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 June 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 July 31, 2020 was 90,355,096.

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)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 429,269	$ 126,266
Short-term investments	256,317	407,491
Accounts receivable, net ($12,090 and $4,845 from a related party)	26,519	28,455
Inventories	8,582	6,887
Prepaid expenses and other current assets ($0 and $125,210 from a related party)	6,481	133,391
Total current assets	727,168	702,490
Restricted time deposits	2,072	2,072
Long-term investments	229	61,118
Property and equipment, net	36,984	42,743
Finance lease right-of-use assets	34,368	39,602
Other assets	6,862	9,372
Total assets	$ 807,683	$ 857,397
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 5,015	$ 6,088
Accrued and other current liabilities ($216 and $36,883 to a related party)	50,464	83,816
Deferred revenue	9,813	490
Finance lease liabilities, current	12,279	12,351
Total current liabilities	77,571	102,745
Long-term portion of lease obligations	940	1,141
Product development obligations	16,959	16,780
Deferred revenue, net of current	138,242	99,449
Finance lease liabilities, non-current	31,586	37,610
Other long-term liabilities	127,242	64,266
Total liabilities	392,540	321,991
Commitments and Contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 125,000 shares authorized; no shares issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Common stock, $0.01 par value; 225,000 shares authorized at March 31, 2020 and December 31, 2019; 90,228 and 87,657 shares issued and outstanding at June 30, 2020 and December 31, 2019	902	877
Additional paid-in capital	1,344,912	1,300,725
Accumulated other comprehensive loss	(1,561)	(747)
Accumulated deficit	(948,381)	(784,720)
Total stockholders' equity	395,872	516,135
Non-controlling interests	19,271	19,271
Total equity	415,143	535,406
Total liabilities, stockholders' equity and non-controlling interests	$ 807,683	$ 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue:				
License revenue (includes $0, $117,470, $0 and $117,470 from a related party)	$ —	$ 150,581	$ —	$ 150,581
Development and other revenue (includes $4,766, $17,223, $9,503 and $22,082 from a related party)	18,957	40,985	38,402	64,848
Product revenue, net	15,693	—	20,648	—
Drug product revenue (includes $8,238, $0, $8,238 and $0 from a related party)	8,238	—	8,238	—
Total revenue	42,888	191,566	67,288	215,429
Operating costs and expenses:				
Cost of goods sold	3,076	—	4,047	—
Research and development	61,414	52,008	116,315	102,505
Selling, general and administrative	63,535	26,739	113,138	48,948
Total operating costs and expenses	128,025	78,747	233,500	151,453
Income (loss) from operations	(85,137)	112,819	(166,212)	63,976
Interest and other, net				
Interest expense	(651)	(736)	(1,284)	(1,507)
Interest income and other, net	644	4,125	3,810	8,303
Total interest and other, net	(7)	3,389	2,526	6,796
Income (loss) before income taxes	(85,144)	116,208	(163,686)	70,772
Provision for (benefit from) income taxes	169	205	(25)	180
Net income (loss)	$ (85,313)	$ 116,003	$ (163,661)	$ 70,592
Net income (loss) per share:				
Basic	$ (0.95)	$ 1.34	$ (1.84)	$ 0.82
Diluted	$ (0.95)	$ 1.26	$ (1.84)	$ 0.77
Weighted average number of common shares used to calculate net income (loss) per share:				
Basic	89,451	86,445	88,835	86,077
Diluted	89,451	91,728	88,835	92,069

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net income (loss)	$ (85,313)	$ 116,003	$ (163,661)	$ 70,592
Other comprehensive income (loss):				
Foreign currency translation adjustments **(Note 1)**	(1,615)	(180)	(1,334)	111
Available-for-sale investments:				
Unrealized gain on investments, net of tax effect	(1,129)	655	520	1,097
Other comprehensive income, net of taxes	(2,744)	475	(814)	1,208
Comprehensive income (loss)	$ (88,057)	$ 116,478	$ (164,475)	$ 71,800

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 March 31, 2020	88,895,630	$ 889	$ 1,319,354	$ 1,183	$ (863,068)	$ 19,271	$ 477,629
Net income	—	—	—	—	(85,313)	—	(85,313)
Change in unrealized gain or loss on investments	—	—	—	(1,129)	—	—	(1,129)
Foreign currency translation adjustments **(Note 1)**	—	—	—	(1,615)	—	—	(1,615)
Shares issued from stock plans, net of payroll taxes paid	1,332,663	13	7,914	—	—	—	7,927
Stock-based compensation	—	—	17,644	—	—	—	17,644
Balance at June 30, 2020	90,228,293	$ 902	$ 1,344,912	$ (1,561)	$ (948,381)	$ 19,271	$ 415,143
Balance at March 31, 2019	86,129,564	$ 861	$ 1,242,460	$ (937)	$ (753,161)	$ 19,271	$ 508,494
Net loss	—	—	—	—	116,003	—	116,003
Change in unrealized gain or loss on investments	—	—	—	655	—	—	655
Foreign currency translation adjustments	—	—	—	(180)	—	—	(180)
Shares issued from stock plans, net of payroll taxes paid	717,508	7	5,681	—	—	—	5,688
Stock-based compensation	—	—	17,642	—	—	—	17,642
Balance at June 30, 2019	86,847,072	$ 868	$ 1,265,783	$ (462)	$ (637,158)	$ 19,271	$ 648,302

FIBROGEN, INC.

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

	For The Six Month Period						
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Non Controlling	
	Shares	Amount	Capital	Loss	Deficit (Note 1)	Interests	Total
Balance at December 31, 2019	87,657,489	$ 877	$ 1,300,725	$ (747)	$ (784,720)	$ 19,271	$ 535,406
Net income	—	—	—	—	(163,661)	—	(163,661)
Change in unrealized gain or loss on investments	—	—	—	520	—	—	520
Foreign currency translation adjustments **(Note 1)**	—	—	—	(1,334)	—	—	(1,334)
Shares issued from stock plans, net of payroll taxes paid	2,570,804	25	9,627	—	—	—	9,652
Stock-based compensation	—	—	34,560	—	—	—	34,560
Balance at June 30, 2020	90,228,293	$ 902	$ 1,344,912	$ (1,561)	$ (948,381)	$ 19,271	$ 415,143
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	—	—	—	—	70,592	—	70,592
Change in unrealized gain or loss on investments	—	—	—	1,097	—	—	1,097
Foreign currency translation adjustments	—	—	—	111	—	—	111
Shares issued from stock plans, net of payroll taxes paid	1,414,970	14	5,258	—	—	—	5,272
Stock-based compensation	—	—	34,072	—	—	—	34,072
Balance at June 30, 2019	86,847,072	$ 868	$ 1,265,783	$ (462)	$ (637,158)	$ 19,271	$ 648,302

