-time and part-time directors, officers, employees and temporary staff worldwide.

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Engagement Owners refers to Employees responsible for engaging with and managing the Services provided by a Third Party.

External Stakeholders refers to the category of Third Parties who are external customers and other relevant stakeholders, including Healthcare Professionals ("HCPs") and Healthcare Organisations ("HCOs"), Scientifically Trained Personnel engaged by the Company to provide Services, Public Officials, Patient Groups and other relevant public and private organisations and groups.

A **Facilitation Payment** (or "grease" payment) is an unofficial payment or anything else of value Given to Public Officials (including HCPs and other individuals employed by Public Sector Organisations) to secure or speed up routine actions that the recipient has a duty to perform. Examples include additional payments required to issue permits or licences, speed passage through immigration controls and release goods held at port or in customs.

Fair Market Value refers to the amount that a service or item would be worth to a typical buyer who is under no duty to purchase and who receives no special advantage. Fair Market Value is determined by the home country of the relevant service provider (who receives payment for the service) or relevant buyer of the item.

Fellowships and **Preceptorships** refer to programmes conducted at host institutions and designed to provide basic training (i.e., training necessary to obtain a degree or licence) or advanced education to HCPs or scientists in a particular specialty, therapeutic area or field of research.

Gift refers to an Item of Value that is provided as a mark of appreciation, commemoration or friendship.

Give, Giving or **Given** means to directly or indirectly offer, promise or give, or to authorise such actions.

Global Policies refers to the mandatory documents that support the Company's *Code of Conduct* by setting out the compliance commitments of the Company and the key principles to be followed to meet those commitments.

Global Standards refers to the mandatory documents that support the Global Policies by describing the compliance rules to be followed to deliver the intent stated in the Global Policies or in the Company's *Code of Conduct*.

Guidelines refers to any of the following materials and may or may not relate to a specific disease state: practice guidelines, treatment guidelines, medication algorithms, disease definitions or Research & Development quality standards. Guidelines are not intended to refer to treatment guidelines or protocols developed by HCOs, where such development is essential to the business of the HCO (such as a formulary or benefit administrator), or those developed by HCP practices.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Healthcare Professionals ("HCPs") and **Healthcare Organisations ("HCOs")** refer to individuals or organisations, respectively, who may or do prescribe, administer, recommend, purchase, pay for, reimburse, authorise, approve or supply any Company Product or service, including any members of the medical, dental, pharmacy or nursing professions, and relevant associated administrative staff; and/or hospitals and other care organisations, health plans, health insurers, managed care organisations, pharmacies, formulary or benefit administrators and clinical research organisations, and relevant staff at such entities.

Hospitality refers to Meals, travel/accommodation, and other directly related, incidental expenses, as well as invitations or tickets to social or entertainment events. Entertainment events include sporting, theatre, music or recreational events.

Interactions refers to the business and personal interactions and activities described in this Policy.

Interacts refers to the conduct of an Interaction.

Investigator Sponsored Study (ISS) refers to a clinical study that is independently initiated, designed and conducted by an external investigator (who assumes both the sponsor and principal investigator role) or medical institution, collaborative research group or academic research organisation (which assumes the sponsor role and appoints principal investigator(s) for the study). For purposes of this Policy, sponsor/investigator is used as a generic term for both situations described above.

Item of Medical Utility refers to an Item of Value primarily designed to educate External Stakeholders or Patients or help External Stakeholders educate Patients about disease management in disease state areas relevant to Authorised Company Products or Uses.

Items of Value refers to Gifts, Items of Medical Utility, items used to assist in screening or diagnosis of Patients, items linked to the safe and effective administration of Company Products, logistical items,
Samples (including Samples vouchers or coupons), awards and Patient Programmes.

Market Access refers to discussions with HCOs (i.e., payers) or Public Officials about regulatory
Authorisation, pricing or reimbursement decisions.

Market Research refers to the systematic gathering and interpretation of quantitative or qualitative data on the market environment from External Stakeholders or Patients using statistical and analytical methods to gain insight and support decision-making. It does not include the gathering and interpretation of "real world evidence" or Company-purchased HCP-level data.

Meals refers to food and/or beverages.

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Meeting refers to a planned gathering of External Stakeholders, which the Company organises or supports, either financially or non-financially. Non-financial support includes in-kind assistance, such as resources, facilities or Employee time. Meetings may be for an internal Employee audience, or for an external audience of External Stakeholders and may be held in-person or virtually.

Non-Interventional Study (NIS) refers, in general terms, to a study where the assignment of the Patient to a particular therapeutic strategy is not decided in advance by a study protocol but falls within the HCP's current practice, and the prescription of the Company Product is clearly separated from the decision to include the Patient in the study.

Non-Promotional Activity refers to any activity that is not a Promotional Activity that is intended to provide scientific or educational information about Company Products, relevant disease areas or health and medicines generally. Non-Promotional Activities may be oral or written and may be conducted through any medium, including the Internet. Non-Promotional Activities may take a number of forms, including, but not limited to, leaflets provided with Company Products, point of sale information, information regarding disease awareness programmes, responses to queries from External Stakeholders or Patients, information provided to inform the development of Guidelines or other information contributing to scientific exchange.

Non-Promotional Materials refers to materials intended to be used during Non-Promotional Activities or to support Non-Promotional Activities.

Our or **Company** refers to AstraZeneca PLC and its consolidated legal entities worldwide, including MedImmune.

Other Third Parties refers to the category of Third Parties who are not External Stakeholders or Patients, including, but not limited to, the media, suppliers, distributors, agents and joint venture, co-promotion, research and licensing partners.

Partnerships refers to the type of Contributions Given by the Company in collaboration with a non-profit, for-profit or Public Sector Organisation for a pre-defined initiative, involving substantive, active Company participation and resulting in the delivery of specific, measurable outcomes. For purposes of this Policy, Partnerships do not include research or commercial collaborations aimed at the development or marketing of Company Products or services for the Company's benefit.

Patient Groups refers to non-profit organisations formally representing the needs of Patients, theirfamilies and other caregivers.

Patient Programmes refers to Items of Value, specifically vouchers, rebates, coupons, co-pay assistance cards, motivational information and other programmes and materials designed to increase access and affordability of Company Products or to enhance therapy compliance.

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Patients refers to the category of Third Parties who are members of the general public and who use or may use Company Products.

Payments for Voluntary or Incidental Activities refers to any compensation or expense reimbursement Given to an individual or organisation as a "thank you" for voluntary activities or for activities that are not necessary to address a genuine business need. They do not include payments made to Third Parties for contracted Services that address a genuine business need.

Policy refers to this *AstraZeneca Global Policy on Ethical Interactions*.

Political Activities refers to attendance or participation in public policy or other political activities, including participation in political conventions or fundraising events for Political Organisations or individual Public Officials and their causes.

Political Organisations refers to political parties and their employees, Political Action Committees ("PACs") and other political organisations. Political Support is distinct from Company Contributions to Public Sector Organisations (See Section 5), as well as payments to Public Officials or Public Sector Organisations (See Sections 7 and 10).

Political Support refers to financial or non-financial support (e.g., funds or in-kind assistance, such as resources, facilities or Employee time) Given to Political Organisations or individual Public Officials and their causes.

Pre-Authorisation Activities refers to Profiling, Market Access and Pre-Authorisation Training activities undertaken by Employees in preparation for Authorisation of a new Company Product or Use.

Pre-Authorisation Training refers to Company-provided education to Representatives and/or their first line managers in preparation for Authorisation of a new Company Product or Use.

Preceptorships and **Fellowships** refer to programmes conducted at host institutions and designed to provide basic training (i.e., training necessary to obtain a degree or licence) or advanced education to HCPs or scientists in a particular specialty, therapeutic area or field of research.

Presentation refers to each segment of a Meeting, where a distinct speaker is used and/or distinct topic is discussed.

Presentation Materials refers to all materials intended to be shown and/or distributed to the speaker or audience before, during or after a Presentation, including but not limited to speaker briefing documents, written summaries of Presentation objectives, slides and reference documents.

Profiling (also known as "disease insight visits") refers to discussions with External Stakeholders to gain an understanding of their involvement in a disease area, including

therapeutic options, medical gaps, External Stakeholder needs or the needs of Patients. For the avoidance of doubt, Profiling is not considered Market Research.

Promote, **Promotion** or **Promotional** refers to the conduct of Promotional Activities.

Promotional Activity refers to any activity that is intended or could be seen to Promote the prescription, administration, recommendation, purchase, payment, reimbursement, authorisation, approval, supply or use of Company Products or services. Promotional Activities may be oral or written and may be conducted through any medium, including the Internet.

Promotional Materials refers to materials intended to be used during Promotional Activities or to support Promotional Activities.

Promotional Speaker Programmes refers to Promotional Meetings organised by the Company to Promote Authorised Company Products or Uses, where the Company engages External Stakeholders

(i.e., "**Promotional Speakers**") to speak to other External Stakeholders on behalf of the Company about such topics.

Promotional Speakers refers to the definition provided within the definition of Promotional Speaker Programmes.

Public Official refers to an individual who:

- Holds a legislative, administrative or judicial position of any kind, whether appointed or elected, or is a candidate for such a position, or
- Exercises a public function for a country or territory of a country, or for any Public Sector Organisation of a country or territory, at the national, regional or local level,
- Acts as an official or agent of an international Public Sector Organisation, or
- Is any other employee (including HCPs) of a Public Sector Organisation.

Public Sector Organisation refers to an agency, enterprise, or other entity of a government that sets or administers public policy or exercises executive, political and/or sovereign power through customs, institutions and laws within a country or territory of a country, at the national, regional or local level. It also includes state-owned and state-controlled entities, such as a state-owned or state-controlled hospital, university, energy company, telecommunications company or other similar state-owned or statecontrolled enterprises.

Receive, Receiving or **Received** means to directly or indirectly solicit, agree to receive or accept, or to authorise such actions.

Relevant Procedures refers to the written local and/or functional policies, standards, procedures and guidelines that contain details, processes and controls for compliance with this Policy and the supporting Global Standards.

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Representatives refers to Employees who are members of any Commercial channel who Promote Company Products directly to External Stakeholders. Representatives may be referred to as sales representatives, service team associates, inside sales agents, medical representatives or other titles, depending upon the relevant local marketing organisation. Representatives include any Third Parties fulfilling such responsibilities on the Company's behalf (i.e., a contract sales force). Representatives do not include other Employees, such as those performing marketing or market access activities.

Reviewers refers to the definition provided within the definition of Applicable Internal Review Procedures.

Sample refers to an Item of Value, specifically a unit of pharmaceutical Company Product that is not to be sold but is provided free of charge to an HCP to allow the HCP and appropriate Patients to determine tolerability and effectiveness of the Company Product.

Scientifically Trained Personnel refers to individuals employed or engaged by the Company who are highly-trained experts, who have relevant, specialised scientific and/or medical knowledge and whose responsibilities include the provision of scientific and/or medical information. This excludes anyone in the Sales, Marketing or other non-Medical Commercial functions, even if they have scientific or medical training or backgrounds.

Section refers to Sections 1 through 14 of this Policy, listed in the Table of Contents. Each Section covers a category of Interactions.

Services refers to the activities performed by a Third Party engaged by the Company. Services include activities performed on behalf of the Company, goods, services or information provided to the Company, or the activities performed in collaboration with the Company.

Sponsorships refers to the type of Contributions Given by the Company to a non-profit, for-profit or Public Sector Organisation for a pre-defined initiative, where the Company's name is associated with the initiative and/or the Company receives other substantial recognition for the Sponsorship.

Sympathy Gift refers to a personal Gift to express sympathy for bereavement or serious illness of the recipient or immediate family member.

Third Party(ies) refers to any person or organisation who is not the Company or an Employee, with whom Employees Interact. The various types of Third Parties are categorised as either External Stakeholders, Patients, or Other Third Parties. Where a Third Party fits into more than one category, the more restrictive rules apply.

Uses refers to the indications, dosing, populations and other uses of Company Products. For purposes of this Policy, references to Uses include both Authorised and Unauthorised Uses of Company Products, unless specifically noted.

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Unauthorised refers to a Company Product or Use that has not yet received Authorisation from the relevant local regulatory agency. An Unauthorised Company Product may also be referred to as “investigational.” An Unauthorised Use (i.e., an “off-label use”) is inconsistent with the local approved labeling for a Company Product.

Voluntary or Incidental Activities refers to any voluntary activities or activities that are not necessary to address a genuine business need.

You(r) or **Employee** refers to all Company full-time and part-time directors, officers, employees and temporary staff worldwide.

REFERENCES

Global Standard on Items of Value and Hospitality
http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global_Compliance/effective/Global%20Standard/LDMS_001_00145832.pdf

Global Standard on Contributions
http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global_Compliance/effective/Global%20Standard/LDMS_001_00145831.pdf

Global Procedure and Guidance Community Investment
http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global_Compliance/effective/Procedure/LDMS_001_00146359.pdf

Global Guidance for Product Donations
http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global_Compliance/Active/Guidance%20Materials/LDMS_001_00146361.pdf

Global Standard on Meetings
http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global_Compliance/effective/Global%20Standard/LDMS_001_00145768.pdf

Global Standard on Engaging Third Parties
http://portalapps.is.astrazeneca.net/azgard-components/ldms-documents/Global_Compliance/effective/Global%20Standard/LDMS_001_00145830.pdf

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Exhibit I
Invoicing Requirements

Subject to any separate instructions to be agreed between the Parties regarding payments to health care professionals or health care organizations in the Territory, as required by applicable laws and regulations, invoices should be sent to:

AstraZeneca AB
AstraZeneca R&D Mölndal
Att. Christina Wågestrand
CVGI iMed Strategy
431 83 Mölndal
Sweden

Invoices shall contain the following information:

a. AstraZeneca's Agreement ID: Elisabeth Björk, Global Product Vice President, Global Medicines Development, ECHO Project ID 10007956
b. the number and date of invoice
c. the latest date of payment according to Agreement
d. description of services
e. name and address of FibroGen
f. FibroGen VAT registration number or EIN/TaxID,
g. AstraZeneca's VAT registration number SE556011748201 (in EC),
h. VAT rate (%), if any,
i. taxable amount per VAT rate, if any,
j. VAT amount, if any
k. legal reference or explanation when VAT is excluded,
l. invoice amount and currency,
m. bank details, preferably IBAN code, otherwise account number and bank code, and SWIFT-address.

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Exhibit 10.4

LICENSE AGREEMENT

This Agreement, made and entered into this 23rd day of May, 1997 (the Effective Date"), by and between the UNIVERSITY OF MIAMI and its SCHOOL OF MEDICINE, having its principal office at 1600 N.W. 10th Avenue, Miami, Florida 33136 (hereinafter "LICENSOR") and FIBROGEN, INC., a corporation duly organized under the laws of Delaware and having its principal office at 260 Littlefield Avenue, South San Francisco, California 94080 and its Affiliates (hereinafter collectively, "FIBROGEN").

WITNESSETH:

WHEREAS, LICENSOR is the sole owner of the Technology and Product identified under the Patent Rights (as hereinafter defined) relating to Connective Tissue Growth Factor, and has the right to grant licenses under said Patent Rights;

WHEREAS, LICENSOR desires to have the Patent Rights utilized in the public interest and is willing to grant an exclusive sublicense thereunder;

WHEREAS, FIBROGEN intends to develop, produce, manufacture, market and/or sell products similar to the Licensed Product(s) (as hereinafter defined) and is willing to commit itself to a diligent program of exploiting the Patent Rights so that public utilization shall result-therefrom; and

WHEREAS, FIBROGEN desires to obtain a sublicense under the Patent Rights upon the terms and conditions hereinafter get forth.

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein, the parties agree as follows:

ARTICLE 1
Definitions

1.1 "Affiliate" shall mean any corporation, company or other entity which directly or indirectly controls, or is controlled by, or is under common control with, FIBROGEN. For this purpose, "control" shall mean direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock of, or at least a fifty percent (50%) interest in the income of such corporation or other business entity, or such other relationship as in fact, constitutes actual control.

1.2 "FIBROGEN" shall mean FIBROGEN and shall include any Subsidiary (as hereinafter defined) or Affiliate (as hereinafter defined) of FIBROGEN.

1.3 "Subsidiary" shall mean any corporation, company or other entity at least fifty percent of whose voting stock is owned or controlled directly or indirectly by FIBROGEN.

1.4 "Patent Rights" shall mean United States Patent Application Serial Number [*] (hereinafter referred to as the "Patent Rights Patent Application"), and the United States and foreign patents issuing from said United States and foreign patent applications or later-filed foreign applications based on the said United States Patents and applications (hereinafter referred to as the "Patent Rights Patent(s)") and any continuations, continuations-in- part, divisions, reissues or extensions of any of the foregoing.

1.5 "Licensed Method(s)" shall mean the methods of treatment comprising the application and/or administration of connective tissue growth factor and related molecules which are covered in whole or in part by (i) a pending claim contained in a Patent Rights Patent Application, or (ii) a valid and unexpired claim contained in a Patent Rights Patent.

1.6 "Licensed Process(s)" shall mean a process for making Licensed Product(s) which is covered in whole or in part by (i) a pending claim contained in a Patent Rights Patent Application, or (ii) a valid and unexpired claim contained in a Patent Rights Patent.

1.7 "Licensed Product(s)" shall mean any product used or sold and any process used by or for FIBROGEN, which at the time of manufacture, use or sale:

(a) is covered in whole or in part by (i) a pending claim contained in a Patent Rights Patent Application in the country in which the Licensed Product(s) is made, used or sold, or (ii) a valid and unexpired claim contained in a Patent Rights Patent in the country in which the Licensed Product(s) is made, used or sold; or

(b) is manufactured by using a process that is a Licensed Process in the country in which such product is made, used or sold.

1.8 "Net Sales" shall mean the sum of all amounts invoiced on account of sales or use of Products by FIBROGEN and any sublicensees to non-Affiliated third-party purchasers or users of Products, less the sum of the following:

(a) discounts allowed in amounts customary in the trade;

(b) sales, use, value-added, tariff duties or other excise taxes directly imposed and with reference to particular sales;

(c) outbound transportation prepaid or allowed; and

(d) amounts allowed or credited on returns.

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"Net Sales" shall not include any sale between or among FIBROGEN and its Affiliates or Subsidiaries, but shall include any subsequent sales by FIBROGEN or its Affiliates or Subsidiaries.

No deductions shall be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed by FIBROGEN and on its payroll, or for cost of collections. Licensed Product(s) shall be considered sold when used, billed out or invoiced. If the Licensed Product is exchanged for a consideration other than money, billings shall be gross selling price of comparable Licensed Product(s) and in arm's-length transactions by FIBROGEN or, if no sales of comparable Licensed Products have been made, then the fair market value thereof.

1.9 "Net Royalties" shall mean the net royalties actually received by FIBROGEN in connection with sublicensing of any of the Patent Rights.

1.10 "Effective Date" shall mean the date first shown above.

1.11 "Territory" shall mean all the countries of the world.

ARTICLE 2
Grant Of License

2.1 LICENSOR hereby grants to FIBROGEN an exclusive worldwide right and license, with the right to sublicense others, to make, have make, use, sell and have sold Licensed Product(a), and to practice Licensed Process(es) and/or Licensed Method(s), to the full end of the term for which the Patent Rights are granted (the "Contract Period") unless sooner terminated according to the terms hereof.

2.2 FIBROGEN agrees to forward to LICENSOR a copy of any and all fully executed sublicense agreements, and further agrees to forward to LICENSOR annually a copy of such reports received by FIBROGEN from its sulicensees during the preceding twelve-month period under the sublicenses as shall be pertinent to a royalty accounting under said sublicense agreements.

2.3 LICENSOR reserves to itself the right to practice under the Patent Rights for the University's noncommercial research and education purposes.

2.4 The license granted hereunder shall not be construed to confer any rights upon FIBROGEN by implication, estoppel or otherwise as to any technology except as specifically set forth herein.

2.5 FIBROGEN agrees that any sublicenses granted by it shall contain such provisions as are necessary for it to meet its obligations under this Agreement and to reasonably protect the interests of LICENSOR with regard to such sublicense.

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2.6 Termination under any of the provisions of this Agreement of the license granted to FIBROGEN in this Agreement shall terminate all sublicenses which may have been granted by FIBROGEN, provided that any sublicensee may elect to continue its sublicense by advising LICENSOR in writing, within sixty days of the sublicensee's receipt of written notice of such termination, of its election and of its agreement to assume in respect to LICENSOR all the obligations (including obligations for payment) contained in its sublicensing agreement with FIBROGEN. Any sublicense granted by FIBROGEN shall contain provisions corresponding to those of this paragraph respecting termination and the conditions of continuance of sublicenses.

ARTICLE III
Due Diligence

3.1 FIBROGEN shall use best faith efforts to bring one or more Licensed Product(s), Licensed Method(s) and/or Licensed Process(es) to market through a diligent program for exploitation of the Patent Rights.

3.2 FIBROGEN's failure to perform in accordance with paragraph 3.1 above shall be grounds for LICENSOR to terminate this Agreement pursuant to Paragraph 13.3 hereof.

3.3 FIBROGEN agrees to submit under confidence annual reports, upon LICENSOR’s request, as to its efforts to develop markets for the Licensed Products and Licensed Method(s). Such reports shall include assurance by FIBROGEN of its intent to actively develop commercial embodiments of the inventions of the Licensed Patents and a summary of its efforts in this regard.

3.4 Unless FIBROGEN has a Licensed Product available for commercial sale prior to January 1, 2008 or FIBROGEN has made available for commercial sale a product which, when administered, may be used in a Licensed Method, FIBROGEN agrees that LICENSOR may terminate this Agreement

ARTICLE 4
Royalties

4.1 For the rights, privileges and license granted hereunder, FIBROGEN shall pay fees and royalties to LICENSOR, in the manner hereinafter provided, to the end of the term of the Patent Rights or until this Agreement shall be terminated as hereinafter provided:

(a) FIBROGEN License Fee of [*] Dollars ($[*]) which said Fee shall be deemed earned and due immediately upon the execution of this Agreement;

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

(b) Running Royalties equal to [*] Of Net Sales of the Licensed Products and/or the sale of product which is labeled for a Licensed Method use; except that on Net Sales by or for sublicensees, FIBROGEN shall pay the lesser of [*] Of Net Sales or [*] of all royalties received by FIBROGEN from any sublicense for Net Sales of the Licensed Products by or for the sublicensee; and

(c) [*] of all License Fees received by FIBROGEN from any sublicensee. As used in the preceding sentence, the term "License Fees" means any fees received by FIBROGEN for license of rights to the Licensed Products, Licensed Methods, Patent Rights, and Licensed Processes, excluding (a) royalties and payments which are advances of future royalties and (b) payments for which FIBROGEN must render technical development services.

4.2 In the case of sales in a country of a Licensed Product or Licensed Method based on a claim of a Patent Rights Patent Application that has not issued as a Patent Rights Patent after [*] ([*]) years from the date of filing, the above-stated royalty rate shall be reduced by [*] ([*]) on Net Sales of such Licensed Product and/or the sale of product which is labeled for a Licensed Method use in such country until such claim issues as a Patent Rights Patent or is rejected with no right of appeal or to which rejection neither party chooses to appeal.

4.3 In the event that FIBROGEN manufactures, uses or sells a product which is related to connective tissue growth factor, including derivatives of connective tissue growth factor, wherein the product is labeled for a Licensed Method use, FIBROGEN's royalty payments under this Article 4 may be reduced in proportion to contributions to the development of the product by FIBROGEN, to be determined through best faith negotiations of the parties.

4.4 If it is necessary to acquire one or more royalty bearing licenses from third parties in order to fully exercise the rights granted by LICENSOR hereunder, then FIBROGEN shall be entitled to a credit against the royalty payments due hereunder, which credit shall be equal to the amount of the royalties actually paid to such third parties, provided, in no case will the royalty otherwise due LICENSOR be reduced by more than fifty percent (50%) for such credit.