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)

	Six Months Ended June 30,	
	2020	**2019**
Operating activities		
Net income (loss)	$ (163,661)	$ 70,592
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	5,737	5,523
Amortization of finance lease right-of-use assets	5,247	5,140
Net accretion of discount on investments	(22)	(2,457)
Unrealized loss (gain) on equity investments	15	(59)
Gain on disposal of property and equipment	—	(10)
Stock-based compensation	34,560	34,072
Tax benefit on unrealized gain on available-for-sale securities	(138)	—
Realized loss on sales of available-for-sale securities	258	—
Changes in operating assets and liabilities:		
Accounts receivable, net	1,903	57,231
Inventories	(2,016)	(1,981)
Prepaid expenses and other current assets	126,874	(131,803)
Other assets	4,025	(200)
Accounts payable	(1,060)	(5,079)
Accrued and other liabilities	(33,501)	917
Deferred revenue	48,117	(46,818)
Accrued interest for finance lease liabilities	(115)	241
Other long-term liabilities	63,956	8,519
Net cash provided by (used in) operating activities	90,179	(6,172)
Investing activities		
Purchases of property and equipment	(1,185)	(2,206)
Advanced payment made for acquisition	(1,419)	—
Purchases of available-for-sale securities and term deposit	(38)	(105,511)
Proceeds from sales of available-for-sale securities	10,606	—
Proceeds from maturities of investments	201,900	100,000
Net cash provided by (used in) investing activities	209,864	(7,717)
Financing activities		
Repayments of finance lease liabilities	(5,992)	(5,850)
Repayments of lease obligations	(201)	(202)
Cash paid for payroll taxes on restricted stock unit releases	(6,858)	(8,065)
Proceeds from issuance of common stock	16,510	13,337
Net cash provided by (used in) financing activities	3,459	(780)
Effect of exchange rate change on cash and cash equivalents	(499)	(2)
Net increase (decrease) in cash and cash equivalents	303,003	(14,671)
Total cash and cash equivalents at beginning of period	126,266	89,258
Total cash and cash equivalents at end of period	$ 429,269	$ 74,587

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 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 both idiopathic pulmonary fibrosis and pancreatic cancer. Pamrevlumab is also currently in a Phase 2 trial for Duchenne muscular dystrophy and is in Phase 2/3 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. 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").

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net income (loss)	$ (85,313)	$ 116,003	$ (163,661)	$ 70,592
Weighted average shares used to compute net income (loss) per share:				
Basic	89,451	86,445	88,835	86,077
Dilutive effect of potential common shares	—	5,283	—	5,992
Diluted	89,451	91,728	88,835	92,069
Net income (loss) per share:				
Basic	$ (0.95)	$ 1.34	$ (1.84)	$ 0.82
Diluted	$ (0.95)	$ 1.26	$ (1.84)	$ 0.77

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 three and six months ended June 30, 2020, 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 9.2 million and 4.4 million, respectively, for the three months ended June 30, 2020 and 2019, and totaling 9.0 million and 3.4 million, respectively, for the six months ended June 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 normal worldwide healthcare system, as well as an impact on its roxadustat sales in China due to the social distancing and other restrictions put in place, particularly during February and March. 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:

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 as of June 30, 2020.

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 six months ended June 30, 2020 and the allowance for doubtful accounts as of June 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 the uncollectability of an available-for-sale security is confirmed 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 control of 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 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 ("NHSA") 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 the Company only due to quality issues and for product within one year of 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 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 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.

2. 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 June 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 June 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 six months ended June 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 AB ("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 June 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 $0.4 million was recognized as revenue during the six months ended June 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.

China Agreement

Effective July 30, 2013, the Company (through its subsidiaries affiliated with China) entered into a collaboration agreement with AstraZeneca for the development and commercialization (but not manufacture) of roxadustat for the treatment of anemia in China ("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 is structured as a 50/50 profit or loss share (as defined) 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 through June 30, 2020 totals $77.2 million.

In December 2019, roxadustat was included on the updated National Reimbursement Drug List ("NRDL") released by China's NHSA 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 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 fourth quarter of 2019. This milestone payment was received during the first quarter of 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.

On July 8, 2020, FibroGen Cayman, FibroGen Beijing and FibroGen International (Hong Kong) Limited (collectively, "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. See Note 10 for details.

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 June 30,		Six Months Ended June 30,	
Agreement	**Performance Obligation**	**2020**	**2019**	**2020**	**2019**
Japan	License revenue	$ —	$ —	$ —	$ —
	Development revenue	$ 164	$ 369	$ 327	$ 615

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 June 30, 2020**	**Deferred Revenue at June 30, 2020**	**Total Consideration Through June 30, 2020**
License	$ 86,024	$ —	$ 86,024
Development revenue	15,458	183	15,641
Total license and development revenue	$ 101,482	$ 183	$ 101,665

The revenue recognized under the Japan Agreement for the three months ended June 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 June 30,		Six Months Ended June 30,	
Agreement	**Performance Obligation**	**2020**	**2019**	**2020**	**2019**
Europe	License revenue	$ —	$ 117,470	$ —	$ 117,470
	Development revenue	$ 4,602	$ 16,854	$ 9,176	$ 21,467

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 June 30, 2020	Deferred Revenue at June 30, 2020	Total Consideration Through June 30, 2020
License	$ 487,951	$ —	$ 487,951
Development revenue	240,184	2,338	242,522
Total license and development revenue	$ 728,135	$ 2,338	$ 730,473

The revenue recognized under the Europe Agreement for the three months ended June 30, 2020 included an increase in revenue of $1.6 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 $31.7 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 Agreement were as follows (in thousands):

		Three Months Ended June 30,		Six Months Ended June 30,	
Agreement	Performance Obligation	2020	2019	2020	2019
U.S. / RoW and China	License revenue	$ —	$ 33,111	$ —	$ 33,111
	Development revenue	13,750	23,762	28,305	42,766
	China performance obligation	$ 441	$ —	$ 594	$ —

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 June 30, 2020	Deferred Revenue at June 30, 2020	Total Consideration Through June 30, 2020
License	$ 341,844	$ —	$ 341,844
Co-development, information sharing & committee services	521,572	4,547	526,119
China performance obligation	684	140,973	141,657
Total license and development revenue	$ 864,100	$ 145,520	$ 1,009,620

The revenue recognized under the U.S./RoW Agreement for the three months ended June 30, 2020 included a decrease of $0.2 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 $90.1 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.

Product Revenue, Net

The Company started roxadustat commercial sales in China in the third quarter of 2019. Product revenue 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 June 30, 2020	Six Months Ended June 30, 2020
Gross revenue	$ 19,833	$ 25,205
Non-key account hospital listing award	(2,566)	(2,566)
Contractual sales rebate	(1,372)	(1,748)
Other discounts and rebates	(202)	(243)
Product revenue, net	$ 15,693	$ 20,648

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. During the three months ended June 30, 2020, a $2.6 million of non-key account hospital listing award was 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.

For the three and six months ended June 30, 2020, the contractual sales rebate was $1.4 million and $1.7 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 period.

The rebates and discounts that the Company's pharmaceutical distributors have earned are eligible to be applied against their 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 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 June 30, 2020
Contract liabilities	$ (1,102)	$ (4,907)	$ 16	$ 9	$ (5,984)	$ 5,595	$ (389)

As of June 30, 2020, the total rebates and discounts as reductions to gross accounts receivable was $5.6 million, and the total contract liabilities was $0.4 million, which was included in accrued and other current liabilities in the condensed consolidated balance sheet.

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

	June 30, 2020	December 31, 2019
Price adjustment	$ 935	$ 936
Contractual sales rebate	1,878	148
Non-key account hospital listing award	2,567	—
Other discounts and rebates	260	18
Provision for credit loss	84	—
Total reductions to gross accounts receivable	$ 5,724	$ 1,102

Drug Product Revenue

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.

During the three months ended June 30, 2020, the Company 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 yield and the related cost to convert the API to bulk product tablets.

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 launch of the products within China. As of June 30, 2020, approximately $2.7 million of the related deferred revenue 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.

3. Fair Value Measurements

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

	June 30, 2020			
	Level 1	Level 2	Level 3	Total
U.S. treasury notes and bills	$ 176,028	$ 50,151	$ —	$ 226,179
Equity investments	229	—	—	229
Money market funds	230,561	—	—	230,561
Certificate of deposit	—	30,138	—	30,138
Total	$ 406,818	$ 80,289	$ —	$ 487,107

	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):

	June 30, 2020			
	Level 1	Level 2	Level 3	Total
Lease obligations	$ —	$ —	$ 1,343	$ 1,343

	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.

4. Leases

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

	Balance Sheet Line Item	June 30, 2020	December 31, 2019
Assets			
Finance:			
Right-of-use assets - cost		$ 49,903	$ 49,909
Accumulated amortization		(15,535)	(10,307)
Finance lease right-of-use assets, net	Finance lease right-of-use assets	34,368	39,602
Operating:			
Right-of-use assets - cost		2,647	2,736
Accumulated amortization		(1,270)	(805)
Operating lease right-of-use assets, net	Other assets	1,377	1,931
Total lease assets		$ 35,745	$ 41,533
Liabilities			
Current:			
Finance lease liabilities	Finance lease liabilities, current	$ 12,279	$ 12,351
Operating lease liabilities	Accrued and other current liabilities	801	983
Non-current:			
Finance lease liabilities	Finance lease liabilities, non-current	31,586	37,610
Operating lease liabilities	Other long-term liabilities	572	942
Total lease liabilities		$ 45,238	$ 51,886

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

	Statement of Operations Line Item	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Finance lease cost:					
Amortization of right-of-use assets	Cost of goods sold; Research and development; Selling, general and administrative expenses	$ 2,653	$ 2,571	$ 5,247	$ 5,140
Interest on lease liabilities	Interest expense	534	609	1,049	1,249
Operating lease cost	Cost of goods sold; Research and development; Selling, general and administrative expenses	255	163	564	289
Sublease income	Selling, general and administrative expenses	(306)	(237)	(598)	(824)
Total lease cost		$ 3,136	$ 3,106	$ 6,262	$ 5,854

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

	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 433	$ 191
Operating cash flows from finance leases	1,010	1,053
Financing cash flows from finance leases	5,992	5,850
Right-of-use assets obtained in exchange for new lease liabilities:		
Finance leases	144	49,676
Operating leases	$ 5	$ 1,212

Lease term and discount rate were as follows:

	June 30, 2020	December 31, 2019
Weighted-average remaining lease term (years):		
Finance leases	3.4	3.6
Operating leases	1.8	2.1
Weighted-average discount rate:		
Finance leases	4.39%	4.42%
Operating leases	4.73%	4.75%

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

Year Ending	Finance Leases	Operating Leases
2020 (Remaining six month period)	$ 7,047	$ 463
2021	13,680	663
2022	13,883	305
2023	12,523	—
Total future lease payments	47,133	1,431
Less: Interest	(3,268)	(58)
Present value of lease liabilities	$ 43,865	$ 1,373

5. Balance Sheet Components

Cash and Cash Equivalents

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

	June 30, 2020	December 31, 2019
Cash	$ 198,708	$ 40,715
Money market funds	230,561	85,551
Total cash and cash equivalents	$ 429,269	$ 126,266

At June 30, 2020 and December 31, 2019, a total of $32.8 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):

	June 30, 2020			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
U.S. treasury notes and bills	$ 225,117	$ 1,062	$ —	$ 226,179
Certificates of deposit	30,000	138	—	30,138
Equity investments	125	104	—	229
Total investments	$ 255,242	$ 1,304	$ —	$ 256,546

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

Inventories

Inventories consisted of the following (in thousands):

	June 30, 2020	December 31, 2019
Raw materials	$ 327	$ 325
Work-in-progress	3,815	2,264
Finished goods	4,440	4,298
Total inventories	$ 8,582	$ 6,887

The provision to write-down excess and obsolete inventory was immaterial for the three and six months ended June 30, 2020.

Prepaid expenses and other current assets

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

	June 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	4,429	6,464
Other current assets	2,052	1,717
Total prepaid expenses and other current assets	$ 6,481	$ 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 2 for details.