4.5 All payments shall be made hereunder in U.S. dollars; provided however, that if the proceeds of the sales upon which such royalty payments are based are received by FIBROGEN in a foreign currency or other form that is not convertible or exportable in dollars, and FIBROGEN does not have ongoing business operations or bank accounts in the country in which the currency is not convertible or exportable, FIBROGEN shall pay such royalties in the currency of the country in which such sales were made by depositing such royalties in LICENSOR's name in a bank designated by the LICENSOR in such country. Royalties in dollars shall be computed by converting the royalty in the currency of the country in which sales were made at the exchange rate for dollars prevailing at the close of the business day of FIBROGEN's period for which royalties are being calculated as published the following day in the Wall Street Journal (or, if it ceases to be published, a comparable publication to be agreed upon from time to time by the parties), and with respect to those countries for which rates are not

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published in the Wall Street Journal, the exchange rate fixed for such date by the appropriate United States governmental agency.

4.6 In the event the royalties set forth herein are higher than the maximum royalties permitted by law or regulation of a particular country, the royalty payable for sales in such country shall be equal to the maximum permitted royalty under such law or regulation.

4.7 In the event that any taxes, withholding or otherwise, are levied by any taxing authority in connection with accrual or payment of any royalties payable to LICENSOR under this Agreement, FIBROGEN shall have the right to pay such taxes to the local tax authorities on behalf of the LICENSOR and the payment to LICENSOR of the net amount due after reduction by the amount of such taxes, shall fully satisfy FIBROGEN's royalty obligations under this Agreement.

ARTICLE 5
Reports And Records

5.1 FIBROGEN shall keep full, true and accurate books of account containing all particulars that may be necessary for the purpose of showing the amounts payable to LICENSOR by way of royalty as aforesaid. Said books of account shall be kept at FIBROGEN's principal place of business or the principal place of business as of the appropriate division of FIBROGEN to which this Agreement relates. Said books and the supporting data shall be open at all reasonable times, but not exceeding [*] per calendar year, for three (3) years following the end of the calendar year to which they pertain, to the inspection of LICENSOR and/or an independent certified public accountant retained or employed by LICENSOR for the purpose of verifying FIBROGEN's royalty or other payment statement.

Such Accountant or Accounting Firm shall not disclose to LICENSOR any information other than that information relating solely to the accuracy of, or necessity for, the reports and payments made hereunder. The fees and expense of the Certified Public Accountant or Accounting Firm performing such verification shall be borne by LICENSOR unless in the event that the audit reveals underpayment of royalties by an amount more than ten (10) percent, the cost of such audit shall be paid by FIBROGEN.

5.2 FIBROGEN, within sixty (60) days after March 31, June 30, September 30, and December 31 of each year, shall deliver to LICENSOR true and accurate reports, giving such particulars of the business conducted during the preceding three month period under this Agreement as shall be pertinent to a royalty accounting hereunder. These shall include at least the following:

(a) all Licensed Product(s) manufactured and sold;

(b) total billings for Licensed Product(s) sold;

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(c) accounting for all the Licensed Process(es) used or sold;

(d) deductions applicable as provided in the definition of Net Sales;

(e) Net Royalties paid FIBROGEN, if relevant to the calculations of royalties to be paid to LICENSOR;

(f) royalties due LICENSOR; and

(g) names and addresses of all sublicensees.

5.3 With each such report submitted, FIBROGEN shall pay to LICENSOR the royalties due and payable under this Agreement. It no royalties shall be due, FIBROGEN shall so report.

5.4 The royalty payments sat forth in this Agreement shall, if overdue, bear interest until payment at a [*] rate per annum. The payment of such interest shall not foreclose LICENSOR from exercising any other rights it may have as a consequence of the lateness of the payment.

ARTICLE 6
Patent Prosecution

6.1 FIBROGEN agrees to pay for the filing, prosecution and maintenance of all Patent Rights, and to diligently pursue same. If, in any country agreed upon by FIBROGEN and LICENSOR for the filing of a Patent Rights Patent Application, FIBROGEN fails so to file, prosecute and maintain, LICENSOR may take over the responsibilities of filing, prosecution and maintenance, at the expense of FIBROGEN, and will thereafter provide FIBROGEN with all relevant documentation.

6.2 FIBROGEN agrees promptly to furnish to LICENSOR copies of:

(a) Patent Rights Patent Applications filed in any Patent Office;

(b) papers received from a Patent Office pertaining to a Patent Rights Patent Application; and

(c) papers filed in a Patent Office pertaining to a Patent Rights Patent Application.

ARTICLE 7
Infringement

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Infringement By Third Parties

7.1 The parties shall promptly inform each other in writing of any alleged infringement by a third party, of which it shall have notice, of any patents within the Patent Rights, and provide the other party with any available evidence of infringement.

7.2 During the term of this Agreement, FIBROGEN shall have the right, but shall not be obligated, to prosecute at its own expense any such infringements of the Patent Rights and, in furtherance of such right, LICENSOR hereby agrees to join FIBROGEN as a nominal party plaintiff in any such suit where required for jurisdictional purposes, and to render to FIBROGEN every assistance within its power, except financial assistance. If LICENSOR should incur any out-of-pocket costs in connection with assisting FIBROGEN with said suit, such costs shall be reimbursed to LICENSOR by FIBROGEN. The total cost of any such infringement action commenced or defended solely by FIBROGEN shall be borne by FIBROGEN, and FIBROGEN shall keep any net recovery or damages for patent infringement derived therefrom, subject to reimbursement to LICENSOR for any royalties past due or withheld and applied pursuant to Section 7.3 below.

7.3 In the event that FIBROGEN shall undertake the enforcement of the Patent Rights by litigation, FIBROGEN may withhold up to [*] of the royalties otherwise thereafter due LICENSOR hereunder, and apply the same toward [*] of its expenses, including reasonable attorney's fees, in connection therewith.

7.4 If within [*] months after having been notified of any alleged infringement, FIBROGEN shall have been unsuccessful in persuading the alleged infringer to desist, and shall not have brought or shall not be diligently prosecuting an infringement action, or if FIBROGEN shall notify LICENSOR at any time prior thereto of its intention not to bring suit against any alleged infringer, then, and in these events only, LICENSOR shall have the right, but shall not be obligated, to prosecute at its own expense any infringement of the Patent Rights. No settlement, consent Judgment or other voluntary final disposition of the suit may be entered into without the consent of FIBROGEN, which consent shall not be unreasonably withheld. The total cost of any such infringement action commenced solely by LICENSOR shall by borne by LICENSOR, and LICENSOR shall keep any recovery or damages for past infringement derived therefrom.

7.5 In any infringement suit that either party may institute to enforce the Patent Rights pursuant to this Agreement, the other party hereto shall, at the request and expense of the party initiating such suit, cooperate in all respects and, to the extent possible, have its employees testify when requested, and make available relevant records, papers, information, samples, specimens, and the like.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Infringement By LICENSOR and FIBROGEN

7.6 FIBROGEN shall promptly notify LICENSOR in writing of any claim of patent infringement which has been asserted against FIBROGEN or LICENSOR, its Affiliate and any sublicensees because of the manufacture, use, promotion or sale of Licensed Products or Licensed Processes or the sale of products used according to the Licensed Methods.

7.7 FIBROGEN shall have the first and primary right and responsibility to defend and control the defense of any such claim, by counsel of its choice and at its expense. FIBROGEN will defend, indemnify and hold harmless LICENSOR, its Trustees, officers, directors, employees and its Affiliates against any and all judgment and damages arising from any and all third party claims of Patent Rights infringement which may be asserted against LICENSOR, and its Affiliates because of the manufacture, use, promotion and sale of products.

7.8 It is understood that any settlement of such action must be approved by LICENSOR, and that such approval shall not be unreasonably withheld. LICENSOR agrees to cooperate with FIBROGEN in any reasonable manner necessary in defending such action. FIBROGEN shall reimburse LICENSOR for any reasonable out-of-pocket expenses incurred in providing such assistance.

7.9 LICENSOR shall have no responsibility with respect to FIBROGEN’s own trademarks and tradename, and FIBROGEN in respect to the use thereof will defend, indemnify and hold harmless LICENSOR against any and all third party claims.

7.10 In the event FIBROGEN deems it necessary to seek a license from any third party in order to avoid infringement or settle an infringement action in any country of such third party's patent rights brought about by the sale of Licensed Products or use of Licensed Processes, [*] of all fees or royalties paid under such license may be deducted from royalty payments due LICENSOR on Sale of Licensed Products in such country to an extent not exceeding [*] of each such royalty payment as it becomes due.

7.11 LICENSOR warrants and represents that it has the lawful right to grant the license provided in this Agreement and that, to its knowledge and belief, it has not granted rights or licenses in derogation of the rights granted to FIBROGEN under this Agreement. LICENSOR agrees that during the term of this Agreement, it shall use reasonable efforts to avoid granting rights to third parties or incurring obligations which will interfere with the rights and obligations of parties under this Agreement, including any rights and obligations that survive termination of this Agreement.

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ARTICLE 8
Product Liability, Indemnification and Warranties

8.1 FIBROGEN agrees to release, indemnify and hold harmless the LICENSOR, its Trustees, officers, faculty, employees and students against any and all losses, expenses, claims, actions, lawsuits and judgments thereon (including attorney's fees through the appellate levels) which may be brought against LICENSOR, its Trustees, officers, faculty, employees or students as a result of or arising out of use, production, manufacturer, sale, lease, consumption or advertisement by FIBROGEN or any third party of any Licensed patent, Product, Invention or Technology licensed under this Agreement.

8.2 LICENSOR MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AND HEREBY DISCLAIMS ALL SUCH WARRANTIES, AS TO ANY MATTER WHATSOEVER, INCLUDING, WITHOUT LIMITATION, THE CONDITION OF ANY INVENTION(S) OR PRODUCT, WHETHER TANGIBLE OR INTANGIBLE, LICENSED UNDER THIS AGREEMENT; OR THE MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE INVENTION OR PRODUCT; OF THAT THE USE OF THE LICENSED PRODUCT WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER RIGHTS, LICENSOR SHALL NOT BE LIABLE FOR ANY DIRECT, CONSEQUENTIAL, OR OTHER DAMAGES SUFFERED BY ANY LICENSEE OR ANY THIRD PARTY RESULTING FROM THE USE, PRODUCTION, MANUFACTURE, SALE LEASE, CONSUMPTION, OR ADVERTISEMENT OF THE PRODUCT.

8.3 The provisions of 8.1 and 8.2 above shall continue beyond the termination of this Agreement.

ARTICLE 9
Assignment

9.1 Except as otherwise provided in this Article, this Agreement is not assignable by FIBROGEN or by operation of law without the prior written consent of LICENSOR at its sole discretion.

9.2 This Agreement shall extend to and be binding upon the successors and legal representatives and permitted assigns of LICENSOR and FIBROGEN.

9.3 FIBROGEN may assign or otherwise transfer this Agreement and the license granted hereby and the rights acquired by it hereunder, so long as such assignment or transfer shall be accompanied by a sale or other transfer of substantially all of FIBROGEN's entire business, or that part of FIBROGEN's business to which the license granted hereby relates.

9.4 FIBROGEN may assign or otherwise transfer this Agreement and the license granted hereby and the rights acquired by it hereunder, so long as such assignment or transfer is made to a FIBROGEN subsidiary or Affiliate.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

ARTICLE 10
Use Of Names

FIBROGEN shall not use the name of the University of Miami, or any of its employees, or any adaptation thereof, in any publication, including advertising, promotional or sales literature without the prior written consent of Mr. Alan J. Fish, Assistant Vice President of Business Services, 327 Max Orovitz Building, 1507 Levante Avenue, Coral Gables, FL 33124- 1432. Notwithstanding this provision, FIBROGEN may state that it has licensed one or more patents comprising the Patent Rights from LICENSOR.

ARTICLE 11
Export Controls

11.1 It is understood that LICENSOR is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities (including the Arms Export Control Act, as amended, and the Export Administration Act of 1979), and that its obligations hereunder are contingent upon compliance with applicable United States export laws and regulations. The transfer of certain technical data and commodities may require a license from the cognizant agency of the United States Government and/or written assurances by LICENSOR that FIBROGEN shall not export data or commodities to certain foreign countries without prior approval of such agency. LICENSOR neither represents that a license shall not be required, nor that, if required, it shall be issued.

ARTICLE 12
Termination

12.1 LICENSOR and FIBROGEN shall have the right to terminate this Agreement if the other party commits a material breach of an obligation under this Agreement or provides a false report and continues in default from more than [*] after receiving written notice of such default or false report. Such termination shall be effective upon further written notice to the breaching party after failure by the breaching party to cure such default. If LICENSOR commits a material breach or defaults, the FIBROGEN has no duty to continue the payment of royalties as set forth in Article IV of this Agreement.

12.2 The license and rights granted in this Agreement have been granted on the basis of the special capability of FIBROGEN to perform research and development work leading to the manufacture and marketing of the Products. Accordingly, FIBROGEN covenants and agrees that in the event any proceedings under the Bankruptcy Act of any amendment thereto, be commenced by or against FIBROGEN, and, if against FIBROGEN, said proceedings shall not be dismissed with prejudice before either an adjudication in bankruptcy or the confirmation of a composition, arrangement, or plan of reorganization, or in the event FIBROGEN shall be

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adjudged insolvent or make an assignment for the benefit of its creditors, or if a writ of attachment or execution be levied upon the license hereby created and not be released or satisfied within [*] days after thereafter, or if a receiver be appointed in any proceedings or action to which FIBROGEN is a party with authority to exercise any of the rights or privileges granted hereunder and such receiver be so discharged within a period of [*] days after his appointment, any such event shall be deemed to constitute a breach of this Agreement by FIBROGEN and, LICENSOR, at the election of LICENSOR, but not otherwise, ipso facto, and without notice or other action by LICENSOR, shall terminate this Agreement and all rights of LICENSOR hereunder and all rights of any and all persons claiming under FIBROGEN.

12.3 FIBROGEN shall have the right to terminate this Agreement upon ninety (90) days notice.

12.4 Any termination of this Agreement shall be without prejudice to LICENSOR's right to recover all amounts accruing to LICENSOR prior to such termination and cancellation. Except as otherwise provided, should this Agreement be terminated for any reason, FIBROGEN shall have no rights, express or implied, under any patent property which is the subject matter of this Agreement, nor have the right to recover any royalties paid LICENSOR hereunder. Upon termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination. FIBROGEN and/or any sublicensee of FIBROGEN may, however, after the effective date of such termination, sell all Licensed Product(s), and complete Licensed Product(s) in the process of manufacture at the time of such termination and sell the same, provided that FIBROGEN shall pay to LICENSOR the royalties thereon as required by Article 4 of this Agreement, and shall submit the report required by Article 5 hereof on the sales of Licensed Product(s).

ARTICLE 13
Payments, Notices And Other Communications

Any notice, payment, report or other communication (hereinafter collectively referred to as "correspondence") required to be given hereunder shall be mailed by certified mail or delivered by hand to the party to whom such correspondence is required or permitted to be given hereunder. If mailed, any such notice shall be deemed to have been given when mailed as evidenced by the postmark at point of mailing. If delivered by hand, any such correspondence shall be deemed to have given when received by the party to whom such correspondence is given, as evidenced by written and dated receipt of the receiving party.

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All correspondence to FIBROGEN shall be addressed as follows:

FibroGen, Inc.
260 Littlefield Avenue
South San Francisco, CA 94080
Attention: President

All correspondence to LICENSOR shall be addressed, in duplicate, as follows:

FOR NOTICE BY MAIL:

University of Miami School of Medicine
Research and Graduate Studies
P.O. Box 016960 (R64) Miami, FL 33101
Attention: Dr. Norman H. Altman

Assistant Vice President for Business Affairs
327 Max Ororvitz Building
1507 Levante Avenue
Coral Gables, FL 33124-1432
Attention: Mr. Alan J. Fish

FOR NOTICE AND PAYMENT:

BY MAIL:
Director
Office of Technology Transfer
P.O. Box 016960 ((M811)
Miami, FL 33101
Attention: Dr. Gary S. Margules

BY HAND:
Director
Office of Technology Transfer
P.O. Box 016960 (M811)
Miami, FL 33101
Attention: Dr. Gary S. Margules

Either party may change the address to which correspondence to it is to be addressed by notification as provided herein.

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ARTICLE 14
Governing Law

This Agreement shall be construed, governed, interpreted and applied in accordance with the laws of the State of Florida, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which such patent was granted.

ARTICLE 15
Captions

The captions and paragraph headings of this Agreement are solely for the convenience of reference and shall not affect its interpretation.

ARTICLE 16
Entire Agreement

This Agreement constitutes the entire Agreement between the parties hereto respecting the subject matter hereof, and supersedes and terminates all prior agreements respecting the subject matter hereof, whether written or oral, and may be amended only by an instrument in writing executed by both parties hereto.

ARTICLE 17
Amendment

No amendment or modification of the terms of this Agreement shall be binding on either party unless reduced to writing and signed by an authorized officer of the party to be bound.

ARTICLE 18
Severability

Should any part or provision of this Agreement be held unenforceable or in conflict with the applicable laws or regulations of any jurisdiction, the invalid or unenforceable part of provision shall be replaced with a provision which accomplishes, to the extent possible, the original business purposes of such part or provision in valid and enforceable manner, and the remainder of the Agreement shall remain binding upon the parties hereto.

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ARTICLE 19
Waiver

No failure or delay on the part of a party in exercising any right hereunder will operate as a waiver of, or impair, any such right. No single or partial exercise of any such right will preclude any other or further exercise thereof or the exercise of any other right. No waiver of any such right will be deemed a waiver of any other right hereunder.

ARTICLE 20
Marking

Prior to the issuance of patents on the Invention(s), FIBROGEN agrees to mark and have sublicensees mark Licensed Products (or their containers or labels) made, sold, or otherwise disposed of by it under the license granted in this Agreement with a proper notice as specified under the patents laws of the United States. All Licensed Product(s) shipped to or sold in other countries shall be marked in such a manner as to conform with the patent law and practice of the country of manufacture or sale.

ARTICLE 21
Standards

FIBROGEN further agrees to maintain satisfactory standards in respect to the nature of the Product manufactured and/or sold by FIBROGEN. FIBROGEN, agrees that all Licensed Product(s) manufactured and/or sold by it shall be of a quality which is appropriate to products of the type here involved. FIBROGEN agrees that similar provisions shall be included by sublicensees of all tiers.

ARTICLE 22
United States Law, Public Law 96-517 as Amended

This Agreement is subject to all of the terms and conditions of Public Law 96-517 as amended, and FIBROGEN agrees to take all action necessary on its part as LICENSEE to enable LICENSOR to satisfy its obligation thereunder, relating to Invention(s).

ARTICLE 23
Certificate of Insurance

23.1 FIBROGEN shall maintain liability insurance coverage for the Licensed Product in the amount of five million dollars ($5,000,000.00) and at no expense to LICENSOR, FIBROGEN shall name LICENSOR as an additional insured. Prior to the first human use of the Licensed Product, FIBROGEN shall provide a certificate of insurance to LICENSOR.

23.2 FIBROGEN agrees to carry and keep in force, at its expense, general liability insurance with limits not less than one million ($1,000,000.00) per person and three million ($3,000,000.00) aggregate to cover liability for damages on account of bodily injury or personal injury or death to any person, or damage to property of any person; such insurance shall not be canceled for any cause without at least thirty (30) days prior written notice to University of Miami. Such insurance shall contain an endorsement naming the University as an additional insured with respect to this Agreement. Insurance Certificates should be sent to the University of Miami, attention Mr. William Coombs, 333 Max Orovitz Building, 1507 Leavante Avenue, Coral Gables, FL 33124-1437.

ARTICLE 24
Survival

24.1 The provisions of Article7, and Article 8 shall survive the termination or expiration of this Agreement and shall remain in full force and effect.

24.2 The provisions of the Agreement which do not survive termination or expiration hereof (as the case may be) shall, nonetheless, be controlling on, and shall be used in construing and interpreting, the rights and obligations of the parties hereto with regard to any dispute, controversy or claim which may arise under, our of, in connection with, or relating to this Agreement.

IN WITNESS WHEREOF, the parties hereto have hereunto set their hands and seals and duly executed this License Agreement on the day and year first set forth below.

Dated: May 23, 1997

UNIVERSITY FOR MIAMI

By: /s/ Alan J. Fish

[name] Alan J. Fish
[title] Assistant Vice Pres. Business Services

Dated: May 2, 1997

FIBROGEN, INC.

By: /s/ Thomas B. Neff

Thomas B. Neff
Chief Executive Officer

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Exhibit 10.5

FIRST AMENDMENT TO
May 23, 1997 LICENSE AGREEMENT

The First Amendment to the May 23, 1997 License Agreement (the "1997 License Agreement") by and between University of Miami (the "University") and FibroGen, Inc., and its Affiliates (the "Company")(collectively, the "Parties") is effective July 29, 1999. Except as otherwise set forth herein, the defined terms in the 1997 License Agreement shall be incorporated by reference herein.

The Parties hereby agree to amend the 1997 License Agreement as follows:

1. Section 1.4 shall be amended and restated in its entirety to read as follows: "Patent Rights" shall mean the University's share of (a) United States Patent No.

[*], United States Patent Application Serial Number [*], and the two United States Patent Applications filed on [*] entitled [*] for which numbers have not yet been assigned, (b) any applications filed prior to this date relating to CTGF, homologs to CTGF, [*] and/or methods of use or treatment thereof which University's employees are joint or sole inventors thereon or any applications filed hereafter for which the Company has provided research funding pursuant to the November 29, 1995 Research Agreement between the Parties, as amended, or any subsequent funding arrangement between the Parties, (c) and the United States and foreign patents issuing from said United States and foreign patent applications collectively, hereinafter referred to as the "Patent Rights Patent Application") or later filed domestic or foreign applications based on the said United States Patents and applications (hereinafter referred to as the "Patent Rights Patents") and any continuations, continuations-in-part, divisions, reissues or extensions of any of the foregoing. In the event that the University has or acquires any rights to United States Patent Nos. [*]; or United States Patent Application Serial Number [*], and foreign application (including PCT No. [*]), continuations, continuations-in-part, divisions, reissues or extensions thereof, such rights shall be included in "Patent Rights", "Patent Rights Patent Application" or "Patent Rights Patents" as appropriate.

2. Section 4.1 (b) shall be amended and restated in its entirety to read as follows:

(b)(i) Subject to clause (ii) below, Company shall pay University a running royalty equal to:

(x) [*] of Net Sales of any Licensed Products and/or the sale of product labeled for a Licensed Method use (a "Royalty Product") in cases other than specified in (y) or (z),

(y) [*] of Net Sales of any Royalty Product in the case that such Royalty Product is also covered by a patent or patent application owned or held by the University of South Florida.

(z) [*] of Net Sales of any Royalty Product in the case that any of the Patent Rights covering such Royalty Product is jointly owned or held by the Company.

(ii) The applicable running royalty set forth in Section 4.2.(b)(i) may be reduced by any royalty obligations of the Company to other third parties (except the University of South Florida) on the sale of Royalty Products; provided, however that the University's royalties shall not be offset by more than seventy-five percent (75%) (i.e. so that the royalty rate may be reduced to [*] in (b)(i)(x) or [*] in (b)(i)((y) and (z)). In the event that the Company reduces the royalty to the University pursuant to the foregoing, the Company must disclose to the University the third party royalty payment and the identity of such third party.

3. Section 4.1(c) shall be amended and restated in its entirety to read as follows:

The Company shall pay the University milestone payments on the first Royalty Product to reach the following milestone in the first major country (United States, Japan, U.K., France, Italy, Spain or Germany):

Upon acceptance of an IND with the FDA or commencement of any human clinical trial	$	50,000
Upon successful completion of Phase II in the U.S. (or comparable foreign clinical trial)	$	100,000
Upon written notice of FDA (or comparable foreign body) approval for marketing	$	[*]

In no event shall the foregoing be construed to require the Company to pay any of the above milestones the University more than once.

In addition, the Company shall pay the University $[*] for any subsequent approval by the first of the FDA or comparable foreign body in a major country for an additional indication for such previously approved Royalty Product or additional Royalty Product (but not the same indication or same Royalty Product in additional markets or countries).

Payment to the University by the Company shall be made within [*] days of the achievement of the applicable milestone.

4. Section 4.4 shall be deleted.

5. With respect to the United States Patent Application No. [*] filed in [*] and any divisionals, continuations or continuations in part thereof or foreign counterparts filed relating to the foregoing, the Company shall pay no more than a [*] royalty in total to the University and/or University of South Florida on sales of Royalty Products and to the extent that questions of inventorship arise as to whether the patent covers such Royalty Product or whether the University should be included as an assignee to such patent, such issue shall be resolved by mutually agreed upon third party patent attorney. The royalty shall be allocated based upon the proportion of patents held by each institution or such other reasonable method of allocation agreed to by the Parties in good faith. For example, assuming that no other offsets apply, if University has 1 solely-held patent, University of South Florida has 3 solely-held patents and they jointly- hold 1 patent, then University of South Florida would be entitled to 70% (3.5/5) and the University would be entitled to 30% (1.5/5) of the [*] royalty. Accordingly, the University of South Florida would receive a [*] royalty and the University would receive a [*] royalty. This Section 5 would not be effective unless University of South Florida agrees to a comparable provision.

6. Section 6.1 is amended to add the following sentence:

The University agrees that the Company shall control the prosecution and maintenance of the United States Patent Applications filed on [*] entitled [*] and any other Patent Rights Patents.

Except as set forth above, the 1997 License Agreement shall remain in full force and effect in accordance with all other terms and conditions specified therein.

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date set forth below.

UNIVERSITY OF MIAMI

/s/Alan Fish Date: 8/5/99

FIBROGEN, INC.

/s/Thomas B. Neff Date: 8/3/99

Thomas B. Neff
Chief Executive Officer

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Exhibit 10.6

AMENDMENT NO. 2
TO
RESEARCH AND COMMERCIALIZATION AGREEMENT

THIS AMENDMENT NO. 2 TO RESEARCH AND COMMERCIALIZATION AGREEMENT ("Amendment") is made and entered into effective as of January 28, 2002 (the "Amendment Date") by and between **MEDAREX, INC.**, 707 State Road, Suite 206, Princeton, NJ 08540, **GENPHARM INTERNATIONAL INC.**, a wholly-owned subsidiary of Medarex, Inc. (together, "Medarex"), and FibroGen, Inc., a Delaware corporation, 225 Gateway Boulevard, South San Francisco, California 94080 and **FIBROPHARMA, INC.**, a wholly-owned subsidiary of **FIBROGEN, INC.** (collectively, "FibroGen"). Capitalized terms used in this Amendment that are not otherwise defined herein shall have the same meanings as such terms are defined in the Agreement (as defined below).

WHEREAS, Medarex and FibroGen entered into a Research and Commercialization Agreement dated as of July 9, 1998 (the "Agreement"), as amended as of June 30, 2001, under which FibroGen acquired a research license and an option to acquire commercial licenses under the Medarex Technology.

WHEREAS, the parties desire to amend the Agreement to extend the term of the Research Period under the Agreement and to clarify the scope of the licenses granted under the Agreement.

Now, THEREFORE, the parties agree as follows:

1. Amendment of the Agreement.

The parties hereby agree to amend the terms of the Agreement as of the Amendment Date as provided below.

1.1 **Amendment of Section 2.6.2.** Section 2.6.2 of the Agreement is hereby amended to read in its entirety as follows:

"2.6.2 With notice to Medarex at least thirty (30) days prior to the first anniversary of the Effective Date, FibroGen may extend the term of the Research Period until the second anniversary of the Effective Date and, with notice to Medarex at least thirty (30) days prior to the second anniversary of the Effective Date, FibroGen may extend the term of the Research Period until the third anniversary of the Effective Date and, with notice to Medarex at least thirty (30) days prior to the third anniversary of the Effective Date, FibroGen may extend the term of the Research Period until February 28, 2002 and, with notice to Medarex at least thirty (30) days prior to February 28, 2002, FibroGen may extend the term of the Research Period until March 31, 2002, and in each case, FibroGen shall continue to make quarterly research support payments (or, if research services are provided by Medarex for less than a full calendar quarter, a research support payment equivalent to a pro rata portion of such quarterly research support payment as applicable) as provided in Section 2.2. If

FibroGen (i) extends the Research Period for at least six (6) months (so that the Research Period is at least eighteen (18) months and Medarex has received at least five hundred seventy thousand dollars ($570,000) of research support payments pursuant to Section 2.2), and (ii) exercises its option and acquires a commercial license pursuant to Section 3.1.2, then FibroGen shall be considered to have exclusivity of all the Antigens listed on Exhibit A in accordance with Section 2.6.5."

2. Scope of Agreement.

2.1 **Mice.** For purposes of clarity, the parties acknowledge and agree that [*] and [*] (as such terms are defined below) are not included in the definition of Mice under the Agreement.

For purposes of this Amendment and the Agreement, "[*]" shall mean any mice comprising both (i) [*] developed by Medarex or otherwise developed through use of Medarex's proprietary HuMAb Mouse; and (ii) [*], including, without limitation, any mouse comprising the nucleic acids described in clause (i) and clause (ii) of this Section that is derived by (X) [*] HuMAb Mouse [*], (Y) introducing nucleic acids obtained, isolated, or derived from a HuMAb Mouse [*], or (Z) introducing nucleic acids obtained, isolated, or derived from a [*] into one or more cells obtained from a HuMAb Mouse.

For purposes of this Amendment and the Agreement, "[*]" shall mean any immunizable [*] mouse developed by [*] that contains [*] thereof that include [*] that provide for [*], and which [*] comprises an [*].

3. Miscellaneous.

3.1 No Other Changes. Except as expressly provided in this Amendment, all terms of the Agreement shall remain in full force and effect.

3.2 Counterparts. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed by their respective authorized officers.

MEDAREX, INC.

By:	/s/Jim Cornett
Name:	Jim Cornett
Title:	VP Business Development
Date:	16 July 2001

FIBROGEN, INC.

By:	/s/ Jack Anthony
Name:	Jack Anthony
Title:	VP Business Development
Date:	6/28/01

GENPHARM INTERNATIONAL, INC.

By:	/s/ Jim Cornett
Name:	Jim Cornett
Title:	VP Business Development
Date:	16 July 2001

FIBROPHARMA, INC.

By:	/s/ Jack Anthony
Name:	Jack Anthony
Title:	VP Business Development
Date:	6/29/01

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Exhibit 10.7

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LICENSE AGREEMENT

This License Agreement (the “Agreement”), effective, subject to Article 22, upon the Effective Time (as defined in the Agreement and Plan of Merger (the "Merger Agreement") between Fibrogen, Inc., FGIM Corp, Imigen Systems, Inc. (the "Imigen Acquisition") ("Effective Date"), is between the Dana-Farber Cancer Institute, Inc., a Massachusetts non-profit organization having a principal place of business at 44 Binney Street, Boston, Massachusetts, 02115 (“DFCI”), and FibroGen, Inc., a Delaware corporation having a principal place of business at 225 Gateway Blvd., South San Francisco, CA 94080 (“LICENSEE”).

Background

WHEREAS DFCI is the owner of certain Licensed Intellectual Property (as defined below) developed or discovered by David Morse Livingston, M.D., while he was employed by DFCI, and William George Kaelin, Jr., M.D., while he was employed by Howard Hughes Medical Institute, a Delaware non-profit corporation (hereinafter referred to as “HHMI”), in HHMI laboratories located at DFCI, and HHMI has assigned its rights in certain patents and patent applications arising from such discoveries to DFCI, pursuant to an agreement between DFCI and HHMI, and DFCI has the right to license such Licensed Intellectual Property to third parties, and

WHEREAS on November 11, 2002, DFCI and Imigen entered into a License Agreement (the “Imigen License”) under which DFCI granted to Imigen a license under certain patents owned by DFCI, and

WHEREAS Imigen has been acquired by LICENSEE through the Imigen Acquisition, and

WHEREAS DFCI and LICENSEE now wish to directly enter into a license agreement regarding certain rights previously licensed under the Imigen License Agreement, and

WHEREAS DFCI desires to have the Licensed Intellectual Property used to promote the public interest by granting a license, and

WHEREAS LICENSEE has represented to DFCI that it has the capabilities and/or experience as well as the financial capacity and the strategic commitment to commercially develop the Licensed Intellectual Property for the public interest, and

WHEREAS LICENSEE desires to obtain a license to DFCI’s rights and DFCI is willing to grant a license to such rights to LICENSEE upon the terms and conditions of this Agreement, subject to certain reserved rights (as defined below),

NOW, THEREFORE, for and in consideration of the premises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, DFCI and LICENSEE hereto expressly agree as follows:

Article 1 - Definitions

1.1 “Agreement” means this License Agreement, including all attached schedules.

1.2 **“**Affiliate” means any company, corporation or other business entity that is controlled by, controlling, or under common control with LICENSEE. For this purpose "control" means direct or indirect beneficial ownership of at least forty percent (40%) interest in the voting stock (or the equivalent) of the company, corporation or other business or having the right to direct, appoint or remove a majority of members of its board of directors (or their equivalents) or having the power to control the general management of the company, corporation or other business, by law or contract.

1.3 “Biological Materials” means the materials supplied by DFCI to LICENSEE under this Agreement, as identified in Schedule 1 and Schedule 2 together with any progeny, or unmodified derivatives of the materials that may be supplied by DFCI or created by LICENSEE.

1.4 “FDA” means the United States Food and Drug Administration.

1.5 “Field of Use” means all fields of use including all therapeutic and diagnostic applications and research laboratory applications directed to discovery of therapeutic products or processes in humans or animals.

1.6 “Licensed Process” means any process that is covered in whole or in part by an unexpired issued or granted claim that has not been found to be invalid by a court of competent jurisdiction or by a pending claim in Patent Rights in a particular territory or any process which incorporates or uses Biological Materials in whole or in part.

1.7 “Licensed Product” means any product that is covered in whole or in part by an unexpired issued or granted claim that has not been found to be invalid by a court of competent jurisdiction or by a pending claim in the Patent Rights in a particular territory or any product manufactured according to, or service or method of use involving, a Licensed Process or any product that incorporates Biological Materials in whole or in part.

1.8 “Licensed Intellectual Property” means Patent Rights or Biological Materials, individually or collectively.

1.9 “Net Sales” means the revenue derived by an entity licensed under this Agreement from the Sales (as defined in Section 1.11) of Licensed Products less the following deductions, which may not exceed reasonable and customary amounts in the country in which the transaction occurs:

(a) Transportation charges or allowances actually paid or granted;

(b) Trade, quantity, cash or other discounts and brokers' or agents' commissions, if any, actually allowed and taken;

(c) Credits or allowances made or given on account of rejects, returns or retroactive price reductions for any amount not collected that are specifically identifiable to Licensed Products;

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

(d) Any tax or governmental charge (including, but not limited to, sales taxes, withholding taxes, value added taxes, customs, and duties) applied directly on sale or transportation, use or delivery of products paid by a licensed entity and not recovered from the purchaser;

(e) Any amount invoiced but for which cash was not actually received by LICENSEE within **[*]** year of the invoice date (however, such amounts shall be treated as Sales if received after the **[*]**-year period).

Net Sales includes the fair market value of any non-cash consideration from sale of Licensed Products received by LICENSEE, its Affiliates or Sublicensees.

Cash payments related to equity investments, research, and development funding, and reimbursement of expenses received by LICENSEE shall be excluded from this definition of “Net Sales”.

1.10 “Patent Rights” means certain patents and patent applications owned by DFCI and listed on Schedule 3; any patent applications from which these claim priority or of which these claim the benefit; any continuing applications related thereto, including all continuations, divisionals, and continuations-in-part (“CIPs”), as further defined below, thereof; any international or foreign counterparts thereof; and any patents issued or granted therefrom, including any patents resulting from any petition for reissue, reexamination, or extension thereof, or any patent resulting from any post-issuance or post-grant proceeding relating thereto. A “CIP” or “CIP application” is an application claiming priority to an application included in the “Patent Rights” in which one or more inventors are added to the application as the result of the addition of new matter supplied by LICENSEE and said inventor(s) are under an obligation to assign his or her rights in the CIP application to LICENSEE. LICENSEE hereby assigns its rights in any such CIP to DFCI and LICENSEE agrees to fully cooperate to perfect that title with the appropriate patent authorities. In no event will CIP applications be filed which would result in the addition of inventor(s) who are not under an obligation to assign to LICENSEE.

Included within "Patent Rights" are new patent applications as described in Section 6.2 below.

1.11 “Sale” or “Sold” mean an arm’s length transaction, involving the transfer of ownership of a Licensed Product to any person or entity for cash consideration by either the LICENSEE, an Affiliate, or Sublicensee. A Sale shall not include a transaction between the LICENSEE and an Affiliate or Sublicensee where the Licensed Product(s) in question will be resold by the Affiliate or Sublicensee provided that the cash payments received by the Affiliate or Sublicensee from the resale of the Licensed Product(s) are included in the calculation of Net Sales.

1.12 “Sublicensee” means any natural person or legal entity, which is not an Affiliate, to which LICENSEE grants a sublicense of some or all of the rights granted to LICENSEE under this Agreement. This definition of “Sublicensee” shall include a third party to whom LICENSEE has granted the right to distribute a Licensed Product(s).

1.13 “Territory” means worldwide.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Article 2 - Grant of Licenses, Reserved Rights and Sublicensing

2.1 **Exclusive License Grant.** Subject to all of the terms and conditions of this Agreement and the non-exclusive license granted to the United States government, DFCI grants to LICENSEE an exclusive license to a) DFCI's right, title and interest under Patent Rights and b) Biological Materials listed in Schedule 1, with the right to grant sublicenses, to make, have made, use, offer to sell, sell and import Licensed Products and to practice Licensed Processes in the Territory in the Field of Use for the term of this Agreement. The license will continue for the term of this Agreement unless the grant is sooner terminated according to Article 8. The foregoing license grant shall be subject to the following:

2.1.1 **Prior transfer of Biological Materials to third parties.** LICENSEE acknowledges that the Biological Materials listed on Schedule 1 may have been transferred, prior to the Effective Date, to non-profit academic or for-profit commercial entities for the purpose of non-exclusive in-house research only.

2.2 DFCI grants to LICENSEE a non-exclusive license to Biological Materials listed in Schedule 2, to make, have made, use, offer to sell, sell and/or import Licensed Products and to practice Licensed Processes, in the Territory in Field of Use for the term of this Agreement, to the extent the product or process is covered in whole or in part by an unexpired issued or granted claim that has not been found to be invalid by a court of competent jurisdiction or by a pending claim in the Patent Rights in a particular territory. The License will continue for the term of this License Agreement unless the grant is sooner terminated according to Article 8.

2.3 **Restricted Transfer of cre-lox containing Biological Materials.** DFCI has informed LICENSEE and LICENSEE acknowledges that certain Biological Materials listed on Schedule 1 and Schedule 2 (the "Cre-Lox Materials") may be covered by U.S. Patents 4,736,866, 5,087,571, and 5,925,803, and any corresponding U.S. or foreign patents and patent applications owned by Bristol-Myers Squibb ("BMS").

Under terms of the Non-Commercial Research Licenses between DFCI and BMS, dated October 20th, 1999, DFCI cannot transfer such Cre-Lox Materials to LICENSEE until DFCI receives written confirmation from BMS that LICENSEE has (i) entered into a license agreement with BMS which expressly permits LICENSEE to receive Cre-Lox Materials from third parties and (ii) has paid the applicable fees to BMS. LICENSEE is responsible for obtaining from BMS the written confirmation that DFCI can transfer such Cre-Lox Materials to LICENSEE, and, in the event such written confirmation is obtained, DFCI is responsible for transferring such Cre-Lox Materials to LICENSEE or its designated Affiliate or Sublicensee.

2.4 **Affiliates**. LICENSEE is entitled to extend its licenses under this Article 2 to its Affiliates, consistent with all of the terms and conditions of this Agreement. If LICENSEE does extend its license and an Affiliate assumes obligations under the Agreement, LICENSEE guarantees performance by the Affiliate. If DFCI has a claim arising under this Agreement against an Affiliate, DFCI may seek a remedy directly against LICENSEE and may, but is not required to, seek a remedy against the Affiliate. Any termination of the Agreement under Article 8 as to LICENSEE also constitutes termination as to any Affiliates.

2.5 **No Implied Licenses.** This Agreement confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents owned in whole or in part by DFCI other than the Patent Rights.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

2.6 **Reserved Rights.** The licenses granted by DFCI are subject to the following reserved rights.

2.6.1 The rights of the United States of America, as set forth in Public Laws 96-517 and 98-620, the regulations promulgated thereunder, and the policy of any funding agencies. Any rights granted hereunder that are greater than permitted by Public Laws 96-517 and 98-620 are subject to modification as required to conform to the provisions of those statutes.

2.6.2 DFCI's right to make and use the Licensed Intellectual Property in the Field of Use for teaching, education and non-commercial research purposes, both laboratory and clinical. It is acknowledged that DFCI reserves the right to use Biological Materials in Schedule 1 in collaboration with third parties (non-profit, for-profit, and governmental) provided such use occurs in laboratories located on DFCI's premises and such use is limited to teaching, education and non-commercial research purposes only.

2.6.3 DFCI's right to supply academic, governmental, or not-for-profit organizations with Biological Materials listed on Schedule 1 or grant to such organizations non-exclusive, non-transferable licenses under Patent Rights solely for non-commercial research purposes in the Field of Use. Under no circumstances may DFCI supply those Biological Materials listed in Schedule 1 or grant any license to the Patent Rights to such organizations for use in human subjects, clinical trials, or for any diagnostic purposes involving human subjects.

2.6.4 DFCI's right to grant to HHMI a paid-up, non-exclusive, irrevocable license to use the Licensed Intellectual Property for its research purposes with no right to sublicense.

2.6.5 DFCI's right to license the use of Biological Materials listed in Schedule 1, to a third party to the extent that such use is covered by a claim in a patent or patent application which (i) lists at least one DFCI employee as an inventor and (ii) is not included under Patent Rights.

2.7 **Sublicensing.** LICENSEE has the right to grant sublicenses under this Agreement consistent with the terms and conditions of this Agreement. LICENSEE remains responsible for the operations of any Sublicensee under this Agreement, as if the operations were carried out by LICENSEE.

2.7.1 **Notice.** LICENSEE shall promptly notify DFCI in writing of the identity of any prospective Sublicensee at the time that LICENSEE enters into a binding term sheet or final sublicense with such prospective Sublicensee. Notwithstanding the foregoing, such notification shall be no less than ten (10) business days after the execution of a binding term sheet or final sublicense with such Sublicensee.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

2.7.2 **Form and Content of Sublicenses.** LICENSEE shall issue any sublicense(s) granted by it under this Agreement in writing and shall attach a copy of this Agreement to all sublicenses. However, LICENSEE, acting reasonably, may redact information from the copy of this Agreement that it considers confidential and not necessary for a Sublicensee to understand LICENSEE's obligations to DFCI relating to sublicensing.

LICENSEE shall include the equivalent of at least the following provisions in all sublicenses:

(a) Sublicensee shall use commercially reasonable efforts to bring the subject matter of the sublicense into commercial use and shall report annually to LICENSEE on its operations under the sublicense.

(b) Sublicensee shall make payments due LICENSEE in relation to Net Sales of Licensed Products in a timely manner, so that LICENSEE may comply with its obligations to make payments to DFCI as set forth in Articles 3 and 4 of this Agreement.

(c) The terms and conditions of Sections 2.1, 2.5, 2.6, Sections 4.2.1 and 4.2.2, 5.2 – 5.5, and Article 7-10 and 12 of this Agreement are binding on the Sublicensee.

(d) Sublicensees have the right to grant further sublicenses subject to LICENSEE's written approval and notice to DFCI. Such notice shall be provided by LICENSEE at least ten (10) days prior to the execution of such sublicenses.

It is expressly understood that LICENSEE and its Sublicensees shall not grant a sublicense to any company engaged in the sales of tobacco or tobacco-related products without the written consent of DFCI.

2.7.3 **Copies of Sublicenses to DFCI.** LICENSEE shall forward to DFCI a copy of any and all fully executed sublicenses. Such copy shall be postmarked within thirty (30) days of the execution of the sublicense. LICENSEE shall also forward to DFCI annually a copy of the reports received by LICENSEE from its Sublicensee during the preceding twelve (12) month period under the sublicenses as shall be pertinent to (i) its operations under the sublicense and (ii) a royalty accounting under the sublicense agreement.

2.7.4 **LICENSEE's Continuing Obligations.** Nothing in this Section 2.7 (Sublicensing) may be construed to relieve LICENSEE of its obligations to DFCI under this Agreement, including but not limited to LICENSEE's obligations under Article 9 - Indemnification, Defense, and Insurance.

Article 3 - Consideration - Amounts and Time for Payment

In partial consideration of the rights granted by DFCI to LICENSEE under this Agreement, LICENSEE shall make the following payments to DFCI according to this Article 3 and Article 4, on behalf of itself, any Affiliate(s) or Sublicensee(s):

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

3.1 Reimbursements and Other Financial Consideration

3.1.1 **Past Patent Expenses**. LICENSEE shall reimburse DFCI for expenses incurred in filing, prosecuting, maintaining, and enforcing Patent Rights prior to the Effective date of the Agreement (the "Incurred Patent Expenses"). The Incurred Patent Expenses shall be paid by LICENSEE to DFCI in two (2) installments as set forth below:

(a) Installment I, totaling $**[*]** for Incurred Patent Expenses as of August 31, 2005, Shall be paid by LICENSEE to DFCI within forty-five (45) days of the Effective Date.

(b) Installment II shall reflect the Incurred Patent Expenses for the period between September 1, 2005 and the Effective Date. The total amount for Installment II shall be invoiced to LICENSEE, presented at one time as a total sum and accompanied by copies of all original invoices contributing thereto, no later than sixty (60) days after the Effective Date. LICENSEE shall pay DFCI Installment II within forty-five (45) days of receiving such invoice from DFCI.

3.1.2 LICENSEE shall not be liable for any additional amounts relating to any patent expenses incurred by DFCI and not included in either Installment I or Installment II.

3.1.3 **Future Patent Expenses**. LICENSEE shall pay all expenses incurred by LICENSEE after the Effective Date, for filing, prosecuting, and maintaining Patent Rights.

3.1.4 **Milestone Payments.**

(a) LICENSEE shall make milestone payments to DFCI within forty-five (45) days of the occurrence of the events occurring after the Effective Date hereto by LICENSEE, Sublicensee, or an Affiliate, as set forth below. Such payments will be due only one time for the first indication of each Licensed Product consisting of a chemical compound with a distinct chemical formula or a biologic with a distinct biological composition as the case may be.

MILESTONE	PAYMENT
FDA approval of an Investigational New Drug (IND) application in the United States	$**[*]**
FDA approval of a New Drug Application or Biologic License Application in the United States	$**[*]**
First marketing approval in the United States, Europe, or Japan	$**[*]**

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

(b) LICENSEE shall make milestone payments to DFCI within ninety (90) days of the occurrence of the relevant event, specified in the table below. Such payments will be due only one time.