Property and Equipment

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

	June 30, 2020	December 31, 2019
Leasehold improvements	$ 100,159	$ 101,548
Laboratory equipment	17,362	17,329
Machinery	7,660	8,217
Computer equipment	8,930	8,399
Furniture and fixtures	5,873	5,822
Construction in progress	1,225	1,792
Total property and equipment	$ 141,209	$ 143,107
Less: accumulated depreciation	(104,225)	(100,364)
Property and equipment, net	$ 36,984	$ 42,743

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2020	December 31, 2019
Preclinical and clinical trial accruals	$ 21,691	$ 16,279
API product price adjustment	—	36,324
Payroll and related accruals	14,266	19,784
Property taxes and other	1,145	2,044
Professional services	5,653	4,842
Other	7,709	4,543
Total accrued liabilities	$ 50,464	$ 83,816

The amount 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. The amount was fully paid during the first quarter of 2020.

Other Long-term Liabilities

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

	June 30, 2020	December 31, 2019
Accrued long-term co-promotional expenses	$ 116,230	$ 53,071
Other long-term tax liabilities	8,653	8,913
Operating lease liabilities, non-current	572	942
Other	1,787	1,340
Total other long-term liabilities	$ 127,242	$ 64,266

The accrued long-term co-promotional expenses of $116.2 million and $53.1 million as of June 30, 2020 and December 31, 2019, respectively, were related to the estimated amount payable to AstraZeneca for its sales and marketing efforts associated with the commercial launch and sales for roxadustat in China. The payment for such amount is not expected to occur within the next year. On July 8, 2020, the Parties into an amendment to the China Agreement, relating to the development and commercialization of roxadustat in China. As a result, such accrued long-term co-promotional expenses will be reduced by approximately $82 million in the third quarter of 2020. See Note 10 for details.

6. Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 10,780	$ 10,450	$ 21,417	$ 20,028
Selling, general and administrative	6,864	7,192	13,143	14,044
Total stock-based compensation expense	$ 17,644	$ 17,642	$ 34,560	$ 34,072

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Stock Options				
Expected term (in years)	5.5	5.3	5.7	5.3
Expected volatility	69.2 %	68.2 %	68.4 %	67.9 %
Risk-free interest rate	0.4 %	2.0 %	0.8 %	2.5 %
Expected dividend yield	—	—	—	—
Weighted average estimated fair value	$ 21.72	$ 24.40	$ 17.75	$ 33.20
ESPPs				
Expected term (in years)	0.5 – 2.0	0.5 – 2.0	0.5 – 2.0	0.5 – 2.0
Expected volatility	49.5 – 77.1 %	48.1 – 62.1 %	49.5 – 77.1 %	48.1 – 62.1 %
Risk-free interest rate	0.2 – 2.9 %	1.3 – 2.9 %	0.2 – 2.9 %	1.3 – 2.9 %
Expected dividend yield	—	—	—	—
Weighted average estimated fair value	$ 17.82	$ 19.07	$ 18.11	$ 19.65

7. Income Taxes

Provision for (benefit from) income tax for the three and six months ended June 30, 2020 were primarily due to the tax effect arising from other comprehensive income related to available-for-sale securities, and foreign taxes. Provisions for income tax for the three and six months ended June 30, 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.

8. 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 $4.8 million and $134.7 million for the three months ended June 30, 2020 and 2019, respectively, and $9.5 million and $139.6 million for the six months ended June 30, 2020 and 2019, respectively. For the three and six months ended June 30, 2020, the Company also recorded $8.2 million drug product revenue from Astellas.

The Company recorded expense related to collaboration agreements with Astellas of $0.2 million and $0.8 million during the three months ended June 30, 2020 and 2019, respectively, and $0.3 million and $1.3 million during the six months ended June 30, 2020 and 2019, respectively.

As of June 30, 2020 and December 31, 2019, accounts receivable from Astellas were $12.1 million and $4.8 million, respectively, and amounts due to Astellas were $0.2 million and $36.9 million, respectively. The amounts due to Astellas as of December 31, 2019 included $36.3 million of a change in estimated variable consideration related to the API product revenue recognized in 2018, at the time the roxadustat listed price was issued by the Japanese Ministry of Health, Labour and Welfare. Such amount 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, respectively, 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 2 for details.

9. Commitments and Contingencies

Contract Obligations

As of June 30, 2020, the Company had outstanding total non-cancelable contract obligations of $26.2 million, including $14.2 million for manufacture and supply of roxadustat, $10.9 million for future milestone payments for research and pre-clinical stage development programs, and $1.1 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 United States, 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 June 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.

10. Subsequent Event

On July 8, 2020, FibroGen Cayman, FibroGen Beijing, and FibroGen International (Hong Kong) Limited (collectively, "FibroGen China") and AstraZeneca AB ("AstraZeneca", and 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 "Amendment").

The Amendment provides for the establishment of a jointly owned entity (the "Distribution Entity") that will perform roxadustat distribution, as well as conduct sales and marketing through AstraZeneca. 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 July 2020, the Company closed the acquisition of an entity for the purpose of the establishment of the Distribution Entity.

While the responsibilities of the Parties under the China Agreement remain largely the same, certain changes were made. The Parties have changed the method under which commercial expenses incurred by AstraZeneca are billed, and the collaboration has been adjusted to more fully account for the cost of manufacturing incurred by FibroGen Beijing.

The Company is in the process of evaluating the accounting impacts resulting from the Amendment and the establishment of the Distribution Entity, which is expected to be significant to its consolidated financial statements starting the third quarter of 2020. Among others, the accrued long-term co-promotional expenses related to the estimated amount payable to AstraZeneca for its sales and marketing efforts associated with the commercial launch and sales for roxadustat will be reduced by approximately $82 million in the third quarter of 2020.

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 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 both idiopathic pulmonary fibrosis ("IPF") and pancreatic cancer. Pamrevlumab is also currently in a Phase 2 trial for Duchenne muscular dystrophy ("DMD") and is in Phase 2/3 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 disease, 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 June 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands, except for per share data)			
Result of Operations				
Revenue	$ 42,888	$ 191,566	$ 67,288	$ 215,429
Operating costs and expenses	128,025	78,747	233,500	151,453
Net income (loss)	(85,313)	116,003	(163,661)	70,592
Net income (loss) per share - basic	(0.95)	1.34	(1.84)	0.82
Net income (loss) per share - diluted	$ (0.95)	$ 1.26	$ (1.84)	$ 0.77

	June 30, 2020	December 31, 2019
	(in thousands)	
Balance Sheet		
Cash and cash equivalents	$ 429,269	$ 126,266
Short-term and long-term investments	256,546	468,609
Accounts receivable	$ 26,519	$ 28,455

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

- $19.0 million and $38.4 million of development revenue recognized under our collaboration agreements with our partners Astellas and AstraZeneca AB (“AstraZeneca”);
- $15.7 million and 20.6 million of net product revenue from roxadustat commercial sales in China; and
- $8.2 million of roxadustat active pharmaceutical ingredient (“API”) delivery to Astellas.