MILESTONE	PAYMENT
The first year in which the cumulative and aggregated Net Sales for all Licensed Products by LICENSEE, Affiliates, and Sublicensees, on a worldwide basis exceeds a total of five hundred million dollars ($500,000,000)	$**[*]**
The first year in which the cumulative and aggregated Net Sales for all Licensed Products by LICENSEE, Affiliates, and Sublicensees, on a worldwide basis exceeds a total of one billion dollars ($1,000,000,000)	$**[*]**

3.1.5 **Running Royalties.** LICENSEE shall pay DFCI the following running royalties as set forth below:

(a) LICENSEE, its Affiliates, or its Sublicensees shall pay DFCI a **[*]** royalty on the Net Sales of Licensed Products or a Licensed Process in the Field of Use. Such royalty rate shall not be subject to any form of royalty stacking reduction. It is also expressly understood that even if a Licensed Product or Licensed Process would, but for the license granted under this Agreement, infringe multiple claims included under Patent Rights, the royalty shall not be additive and shall not exceed the royalty stated in this Section 3.1.5(a).

(b) For any Licensed Product or Licensed Process covered solely by a claim in a pending patent application included in the Patent Rights, LICENSEE, its Affiliates, or its Sublicensees shall have the right to deduct from the royalty payment due DFCI, as specified above in Section 3.1.5(a), fifty percent (50%) of such royalty payment. The unpaid royalty payment balance in each territory shall be due and payable by LICENSEE to DFCI sixty (60) days after such claim is issued or granted in such territory.

3.1.6 **Sublicense Fees.** For each sublicense granted by LICENSEE to a Sublicensee in the Field of Use, LICENSEE shall pay to DFCI the sum of **[*]** for each fully executed sublicense executed after the Effective Date of this Agreement that grants rights to one or more Licensed Products in the Field of Use to be paid thirty (30) days from the date of full execution of that sublicense.

3.1.7 **Maintenance Fees.** Upon the achievement of certain events by LICENSEE specified below, LICENSEE will pay to DFCI; (i) an annual license maintenance fee and (ii) an equivalent sublicense maintenance fee for each fully executed sublicense in effect, collectively the “Maintenance Fees”. Such Maintenance Fees

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shall be due beginning on the first anniversary date of this Agreement and due annually thereafter on the anniversary date:

EVENT	MAINTENANCE FEE
After the issuance in the United States of the first patent within Patent Rights claiming subject matter in the Field of Use	**$[*]**
After (i) the issuance in the United States and (ii) grant in an EPO member state and Japan of the first patent within Patent Rights claiming subject matter in the Field of Use	**$[*]**

Notwithstanding the foregoing, no license maintenance fee will be due after LICENSEE, an Affiliate, or Sublicensee begins to commercially sell a Licensed Product. For the avoidance of doubt, the above fees are triggered by the first issuance of a patent in the Field of Use and not due for each issuance of a patent in the Field of Use.

The fees specified in this Section 3.1.7 are not refundable, not creditable, and not an advance against any fees, royalties, or reimbursement of any costs incurred hereunder.

3.2 **Waiver or Deferral.** Waiver or deferral by DFCI of any payment owed under any paragraph under Section 3.1 may not be construed as a waiver or deferral of any subsequent payment owed by LICENSEE to DFCI.

3.3 **Combination Packages.** If a Licensed Product in the Field of Use is sold in a combination package or kit containing other active products or processes, then Net Sales for purposes of determining royalty payments on the combination package will be calculated using one of the following methods, but the royalties payable to DFCI may not be reduced to less than **[*]** of that provided for in Section 3.1.5 (a) of this Agreement:

By multiplying the net selling price of the combination by the fraction A/A+B, where A is the gross selling price, during the royalty-paying period in question, of the Licensed Product sold separately, and B is the gross selling price during the royalty period in question, of the other active products sold separately; or

If no separate sales are made of the Licensed Product or any of the active products in such combination package during the royalty-paying period in question, Net Sales for the purposes of determining royalty payments, must be calculated by dividing the net selling price of the combination by the number of functions performed by the combination sold where such combination contains active agents other than those licensed under this Agreement.

Article 4 - Royalty Reports, Payments and Financial Records

4.1 **Royalty Reports**. Within sixty (60) days after March 31, June 30, September 30, and December 31, of each year in which this Agreement is in effect, LICENSEE shall deliver to DFCI full, true and accurate reports of its activities and those of its Affiliates, if any, relating to this Agreement during the preceding three (3) month period. LICENSEE shall deliver reports containing equivalent information pertaining to its Sublicensee(s) within sixty (60) days of receipt of a royalty report from such Sublicensee ("Sublicensee Report"). Notwithstanding the foregoing,

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

LICENSEE shall have the option to provide such Sublicensee reports either individually or as a consolidated report and shall provide such reports no less frequently than every six (6) months. All reports must include at least the following:

(a) Number of Licensed Products manufactured and Sold by LICENSEE, and any Affiliates or Sublicensees, in each country of the Territory;

(b) Total billings for the Licensed Products Sold; by LICENSEE, and any Affiliates or Sublicensees, in each country of the Territory;

(c) Total billings for the use of Licensed Process Sold; by LICENSEE, and any Affiliates or Sublicensees, in each country of the Territory;

(d) Deductions applicable to determining Net Sales;

(e) The nature and amount of Sublicense Revenue received by LICENSEE as set forth in Section 3.1.5(a) and the amount owed to DFCI;

(f) Identification of any events that fulfill the milestones as set forth in Section 3.1.4 and the amount owed to DFCI;

(g) Total royalties due to DFCI;

(h) Number of sublicenses executed as set forth in Section 2.7 and the amount owed to DFCI as set forth in Sections 3.1.4, 3.15 and 3.1.6;

(i) An accounting of amounts invoiced but not yet received by FibroGen pursuant to Section 1.9(e).

With each report, LICENSEE shall pay to DFCI the royalties due and payable. If no royalties are due, LICENSEE shall so report. If multiple Licensed Products are covered by the license granted under this Agreement, LICENSEE shall separately identify each Licensed Product in the royalty report and specify which Licensed Intellectual Property covers that Licensed Product.

Ninety (90) days following any such payment, LICENSEE shall take reasonable business efforts to make any necessary adjustments (including any necessary credits, and offsets) to ensure that the amount paid to DFCI is in compliance with the terms of this Agreement.

4.2 **Record Keeping**.

4.2.1 **Books and Records.** LICENSEE shall keep, and shall require its Affiliates and Sublicensees to keep, true books of account containing an accurate record (together with supporting documentation) of all data necessary for determining the amounts payable to DFCI. LICENSEE shall keep its records at its principal place of business or the principal place of business of the appropriate division of LICENSEE to which this Agreement relates and shall require its Affiliates and Sublicenses to keep their books and records in the same manner.

4.2.2 **Inspections.** In order for DFCI to determine the correctness of any report or payment made under this Agreement, LICENSEE shall make its records available

to DFCI for inspection, for a period of three (3) years following the end of the calendar year to which they pertain. LICENSEE shall also require any Affiliates or Sublicensees to make their records available for inspection by DFCI, in the same manner as provided in this Section 4.2.2.

DFCI may inspect the records during regular business hours by a certified public accountant selected by DFCI and reasonably acceptable to the licensed entity whose records are being inspected**.** In conducting inspections under this Section 4.2.2, LICENSEE agrees that DFCI's accountant may have access to all records which DFCI reasonably believes to be relevant to calculating royalties owed to DFCI under Article 3.

DFCI is responsible for the cost of any inspection, unless the examination shows an underreporting or underpayment by any entity in excess of five percent for any twelve (12) month period, in which case LICENSEE shall pay the cost of the inspection as well as any additional sum that would have been payable to DFCI had the LICENSEE reported correctly, plus interest as set forth in Section 4.5.

4.3 **Form of Payments and Taxes.** LICENSEE must make all payments to be made to DFCI in Boston, Massachusetts, or at such other place or in such other way as DFCI may reasonably designate. Payments must be paid by check or wire transfer.

LICENSEE shall pay all amounts payable to DFCI under this Agreement in United States funds. All taxes levied on payments accruing to DFCI under this Agreement shall be paid by DFCI from its own account, including taxes levied thereon as income to DFCI. Any withholding taxes imposed on any payments made to DFCI shall be deducted from the payments made to DFCI, paid to the proper taxing authority, and a receipt of payments of the tax secured and properly delivered to DFCI. Each party agrees to assist the other party in claiming exemption from such deductions or withholding under any double taxation or similar agreement or treaty from time to time in force. LICENSEE shall reasonably inform DFCI of any such taxes actually due on a payment owed to DFCI if LICENSEE becomes aware that such tax is due.

4.4 **Currency Conversion.** If any currency conversion is required in connection with any payment owed to DFCI, the conversion will be made at the buying rate for the foreign currency as quoted by the Wall Street Journal on the last business day of the month to which such payment pertains.

4.5 **Interest.** Any payment owed to DFCI under this Agreement that is not made when due will accrue interest beginning on the first day following the due date specified in Article 3. The interest will be calculated at the annual rate of the sum of (a) **[*]** plus (b), the prime interest rate quoted by Bank of America on the date the payment is due, the interest being compounded on the last day of each calendar quarter. However, the annual rate may not exceed the maximum legal interest rate in Massachusetts. The payment of interest as required by this Section does not foreclose DFCI from exercising any other rights or remedies it has as a consequence of the lateness of any payment.

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Article 5 - Operations under the License

5.1 Due Diligence

5.1.1 **General Obligations.** LICENSEE shall use commercially reasonable efforts to diligently use Licensed Intellectual Property to develop and commercialize a diagnostic or therapeutic Licensed Product(s) in the Field of Use.

5.1.2 **Development and Commercialization Reports.** On or before each anniversary of the Effective Date, LICENSEE shall provide to DFCI a written report describing the efforts by LICENSEE, or any Affiliates or Sublicensees, to bring one or more Licensed Products to the therapeutic or diagnostic marketplace in Field of Use. In order to fulfill its obligation under this Section 5.1.2, LICENSEE shall be permitted to provide DFCI with a copy of letters or reports, and other information generally provided to shareholders of FibroGen.

Notwithstanding the foregoing, such reports and letters must be in sufficient detail to permit DFCI to monitor LICENSEE's compliance with due diligence provisions of this Agreement. At a minimum, LICENSEE shall include in these reports: (a) a summary of LICENSEE's progress and (that of any Sublicensee) in the reporting year, related to exploiting the Licensed Intellectual Property including an identification of all Licensed Products that LICENSEE intends to develop, if any; and (b), a summary of all sublicenses that are currently in force and those that have been terminated, if any, in the reporting year.

5.1.3 **Failure to Perform.** LICENSEE's failure to perform with any due diligence requirement provided in any paragraph in this Section 5.1 is grounds for DFCI to terminate this Agreement according to Section 8.2 or to convert this Agreement to a non-exclusive license agreement, at DFCI's option.

5.2 **U.S. Manufacture.** LICENSEE shall manufacture Licensed Products as required by 35 U.S.C. 204 and 37 C.F.R. 401 et. seq., as amended. LICENSEE shall also require any Affiliate(s) or Sublicensee(s) to comply with this U.S. manufacture requirement.

If LICENSEE provides compelling evidence to DFCI that domestic manufacture of a Licensed Product is not commercially feasible, at LICENSEE's request, DFCI will cooperate with LICENSEE to seek a waiver from the United States government with respect to the United States manufacture requirement. If a waiver is to be sought, LICENSEE shall provide DFCI with the required information, prepare the initial paperwork necessary for applying for or obtaining the waiver and bear all costs associated with the waiver process. LICENSEE acknowledges that DFCI cannot guarantee that a waiver can or will be obtained.

5.3 **Other Government Laws.** LICENSEE shall comply with, and ensure that its Affiliates and Sublicensees comply with, all government statutes and regulations that relate to Licensed Products. These include but are not limited to FDA statutes and regulations, the Export Administration Act of 1979, as amended, codified in 50 App. U.S.C. 2041 et seq. and the regulations promulgated thereunder or other applicable export statutes or regulations.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

5.4 **Patent Marking**. LICENSEE shall mark, and shall require its Sublicensees and Affiliates to mark, all Licensed Products sold in the United States with the word "Patent" and the number or numbers of Patent Rights applicable to the Licensed Product.

5.5 **Publicity – Use of Name.** LICENSEE, its Affiliate and Sublicensees are not permitted to use the names of DFCI, its related entities or its employees, or any adaptations thereof, in any advertising, promotional or sales literature, or in any securities report required by the Securities and Exchange Commission (except as required by law), without the prior written consent of DFCI in each case. However, LICENSEE may (a) refer to publications in the scientific literature by employees of DFCI; (b) state that a license from DFCI has been granted as provided in this Agreement, or (c) use the name of DFCI in any other use required by law. LICENSEE may request DFCI to agree in advance to certain standard language for repeated use by LICENSEE in printed materials to avoid delays in the distribution of such materials due to the need to obtain written consent from DFCI. DFCI will, in good faith, consider such request from LICENSEE. All requests and inquiries by LICENSEE regarding publicity in connection with this Section 5.5 should be directed to:

DFCI Communications Department
44 Binney Street
Boston, MA 02115

LICENSEE acknowledges that under HHMI policy, LICENSEE may not use the name of HHMI or of any HHMI employee (including Dr. Kaelin) in a manner that reasonably could constitute an endorsement of a commercial product or service; but that use for other purposes, even if commercially motivated, is permitted provided that (1) the use is limited to accurately reporting factual events or occurrences, and (2) any reference to the name of HHMI or any HHMI employees in press releases or similar materials intended for public release is approved by HHMI in advance. Notwithstanding the foregoing, LICENSEE may identify HHMI employees (by name and affiliation) in its press releases or other corporate communications (such as shareholder reports, information appearing on web sites, etc.) as inventors of the technology licensed hereunder or participation on a scientific advisory board, without obtaining advance approval from HHMI, if no further information about or quotes from such HHMI employees are included.

Article 6 - Patent Preparation, Filing, Prosecution, and Maintenance

6.1 **Responsibility**. Upon request of LICENSEE and at LICENSEE's expense, DFCI shall provide (or shall instruct DFCI's outside counsel to provide) to LICENSEE (or to an outside patent counsel of LICENSEE's choice) copies of all correspondence and documentation related to the Patent Rights, including copies of all original files, and all official and internal correspondence related thereto, and any associated documents. LICENSEE, in its sole discretion, is responsible for preparing, filing, prosecuting, and maintaining all patent applications and patents covered by the Patent Rights, and is solely responsible for making strategic decisions regarding such Patent Rights and for paying all costs. DFCI shall not file any application that claims priority to, or benefit of, an application included in Patent Rights without LICENSEE'S prior written consent. DFCI will request that the law firms currently responsible for prosecution of the Patent Rights, transfer all file histories to LICENSEEE at the address provided in Section 6.3 below (attention Intellectual Property Department) within thirty (30) days of the Effective Date of this Agreement. DFCI shall execute Revocation Of Power Of Attorney With New Power Of Attorney And Change Of Correspondence Address documents for filing with the USPTO, in a timely manner not to exceed thirty (30) days, upon receipt of a request from FibroGen or its designated counsel. For purposes

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of this Agreement, "prosecuting" or "prosecution" include all prosecution and any interference, reissue, or reexamination proceeding or opposition or other post-issuance or post-grant proceeding. LICENSEE shall provide DFCI with sufficient notification of LICENSEE's intention to file U.S. CIP applications and/or foreign equivalent patent applications claiming priority to an application included in the Patent Rights. LICENSEE shall provide, or cause its agent to provide, copies of all correspondence between LICENSEE and/or LICENSEE's counsel and the United States Patent and Trademark Office or the various foreign patent offices and shall give DFCI reasonable opportunity to advise LICENSEE or LICENSEE's counsel on such matters.

6.2 LICENSEE shall have the right to elect not to financially support the preparation, filing, prosecution, and maintenance of any patent application or patent included within Patent Rights. In such case, LICENSEE shall relinquish its rights to those patent applications or patents included within Patent Rights as provided in Section 6.5 below. Notwithstanding the foregoing, a strategic decision to discontinue the pursuit of a non-provisional patent application contained in the Patent Rights, shall not be construed as LICENSEE relinquishing its rights to the subject matter described therein if DFCI agrees in writing with such decision. LICENSEE's strategic decision to discontinue the pursuit of a provisional patent application contained in the Patent Rights in favor of filing a new patent application (NPA) claiming the subject matter described in such provisional application shall not be construed as LICENSEE relinquishing its rights to the subject matter described therein if DFCI agrees in writing with such decision. If one or more inventors are added to the NPA as the result of the addition of new matter supplied by LICENSEE and said added inventor(s) are under an obligation to assign his or her rights in the NPA to LICENSEE, LICENSEE hereby assigns its rights in the NPA to DFCI and LICENSEE agrees to fully cooperate to perfect that title with the appropriate patent authorities. In no event will NPAs be filed which would result in the addition of inventor(s) who are not under an obligation to assign to LICENSEE.

6.3 DFCI designates the following individual or department, or any designee thereof, to be available to consult with LICENSEE and to coordinate any reasonable response to a request from LICENSEE (see Section 6.4, infra), and to receive any patent-related correspondence:

DFCI Patent Counsel
Office of Patent Counsel
Dana-Farber Cancer Institute
44 Binney Street
Boston, MA 02115

Upon DFCI's reasonable request, LICENSEE shall be available to consult with DFCI on matters relating to preparing, filing, prosecuting, or maintaining any of the applications or patents within Patent Rights, which matters may be of particular interest to DFCI. LICENSEE, acting reasonably, shall consider the legitimate interests of DFCI in performing its responsibility under Section 6.1. LICENSEE designates the following individual or department, or any designee thereof, to be available to consult with DFCI and to receive any patent-related correspondence:

Vice President, Intellectual Property
Intellectual Property Department
FibroGen, Inc.
225 Gateway Blvd.
South San Francisco, CA 94080

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

6.4 **Cooperation.** DFCI shall cooperate with LICENSEE in preparing, filing, prosecuting, and maintaining the patent applications and patents within Patent Rights. This cooperation is limited to making any DFCI personnel (including any named DFCI inventors or any other involved parties who are employed in the laboratories of Dr. Kaelin and\or Dr. Livingston) available to answer questions, providing copies of any reasonably requested documents, including copies of pages in laboratory notebooks, manuscripts, etc., as may be necessary to provide required support and documentation for preparing, filing, prosecuting, and maintaining all patent applications and patents or for use in any post-issuance or post-grant procedure; and obtaining necessary signatures on documents, including, for example, any power of attorney, declaration, or assignment papers. DFCI will also direct any outside counsel involved in drafting, filing, prosecution, or maintenance of the patents and patent applications listed in Schedule 3 to cooperate fully with LICENSEE. LICENSEE will pay all associated costs, if any, incurred as a result of LICENSEE's requests for cooperation. DFCI shall provide prompt notice to LICENSEE of any matter that comes to its attention that may affect the patentability, validity, or enforceability of any patent application or patent within Patent Rights.

6.5 **Relinquishing Rights.** If LICENSEE elects not to prepare, prosecute, and/or maintain a patent or patent application within Patent Rights in any country of the licensed Territory, LICENSEE shall give ninety (90) days advance written notice to DFCI; relinquish responsibility for prosecution of such patent or patent application; and surrender its license under such patent or patent application. However, if LICENSEE relinquishes rights to any patent or application within Patent Rights to which an interference proceeding or opposition has been declared or filed, the notice period is one hundred and eighty (180) days. If LICENSEE so relinquishes its rights, it will remain responsible for all patent-related expenses incurred by DFCI during the applicable notice period. Thereafter, LICENSEE will have no further obligation to pay any patent expenses for the patents or patent applications that it relinquished.

6.6 **Prosecution by DFCI.** If LICENSEE relinquishes its rights within Patent Rights as described in Section 6.5, DFCI shall thereafter have the right, but not any obligation, to prosecute, obtain issuance of, and/or maintain such Patent Rights relinquished by LICENSEE in such country(ies) or region(s) at its own cost, and any such applications and resultant patents shall not be subject to this Agreement.

Article 7 - Patent Infringement and Enforcement

7.1 **Substantial Infringement**. For the purposes of this Agreement, "Substantial Infringement" shall mean any infringement, of any of the Patent Rights, that LICENSEE deems material to its business. If at any time during the term of this Agreement, LICENSEE becomes aware of an apparent Substantial Infringement, LICENSEE will promptly notify DFCI of such infringement. In the event that LICENSEE chooses to take any action with respect to the Substantial Infringement, LICENSEE shall, upon the request of DFCI, provide DFCI with an explanation of LICENSEE's reasoning in choosing to take such action.

7.2 **Action by LICENSEE**.

7.2.1 **Procedure.** LICENSEE shall have the first right, but not the obligation, to enforce the Patent Rights and to prosecute apparent Substantial Infringers, at its expense and in its own name, when it believes such action may be reasonably necessary and justified. Before LICENSEE files a lawsuit in a court of law with respect to the infringement, LICENSEE shall consider in good faith the views of DFCI,

particularly as they relate to the potential effects on the public interest. LICENSEE shall join DFCI as a party-plaintiff if such joinder is required by law (including, but not limited to, joinder of DFCI if deemed to be an indispensable party), at LICENSEE's expense. LICENSEE shall have the right to join Affiliates and Sublicensees into any such legal proceeding.

7.2.2 **Timing.** If LICENSEE notifies DFCI that it intends to prosecute the alleged Substantial Infringer, then LICENSEE has **[*]** months from the date of its notice to DFCI to either (a) cause the infringement to terminate or (b) file a lawsuit in a court of law against the infringer. If any such lawsuit is brought by LICENSEE in its own name it will be at LICENSEE's expense and on its own behalf. LICENSEE has the right to join DFCI as a party-plaintiff if required by law, at LICENSEE's expense.

7.2.3 **Action at Request of DFCI**. DFCI may request LICENSEE to take steps to protect the Patent Rights from an apparent Substantial Infringement. LICENSEE shall notify DFCI, within **[*]** months of receiving a written request from DFCI, of action it intends to take, if any, to compel termination of the alleged infringing action or to file a lawsuit in a court of law against the alleged infringer.

7.2.4 **DFCI's Right to Join**. DFCI independently has the right to join any lawsuit brought by LICENSEE under this Section 7.2 and shall, in such case, fund a pro rata share of the cost of the legal proceeding from the date of joining. If DFCI elects to join as a party plaintiff pursuant to this Section 7.2.4, DFCI may jointly participate in the action with LICENSEE, but LICENSEE will have the right to designate lead counsel.

7.2.5 **Settlement**. In any legal proceeding initiated by LICENSEE, LICENSEE shall not enter into any settlement, consent judgment, or other voluntary final disposition in which a license to Patent Rights (or covenant not to sue with respect to such Patent Rights) would be granted to the third party defendant pursuant to which DFCI's future financial compensation would be significantly affected (such as future royalties as would be owed under a sublicense granted hereunder) or patent rights would be forfeited, without the consent of DFCI (which shall not be unreasonably withheld).

7.2.6 **Reduction of Royalties**. If LICENSEE initiates legal proceedings under this Section 7.2 in any country and DFCI does not independently join the proceeding, LICENSEE may deduct up to **[*]** of LICENSEE's documented costs, including reasonable attorney fees, from running royalties payable to DFCI from sales of Licensed Products covered by the patent(s)-in suit. However, LICENSEE may not reduce DFCI's royalty payments by more than **[*]** of the amount otherwise due under Section 3.1.5. If **[*]** of LICENSEE's costs and expenses exceeds the amount of royalties deducted by LICENSEE for any calendar year, LICENSEE may, to that extent, reduce the royalties due to DFCI in succeeding calendar quarters for so long as LICENSEE as the Substantial Infringement continues. However, LICENSEE may not reduce total royalties due to DFCI in a given calendar quarter by more than **[*]**. LICENSEE's right to reduce royalty payments to DFCI under this Section 7.2.6 applies only for so long as the Substantial Infringement continues.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

7.3 Action by DFCI

7.3.1 **Procedure**. If LICENSEE notifies DFCI that it does not intend to prosecute a Substantial Infringement, or if LICENSEE fails to cause the Substantial Infringement to terminate, or fails to file a lawsuit in a court of law to compel termination within **[*]** months of the date of its notice to DFCI pursuant to Section 7.1 or Section 7.2.3, above, then DFCI may initiate legal proceedings against the alleged infringer, at DFCI's expense and on its own behalf according to the terms of this Section 7.3. Before DFCI commences any legal proceeding with respect to the infringement, DFCI shall consider in good faith the views of LICENSEE. DFCI has the right to join LICENSEE as a party-plaintiff, if required by law, at DFCI's expense.

7.3.2 **LICENSEE's Right To Join**. LICENSEE independently has the right to join any legal proceeding brought by DFCI under this Section 7.3 and shall, in such case, fund a pro rata share of the cost of the legal proceeding from the date of joining. If LICENSEE elects to join as a party plaintiff pursuant to this Section 7.3.2 or, LICENSEE may jointly participate in the action with DFCI, but DFCI will have the right to designate lead counsel.

7.3.3 **Settlement**. Regardless of whether LICENSEE is joined or joins any legal proceeding initiated by DFCI (as described in Section 7.3.2), no settlement, consent judgment, or other voluntary final disposition of such legal proceeding may be entered into without the consent of DFCI.

7.4 **Cooperation.** If one party files a lawsuit in a court of law or brings any other action related to enforcement of the Patent Rights or otherwise related to the Patent Rights against a third party pursuant to this Article 7 or is prevented from filing such a lawsuit or bringing such an action against the third party due to lack of standing to sue, the other party (and any Affiliates or Sublicensee of that party) shall cooperate with and supply all assistance reasonably requested by the party initiating the proceedings, at the initiating party's request and expense.

7.5 **Distribution of Amounts Paid by Third Parties.** In any legal proceeding brought by DFCI under Section 7.3 and funded solely by DFCI, any damages or other amounts recovered as a result of the proceeding will be retained by DFCI. In any other legal proceeding, any damages or other amounts will be distributed as follows: The damages or other amounts will first be used to reimburse LICENSEE, it's Affiliates or Sublicensees, and DFCI for litigation costs not paid from royalties and then to reimburse DFCI a sum equivalent to the total amount of royalties and minimum royalties deducted by LICENSEE under Section 7.2.6. The balance, if any, will be divided pro rata based on the relative contributions of the parties. It is expressly understood that any party not contributing to the funding of a proceeding will not share in any amounts recovered as a result of the proceeding.

7.6 **Declaratory Judgment Actions.** In the event that any third party initiates a declaratory judgment action alleging the invalidity or unenforceability of the Patent Rights, or if any third party brings an infringement action against LICENSEE or its Affiliates or Sublicensees because of the exercise of the rights granted LICENSEE under this Agreement, then LICENSEE shall have the right to defend such action under its own control and at its own expense; provided, however, that DFCI shall (a) have option of joining as co-defendant if it chooses to do so; or (b) join as co-defendant if required by law; and (c) cooperate as necessary with LICENSEE in LICENSEE's

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defense. LICENSEE shall NOT enter into any settlement, consent judgment or other voluntary final disposition of any action under this Section 7.6 without the consent of DFCI, which consent shall not be unreasonably withheld unless the settlement includes any express or implied admission of liability or wrongdoing on DFCI's part, in which case DFCI's right to grant or deny consent is absolute and at its sole discretion. Any recovery shall be first applied to reimburse each party pro rata for any out-of pocket expenses it may have incurred with respect to defense of such action and the remainder shall be distributed as described in Section 7.5.

Article 8 - Term and Termination

8.1 **Term.** Unless terminated earlier under the provisions of this Agreement, this Agreement will terminate on a country by country basis on the expiration date of the last to expire of patent within Patent Rights. If a Licensed Product or Licensed Process is not covered in whole or in part by an unexpired issued or granted claim, or by a pending claim in the Patent Rights and incorporates Biological Materials then this Agreement with respect to that Licensed Product shall terminate twenty (20) years from the Effective Date.

8.2 **Termination by DFCI.** If LICENSEE materially breaches any provision of this Agreement, then DFCI will provide LICENSEE with written notice of default specifying the nature of the breach. LICENSEE will have a period of sixty (60) days to cure such breach. Should LICENSEE fail to cure the breach within the sixty (60) day period, then DFCI shall have the right to terminate this Agreement immediately upon LICENSEE'S receipt of a notice of termination from DFCI. Unless otherwise indicated below, it is expressly understood that this Agreement and all licenses hereunder shall remain in effect for any Field of Use for which LICENSEE has not defaulted. DFCI has the right to immediately terminate this Agreement and all licenses granted hereunder by providing LICENSEE with written notice of termination, upon the occurrence of any of the following events:

(a) LICENSEE ceases to carry on its business and development activities with respect all Licensed Products in the Field of Use.

(b) LICENSEE fails to pay on schedule any royalty or other payment that has become due and is payable under Articles 3 or 4 of this Agreement and has not cured the default by making the required payment, together with interest due, pursuant to Section 4.5, herein, within thirty (30) days of receiving a written notice of default from DFCI requesting such payment.

(c) LICENSEE fails to comply with any due diligence obligation provided for in Section 5.1 unless LICENSEE has cured the default by meeting the obligation within sixty (60) days of receiving written notice of default from DFCI.

(d) LICENSEE defaults in its obligations to procure and maintain insurance under Sections 9.6 - 9.9.

(e) LICENSEE has been convicted of a felony relating to the manufacture, use, sale or importation of Licensed Products.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

(f) LICENSEE materially breaches any other provision of this Agreement, unless LICENSEE has cured the breach within ninety (90) days of receiving written notice from DFCI specifying the nature of the breach.

8.3 **Termination by LICENSEE.** LICENSEE has the right to terminate this Agreement without cause by giving DFCI ninety (90) days prior written notice.

8.4 **Effect of Termination**.

8.4.1 **No Release.** Upon termination of this Agreement for any reason, nothing in this Agreement may be construed to release either party from any obligation that matured prior to the effective date of the termination.

8.4.2 **Survival.** The provisions of Section 3.1.2 and 3.1.3 (Patent Expenses) Article 4 (Royalty Reports, Payments and Financial Records), Section 5.5 (Publicity – Use of Names), Section 8.4.3 (Inventory), Sections 9.1 – 9.5 (Indemnification and Defense), Sections 9.7 – 9.9 (Insurance), Article 10 (Warranty Disclaimers) and Article 12 (Dispute Resolution) survive termination of this Agreement.

8.4.3 **Inventory.** LICENSEE, any Affiliate(s) and any Sublicensees whose sublicenses are not converted as provided in Section 8.4.5, may, after the effective date of termination, sell all Licensed Products that are in inventory as of the date of written notice of termination, and complete and sell Licensed Products which the Affiliates or Sublicensees can clearly demonstrate were in the process of manufacture as of the date of written notice of termination, provided that LICENSEE shall pay to DFCI the royalties thereon as required by Article 3 and shall submit the reports required by Article 4 on the sales of Licensed Products.

8.4.4 **Use of Biological Materials.** LICENSEE, any Affiliate(s) and any Sublicensees whose sublicenses are not converted as provided in Section 8.4.5, shall cease to use the Biological Materials and shall certify their proper and humane disposition.

8.4.5 **Sublicenses.** Any sublicenses will terminate contemporaneously with this Agreement. However, any Sublicensee not in default under its sublicense may request conversion of the sublicense to a license directly between DFCI and Sublicensee. DFCI shall not unreasonably withhold its acceptance of such conversion under substantially the same financial terms and as those contained the sublicense, however, as a condition of DFCI's acceptance, the Sublicensee must first agree to be bound by all of the non-financial provisions of this Agreement.

Article 9 - Indemnification, Defense and Insurance

9.1 LICENSEE shall indemnify, defend and hold harmless DFCI and its trustees, officers, medical and professional staff, employees, and agents and their respective successors, heirs and assigns collectively, (the "DFCI Indemnitees"), against any claim, liability, damage, deficiency, obligation, cost, loss or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the DFCI Indemnitees, or any one of them, in connection with any claims, suits, actions, demands or judgments (a) arising out of the design, production, manufacture, sale, use in commerce, lease, or promotion by LICENSEE or by a Sublicensee, Affiliate, or agent of LICENSEE, of any product, process or service relating to, or developed pursuant to, this

Agreement or (b) arising out of any other activities to be carried out pursuant to this Agreement. LICENSEE shall indemnify, defend by counsel reasonably acceptable to HHMI, and hold harmless HHMI and its trustees, officers, employees, and agents (collectively, "HHMI Indemnitees") from and against any claim, liability, cost, expense, damage, deficiency, loss, or obligation, of any kind or nature (including, without limitation, reasonable attorneys' fees and other costs and expenses of defense) (collectively, "Claims"), based upon, arising out of, or otherwise relating to this Agreement, including without limitation any cause of action relating to product liability. DFCI Indemnitees and HHMI Indemnitees may be referred to in this Agreement collectively as the "Indemnitees"). This Section will not apply to any Claim that is determined with finality by a court of competent jurisdiction to result solely from the gross negligence or willful misconduct of an Indemnitee.

9.2 LICENSEE shall, at its own expense, provide attorneys reasonably acceptable to DFCI to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.

9.3 If any such action is commenced or claim made or threatened against DFCI or other Indemnitees as to which LICENSEE is obligated to indemnify it (them) or hold it (them) harmless, DFCI or the other Indemnitees shall promptly notify LICENSEE of such event. In the case of any HHMI Indemnitee, notice shall be given reasonably promptly following actual receipt of written notice of the action or claim by an officer or attorney of HHMI. LICENSEE shall assume the defense of, and may settle, that part of any such claim or action commenced or made against DFCI (or other Indemnitees) which relates to LICENSEE's indemnification and LICENSEE may take such other steps as may be necessary to protect it. LICENSEE will not be liable to DFCI or other Indemnitees on account of any settlement of any such claim or litigation affected without LICENSEE's consent. The right of LICENSEE to assume the defense of any action is limited to that part of the action commenced against DFCI and/or Indemnitees that relates to LICENSEE's obligation of indemnification and holding harmless. Notwithstanding the foregoing, LICENSEE shall not settle any Claim against an HHMI Indemnitee without HHMI's written consent, where (a) such settlement would include any admission of liability on the part of any HHMI Indemnitee, (b) such settlement would impose any restriction on any HHMI Indemnitee's conduct of any of its activities, or (c) such settlement would not include an unconditional release of all HHMI Indemnitees from all liability for claims that are the subject matter of the settled Claim.

9.4 LICENSEE shall require any Affiliates or Sublicensee(s) to indemnify, hold harmless and defend DFCI and HHMI under the same terms set forth in Sections 9.1 – 9.3 and Section 9.5.

9.5 HHMI is not a party to this Agreement and has no liability to any LICENSEE, sublicensee, or user of anything covered by this Agreement, but HHMI is an intended third-party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.

Insurance.

9.6 At such time as any product, process or service relating to, or developed pursuant to, this Agreement is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by LICENSEE or by a Sublicensee, Affiliate or agent of LICENSEE, LICENSEE shall, at its sole cost and expense, procure and maintain policies of commercial general liability insurance in amounts not less than $2,000,000 per incident and $2,000,000 annual aggregate and naming the Indemnitees as additional insureds. Such commercial general liability

insurance must provide (a) product liability coverage and (b) contractual liability coverage for LICENSEE's indemnification under Sections 9.1 through 9.5 of this Agreement. If LICENSEE elects to self-insure all or part of the limits described above (including deductibles or retentions which are in excess of $250,000 annual aggregate), such self-insurance program must be acceptable to the DFCI and the DFCI's associated Risk Management Foundation. The minimum amounts of insurance coverage required under these provisions may not be construed to create a limit of LICENSEE's liability with respect to its indemnification obligation under Sections 9.1 through 9.5 of this Agreement.

9.7 LICENSEE or its insurance carrier shall provide DFCI with written evidence of such insurance upon request of DFCI. LICENSEE or its insurance carrier shall promptly notify DFCI, in the event that LICENSEE receives notice of cancellation, non-renewal or other material change in such insurance. LICENSEE acknowledges its obligation to maintain insurance coverage as described in Section 9.6. As such, in the event that LICENSEE receives notice of cancellation, non-renewal or other material change of such insurance, LICENSEE must elect to either (i) obtain replacement insurance providing comparable coverage or, (ii) implement a self-insurance program acceptable to DFCI and DFCI's associated Risk Management Foundation. LICENSEE shall provide written notice and proof that it has either obtained replacement insurance or implemented self-insurance program to DFCI at least fifteen (15) days prior to the cancellation or material change in such insurance coverage. Notwithstanding the foregoing, in the event that LICENSEE elects (ii) above, LICENSEE must provide DFCI and DFCI's associated Risk Management Foundation with sufficient information to allow a review and acceptance of LICENSEE’s self-insurance program prior to aforementioned fifteen (15) day period.

If LICENSEE does not notify DFCI and provide proof that it has either obtained replacement insurance coverage or implemented a self insurance program acceptable to DFCI at least fifteen (15) days prior to the effective date of cancellation or material change in such insurance coverage, DFCI has the right to terminate this Agreement effective the date the insurance coverage is cancelled, not renewed or otherwise materially changed without additional waiting periods. In such event, DFCI agrees to provide written notice within twenty-four (24) hours pursuant to Article 11 (“Notices”) to LICENSEE that this Agreement is terminated under Article 8.2.

9.8 LICENSEE shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during (a) the period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by LICENSEE or by a Sublicensee, Affiliate or agent of LICENSEE.

9.9 LICENSEE shall require any Affiliates or Sublicensee(s) to maintain insurance in favor of DFCI and the Indemnitees under the same terms set forth in Sections 9.6 – 9.8.

Article 10 - Disclaimer of Warranties

10.1 DFCI MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY PATENT, TRADEMARK, SOFTWARE, NON-PUBLIC OR OTHER INFORMATION, OR TANGIBLE RESEARCH PROPERTY, LICENSED OR OTHERWISE PROVIDED TO LICENSEE HEREUNDER AND HEREBY DISCLAIMS THE SAME.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

10.2 DFCI DOES NOT WARRANT THE VALIDITY OF THE PATENT RIGHTS LICENSED HEREUNDER AND MAKES NO REPRESENTATION WHATSOEVER WITH REGARD TO THE SCOPE OF THE LICENSED PATENT RIGHTS OR THAT SUCH PATENT RIGHTS MAY BE EXPLOITED BY LICENSEE, AFFILIATE OR SUBLICENSEE WITHOUT INFRINGING OTHER PATENTS. DFCI MAKES NO REPRESENTATION THAT BIOLOGICAL MATERIALS OR THE METHODS USED IN MAKING OR USING SUCH BIOLOGICAL MATERIALS ARE FREE FROM LIABILITY FOR PATENT INFRINGEMENT OR THAT SUCH MATERIALS ARE NOT SUBJECT TO CLAIMS OF JOINT OWNERSHIP BY THIRD PARTIES.

10.3 THE LIABILITY OF DFCI, ITS AGENTS, OR ITS EMPLOYEES, WITH RESPECT TO ANY AND ALL SUITS, ACTIONS, LEGAL PROCEEDINGS, CLAIMS, DEMANDS, DAMAGES, COSTS AND EXPENSE ARISING OUT OF THE PERFORMANCE OR NON PERFORMANCE OF ANY OBLIGATION UNDER THIS AGREEMENT WHETHER BASED ON CONTRACT, WARRANTY, TORT (INCLUDING WITHOUT LIMITATION NEGLIGENCE), STRICT LIABILITY, STATUTORY OR OTHERWISE SHALL BE LIMITED TO DIRECT, ACTUAL DAMAGES INCURRED AS A RESULT OF DFCI's FAILURE TO PERFORM ITS OBLIGATIONS AS REQUIRED BY THIS AGREEMENT AND SHALL NOT EXCEED IN THE AGGREGATE A SUM EQUAL TO THE TOTAL AMOUNTS PAYABLE TO DFCI UNDER THIS AGREEMENT.

10.4 DFCI acknowledges that it has the right to enter into this Agreement.

10.5 FibroGen acknowledges that the license agreement between Imigen and FibroGen, effective October 13, 2003, is no longer an effective instrument.

Article 11 - Notices

11.1 **Notices to DFCI.** Unless otherwise specified in this Agreement, reports, notices and other communications from LICENSEE to DFCI as provided hereunder must be sent to:

Sr. Vice President for Research
Dana-Farber Cancer Institute
44 Binney Street
Boston, MA 02115

With a copy sent to:
Vice President
Dana-Farber Cancer Institute
Office of Research and Technology Ventures
44 Binney Street
Boston, MA 02115

or other individuals or addresses as DFCI subsequently furnish by written notice to LICENSEE.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

11.2 **Notices to LICENSEE.** Unless otherwise specified in this Agreement, reports, notices and other communications from DFCI to LICENSEE as provided hereunder must be sent to:

FibroGen, Inc.
225 Gateway Blvd
South San Francisco, CA, 94080
Attention: President
CC: Legal Department
650 –866-7200 (Phone)
650 –866-7201 (Fax)

or other individuals or addresses as LICENSEE subsequently furnish by written notice to DFCI.

Article 12 - Dispute Resolution

12.1 **Negotiation between the Parties**. The parties shall first attempt to resolve any controversy that arises from this Agreement, or claim for breach of the Agreement, by good faith negotiations, first between their respective business development representatives and then, if necessary, between senior representatives for the parties, such as the Sr. Vice President for Research or President of DFCI or the President of LICENSEE.

12.2 **Non-Binding Mediation.** If the controversy or claim cannot be settled through good faith negotiation between the parties, the parties agree first to try in good faith to settle their dispute by non-binding mediation under the Mediation Rules of the American Arbitration Association, before resorting to arbitration, litigation or other dispute resolution procedure. For the sake of clarity, no dispute affecting the rights or property of HHMI shall be subject to binding arbitration unless HHMI so agrees after the dispute arises.

Article 13 - Independent Contractor

For the purpose of this Agreement and all services to be provided hereunder, both parties are and will be deemed to be, independent contractors and not agents or employees of the other. Neither party has authority to make any statements, representations or commitments of any kind, or to take any action, that will be binding on the other party.

Article 14 - Severability

If any one or more of the provisions of this Agreement is held to be invalid, illegal or unenforceable, the validity, legality or enforceability of the remaining provisions of this Agreement will not in any way be affected or impaired thereby.

Article 15 - Non-assignability

Neither this Agreement nor any part of the Agreement is assignable by either party without the express written consent of the other, which consent a party will not unreasonably withhold. However, LICENSEE may assign this agreement in conjunction with the sale of essentially all of its related business assets. Any attempted assignment without such consent is void.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Article 16 - Entire Agreement

This instrument contains the entire Agreement between the parties. No verbal agreement, conversation or representation between any officers, agents, or employees of the parties either before or after the execution of this Agreement may affect or modify any of the terms or obligations herein contained.

Article 17 - Modifications in Writing

No change, modification, extension, or waiver of this Agreement, or any of the provisions herein contained is valid unless made in writing and signed by a duly authorized representative of each party.

Article 18 - Governing Law

The validity and interpretation of this Agreement and the legal relations of the parties to it are governed by the laws of the State of New York without regard to any choice of law principal that would dictate the application of the law of another jurisdiction.

Article 19 - Captions

The captions are provided for convenience and are not to be used in construing this Agreement.

Article 20 - Construction

The parties agree that they have participated equally in the formation of this Agreement and that the language herein should not be presumptively construed against either of them.

Article 21 - Force Majure

Either party shall be excused from any performance required hereunder if such performance is rendered impossible or unfeasible due to any catastrophe or other major event beyond its reasonable control, including, without limitation, war, riot, and insurrection; laws, proclamations, edicts, ordinances, or regulations; strikes, lockouts, or other serious labor disputes; and flood, fires, explosions, or other natural disasters. When such events have abated, the parties' respective obligations shall resume.

Article 22 - Lapse

The terms contained in this Agreement shall be null and void if the certificate of merger with the Secretary of State of the State of Delaware for the Imigen Acquisition is not filed on or before February 28, 2006.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

IN WITNESS WHEREOF, the parties hereto have caused this agreement to be executed in quadruplicate by their duly authorized representatives as of the date first above written.

DANA-FARBER CANCER INSTITUTE, INC.		FIBROGEN, INC.	
By:	/s/ Anthony del Campo	By:	/s/ Thomas B. Neff
	Anthony A. del Campo, MBA V. P., Research and Technology Ventures		Thomas B. Neff Chief Executive Officer
Date:	2/1/2006	Date:	26 Jan 06

L:2836

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Schedule 1

Exclusively Licensed Biological Materials

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Schedule 2

Non-Exclusively Licensed Biological Materials

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Schedule 3

Patent Rights

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Exhibit 10.8

[*] = **Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.**

AMENDMENT NO. 2 TO MASTER SUPPLY AGREEMENT

THIS AMENDMENT NO. 2 (the "Second Amendment") is effective as of July 24, 2020 (the "Second Amendment Effective Date") by and among: FibroGen, Inc. and its Affiliates (collectively, "**FibroGen**"); and Shanghai SynTheAll Pharmaceutical Co., Ltd (d/b/a "□□□□□□ □□□□") ("**Shanghai STA**"); and STA Pharmaceutical Hong Kong Limited (d/b/a "□□□□□□□□□□□") ("**STA Hong Kong**") (STA Hong Kong, Shanghai STA, and each of their Affiliates are collectively referred to as "**STA**"). This Second Amendment amends the Master Supply Agreement entered into by and between STA and FibroGen on March 2, 2020 as amended by Amendment No. 1 on May 11, 2020 (collectively, the "Master Supply Agreement"). STA and FibroGen shall be referred to individually herein as a "Party", and collectively as, the "Parties". The Master Supply Agreement and this Second Amendment are collectively, "the Agreement".

WHEREAS, the Parties desire to amend the Master Supply Agreement to allow for certain Manufacturing Services and the production of certain Products to be performed at the [*] Facility (defined in Sect. 3.1) pursuant to the requirements set forth in Sect. 3.1 of the Agreement; and

WHEREAS, the Parties desire to continue the relationship as set forth under the Master Supply Agreement as amended by this Second Amendment.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

(1) Unless otherwise defined herein, all capitalized terms and phrases used in this Second Amendment shall have the meaning ascribed to them in the Master Supply Agreement.

(2) Sect 1.69 of the Master Supply Agreement is hereby deleted in its entirety and replaced with the following:

> "1.69 "**STA Facility**" means the facility listed in Section 3.1 hereto, which facility is owned and operated by STA and will be used for the performance of Manufacturing Services and the production of Products. [*]"

(3) Sect. 3.1 of the Master Supply Agreement is hereby deleted in its entirety and replaced with the following:

> "3.1 STA Facility. With the exception of FG-[*] as set forth in this Sect. 3.1, all Product manufactured for FibroGen hereunder shall be manufactured solely by STA at the STA Facility located at [*]. The STA Facility may not be changed without a signed writing by STA and FibroGen. [*]"

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

(4) This Second Amendment, together with the Master Supply Agreement as amended by Amendment No.1, contains the entire understanding of the Parties with respect to the subject matter hereof. Except as otherwise provided herein, the Master Supply Agreement has not been modified or amended and remains in full force and effect. All express or implied agreements and understandings, either oral or written, heretofore made with respect to subject matter herein are expressly superseded in this Second Amendment.

(5) This Second Amendment may be executed in counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Counterparts may be signed and delivered by facsimile and/or via portable document format (pdf), each of which shall be binding when sent.

IN WITNESS WHEREOF, the Parties have executed this Second Amendment to the Master Supply Agreement as of the Second Amendment Effective Date.

STA PHARMACEUTICAL HONG KONG LIMITED

By:	/s/ Xiaoyong Fu
Name:	Xiaoyong Fu
Title:	SVP
Date:	8/26/2020

FIBROGEN, INC.