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

- 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 and six months ended June 30, 2020 increased compared to the same periods a year ago primarily due to the following:

- Higher outside service expenses associated with co-promotional activities expenses with AstraZeneca sales and marketing efforts in China related to the commercial activities of roxadustat;
- 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; and
- Higher drug development expenses mainly associated with higher drug substance manufacturing activities and supplies related to pamrevlumab, and higher drug substance manufacturing activities related to roxadustat in its global program.

During the three months ended June 30, 2020, we had a net loss of $85.3 million, or net loss per basic and diluted share of $0.95, as compared to a net income of $116.0 million for the same period a year ago, due to a decrease in revenue and an increase in operating costs and expenses. During the six months ended June 30, 2020, we had a net loss of $163.7 million, or net loss per basic and diluted share of $1.84, as compared to a net income of $70.6 million for the same period a year ago, due to a decrease in revenue and an increase in operating costs and expenses.

Cash and cash equivalents, investments and accounts receivable totaled $712.3 million at June 30, 2020, an increase of $89.0 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: 爱瑞卓®) 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 second quarter, roxadustat was listed at hospitals which represent approximately 45% 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 completed our mid-cycle review meeting with the FDA in June 2020 and continue to expect an FDA decision on this NDA by the Prescription Drug User Fee Act goal date of December 20, 2020. The FDA has indicated that an Advisory Committee meeting is not planned at this time.

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, and India.

During the second quarter of 2020, we announced data from roxadustat clinical trials conducted by Astellas. These data were presented in virtual oral sessions of the 57th European Renal Association-European Dialysis and Transplant Association.

The Phase 3 DOLOMITES study evaluated the efficacy and safety of roxadustat compared to darbepoetin alfa for the treatment of anemia in non-dialysis dependent patients. In the primary endpoint analysis, the study demonstrated non-inferiority of roxadustat to darbepoetin alfa in the proportion of patients achieving correction of hemoglobin (Hb) levels during the first 24 weeks of treatment (89.5% vs 78.0%; a difference of 11.51%), with a lower bound of 95% confidence interval > 0%.

Roxadustat was superior to darbepoetin alfa in decreasing low-density lipoprotein cholesterol with a least square mean (LSM) difference of -0.403 mmol/L ($p<0.01$) and superior in time to first intravenous iron use with a hazard ratio (HR) of 0.45 (95% CI: 0.26, 0.78; p=0.004). The non-inferiority of roxadustat to darbepoetin alfa on hypertension risk was demonstrated for mean arterial pressure change from baseline to weeks 12-28 with a LSM difference of -0.372 mmHg (95% CI: -1.587, 0.842) and time to occurrence of hypertension; HR 0.83 (95% CI: 0.56, 1.22). Regarding safety, the overall incidence of treatment-emergent adverse events was comparable between roxadustat and darbepoetin alfa (91.6% and 92.5%, respectively).

With a relatively small sample size (roxadustat n=323, darbepoetin n=293), non-confirmatory analysis of adjudicated major adverse cardiac events ("MACE"), and MACE plus hospitalized unstable angina and hospitalized congestive heart failure ("MACE+") outcomes showed HR point estimates of 0.81 (95% CI: 0.52, 1.25) and 0.90 (95% CI: 0.61, 1.32) for roxadustat as compared to darbepoetin.

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.

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.

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.

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.

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

In June 2020, we announced initiation of 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. The primary objective of this study is to assess the effect of pamrevlumab on blood oxygenation in patients with COVID-19 infection. Patients will be randomized to treatment with pamrevlumab or standard of care in a 1:1 ratio. Based on the investigator's decision, a subgroup of patients may continue treatment for up to 12 weeks.

We have also initiated 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. This multicenter trial will enroll approximately 130 patients with COVID-19. The primary objective of this study is to assess the effect of pamrevlumab on blood oxygenation in patients with COVID-19 infection, and patients will be randomized to treatment with pamrevlumab or standard of care in a 1:1 ratio. The primary efficacy assessment is the proportion of hospitalized COVID-19 patients who have not received mechanical ventilation and/or extracorporeal membrane oxygenation (ECMO) and remain alive at Day 28.

Idiopathic Pulmonary Fibrosis

We are conducting ZEPHYRUS, our Phase 3 trial of pamrevlumab in IPF patients, and are preparing to initiate ZEPHYRUS-2, a second IPF Phase 3 study. 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. In order to minimize the risk of exposure to COVID-19 in this vulnerable IPF patient population with compromised lung function, we paused enrollment in ZEPHYRUS in the first quarter of 2020. We have now re-opened enrollment in ZEPHYRUS and will initiate the ZEPHYRUS-2 trial as COVID-19 conditions improve.

Locally Advanced Unresectable Pancreatic Cancer

In 2019, we initiated 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 are working with clinical trial sites and investigators in order to mitigate risks and other challenges associated with COVID-19 and the restrictions instituted to combat COVID-19.

Duchenne Muscular Dystrophy

In the third quarter of 2020, we expect to initiate a Phase 3 clinical trial, LELANTOS, evaluating pamrevlumab as a treatment for DMD. LELANTOS will be 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.

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 June 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 six months ended June 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 addition, as of June 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 June 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 is structured as a 50/50 profit share. AstraZeneca will conduct commercialization activities in China and fund roxadustat launch costs in China and will only receive reimbursement once FibroGen Beijing has achieved profitability. As of June 30, 2020, we accrued $116.2 million of cumulative co-promotional expenses related to the estimated amount payable to AstraZeneca for such sales and marketing efforts.

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 $0.4 million was recognized as revenue during the six months ended June 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.

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 "Amendment").

The Amendment provides for the establishment of a jointly owned entity (the "Distribution Entity") that will perform roxadustat distribution, as well as conduct sales and marketing through AstraZeneca. 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 July 2020, the Company closed the acquisition of an entity for the purpose of the establishment of the Distribution Entity.