By:	/s/ Michael Martinelli
Name:	Michael Martinelli
Title:	SVP Tech Dev
Date:	8/28/2020

SHANGHAI SYNTHEALL PHARMACEUTICAL CO., LTD.

By:	/s/ Xiaoyong Fu
Name:	Xiaoyong Fu
Title:	SVP
Date:	8/26/2020

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Exhibit 10.9

MASTER SUPPLY AGREEMENT

This Master Supply Agreement (the "**Agreement**") is entered into and effective as of **September 10, 2020** (the "**Effective Date**"), by and between **FibroGen, Inc.**, a Delaware corporation, having its principal place of business at 409 Illinois Street, San Francisco, California 94158, United States of America ("**FibroGen**"); and **AstraZeneca UK Limited.**, a company incorporated in England under No. 364842 whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus CB2 0AA, England ("**AstraZeneca**"). AstraZeneca and FibroGen may be referred to individually as a "**Party**", and collectively as the "**Parties**". AstraZeneca and each of its Affiliates shall collectively be referred to herein as "AstraZeneca". FibroGen and each of its Affiliates shall collectively be referred to herein as "FibroGen".

RECITALS

WHEREAS, FibroGen owns or controls certain technology and intellectual property relating to the compound known as roxadustat (or FG-4592);

WHEREAS, AstraZeneca and FibroGen are parties to that certain Amended and Restated License, Development and Commercialization Agreement, entered into as of October 16, 2014 and effective as of July 30, 2013 (the "**Collaboration Agreement**"), under which FibroGen granted AstraZeneca certain rights to joint continued development and commercialization of roxadustat in the Territory (as defined below); and

WHEREAS, as contemplated in the Collaboration Agreement, AstraZeneca and FibroGen now desire to memorialize terms under which FibroGen will supply Product (defined below) to AstraZeneca for AstraZeneca's use in commercialization, including labeling and packaging of products containing roxadustat, on the terms set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the Parties hereto agree as follows:

ARTICLE 1
DEFINITIONS

The following capitalized terms, whether used in the singular or plural, shall have the meanings ascribed to them below for purposes of this Agreement:

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

1.1 **"Affiliate"** means, with respect to either Party, any other corporation or business entity that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, the term "control" means direct or indirect ownership of more than fifty percent (50%) of the outstanding voting securities or other ownership interests or the power to direct or cause the direction of the management or policies of such entity, whether through the ownership of voting securities, by contract, or otherwise.

1.2 **"Annual Net Sales"** has the meaning set forth in the Collaboration Agreement.

1.3 **"API"** means the active pharmaceutical ingredient roxadustat, also known as FG-4592 or AZD9941.

1.4 **"API Batch(es)"** means the quantity of active pharmaceutical ingredients produced per batch(es) actually produced by FibroGen's then-current manufacturer.

1.5 **"Applicable Law(s)"** means all laws, rules, and regulations in the Territory applicable to the activities performed under this Agreement.

1.6 **"AstraZeneca Sublicensee"** means a Sublicensee, as such term is defined in the Collaboration Agreement.

1.7 **"Batch(es)"** means a specific quantity defined in **Exhibit A** of Bulk Drug Product that is intended to have uniform character and quality, within specified limits.

1.8 **"Binding Period"** shall have the meaning ascribed in Section 3.1of this Agreement.

1.9 **"Bulk Drug Product"** means drug product containing API, in a formulation consistent with the Specifications (including, but not limited to a tablet formulation) and packaged in accordance with the Specifications, supplied in bulk by FibroGen to AstraZeneca.

1.10 **"Calendar Year"** means each successive period of twelve (12) calendar months commencing on January 1.

1.11 **"Certificate of Analysis"** means a document certifying that a particular Batch of Product was tested and conforms to the Specifications and the Quality Assurance Agreement. Unless otherwise agreed to in a signed writing by both Parties, the Certificate of Analysis shall be in the English language.

1.12 **"Certificate of Compliance"** means a document that states a particular Batch of Product was manufactured in compliance with the Quality Assurance Agreement and: (a) lists the manufacturing date, unique Batch number, Product number, and quantity of Product in such Batch; (b) certifies that such Batch was manufactured in accordance with all Applicable Laws, including cGMP; and (c) certifies all excursions and investigations associated with the Batch have been closed and found not to impact the Batch. The Parties shall from time to time agree upon a format or formats for the Certificate of Compliance to be used under this Agreement. Unless otherwise agreed to in a signed writing by both Parties, the Certificate of Compliance shall be in the English language.

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1.13 **"cGMP"** means the current good manufacturing practices for the manufacture of pharmaceutical products, including but not limited to: (a) the United States Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. §321 et seq.) and the regulatory requirements for current good manufacturing practices as promulgated by the FDA thereunder, including without limitation 21 C.F.R. §§ 210, 211, and Part 11 (as applicable to electronic systems used in the manufacture of product); and/or (b) the regulatory requirements for current good manufacturing practices as promulgated by the International Conference on Harmonization (ICH), Guidance for Industry Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients; and/or the European Community Directive 2003/94/EC of October 8, 2003; and (c) the EC Guide to Good Manufacturing Practices for Medicinal Intermediate Products; and (d) 2003/94/EEC Directive (as supplemented by Volume 4 of EudraLex published by the European Commission), as amended, if and as implemented in the relevant constituent country; and (e) all additional applicable Regulatory Authority regulations that replace, amend, modify, supplant or complement any of the foregoing; and/or (f) any and all current Good Manufacturing Practices applicable to the manufacture, testing and/or any other processing of pharmaceutical products in other countries and territories worldwide where the respective Finished Products are sold or otherwise marketed from time to time provided that FibroGen is informed about such other Good Manufacturing Practices by AstraZeneca in accordance with Quality Assurance Agreement and FibroGen confirms in writing that it will comply with such other Good Manufacturing Practices within a reasonable time so as not to delay release of the Finished Product by AstraZeneca.

1.14 **"Confidential Information"** has the meaning given to such term in the Collaboration Agreement.

1.15 **"Control" or "Controlled"** means possession of the right to grant a license or sublicense as provided for herein without violating (a) any law or governmental regulation applicable to such license or sublicense, or (b) the terms of any agreement or other arrangement with any Third Party that exists as of the Effective Date, or if such right is acquired after the Effective Date, as of the date the Party first gained possession of such right.

1.16 **"Definitive Price Per Tablet"** has the meaning set forth in Section 6.1.1(c).

1.17 **"Delivery Year"** has the meaning set forth in Section 6.5(a)(i) of the Collaboration Agreement.

1.18 **"Drug Product Blend"** means [*] at the Product manufacturer. For clarity, a "drug product blend" refers to a mixture that contains API, excipients and is lubricated and ready for compression into Bulk Drug Product.

1.19 **"Executed Batch Records"** means the collection of records that provides a traceable history of how a Batch of Product was produced.

1.20 **"Facility(ies)"** means the facility(ies) as described in Section 4.1 hereto.

1.21 **"FDA"** means the United States Food and Drug Administration, or any successor agency thereto, having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products in the United States.

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1.22 **"Finished Product"** means Bulk Drug Product in finished packaging (performed by AstraZeneca) that is ready to be sold and/or has been sold to the public that includes Bulk Drug Product supplied hereunder.

1.23 **"Forecast(ing)"** shall mean Rolling Forecast and Annual Forecast as defined in Section 3.1 and Section 3.2.1 respectively.

1.24 **"Generic Product"** has the meaning set forth in the Collaboration Agreement.

1.25 **"Intellectual Property"** means all Patents, copyrights, trade secrets, know-how, inventions, and all other intellectual property rights that are owned or Controlled by a Party (whether patentable or not), including all applications and registrations with respect thereto.

1.26 **"JOC"** means Joint Operations Committee as further defined in Section 2.2.

1.27 **"Latent Defects"** has the definition set forth in Section 5.1.2.

1.28 **"Manufacturing Process"** means the production process for the manufacture of Product.

1.29 **"Manufacturing Services"** has the meaning set forth in Section 2.1.

1.30 **"Net Sales"** has the meaning set forth in the Collaboration Agreement.

1.31 **"Non-Conforming"** means with respect to Product, damage to or defect in any packaging, missing or defective documentation and such Product fails to conform to any of the requirements and acceptance criteria of this Agreement including the Specifications, Quality Assurance Agreement, and warranties set forth in Section 11.3, as applicable.

1.32 **"Order Acknowledgement"** has the meaning set forth in Section 3.3.3.

1.33 **"Package(ing)"** means such packaging as specified in the Specification.

1.34 **"Patents"** has the meaning set forth in Section 1.96 of the Collaboration Agreement.

1.35 **"Preliminary Price Per Tablet"** has the meaning set forth in Section 6.1.1(a) hereof.

1.36 **"Product"** shall mean Bulk Drug Product.

1.37 **"Purchase Order"** means a written order with a unique numbers submitted by AstraZeneca (or an Affiliate of AstraZeneca) to FibroGen, for FibroGen to manufacture (or have manufactured) and deliver on specified delivery dates, and AstraZeneca to purchase, a specific quantity of Product, as provided in Section 3.1

1.38 **"Quality Assurance Agreement"** has the meaning set forth in Section 9.1 hereof.

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1.39 **"Quality Matters"** has the meaning set forth in Section 8.1 of this Agreement.

1.40 **"Quantity Shortfall"** means the quantity Transferred by Transfer Date by FibroGen to AstraZeneca is [*] of the scheduled Transfer Date.

1.41 **"Raw Material"** means all excipients, components, and Packaging that are required to perform the Manufacturing Services, and shall exclude Finished Product labeling or packaging for sale to end users in the Territory.

1.42 **"Regulatory Authority(ies)"** means the FDA, or any court or government body or other applicable, national, supra-national, multi-national, state, foreign, provincial, regional or local regulatory agency, department, board, commission, bureau, body or other regulatory or administrative government entity, involved in or responsible for regulation of the Product and relevant subject, as the context requires in this Agreement.

1.43 **"Regulatory Filing"** means any or all applications (including marketing authorization applications or new drug applications) submitted to Regulatory Authorities for the purpose of registering the Product, Finished Product, Specifications and/or the Manufacturing Process as required by statute or regulation, and any amendments or supplements thereto, and any other filings required by the Regulatory Authorities relating to the manufacture, testing, sale or distribution of Product and/or Finished Product (as applicable).

1.44 **"Requested Transfer Date"** means the date of delivery AstraZeneca requested in Purchase Order according to the terms of this Agreement, and is subject to Section 3.3.1.

1.45 **"RoW"** has the meaning set forth in the Collaboration Agreement.

1.46 **"Shelf Life"** means [*].

1.47 **"Shipping Requirements"** means AstraZeneca's methods of packaging, monitoring and shipping any and all Product, or as specified in a given Purchase Order in accordance with this Agreement.

1.48 **"Specifications"** means the applicable Specifications for the Product agreed on by the Parties and as defined in the Quality Assurance Agreement.

1.49 **"Stockpile" or "Stockpiled"** shall have the mean the safety stock as described in Section 3.4.1.

1.50 **"Subcontractor"** means any independent entity that FibroGen contracts to perform any Manufacturing Services or meet any obligations that are required under the terms and conditions of this Agreement, as further described in Section 4.5.

1.51 **"Supply Failure"** means the failure by FibroGen to Transfer at least [*] of Product ordered by AstraZeneca during any [*] period under this Agreement.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

1.52 **"Territory"** has the meaning set forth in the Collaboration Agreement.

1.53 **"Third Party"** means any party other than AstraZeneca, FibroGen, and their respective Affiliates.

1.54 **"Total Definitive Price"** has the meaning set forth in Section 6.1.1(c).

1.55 **"Total Preliminary Price"** has the meaning set forth in Section 6.1.1(c).

1.56 **"Transfer"** means in the case of FibroGen, to deliver Product to AstraZeneca pursuant to Section 5.3.

1.57 **"Transfer Date"** means the date specified for Transfer of Product in accordance with this Agreement, which shall be specified in the Purchase Order.

ARTICLE 2
SUPPLY ARRANGEMENT

2.1 General Supply. This Agreement establishes the general terms and conditions applicable to FibroGen's manufacturing and supply of Product to AstraZeneca. Subject to the terms and conditions of this Agreement, FibroGen hereby agrees, either directly or through one or more Third Party Subcontractors, to manufacture and supply AstraZeneca with the amounts of Product ordered by AstraZeneca in accordance with (and consistent with) its Forecasts and the other ordering terms of this Agreement. Such manufacture and supply of Product (collectively, the **"Manufacturing Services"**) shall be performed in the manner consistent with industry standards and in compliance with the terms and conditions of the Forecast, this Agreement, the Quality Assurance Agreement, the Specifications, and all Applicable Laws. [*]. If a new Product manufacturer is used by FibroGen, as agreed by the Parties and in accordance with the Quality Agreement (or a new Product Specification is agreed on and/or any other aspect of manufacture, including the facilities, equipment, processes, Raw Materials, Subcontractors, vendors, or record-keeping procedures), [*].

2.2 Joint Operations Committee. AstraZeneca and FibroGen shall establish a joint operations committee (the "Joint Operations Committee" or "JOC") consisting of [*] appointed by each party meeting quarterly or as otherwise scheduled. The JOC shall be responsible for reviewing the ongoing relationship of the Parties, reviewing Rolling Forecasts and FibroGen's planning for purchasing API and intermediates to meet the demands in the Rolling Forecasts, considering and attempting to achieve resolution of any disputes referred to it and addressing such other matters as the Parties may mutually agree. The JOC must agree [*] in order to act. For the avoidance of doubt, the JOC is not authorized to amend this Agreement.

2.3 Exclusive Arrangement. Subject to the terms and conditions of this Agreement, AstraZeneca agrees to purchase from FibroGen, and FibroGen agrees to manufacture and supply to AstraZeneca, subject to Section 17.1 (Term). FibroGen shall be free to supply Product to any Third Party worldwide, subject to the exclusive rights granted to AstraZeneca pursuant to the Collaboration Agreement. For clarity and pursuant to Section 6.1 of the Collaboration Agreement, FibroGen shall have the right to manufacture Product outside the Territory to fulfill its supply obligations under this Agreement and the Collaboration Agreement. Subject to the terms of the Collaboration Agreement, FibroGen

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shall have the right to satisfy its obligations under Article 6 of the Collaboration Agreement through a Third Party contract manufacturer. In connection with FibroGen's manufacture of Products for use under the Collaboration Agreement, FibroGen shall have the right to manufacture in the Territory for supply of products under the Astellas Agreements (defined in the Collaboration Agreement).

ARTICLE 3
FORECASTS AND PURCHASE ORDERS

3.1 Forecasts. During the [*] for the term of this Agreement, AstraZeneca shall provide FibroGen a good faith monthly rolling forecast of its anticipated Product requirements comprised of Bulk Drug Product tablets for the next [*], as set forth in **Exhibit A,** and will commence on [*] (each, a "**Rolling Forecast**"). Each Rolling Forecast shall set forth the month during which the Requested Transfer Dates shall occur for each delivery of Product. The first [*] of any Rolling Forecast shall be a binding commitment on AstraZeneca (the "**Binding Period**").

3.2 The Parties agree that FibroGen shall rely on the Rolling Forecast for FibroGen's manufacture of API to meet such Rolling Forecast. [*]. In addition, the JOC shall review the Rolling Forecast and planning for purchase of API and intermediates planning.

3.2.1 In addition, at least [*], AstraZeneca shall provide a non-binding forecast that covers [*] of AstraZeneca's best estimates of its anticipated delivery requirements for Products [*].

3.3 Product Purchase Order(s)

3.3.1 If a Purchase Order is not consistent with all of the applicable Rolling Forecasts, then FibroGen shall use reasonable efforts to manufacture such excess amounts but shall not be obligated to supply such amount.

3.3.2 Each Purchase Order complying with the requirements of this Article 3 and consistent with the Rolling Forecast shall, following FibroGen's Order Acknowledgement of the Purchase Order, be valid and binding and shall be part of and incorporated into this Agreement and subject to all of the terms and conditions of this Agreement.

3.3.3 Each Purchase Order shall specify:

(a) [*];

(b) [*].

(c) [*];

(d) AstraZeneca's order number;

(e) AstraZeneca's and FibroGen's stock keeping unit (SKU);

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

(f) [*]

3.4 [*].

3.4.1 API Stockpile. AstraZeneca may choose to ensure adequate API supply for upside demand (above what is originally forecasted for a time period) by collaborating with FibroGen to initiate an API stockpiling plan. Concurrent with the Forecasts provided in Section 3.1, AstraZeneca may propose a non-binding schedule for quantities of API it would like to have Stockpiled during the applicable time periods. FibroGen will provide feedback at the JOC on what quantities of Stockpiles are practicable for different lead times. AstraZeneca shall submit orders to FibroGen for any agreed quantities of API for stockpiling purposes.

3.4.2 If there is any material conflict between a Purchase Order or an Order Acknowledgement and the terms and conditions of this Agreement, this Agreement prevails, followed by the Purchase Order, and such conflicting terms are rejected and of no effect, unless the Parties mutually agree otherwise in writing.

3.5 Shortfalls in Supply. In the case of an anticipated Quantity Shortfall, FibroGen shall promptly inform AstraZeneca in writing and provide AstraZeneca with a reasonably detailed description of the Quantity Shortfall, and a proposed plan for delivering the remaining amounts of the corresponding Purchase Order. FibroGen shall use reasonable commercial efforts to allocate an amount of its remaining manufacturing capacity to supply the remaining amounts [*] and according to the schedule as agreed by Parties.

3.6 Supply Failure. In the case of a Supply Failure, FibroGen and AstraZeneca shall meet and work together reasonably and in good faith to seek a prompt and commercially reasonable solution to the problem causing the Supply Failure. FibroGen shall use reasonable commercial efforts to cure such failure as soon as practicable. As soon as FibroGen becomes aware FibroGen shall promptly inform AstraZeneca in writing and provide AstraZeneca with a reasonably detailed explanation why there is or will be a Supply Failure and an indication when Transfer of the full Product to be supplied to AstraZeneca pursuant to the applicable Purchase Order is expected. The Parties will discuss the Supply Failure and possible remedies for such Supply Failure at the JOC. [*]. For clarity, a Supply Failure will not be deemed to occur if (and to the extent that) (i) such failure is caused by a force majeure event as set out in Article 18.1, (ii) such failure is due to the Parties' good faith dispute as to whether the Product conforms to the Specifications, or is Non-Conforming pursuant to Section 5.1 hereof.

ARTICLE 4
OTHER MANUFACTURING OBLIGATIONS

4.1 Permits. FibroGen or its Subcontractors shall be responsible for all permits, licenses, and scheduling related to the manufacturing facilities at which Bulk Drug Product is manufactured by or for FibroGen (the "**Facilities**") and for the operation of such Facilities in compliance with all Applicable Law, including cGMP. FibroGen shall be wholly accountable and liable for the safety, health and environmental aspects of all work performed on its or any of its Subcontractor's premises.

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4.2 Manufacturing Standards. FibroGen, either directly or through one or more Third Party Subcontractors, shall manufacture all Product in accordance with Applicable Law including all applicable cGMPs and industry standards, and in compliance with the terms and conditions of the applicable Purchase Order, this Agreement, and the Quality Assurance Agreement.

4.3 Documentation for Manufacture of Bulk Drug Product. FibroGen shall keep complete, accurate accounts, data and records pertaining to the manufacture of the Bulk Drug Product, including without limitation (a) Executed Batch Records for Product manufactured in accordance with cGMP and (b) any other records required to be maintained under the Collaboration Agreement, Quality Assurance Agreement, or Applicable Laws. FibroGen shall retain all such records for a period of at least five (5) years following the date of manufacture, or longer if required by the Quality Assurance Agreement or Applicable Laws, and shall provide such records to AstraZeneca upon reasonable advance notice. FibroGen shall notify AstraZeneca in writing prior to the destruction of any records retained under this Section and, at AstraZeneca's request, shall transfer such records to AstraZeneca at AstraZeneca's reasonable expense.

4.4 Analytical Testing. FibroGen, or a designated Subcontractor, shall perform the analytical testing on Raw Materials and Bulk Drug Products as set forth in the Specifications and Quality Agreement, and/or as otherwise agreed to in a signed writing by FibroGen and AstraZeneca.

4.5 Subcontracting. FibroGen has the right to subcontract some or all of the Manufacturing Services to whichever Third Parties it desires to use who meet the quality standards agreed by the Parties, and to the extent that AstraZeneca has genuine concerns and can demonstrate with reasonable documentation to FibroGen the basis for its concern with respect to the performance of the work for which the Subcontractor is to be engaged, the choice of such Subcontractor shall be subject to AstraZeneca's approval. In the event that FibroGen retains a Subcontractor, FibroGen shall remain fully liable to AstraZeneca for performance of FibroGen's obligations under this Agreement and the Quality Assurance Agreement.

4.6 Governance. For any governance issues hereunder required to be resolved by the approval of both Parties, the JOC shall make such determinations.

4.7 Expectations of Third Parties. FibroGen recognizes AstraZeneca's commitment to working only with suppliers who embrace standards of ethical behaviour that are consistent with the AstraZeneca's Global Standard: Expectations of Third Parties which can be found at: https://www.astrazeneca.com/content/dam/az/Sustainability/2018/Global%20Standard%20Expectations%20of%20Third%20Parties%20final.pdf , as amended from time to time, and in particular those principles headed "Anti-Bribery and Anti-Corruption" ("**Supplier Expectations**"), which are attached as Exhibit B and hereby incorporated into this Agreement.

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4.8 Anti-Bribery and Anti-Corruption. Each Party represents and warrants to the other Party that neither it nor any of its employees, agents or other representatives has or will perform any of the following acts, either directly or through a Third Party, in connection with this Agreement: (i) pay, offer or promise to pay, or authorize the payment of, any money; (ii) give or promise to give, or authorize the giving of, any services or anything else of value; or (iii) enter into any other transactions, to or with any official or employee of any governmental authority or instrumentality, or of a public international organization, or of any agency or subdivision thereof, or to any political party or official thereof or to any candidate for political office, in each case for the purpose of: (1) influencing any act or decision of that person in his/her official capacity, including a decision to fail to perform his/her official functions with such governmental agency or instrumentality or such public international organization or such political party; (2) inducing such person to use his/her influence with such governmental agency or instrumentality or such public international organization or such political party to affect or influence any act or decision thereof; or (3) securing any improper advantage, for the prevention of fraud, bribery and corruption, racketeering, money laundering or terrorism, and product safety, including the US Foreign Corrupt Practices Act, the UK Bribery Act, the US Drug Quality and Security Act ("**DQSA**") and the European Parliament Falsified Medicines Directive (Directive 2011/62/EU) ("**FMD**").

4.9 Trade Controls: Each Party represents, warrants and undertakes that it is not on any applicable official national or international sanctioned party lists and that performance of this Agreement will not violate applicable embargo regulations. Each Party has the right, at such Party's sole expense, to conduct screening checks of the other Party, including verification of such other Party's identity, including full name, country location and address, against official national and international sanctioned party lists and embargo regulations.

4.10 Destruction of Waste. FibroGen shall cause all waste generated on mutually acceptable timelines, during the Term and upon termination of this Agreement or a Purchase Order, to be destroyed. Such waste shall be secured pending destruction. FibroGen or its Subcontractors shall keep a record of destruction of any waste and promptly issue certificates of destruction. The records shall be kept for a period of at least two years and made available to AstraZeneca on written request.

4.11 Standard Operating Procedures. FibroGen shall procure that any Subcontractors shall maintain standard operating procedures and full records detailing production amounts and the dispersal of produced Products to ensure that Product security features of the Products are secured and controlled. The records and standard operating procedures shall be kept for a period of at least two (2) years and made available to AstraZeneca on request.

4.12 Subcontractors FibroGen shall include in all of its contracts with its subcontractors for the supply of Products carrying AstraZeneca's name, insignia, symbol, trademark, trade name, logotype or similar, provisions similar to this Article 4.