While the responsibilities of the Parties under the China Agreement remain largely the same, certain changes are being made. The Parties have changed the method under which commercial expenses are billed, and the collaboration will be adjusted to more fully account for the cost of manufacturing. These changes will be implemented retroactively to April 1, 2020. AstraZeneca's billings for sales and marketing are now subject to an annual cap at a percentage of net sales, until they have been fully reimbursed for their costs, at which point AstraZeneca will invoice based on actual costs, subject to the annual cap.

Once the Distribution Entity is fully operational expected in early 2021, AstraZeneca will invoice the Distribution Entity for its sales and marketing services provided to the Distribution Entity, and FibroGen Beijing will manufacture and supply commercial product to the Distribution Entity.

FibroGen is expected to recognize revenue based on its sales to the Distribution Entity.

Development costs will continue to be shared 50/50 between the Parties.

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

We are in the process of evaluating the accounting impacts resulting from the Amendment and the establishment of the Distribution Entity, which is expected to be significant to our consolidated financial statements starting the third quarter of 2020. Among others, the accrued long-term co-promotional expenses related to the estimated amount payable to AstraZeneca for its sales and marketing efforts associated with the commercial launch and sales for roxadustat will be reduced by approximately $82 million in the third quarter of 2020.

Additional Information Related to Collaboration Agreements

Total cash consideration received through June 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 June 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 June 30,		Change		Six Months Ended June 30,		Change	
	2020	2019	$	%	2020	2019	$	%
			(dollars in thousands)					
Revenue:								
License revenue	$ —	$ 150,581	$ (150,581)	(100) %	$ —	$ 150,581	$ (150,581)	(100) %
Development and other revenue	18,957	40,985	(22,028)	(54) %	38,402	64,848	(26,446)	(41) %
Product revenue, net	15,693	—	15,693	100 %	20,648	—	20,648	100 %
Drug product revenue	8,238	—	8,238	100 %	8,238	—	8,238	100 %
Total revenue	$ 42,888	$ 191,566	$ (148,678)	(78) %	$ 67,288	$ 215,429	$ (148,141)	(69) %

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 six months ended June 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 June 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 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 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 six months ended June 30, 2020, our $15.7 million of net product revenue from roxadustat sales in China was affected by the COVID-19 pandemic and the fact that patient and physician interaction was limited during a significant portion of the period, particularly in February and March. However, it is difficult to estimate how much sales were affected by COVID-19 due to the limited history of roxadustat product revenue to compare to.

Total revenue decreased $148.7 million, or 78% for the three months ended June 30, 2020, and $148.1 million, or 69% for the six months ended June 30, 2020, compared to the same periods a year ago for the reasons discussed in the sections below.

License Revenue

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2020	2019	$	%	2020	2019	$	%
	(dollars in thousands)							
License revenue:								
Astellas	$ —	$ 117,470	$ (117,470)	(100) %	$ —	$ 117,470	$ (117,470)	(100) %
AstraZeneca	—	33,111	(33,111)	(100) %	—	33,111	(33,111)	(100) %
Total license revenue	$ —	$ 150,581	$ (150,581)	(100) %	$ —	$ 150,581	$ (150,581)	(100) %

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

License revenue recognized under our collaboration agreements with Astellas in the three and six months ended June 2019 was 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 six months ended June 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 June 30,		Change		Six Months Ended June 30,		Change	
	2020	2019	$	%	2020	2019	$	%
	(dollars in thousands)							
Development revenue:								
Astellas	$ 4,766	$ 17,223	$ (12,457)	(72) %	$ 9,503	$ 22,082	$ (12,579)	(57) %
AstraZeneca	14,191	23,762	(9,571)	(40) %	28,899	42,766	(13,867)	(32) %
Total development revenue	18,957	40,985	(22,028)	(54) %	38,402	64,848	(26,446)	(41) %

Development and other revenue decreased $22.0 million, or 54% for the three months ended June 30, 2020 and $26.4 million, or 41% for the six months ended June 30, 2019, compared to the same period a year ago. Development revenue recognized under our collaboration agreements with Astellas for the three and six months ended June 30, 2019 included the allocated revenue of $12.0 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 three and six months ended June 30, 2019 included the allocated revenue of $8.4 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 six months ended June 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 June 30, 2020	Six Months Ended June 30, 2020
	(dollars in thousands)	
Gross revenue	$ 19,833	$ 25,205
Non-key account hospital listing award	(2,566)	(2,566)
Contractual sales rebate	(1,372)	(1,748)
Other discounts and rebates	(202)	(243)
Product revenue, net	$ 15,693	$ 20,648

We started roxadustat commercial sales in China in the third quarter of 2019. 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 six months ended June 30, 2020 was $19.8 million and $25.2 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 months ended June 30, 2020, a $2.6 million of non-key account hospital listing award was 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. Of this amount, $0.9 million was related to prior year activities, and $0.8 million was related to activities in the first quarter of 2020.

The contractual sales rebate for the three and six months ended June 30, 2020 was $1.4 million and $1.7 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, including sales return allowance, were immaterial for the periods.

Drug Product Revenue

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.

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 yield and the related cost to convert the API to bulk product tablets.

Operating Costs and Expenses

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2020	2019	$	%	2020	2019	$	%
	(dollars in thousands)							
Operating costs and expenses								
Cost of goods sold	$ 3,076	$ —	$ 3,076	100 %	$ 4,047	$ —	$ 4,047	100 %
Research and development	61,414	52,008	9,406	18 %	116,315	102,505	13,810	13 %
Selling, general and administrative	63,535	26,739	36,796	138 %	113,138	48,948	64,190	131 %
Total operating costs and expenses	$ 128,025	$ 78,747	$ 49,278	63 %	$ 233,500	$ 151,453	$ 82,047	54 %

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 that has paused enrollment. However, the overall impact of COVID-19 on our expenses was not significant. In the three and six months ended June 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 increased $49.3 million, or 63% for the three months ended June 30, 2020, and $82.0 million, or 54%, 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. Cost of goods sold was $3.1 million and $4.0 million for the three and six months ended June 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 six months ended June 30, 2020 and 2019:

Product Candidate	Phase of Development	Three Months Ended June 30,		Six Months Ended June 30,	
		2020	2019	2020	2019
		(in thousands)			
Roxadustat	Phase 3	$ 34,332	$ 29,492	$ 60,344	$ 59,633
Pamrevlumab	Phase 2/3	23,320	14,748	45,401	27,102
FG-5200	Preclinical	1,002	1,345	2,032	2,722
Other research and development expenses		2,760	6,423	8,538	13,048
Total research and development expenses		$ 61,414	$ 52,008	$ 116,315	$ 102,505

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 $9.4 million, or 18% for the three months ended June 30, 2020, compared to the same period a year ago, as a result of the following:

- Increase of $10.4 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 $1.9 million in facility related expense, primarily due to higher allocated overhead costs, higher depreciation expenses related to China facilities and general maintenance expenses; and
- Decrease of $2.7 million due to capitalization of inventory manufacturing costs associated with roxadustat production.

Research and development expenses increased $13.8 million, or 13% for the six months ended June 30, 2020, compared to the same period a year ago, as a result of the following:

- Increase of $12.8 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 $4.1 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 $3.4 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;
- Increase of $1.4 million in stock-based compensation expense, primarily due to the cumulative impact of stock option grant activities;
- Decrease of $5.6 million due to capitalization of inventory manufacturing costs associated with roxadustat production; and
- Decrease of $2.4 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-promotional 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 increased $36.8 million, or 138% for the three months ended June 30, 2020 compared to the same period a year ago, as a result of the following:

- Increase of $30.1 million in outside service expenses, due to the recognition of our share of co-promotional expenses incurred during the current period with AstraZeneca sales and marketing efforts related to the commercial launch of roxadustat in China;
- Increase of $4.4 million in legal expenses primarily associated with patent-related activities in the United Kingdom; and
- Increase of $2.4 million in employee-related costs primarily due to higher headcount in the sales and marketing functions in China and higher compensation levels.

SG&A expenses increased $64.2 million, or 131% for the six months ended June 30, 2020 compared to the same period a year ago, as a result of the following:

- Increase of $57.0 million in outside service expenses, due to the recognition of our share of co-promotional expenses incurred during the current period with AstraZeneca sales and marketing efforts related to the commercial launch of roxadustat in China;
- Increase of $5.0 million in legal expenses primarily associated with patent-related activities in United Kingdom; and
- Increase of $3.4 million in employee-related costs primarily due to higher headcount in the sales and marketing functions in China and higher compensation levels.

Interest and Other, Net

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2020	2019	$	%	2020	2019	$	%
	(dollars in thousands)							
Interest and other, net:								
Interest expense	$ (651)	$ (736)	$ 85	(12) %	$ (1,284)	$ (1,507)	$ 223	(15) %
Interest income and other, net	644	4,125	(3,481)	(84) %	3,810	8,303	(4,493)	(54) %
Total interest and other, net	$ (7)	$ 3,389	$ (3,396)	(100) %	$ 2,526	$ 6,796	$ (4,270)	(63) %

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 $3.5 million, or 84% for the three months ended June 30, 2020, and $4.5 million, or 54% for the six months ended June 30, 2020, compared to the same periods a year ago, primarily due to lower interest earned on our cash, cash equivalents and investments of $2.3 million and $4.1 million, respectively, associated with the lower average balances.

In addition, 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 changed resulted in a decrease of $1.0 million in unrealized foreign currency gain during the three and six months ended June 30, 2020.

Income Taxes

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(dollars in thousands)			
Income (loss) before income taxes	$ (85,144)	$ 116,208	$ (163,686)	$ 70,772
Provision for (benefit from) income taxes	169	205	(25)	180
Effective tax rate	(0.2)%	0.2%	- %	0.3%

Provision for (benefit from) income tax for the three and six months ended June 30, 2020 were primarily due to the tax effect arising from other comprehensive income related to available-for-sale securities and foreign taxes. Provisions for income tax for the three and six months ended June 30, 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 June 30, 2020, we had cash and cash equivalents of $429.3 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 June 30, 2020, we had short-term and long-term investments of $256.3 million and $0.2 million, respectively. As of June 30, 2020, a total of $32.8 million of our cash and cash equivalents was held outside of the U.S. in our foreign subsidiaries 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:

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ 90,179	$ (6,172)
Investing activities	209,864	(7,717)
Financing activities	3,459	(780)
Effect of exchange rate changes on cash and cash equivalents	(499)	(2)
Net increase (decrease) in cash and cash equivalents	$ 303,003	$ (14,671)

Operating Activities

Net cash provided by operating activities was $90.2 million for the six months ended June 30, 2020 and consisted primarily of net loss of $163.7 million adjusted for non-cash items of $45.7 million, offset by a net increase in operating assets and liabilities of $208.2 million. The significant non-cash items included stock-based compensation expense of $34.6 million, depreciation expense of $5.7 million and amortization of finance lease ROU of $5.2 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 $126.9 million and Deferred revenue of $48.1 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 long-term liabilities of $64.0 million, primarily due to the additional accrual of co-promotional expenses with AstraZeneca for sales and marketing efforts related to the commercial launch of roxadustat in China that are not expected to be paid in the next year;
- Other assets of $4.0 million, primarily related to the return and consumption of input value added tax by FibroGen Beijing; and
- Accounts receivable of $1.9 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;

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

- Accrued and other liabilities of $33.5 million, primarily driven 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; as well as driven by the timing of invoicing and payment; and
- Inventories of $2.0 million, driven by the increased inventory level related to FibroGen Beijing's productions of roxadustat for commercial sales purposes.

Net cash used in operating activities was $6.2 million for the six months ended June 30, 2019 and consisted primarily of net income of $70.6 million adjusted for non-cash items of $42.2 million, offset by a net decrease in operating assets and liabilities of $119.0 million. The significant non-cash items included stock-based compensation expense of $34.1 million, depreciation expense of $5.5 million, amortization of finance lease ROU of $5.1 million, and net amortization of premium and discount on investments of $2.5 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 $131.8 million and deferred revenue of $46.8 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 June 30, 2019, net of the associated deferred revenues of $2.0 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;
- Inventories of $2.0 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 $57.2 million, primarily related to the collection of $43.9 million from Astellas for the roxadustat API delivery in December 2018 under an amendment to the Japan Agreement, 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 $8.5 million primarily due to the accrual of co-promotional expenses for our preparation for commercial operation that is not expected to be paid in the next year.

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 $209.9 million for the six months ended June 30, 2020 and consisted primarily of $201.9 million of proceeds from maturities of investments, and $10.6 million of proceeds from sales of available-for-sale securities.