4.13 Security Measures. Products shall be delivered by FibroGen in a secure manner appropriate to the transportation route and destination and according to the Specifications. [*].

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4.14 Security Breaches. Each Party will ensure that all FibroGen Materials, including Product, while under their respective supervision and control (or that of its Affiliates or authorized subcontractors) are under appropriately secure conditions with procedures in place to (a) protect the materials against diversion and theft, detect counterfeit and take measures therefrom, and (b) include mechanisms for full accounting and reconciliation of such FibroGen Materials, including Product, in each case, as may be more fully set forth under the Quality Agreement. Each Party will promptly notify the other should any breach or discrepancy thereof occur, and each Party will work cooperatively with the other to amicably resolve any such breach or discrepancy thereof, as directed by the Parties' Joint Product Security Advisory Committee. Any incident of breach of the security of the Products, machinery, other tools of production or information pertaining to this Agreement or the relevant Purchase Order shall be reported to the other Party within [*] of such incident. Each Party shall provide all reasonable assistance to the other Party during any investigation that such other Party may initiate in relation to such incident.

4.15 Improvement Plan. Either Party shall have the right to audit the other Party, its Affiliates and authorized Subcontractors to ensure adherence to this Article 4, and each Party may request that the Parties agree on an improvement plan containing measures to be taken by such other Party to address any concerns that emerge.

ARTICLE 5
ACCEPTANCE/REJECTION; TRANSFER

5.1 Evaluation of Product.

5.1.1 Documentation and Product Review. Each shipment of Product Transferred to AstraZeneca shall be accompanied by (a) the Batch Records including a Certificate of Analysis and a Certificate of Compliance, and (b) an invoice. Within [*], AstraZeneca shall determine whether the deliverables (comprised of such Batch containing Product, packaging, and relevant Batch Records) are conforming or Non-Conforming pursuant to the Specifications, the Quality Agreement and this Agreement. Upon failure of AstraZeneca to respond by [*], the Batch shall be deemed accepted and, AstraZeneca shall have no right to reject such Batch and such Product shall be deemed "Accepted". If, however, within [*], AstraZeneca makes a determination that there is Non-Conforming Product, AstraZeneca shall promptly notify FibroGen of such determination that a Batch does not conform to the Specifications or is otherwise Non-Conforming, and provide a sample of the alleged Non-Conforming Product if reasonably appropriate (a "**Complaint**"), then FibroGen shall conduct an appropriate investigation in its discretion to determine whether FibroGen agrees with AstraZeneca that Product is Non-Conforming Product and to determine the cause of any nonconformity.

5.1.2 Latent Defects. The Parties recognize that some Product may be Non-Conforming, but that such nonconformity cannot reasonably be discovered [*] ("**Latent Defects**"). If Bulk Product contains a Latent Defect and AstraZeneca promptly notifies FibroGen of the details of such Latent Defect within [*], AstraZeneca shall have the right to bring a Complaint to FibroGen for Non-Conforming Product, together with a sample of the Product containing the alleged Latent Defect unless not reasonably possible and this Section 5.1 shall apply.

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5.1.3 Cooperation in Investigations; Disposition of Non-Conforming Product. In the event that the Parties do not agree on whether a Product is Non-Conforming, the Parties shall promptly meet in good faith to determine the origin of the Non-Conformance, including by review of any applicable reserve samples of the applicable Batch of Product retained at FibroGen and through Sections 5.1 and 5.2 hereof, which shall apply if there is a dispute between the Parties regarding whether the Product is Non-Conforming and procedures used to generate and test the Product. If, [*] of such discussion (or such other time period that the Parties might agree), the Parties are still unable to agree on whether or not such Product is Non-Conforming, the Parties shall submit the Product in question to a mutually agreed independent Third Party expert nominated by the JOC that has the capability of testing the Product to determine (a) whether or not is Non-Conforming; and if possible (b) whether FibroGen (or its Subcontractors) or AstraZeneca (or its subcontractors) caused the Non-Conformance. [*]. If the Third Party expert accepts only the instruction to determine whether or not it is Non-Conforming, then the Parties will proceed with the instruction and the remainder of this Section will apply to the Third Party expert's decision. The determination by such independent Third Party expert is final, absent a clear error in numerical calculation or analysis. [*]. For the avoidance of doubt, where the independent Third Party expert does not determine the cause of, or which Party caused the Non-Conformance, then AstraZeneca and FibroGen shall have good faith discussions to agree on how the unknown cause of the Non-Conformance shall be resolved.

5.2 Remedy for Non-Conforming Product.

5.2.1 If FibroGen agrees with AstraZeneca, or if the independent Third Party expert retained under Section 5.1.3 determines, that certain units of Product are Non-Conforming and such non-conformance is reasonably believed to have been caused by FibroGen (or its Subcontractors), [*]. If the independent Third Party expert reasonably believes that such Non-Conforming Products was caused by AstraZeneca (or its subcontractors), [*]. If the independent Third Party expert cannot reasonably determine or reasonably attribute the cause of the non-conformity, the Parties agree to collaboratively and equally share [*].

5.2.2 FibroGen shall cooperate with AstraZeneca in determining the cause of any Non-Conformance, including quality problems involving a Product, identifying corrective/preventive actions and ensuring the implementation and effectiveness thereof.

5.3 Transfer Terms and Instructions; Storage. Pursuant to the Collaboration Agreement, Transfer of Bulk Drug Product shall be made Ex Works (EXW Incoterms 2010) at Facility, and title with all risk of loss shall transfer to AstraZeneca upon such Transfer. If the Purchase Order does not specify disposition of Product, FibroGen will store such Product in accordance with the storage requirements (as defined in the Specifications and the MBR, as applicable, and this Agreement) until such time as AstraZeneca requests shipment or other disposition or use of such Product, and Transfer of such items to AstraZeneca shall occur upon placement into storage. AstraZeneca shall be solely responsible for arranging for customs, transportation and importation of Bulk Drug Product into the destination country (or, if applicable, intermediary countries along the shipping route). AstraZeneca shall bear the costs of such carrier, including the costs of insurance of the shipment, and all customs, duties, sales taxes and other governmental charges related to the transportation, storage, and importation and sale of Bulk Drug Product and Finished Product. FibroGen shall Transfer each shipment of Bulk Drug Product by the confirmed Transfer Date, and, if reasonably requested by FibroGen, FibroGen may

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Transfer and AstraZeneca shall pick up Purchase Orders as they are ready for collection and in accordance with this Agreement.

5.3.1 Storage. If AstraZeneca fails to take possession of Bulk Drug Product on any scheduled Transfer Date FibroGen shall, through its manufacturer, store such Bulk Drug Product and have the right to invoice AstraZeneca following such scheduled Transfer Date for reasonable administration, handling and storage costs incurred. FibroGen will store API for the manufacture of Bulk Drug Product to meet AstraZeneca's Rolling Forecasts.

5.3.2 However, for any API which FibroGen was planning to use for Bulk Drug Product that is removed from a Rolling Forecast or not ultimately ordered pursuant to Article 3 ("**Excess API**"), and provided that FibroGen's aggregate third party storage costs of such Excess API are expected to exceed [*] USD during any [*] month period, FibroGen will so notify AstraZeneca and provide to AstraZeneca reasonable written documentation of the storage costs and Excess API volume relevant to the Rolling Forecast, and then FibroGen may elect to transfer the storage of such Excess API to a mutually approved AstraZeneca facility. Such storage into the AstraZeneca facility are for the benefit of both Parties in mitigating further warehousing costs and thus, such AstraZeneca's storage services (which includes storage services by AstraZeneca's third parties) will be provided [*]. Notwithstanding such storage arrangement, Excess API that is warehoused in an AstraZeneca (or AstraZeneca's Third Party) facility is and shall continue to be FibroGen's exclusive property, and FibroGen may freely move or transfer any such product from the AstraZeneca facility (or AstraZeneca Third Party facility) at any time. For clarity, storage of Excess API under this Section is at a convenience to AstraZeneca and does not affect or extend the Excess API ownership or the Product's Transfer Date.

ARTICLE 6
PAYMENTS; INVOICING

6.1 Payments for Transfer of Bulk Drug Product. Pursuant to Section 6.5(a) of the Collaboration Agreement, FibroGen will supply to AstraZeneca (or its designated Affiliate or AstraZeneca Sublicensee) Bulk Drug Product for commercial use at a transfer price equal to [*] during the Calendar Year in which such Bulk Drug Product is Transferred.

6.1.1 Invoicing at Transfer and Annual True Up.

(a) The Parties shall agree on an initial preliminary transfer price per tablet for each strength (the respective "**Preliminary Price Per Tablet**"), which shall be equal to [*] multiplied by the "**Estimated Average Selling Price Per Tablet**", which is defined as the fraction (A)/(B), where (A) shall be the estimated [*] for such strength in the Territory for the following Delivery Year and (B) shall be the estimated [*] in the Territory during such Delivery Year (all estimations and currency exchanges to be made by the Parties in good faith), provided that for the first Delivery Year, AstraZeneca will provide the estimated Preliminary Price Per Tablet fifteen (15) days before the first order of Product. For any currency conversions used by AstraZeneca, AstraZeneca will include with any applicable reports the exchange rates used for such sales. For all subsequent years, the Preliminary Price Per Tablet will be defaulted to equal the most recent Definitive Price Per Tablet. In any given Delivery Year, where an event can be anticipated which means this is not

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appropriate, the Preliminary Price Per Tablet can revert to the original calculation (i.e. [*]). For clarity, in each Delivery Year, there will be a Preliminary Price Per Tablet calculation for every tablet strength.

(b) FibroGen will invoice AstraZeneca upon Transfer of each shipment of Bulk Drug Product [*]. AstraZeneca will pay within [*] after its receipt of such invoice.

(c) Within [*] following the end of each Delivery Year, the Parties will calculate the definitive transfer price per tablet for each strength ("**Definitive Price Per Tablet**") for such year, which shall be equal to [*] multiplied by the fraction (A)/(B), where (A) shall be the actual [*] for such strength during the Delivery Year and (B) shall be the actual [*] in the Territory during such Delivery Year (excluding [*]). For clarity, in each Delivery Year, there will be a Definitive Price Per Tablet calculation for every tablet strength ordered by AstraZeneca.

(d) For each strength of Bulk Drug Product, a reconciliation is performed by calculating the difference between the most recent Preliminary Price Per Tablet and the Definitive Price Per Tablet for the previous calendar year multiplied by the number of tablets of Bulk Drug Product (a) Transferred the previous Delivery Year; (b) held in AstraZeneca's inventory at the beginning of the previous Delivery Year; plus (c) Transferred in the current Delivery Year prior to the reconciliation (thus marking to market all such product) (the "**Total Reconciliation Amount**"). If the Definitive Price Per Tablet exceeds the Preliminary Price Per Tablet, then AstraZeneca shall pay the Total Reconciliation Amount to FibroGen within [*] after its receipt of an invoice from FibroGen for such amount. If the Preliminary Price Per Tablet exceeds the Definitive Price Per Tablet, FibroGen shall issue a credit note to AstraZeneca for the Total Reconciliation Amount. AstraZeneca shall be entitled to set off the amount due under the credit note against any subsequent payments owed by AstraZeneca to FibroGen under the Collaboration Agreement (or, in the absence of any such subsequent payments, such credit note shall be settled by FibroGen within [*] after its receipt thereof).

(e) Quarterly Reporting. Within fifteen (15) calendar days following the end of each Calendar Quarter, AstraZeneca shall report to FibroGen an estimate of its aggregate Net Sales and the number of tablets sold of Drug Product for each strength in the Territory.

6.2 Additional Costs. Additional services or change orders must be agreed on in advance by the Parties and invoiced separately.

6.4 Taxes and fees. All taxes including sales and use taxes, VAT, duties, surcharges, withholding taxes, and other amounts (excluding taxes based on net income and franchise taxes) assessed in respect of Product and as applicable, Final Product or in connection with the sale or delivery of Product and Final Product hereunder, whether assessed prior to or upon provision or sale, and whether assessed on AstraZeneca or FibroGen, are the responsibility of AstraZeneca, and either AstraZeneca shall reimburse FibroGen for all such sales and use taxes, VAT, duties, surcharges, withholding taxes or other amounts paid by FibroGen or such sums will be added to invoices directed at AstraZeneca. If any deduction or withholding in respect of tax or otherwise is required by the applicable treaty to be made from any of the sums payable hereunder, AstraZeneca shall be obliged to pay to FibroGen such greater sum as will leave FibroGen, after deduction or

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withholding as is required to be made, with the same amount as it would have been entitled to receive in the absence of any such requirement to make a deduction or withholding.

6.5 Adjustment for Generic Entry. Pursuant to Section 6.5(c) of the Collaboration Agreement, if at any time FibroGen's net margin percentage on any Bulk Drug Product supplied to AstraZeneca falls [*] after a Generic Product (defined in the Collaboration Agreement) is sold in any country in the Territory, FibroGen shall have the right to renegotiate the manufacturing and supply payment terms under this Agreement and the Quality Assurance Agreement. Upon FibroGen's request, the Parties shall renegotiate reasonable terms in good faith, taking into account also the overall profitability of such Finished Product to AstraZeneca.

ARTICLE 7
REGULATORY OBLIGATIONS

7.1 Regulatory Matters Generally. The Parties' respective rights and obligations with respect to Regulatory Filings, communications with Regulatory Authorities, Finished Product recalls, and other regulatory matters relating to Product and/or Finished Product (as applicable) are set forth in the Collaboration Agreement and/or the Quality Assurance Agreement.

ARTICLE 8
SAFETY; ADVERSE EVENT REPORTING

8.1 Safety. In accordance with the safety or pharmacoviligence agreement, each Party shall promptly notify the other of any information or notice of which it becomes aware concerning the Product and Finished Product, including, without limitation, any threatened or pending action by any Regulatory Authority.

8.2 Adverse Event Reporting/Handling. Reporting shall be set forth in the safety or pharmacovigilance agreement.

ARTICLE 9
QUALITY ASSURANCE

9.1 Quality Assurance Agreement. The Parties shall agree upon and execute a quality assurance agreement to cover the manufacture, supply and production of Bulk Drug Product(s) by FibroGen to AstraZeneca and other responsibilities of the Parties with respect to Finished Product pursuant to the requirements set forth in the Collaboration Agreement ("**Quality Assurance Agreement**"), as may be amended from time to time by a signed writing of the Parties. The Quality Assurance Agreement shall set forth the responsibilities of the Parties with respect to quality assurance, document retention, notification obligations, audit and inspection rights, and similar matters with respect to the manufacture of Product and Finished Product (as applicable) including Finished Product recalls and withdrawals, returned goods, and authorization for Finished Product recalls, and other such matters as described in Exhibit K of the Collaboration Agreement ("**Quality Matters**"). The Parties agree that the Quality Assurance Agreement shall be amended prior to the inclusion of Finished Product intended to be manufactured for markets other than Territory. AstraZeneca agrees to

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provide FibroGen with written notification at least [*] prior to AstraZeneca's filing of Regulatory Filings (including marketing authorization applications) in such other markets. A breach of the Quality Assurance Agreement constitutes a breach of this Agreement. If there is any inconsistency between the Quality Assurance Agreement and this Agreement, the Quality Assurance Agreement shall take precedence for all quality matters and this Agreement for all other matters.

9.2 Quality Control. FibroGen shall ensure that all Product manufactured for supply to AstraZeneca pursuant to this Agreement is subject to quality control testing in conformance with cGMP regulatory standards.

9.3 Responsibility for Quality Assurance and Quality Control. Responsibility for quality assurance and quality control of Bulk Drug Product shall be allocated between AstraZeneca and FibroGen as set forth in the Quality Assurance Agreement.

9.4 Audits. AstraZeneca shall carry out audits pursuant to the Quality Assurance Agreement.

9.5 Shelf-Life. FibroGen shall only supply Bulk Drug Product that has used up [*] at Transfer (unless otherwise agreed in advance with AstraZeneca).

ARTICLE 10
OWNERSHIP OF INTELLECTUAL PROPERTY AND MATERIALS

10.1 Intellectual Property. This Agreement shall not affect the ownership of any Intellectual Property owned by or licensed to either Party or any rights granted in the Collaboration Agreement with respect to such Intellectual Property.

ARTICLE 11
REPRESENTATIONS AND WARRANTIES

11.1 AstraZeneca. AstraZeneca hereby represents and warrants to FibroGen that, as of the Effective Date:

11.1.1 Power and Authority. AstraZeneca is duly formed and validly existing under the laws of its jurisdiction of formation and has all requisite corporate power and authority to execute and enter into this Agreement and to perform its obligations hereunder.

11.1.2 Execution, Delivery and Performance of the Agreement. AstraZeneca has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement. This Agreement has been duly executed and delivered on behalf of AstraZeneca, and constitutes a legal, valid, binding obligation, enforceable against AstraZeneca and its successors and assigns in accordance with its terms and conditions.

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11.2 FibroGen. FibroGen hereby represents and warrants to AstraZeneca that, as of the Effective Date:

11.2.1 Power and Authority. As of the Effective Date, FibroGen is duly formed and validly existing under the laws of its jurisdiction of formation and has all requisite corporate power and authority to execute and enter into this Agreement and to perform its obligations hereunder.

11.2.2 Execution, Delivery and Performance of Agreement. FibroGen has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement. This Agreement has been duly executed and delivered on behalf of FibroGen, and constitutes a legal, valid, binding obligation, enforceable against FibroGen in accordance with its terms. The execution, delivery and performance of this Agreement does not breach, conflict with, violate, contravene or constitute a default under any contracts, arrangements or commitments to which FibroGen is a party or by which it is bound nor does the execution, delivery and performance of this Agreement by FibroGen violate any order, law or regulation of any court or Regulatory Authority having authority over it.

11.2.3 Confidential Information. FibroGen has the right to supply to AstraZeneca the Confidential Information that is supplied by FibroGen to AstraZeneca.

11.2.4 Debarment. FibroGen does not and shall not employ, contract with or retain any person directly or indirectly to perform Manufacturing Services under this Agreement or any Purchase Order if such person is debarred under 21 U.S.C. 335a(a) or 335a(b), or other equivalent laws, rules, regulations or standards of any other relevant jurisdiction (as may be amended from time to time). FibroGen shall promptly disclose in writing to AstraZeneca if any FibroGen employee, Subcontractor, or agent is debarred, or if any action or investigation is pending or, to the best of FibroGen's knowledge, threatened, relating to the debarment of FibroGen or any person performing Manufacturing Services related to this Agreement or any Purchase Order.

11.3 Product Warranty. FibroGen hereby represents and warrants to AstraZeneca that each Batch of Product: (a) will, at the time of Transfer, have been manufactured and analyzed in conformance with the then-current Quality Assurance Agreement, the then-current Specifications and cGMPs; (b) will, at the time of Transfer, conform to the Specifications in all material aspects; and (c) will be transferred free and clear of any liens or encumbrances of any kind.

11.4 Expert Compliance. Each Party acknowledges that information or materials disclosed in connection with the Manufacturing Services may be considered technical materials or data that is subject to compliance with the export control laws and regulations of the United States and other countries, and hereby agrees to comply with such laws to the extent they apply.

ARTICLE 12
INDEMNIFICATION

12.1 Indemnification by AstraZeneca. Subject to Section 12.2, AstraZeneca shall indemnify, defend and hold FibroGen, FibroGen's Affiliates, and their respective directors, officers, employees and agents (the "**FibroGen**

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Indemnitee(s)") harmless from and against all losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys' fees and expenses) (collectively, the "Losses") incurred by FibroGen Indemnitees to the extent such Losses arise out of or result from any claim, lawsuit or other action or threat by a Third Party arising out of AstraZeneca's [*].

12.2 Indemnification by FibroGen. Subject to Section 12.1, FibroGen shall indemnify, defend and hold AstraZeneca, AstraZeneca's Affiliates, and their respective directors, officers, employees and agents (the "**AstraZeneca Indemnitee(s)**") harmless from and against all Losses incurred by AstraZeneca Indemnitees to the extent such Losses arise out of or result from any claim, lawsuit or other action or threat by a Third Party arising out of [*], in each case except to the extent any such Loss arises out of or results from an AstraZeneca Indemnitee's gross negligence, willful misconduct, or breach of this Agreement (including any Purchase Orders hereunder), and the Quality Assurance Agreement.

12.3 Indemnification Procedures.

12.3.1 Identification of Indemnitor and Indemnitee. An "**Indemnitor**" means the indemnifying Party. An "Indemnitee" means the indemnified Party and their respective directors, officers, employees and agents.

12.3.2 Indemnification Procedures. An Indemnitee which intends to claim indemnification under Section 12.1 or Section 12.2 hereof shall promptly notify the Indemnitor in writing of any claim, lawsuit or other action in respect of which the Indemnitee or any of their respective directors, officers, employees and agents intend to claim such indemnification. The Indemnitee shall permit, and shall cause their respective directors, officers, employees and agents to permit, the Indemnitor, at its discretion, to settle any such claim, lawsuit or other action and agrees to the complete control of such defense or settlement by the Indemnitor; provided, however, that such settlement shall not adversely affect the Indemnitee's rights under this Agreement or impose any obligations on the Indemnitee in addition to those set forth herein. Indemnitor shall not settle any claim that does not fully and unconditionally release the Indemnitee. No such claim, lawsuit or other action shall be settled without the prior written consent of the Indemnitor and the Indemnitor shall not be responsible for any legal fees or other costs incurred other than as provided herein. The Indemnitee and their respective directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any claim, lawsuit or other action covered by this indemnification, all at the reasonable expense of the Indemnitor. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and expense.

ARTICLE 13
LIMITATION OF LIABILITY

13.1 Disclaimer of Consequential Damages; Disclaimer of Warranty. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, LOSS OF BUSINESS OR LOSS OF GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. [*].

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13.2 Subject to Section 13.1, each Party's total liability arising under or in connection with this Agreement, whether arising [*], or otherwise, shall be limited to [*], except to the extent arising out of:

[*].

ARTICLE 14
INSURANCE

14.1 Insurance. During the term, FibroGen shall maintain, at its own cost and expense, in force the following insurance policies with reputable insurance companies against the liability referred to in this Agreement. In the event that any of the required polices of insurance are written on a claims made basis, then such policies shall be maintained during the Term of this Agreement and for a period of not less than two (2) years following the expiration or termination of this Agreement:

14.1.1 Products and Completed Operations Liability Insurance with a per occurrence limit of [*].

14.1.2 Commercial General Liability Insurance for [*].

ARTICLE 15
CONFIDENTIALITY

15.1 Confidentiality. All information that is disclosed or provided by a Party to the other Party under this Agreement shall be deemed disclosed or provided by such Party to the other Party under the Collaboration Agreement, and subject to the confidentiality provisions set forth in Article 12 of the Collaboration Agreement.

ARTICLE 16
PRESS RELEASES; USE OF NAMES

16.1 Press Releases. Neither Party shall issue nor disclose any press release, publicity or other form of public written disclosure related to this Agreement and/or Manufacturing Services for AstraZeneca without receiving the other Party's prior written consent, which consent shall not be unreasonably withheld.

16.2 Use of Names. Neither Party shall make use of the name, trademark, logo or symbol of the other Party nor any Affiliate of the other Party, nor any of their respective officers, directors, employees, or agents, in any advertising or promotional material, or otherwise, in connection with this Agreement or any related agreements, without the prior written consent of such other Party, which consent shall not be unreasonably withheld.

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ARTICLE 17
TERM; TERMINATION

17.1 Term. Unless sooner terminated pursuant to Section 17.2 or extended by the mutual written agreement of the Parties, the term of this Agreement shall commence on the Effective Date, and shall continue as detailed herein below in accordance with Section 6.3 of the Collaboration Agreement. For the supply of Bulk Drug Product, this Agreement and the obligation to purchase and supply Bulk Drug Product shall have a term of five (5) years, which will automatically renew for succeeding five (5)-year terms unless written notice is received by FibroGen two (2) years in advance of the end of the applicable term. If AstraZeneca wishes to manufacture Bulk Drug Product itself, it shall provide FibroGen [*] advance written notice prior to expiration of then-current term, and FibroGen will continue to be the API supplier with an initial term that shall continue for [*] from the Effective Date of this Agreement, after which AstraZeneca would have the right (i) to extend the term for an additional [*] or (ii) subsequently, to give written notice not more than once every [*], of its intention to assume responsibility for API manufacture upon the Collaboration Agreement's Section 6.4 and agreement of terms mutually agreed by the Parties, including [*], as stated in Section 6.3 of the Collaboration Agreement.

17.2 Termination. This Agreement may be terminated as follows:

17.2.1 Termination of Collaboration. This Agreement shall automatically terminate upon termination of the Collaboration Agreement for any reason.

17.2.2 Material Breach. Either Party may terminate this Agreement by written notice to the other Party, for any material breach of the Agreement, Purchase Order, or the Quality Assurance Agreement by the other Party, if such breach is not cured [*] after the breaching Party receives written notice of such breach from the non-breaching Party. Such termination shall be effective upon expiration of such cure period.

17.2.3 Insolvency. Either Party may terminate this Agreement upon notice to the other Party, upon (a) the dissolution, termination of existence, liquidation or business failure of the other Party; (b) the appointment of a custodian or receiver for the other Party who has not been terminated or dismissed within [*] of such appointment; or (c) the institution by the other Party of any proceeding under national, federal or state bankruptcy, reorganization, receivership or other similar laws affecting the rights of creditors generally or the making by such Party of a composition or any assignment for the benefit of creditors under any national, federal or state bankruptcy, reorganization, receivership or other similar law affecting the rights of creditors generally, which proceeding is not finally dismissed within [*] of filing. All rights and licenses granted pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code, licenses of rights of "intellectual property" as defined therein.

17.2.4 Cumulative Remedies. Any right to terminate this Agreement shall be in addition to and not in lieu of all other rights or remedies that the Party giving notice of termination may have at law or in equity or otherwise.

17.3 Consequences of Termination.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

17.3.1 Generally. If this Agreement is terminated pursuant to Section 17.2, FibroGen shall use reasonable commercial efforts to wind-down all Manufacturing Services in accordance with its responsibilities under Applicable Laws, and use reasonable commercial efforts to reduce or eliminate further costs, and to cancel, if permitted under the terms of applicable agreements, any Third Party obligations. [*].

17.4 Accrued and Surviving Rights. The expiration or termination of this Agreement shall be without prejudice to any rights or obligations that may have accrued prior to such expiration or termination, and shall not affect any provision which is expressly or by implication intended to come into or continue in force on or after expiration or termination including but not limited to, [*].

ARTICLE 18
FORCE MAJEURE

18.1 Force Majeure. Neither Party shall be liable hereunder for any failure in performance if such delay or failure is not within a Party's reasonable control, including if caused by fire, flood, explosion, storm, acts of God, pandemic, acts of any government or government agency or other causes beyond such Party's reasonable control ("**Force Majeure**"), provided that, upon the occurrence of any event of force majeure, (a) the Party whose performance is thereby affected shall promptly notify the other Party of the force majeure event and the circumstances so surrounding and of the expected duration thereof and shall take all reasonable steps to mitigate such delay or failure to perform; (b) the Parties shall in good faith discuss the delay caused by the Force Majeure event and any adjustments to address such delay; (c) the suspension of performance shall be of no greater scope and no longer duration than is reasonable necessary; and (d) if the delay or failure to perform continues for more than [*], then: (i) the unaffected Party may terminate this Agreement upon written notice to the affected Party; or (ii) where the unaffected Party is AstraZeneca, then AstraZeneca shall: (1) be permitted reasonable access to relevant information in the possession of FibroGen and its affiliates relating to the manufacturing processes for the Product; (2) have the right to contact FibroGen's suppliers (including suppliers of API), in each case, to assess the feasibility of (including contracting with) such suppliers manufacturing and supplying the Product to AstraZeneca; solely in the event of a supply failure by FibroGen; and [*].

18.2 [*].

ARTICLE 19
MISCELLANEOUS

19.1 Notices. Any notice required or permitted to be given under this Agreement by any Party shall be in writing and shall be (a) delivered personally, (b) sent by registered mail, return receipt requested, postage prepaid, (c) sent by a nationally-recognized courier service guaranteeing next-day or second day delivery, charges prepaid, or at such other addresses as may from time to time be furnished by similar notice by any Party. The effective date of any notice under this Agreement shall be the date of receipt by the receiving Party.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

If to FibroGen:
FibroGen, Inc.
409 Illinois Street
San Francisco, California 94158 U.S.A.
Attn: Legal Department

If to AstraZeneca:
AstraZeneca UK Limited Silk Road
Macclesfield, Cheshire, SK10 2NA, England
Attn: Head of Supply and Planning

With a copy to:
Email: legalnotices@astrazeneca.com
Attention: Legal Department

19.2 Governing Law; Dispute Resolution. This Agreement shall be governed by, construed and interpreted in accordance with the governing law provisions set forth in the Collaboration Agreement. The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute in accordance with the Collaboration Agreement.

19.3 Headings. All headings in this Agreement are for convenience of reference only and shall not affect the interpretation of this Agreement.

19.4 Exhibits. All exhibits or appendices referred to herein form an integral part of this Agreement and are incorporated into this Agreement by such reference.

19.5 Assignment. Neither Party may assign or transfer the Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment without the other Party's consent to such Party's Affiliate or to a successor to all or substantially all of the assets or business of such Party to which this Agreement pertains, whether by asset sale, stock sale, merger, acquisition, or otherwise. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. Any purported assignment that is not in conformance with this Section shall be null, void and of no legal effect. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the successors and assigns of the Parties.

19.6 Severability. If any part of this Agreement shall be found to be invalid or unenforceable under Applicable Law in any jurisdiction, such part shall be ineffective only to the extent of such invalidity or unenforceability in such jurisdiction, without in any way affecting the remaining parts of this Agreement in that jurisdiction or the validity or enforceability of the Agreement as a whole in any other jurisdiction. In addition, the part that is ineffective shall be reformed in a mutually agreeable manner so as to as nearly approximate the intent of the Parties as possible.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

19.7 Independent Contractors. Each of the Parties is an independent contractor and nothing herein contained shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between the Parties. Neither Party shall at any time enter into, incur, or hold itself out to Third Parties as having authority to enter into or incur, on behalf of the other Party, any commitment, expense, or liability whatsoever.

19.8 Conflict. This Agreement is subject to the Collaboration Agreement. In the event of a conflict between this Agreement and the Collaboration Agreement, the Collaboration Agreement shall govern, except as otherwise specified in the Collaboration Agreement, including as specified in Section 6.3 thereof. In the event of a conflict between this Master Supply Agreement and the Quality Assurance Agreement, this Master Supply Agreement will control with respect to supply maters, and the Quality Assurance Agreement, once executed, will control with respect to Quality Matters, as defined in Section 9.1 hereto. The terms and conditions of the body of this Agreement shall prevail in the event of a conflict between or among the provisions of the body of this Agreement and any Purchase Orders hereto.

19.9 Waiver. No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition or of any other term, provision or condition of this Agreement.

19.10 Entirety; Amendments. This Agreement, including any exhibits or ancillary documents attached hereto or referenced herein, constitutes the full understanding of the Parties and a complete and exclusive statement of the terms of their agreement with respect to the specific subject matter hereof, and no terms, conditions, understandings or agreements purporting to modify or vary the terms thereof shall be binding unless hereafter made in a written instrument referencing this Agreement and signed by each of the Parties.

19.11 Counterparts. This Agreement and any amendment hereto may be executed in any number of counterparts, each of which shall for all purposes be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by portable document format (pdf), facsimile or original, and a pdf or facsimile signature shall be deemed to be and shall be as effective as an original signature.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date.

FIBROGEN, INC.		**ASTRAZENECA UK LIMITED**	
By:	/s/Mike Martinelli	By:	/s/ [*]
Name:	Michael Martinelli, PhD	Name:	[*]
Title:	SVP, TECHNICAL DEVELOPMENT, DRUG DEVELOPMENT	Title:	Global Category Manager
Date:	14 September 2020	Date:	14 September 2020

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Exhibit A

Bulk Drug Product [*]

[*]

EXHIBIT B

AstraZeneca's Global Standard: Expectations of Third Parties

Expectations of Third Parties

AstraZeneca
Global Standard

AstraZeneca

This Global Standard sets out AstraZeneca's ethical business expectations of Third Parties with which it interacts to ensure their conduct is consistent with our own.

Who is this Standard for?

All Third Parties acting for or on behalf of AstraZeneca. All Procurement Professionals and Engagement Owners across the AstraZeneca business for use with their Third Party interactions.

AstraZeneca's commitment to responsible business extends to ensuring that our ethical standards are integrated into our business processes and decisions worldwide. This commitment extends to our Third Parties and requires that we work only with Third Parties with standards of ethical behaviour that are consistent with our own.

This Global Standard explains what our expectations are in areas of specific relevance to our interactions with Third Parties.

Guiding Principles

The following outlines the key principles that a Third Party should work to in order to operate in an ethical manner consistent with AstraZeneca's expectations.

Organization & Culture

Third Party has a governance structure & culture that reinforces ethical and lawful behaviour & ensures all aspects of its business are compliant to financial, legal and ethical standards. It extends this expectation to any other Third Party intermediaries acting on its behalf.

Risk Identification & Assessment

Third Party has annual internal/external reviews that measure its risk controls and identify the actions needed to deliver any necessary improvement. This includes assessing the risk of activities carried out by Third Parties acting on its behalf.

It defines roles for leaders in terms of responsibility for all aspects of running the organization, including the identification, assessment and mitigation of risks to ensure business continuity.

Standard Setting

Third Party has an established governance structure consistent with the size and nature of the business which defines policies/ways of working and controls

for managing its business ethically. Ways of working are less formal polices that employees would recognise and be able to explain to an independent party (applicable to organisations with fewer than 15 employees).

It shares these with its own Third Parties so that they are clear what standards are expected of them and, where appropriate, assesses if their policies are adequate. Third Party identifies and complies with all applicable laws, regulations, codes and standards, both in the country in which the Third Party works and in the country in which the service or products will be provided.

Third Party complies with all relevant contractual customer requirements, even where these are higher than local or national laws.

Training and Competency

Third Party has a training program that achieves an appropriate level of knowledge, skills and abilities in management and workers to address the expectations in this Standard.

Control Activities

Third Party has monitoring in place, to ensure that processes are being adequately followed and risk control measures are effective. Identified process and control failures should be addressed.

Reporting, Investigation and Remediation

Third Party encourages its employees to report concerns or illegal activities in the workplace without threat of reprisal, intimidation or harassment. Third Party investigates such reports and other incidents and takes corrective action if needed.

What This Means in Practice

Third Party is free to determine what methods it uses to meet the expectations in this Standard. It is acknowledged that local laws, values and cultural expectations may influence how these principles are applied in practice but they must be in the spirit of this Standard.

For certain highly sensitive areas, the Third Party may be expected to work exactly to AZ policies and standards but this will be specified in the contract.

In most cases, prior to contracting with a Third Party, AstraZeneca assesses how well the above principles are being applied to both the governance of the Third Party and the relevant risk areas outlined in this

Standard. This is delivered through our Third Party Risk Management framework. On-going Third Party relationships are subject to periodic re-assessment to ensure standards have been maintained including responding to any changes in the conduct, reputation or risks related to the particular Third Party. For more information on the framework, please refer to the AstraZeneca external website http://www.astrazeneca.com/Responsibility/Working-with-suppliers.

AstraZeneca expects the same standards of its own employees and actively encourages Third Parties to report any incidents they believe contravene any of the principles outlined in this Standard. Details on how to raise a concern can be found at azethics.com.

1. Anti-Bribery and Anti-Corruption

Third Party has a zero tolerance for bribery or corruption and does not give or receive bribes when conducting business.

Third Parties shall not:

- Offer, give, request or accept bribes or permit sub-contractors or others to do so on their behalf. This includes:
    - Offering or giving – directly or indirectly – money or anything else of value, including gifts and hospitality, to any person or organisation that is intended to, or could be seen as an attempt to influence or reward them to behave improperly in order to obtain or retain business or secure a business advantage for themselves, their organisation or AstraZeneca, or as an attempt to influence or reward an official action or decision (e.g., by a public official).
    - Requesting or accepting – directly or indirectly – money or anything else of value, including gifts and hospitality, if it is intended to, or could be seen as an attempt to compromise their independence or judgement, or to improperly influence a business decision for themselves, their organisation or AstraZeneca.

When specifically authorised by AstraZeneca, Third Parties may:

- Provide services to AstraZeneca or on AstraZeneca's behalf.
- Provide appropriate hospitality or items of value e.g. medical textbooks. However, under no circumstances, may Third Parties give gifts of a personal nature (e.g. gift cards, restaurant vouchers) on AstraZeneca's behalf.
- Give contributions on AstraZeneca's behalf.
- Participate in political activities (e.g. lobbying).

However, under no circumstances may Third Parties give any political support (e.g. finance or resource political campaigns on behalf of AstraZeneca).

Third Parties interacting with Public Officials on behalf of AstraZeneca shall:

- Comply with the specific requirements of contracts and agreements with AstraZeneca, such as not making any facilitation payments, either directly or indirectly, to public officials (including healthcare professionals and other individuals employed by public sector organisations), regardless of whether such payments are nominal in amount, unless under duress (i.e. where there is reasonable fear for personal safety).
- Promptly report in writing to the AstraZeneca Engagement Owner all incidents where they are involved in the following situations:
    a. Facilitation Payments are requested but not paid; or
    b. Payments are demanded under duress, whether paid or not.

2. Conflicts of Interest

Third Party does not allow Conflicts of Interest to influence or compromise the professional duties and decisions of the Third Party or its employees.

Third Parties shall:

- Inform the AstraZeneca Engagement Owner in writing of any actual, apparent or potential conflicts of interest relevant to the Third Party's performance of services for AstraZeneca, at the time they become known.
- Have financial controls in place to prevent conflicts of interest affecting procurement and financial decision making.

3. Employment Principles

Third Party operates in line with internationally recognised human rights, and promotes and maintains a culture of respect and equal opportunities.

Anti-Slavery And Anti-Trafficking

Third parties shall not engage in any form of Slavery and/or Trafficking.

An individual is considered to be in Slavery if he/she is:

- Forced to work - through mental or physical threat;
- Owned or controlled by an 'employer', usually through mental or physical abuse or the threat of abuse;
- De-humanised, treated as a commodity or bought and sold as 'property'; and/or
- Physically constrained or has restrictions placed on his/ her freedom of movement, against their will or with the knowledge and intent to enslave or traffic.

Trafficking involves purposeful transportation of any person being recruited, harboured or brought into a situation of exploitation through the use of violence,

deception or coercion and/or forced to work against their will.

Non-Discrimination And Fair Treatment

- Third Parties shall provide a workplace free of harassment and discrimination. Discrimination for reasons such as race, colour, age, gender, sexual orientation, ethnicity, disability, religion, political affiliation, union membership or marital status is not condoned.
- Decisions about recruitment, development and promotion are based purely on merit, performance and ability.

Child Labour

Third Parties shall:

- Not use child labour. The minimum age for employment is 15 years of age (or 14 in accordance with developing country exceptions under International Labour Organisation (ILO) Convention no.138). If local minimum age law stipulates a higher age for work or mandatory schooling, the higher age applies.
- Not employ workers under 18 at night or in hazardous conditions.

Freely Chosen Employment

- Third Parties shall not use forced, bonded or indentured labour or involuntary prison labour.

Wages, Benefits & Working Hours

Third Parties shall:

- Pay employees according to applicable wage laws, including any relevant overtime hours and mandated benefits, and legal minimum wages. Third parties shall also, where notified by AstraZeneca that is has recognised and wishes to implement a national “living wage”, pay employees such a living wage.
- Communicate with the employee the basis on which they are being compensated in a timely manner.
- Communicate with the employee whether overtime is required and the wages to be paid for such overtime.

Freedom Of Association

- Third Parties shall respect the rights of employees, as defined in local laws, to associate freely, join or not join labour unions, seek representation and join employees’ councils.

4. Safety, Health and the Environment

Third Party carries out business in an environmentally responsible manner and promotes a safe and healthy workplace for all their employees, including those who work on their behalf worldwide.

Protection Of The Health And Safety Of People

Third Parties shall:

- Protect people from unhealthy exposure to physical, psychological, chemical and biological hazards. Significant releases of chemicals are prevented or otherwise mitigated through reliable process safety controls.
- Make information relating to SHE risks, chemicals and other hazardous materials, including pharmaceutical materials available and use it to manage risks and train and protect people.
- Put registrations/notification approvals and applicable legal documentation for the manufacture, import and transport of hazardous materials in place as required by local and international regulations.

Environmental Protection & Conservation

Third Parties shall:

- Manage business activities in a way that, as far as practical, avoids the use of hazardous materials, conserves water, energy and other natural resources and minimizes the generation of waste through avoidance, reuse and/or recycling.
- Ensure any emissions to air, water and land are in compliance with laws and regulations and controlled or treated to the extent necessary to eliminate, or otherwise minimize the risk of, adverse affects on human health or the environment.
- Adhere to all relevant AstraZeneca sourcing policies and support any necessary extended supply chain due diligence.

5. Trade Controls and Competition

Third Party complies with all competition and anti-trust laws applicable in the countries where it operates. It is committed to importing, exporting and engaging in all other forms of trade in a legal and ethical manner.

Trade Controls

- Third Parties shall comply with applicable trade regulations including licensing requirements, boycotts, embargoes and other trade restrictions that have been approved by recognised national and international authorities.

Competition

Third Parties shall:

- Only seek competitive advantage through lawful means and conduct their business consistent with fair and vigorous competition.
- Only engage in dialogue with competitors when there is a legitimate business reason to do so, and the dialogue is such that it will not restrict competition (e.g. is limited to public or non-commercial information).
- Not abuse their position, if it is dominant or has a monopoly, to exclude competitors or exploit customers.

6. Data Privacy

Third Party collects, uses, retains and discloses AstraZeneca personal data in a fair, transparent and secure way.

Third Parties shall:

- Only use AstraZeneca Personal Data under our instructions and not use it for their own purposes.
- Ensure that effective organisational and security measures (both technological and physical) are applied to all AstraZeneca Personal Data to ensure the privacy of affected individuals.
- Appoint a representative who is accountable for data privacy and security in their company.
- Ensure information is protected and kept secure at all times from unauthorised use, damage, disclosure, diversion or removal, whether through accident, improper act or breach of trust.
- Ensure employees who will have access to AZ Personal Data are appropriately trained in their responsibilities around processing and protecting the Personal Data.

7. Research & Development Ethics

Third Party conducts high quality science delivered to high ethical standards in all areas of research and development.

Specifically in the areas of:

- Supply or use of biological samples especially human embryonic stem cells (hESCs), and genetically modified organisms (GMOs).
- Animal research & supply.
- Clinical trials and patient safety.

Third Parties shall:

- Provide assurance that they comply with all national or state laws, regulations & recognised international quality and safety standards applicable to the proposed work including biosafety containment in all countries in which they operate.
- Ensure that the appropriate informed consent & personal data protection procedures are in place and applied consistently.

Animal Research And Welfare

Third Parties shall apply the following principles to all animal studies and to the breeding and supplying of animals for use in such studies:

- A humane approach must be adopted in the care and treatment of all animals, and the greatest consideration given to their health and welfare, consistent with meeting the necessary scientific objectives.
- All animal studies must be carefully considered and justified to ensure that the principles of the 3Rs (replacement, reduction, refinement) are applied.
- Animal studies should not involve wild-caught non-human primates or great ape species.

8. Product Security

Third Party tackles the threat of counterfeit and illegally traded medicines and improving the security of the end-to-end supply chain.

Third Parties shall:

- Not be involved in any activity related to counterfeit or illegally traded medicines.
- Counterfeit medicines are those that are deliberately and fraudulently mislabelled with respect to identity and/or source. Illegally traded medicines include illegally diverted, fraudulently traded, tampered with and/or stolen medicines.
- Inform AstraZeneca in a timely manner in the event of any incident related to illegally traded or counterfeit medicines and assist AstraZeneca in any subsequent investigation.
- Provide a secure environment for all activities relating to AstraZeneca medicines and take the necessary steps to ensure the authenticity of medicines through the end to end supply chain. This includes:
    - Procedures and records to ensure traceability of finished products as well as any waste, surplus, returned or discarded products, including packaging.

9. Product Communications

Third Party provides information about our medicines and other products consistent with AstraZeneca's high ethical standards.

Third Parties shall:

- Only provide information about AstraZeneca products when authorised to do so. This includes communications about our products in person or through written material, and delivered through any medium, including the Internet.
- Promote AstraZeneca products in an ethical, fair and balanced way.
- Use only promotional materials and other product information that have been approved through appropriate AstraZeneca review procedures.
- Not engage in direct to consumer/direct to patient communications unless permitted by local laws and authorised by AstraZeneca.

10. Confidentiality and Insider Trading

Third Party protects confidential information from improper disclosure.

Third Parties shall:

- Agree to confidentiality agreements if confidential information is to be shared & ensure any authorised communication of confidential information is limited to individuals who have a "need to know".
- Prohibit their employees from insider trading for their own or other's personal profit.

These requirements apply even to misuse of Confidential information after a Third Party has finished doing business with AstraZeneca.

Glossary and Definitions

AstraZeneca	For the purposes of this document the term AstraZeneca refers to AstraZeneca, MedImmune and all other companies within AstraZeneca group, unless the AstraZeneca Senior Executive Team makes an exception.
Code of Conduct	This is AstraZeneca's guide to understanding how AstraZeneca's high level values are to be translated into consistent actions worldwide. It provides guidance about what is expected of each AstraZeneca employee.
Confidential information	Information that gives AstraZeneca and the Third Party a competitive edge. This includes, but is not limited to-intellectual property and know-how; managerial information and statements of strategic intent; pricing or stock-market sensitive data and statements.
Engagement Owner	Employees responsible for engaging and managing services provided by a Third Party.
ILO	International Labour Organization. An international organization responsible for drawing up and overseeing international labour standards. It is the only 'tripartite' United Nations agency that brings together representatives of governments, employers and workers to jointly shape policies and programmes promoting Decent Work for all.
Personal Data	Any information about an identified or identifiable natural person.
Product information	Any information, material or activity, promotional or non-promotional, designed to inform healthcare professionals and organisations, patients, investors, the media and others about the characteristics and use of our products.
Incidents	Include theft of material, discovery of counterfeit or fraudulent activity, demonstration by activists, threat to staff, SHE, bribery and corruption or any other area covered by this document.
Third Party	Any person, company or organisation, other than an AstraZeneca legal entity or an AstraZeneca employee, with which AstraZeneca engages to satisfy a genuine and legitimate business need.

Exhibit 31.1

CERTIFICATION

I, Enrique Conterno, certify that;

1. I have reviewed this Form 10-Q of FibroGen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2020

/s/ Enrique Conterno

Enrique Conterno
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Pat Cotroneo, certify that;

1. I have reviewed this Form 10-Q of FibroGen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2020

/s/ Pat Cotroneo

Pat Cotroneo

Senior Vice President, Finance and Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended ("Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Enrique Conterno, Chief Executive Officer of FibroGen, Inc. ("the Company"), and Pat Cotroneo, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2020, to which this Certification is attached as Exhibit 32.1 ("Periodic Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 5, 2020

In Witness Whereof, the undersigned have set their hands hereto as of the 5th day of November, 2020.

/s/ Enrique Conterno
Enrique Conterno
Chief Executive Officer

/s/ Pat Cotroneo
Pat Cotroneo
Senior Vice President, Finance and
Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of FibroGen, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.