Net cash used in investing activities was $7.7 million for the six months ended June 30, 2019 and consisted of cash used in purchases of available-for-sale securities and term deposit of $105.5 million and purchased of property and equipment of $2.2 million, partially offset by proceeds from maturities of investments of $100.0 million.

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 $3.5 million for the six months ended June 30, 2020 and consisted primarily of $16.5 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 $6.9 million of cash paid for payroll taxes on restricted stock unit releases, and $6.0 million of repayments of finance lease liabilities.

Net cash used in financing activities was $0.8 million for the six months ended June 30, 2019 and consisted primarily of $8.1 million of cash paid for payroll taxes on restricted stock unit releases and $5.9 million of repayments of finance lease liabilities partially offset by $13.3 million of proceeds from the issuance of common stock upon exercise of stock options and purchases under our ESPP.

Off-Balance Sheet Arrangements

During the three and six months ended June 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 June 30, 2020, we had outstanding total non-cancelable contract obligations of $26.2 million, including $14.2 million for manufacture and supply of roxadustat (including $12.1 million for the above-mentioned agreement), $10.7 million for future milestone payments for research and pre-clinical stage development programs, and $1.1 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 six months ended June 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 control of 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 management's evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of June 30, 2020 at the reasonable assurance level.

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 June 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.

Risks Related to Our Financial Condition and History of Operating Losses

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 chronic kidney disease ("CKD"), myelodysplastic syndromes ("MDS"), and chemotherapy-induced anemia, and pamrevlumab in idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer, Duchenne muscular dystrophy ("DMD"), and Severe Acute Respiratory Syndrome Coronavirus 2019 Disease ("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 June 30, 2020, we had an accumulated deficit of $948.4 million. As of June 30, 2020, we had capital resources consisting of cash, cash equivalents and short-term investments of $685.6 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 AB ("AstraZeneca") and Astellas Pharma Inc. ("Astellas"), and the potential to receive milestone and other payments from these partners, and despite commercialization efforts in the People's Republic of China ("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.

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 China for CKD anemia for patients on dialysis and not on dialysis, and for roxadustat in Japan for CKD anemia in dialysis patients, we 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 and 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 IPF, pancreatic cancer, 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.

The clinical and commercial success of roxadustat and pamrevlumab will depend on a number of factors, many of which are beyond our control, and we may be unable to complete the development or commercialization of roxadustat or pamrevlumab.*

The clinical and commercial success of roxadustat and pamrevlumab will depend on a number of factors, including the following:

- the timely initiation and completion of our clinical trials, including for the duration of the COVID-19 pandemic, which could cause delays in our clinical trial initiation and patient enrollment and completion;
- our ability to demonstrate the safety and efficacy of our product candidates to the satisfaction of the relevant regulatory authorities;

- the ultimate approval criteria (which may include non-inferiority margins and statistical analyses methods), indications, patient populations, and ultimate benefit-risk analysis used by regulatory authorities in their approval processes;
- whether we are required by the United States ("U.S.") Food and Drug Administration ("FDA") or other regulatory authorities to conduct additional clinical trials, and the scope and nature of such clinical trials, prior to approval to market our products;
- the clinical indications for which the product is approved and the labeling required by regulatory authorities for use with the product, including any warnings that may be required in the labeling;
- the receipt or timely receipt of marketing approvals from the FDA and foreign regulatory authorities, including pricing and reimbursement determinations;
- the ability to successfully commercialize, market, sell and distribute our product candidates, if approved, for marketing and sale by the FDA or foreign regulatory authorities, whether alone or in collaboration with others;
- whether we or our partners are able to recruit and retain adequate numbers of effective sales and marketing personnel for the sale of our products;
- whether we will maintain sufficient funding to cover the costs and expenses associated with creating and sustaining a capable sales and marketing organization and related commercial infrastructure;
- whether we can compete successfully as a new entrant in the treatment of anemia caused by CKD;
- our ability and the ability of our third-party manufacturing partners to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability;
- our success in educating health care providers, patients and the healthcare community about the benefits, risks, administration and use of our product candidates, if approved;
- acceptance of our product candidates, if approved, as safe and effective by patients and the healthcare community;
- the success of efforts to enter into relationships with large dialysis organizations involving the administration of roxadustat to dialysis patients;
- the achievement and maintenance of compliance with all regulatory requirements applicable to us and our product candidates;
- the maintenance of an acceptable benefit/risk profile of our products following any approval;
- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competitive treatments;
- the restrictions on the use of our products together with other medications, if any;
- our ability to negotiate, obtain and sustain an adequate level of pricing or reimbursement for our products by third-party payors;
- the availability of adequate coverage and reimbursement or pricing by third-party payors and government authorities;
- our ability to enforce successfully our intellectual property rights for our product candidates and against the products of potential competitors;
- our ability to avoid or succeed in third-party patent interference or patent infringement claims; and
- sufficient stability data for launch and market supply.

Many of these factors are beyond our control. Successful commercialization of our products will require significant resources and time, and there is a risk that we may not successfully commercialize them. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our products and generate revenues, which would deprive us from additional working capital and would materially harm our ability to achieve profitability through the sale of or royalties from our product candidates.

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, either directly or 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 or little 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 setting our marketing, pricing and reimbursement strategy, facilitating adoption by hospitals, 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 for our product candidates 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 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 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 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 clinical research organizations ("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 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, controlled Phase 3 clinical trials required for approval.

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;
- 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 Phase 3 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 the 2019 Form 10-K 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 third-party manufacturers and other service providers on which we rely cannot manufacture sufficient quantities of our products and product candidates, or at sufficient quality, or perform other services we require, 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.

The FDA and European Medicines Agency ("EMA") will do their own benefit risk analysis and may reach a different conclusion than we or our partners have internally, 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 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, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.*

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. Price listing for and subsequent launch of vadadustat in Japan is expected in Q3 2020. 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. 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 and subsequent launch of daprodustat in Japan is expected in Q3 2020. 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 submitted an NDA for treatment of anemia associated with CKD in Japan in November 2019, supported by the six Phase 3 studies conducted in CKD patients on dialysis and not on dialysis in Japan, 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 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. Two domestic companies, Jiangsu Hengrui Medicine Co., Ltd. and Guandong Sunshine Health Investment Co., Ltd, have been permitted by the NMPA to conduct clinical trials for CKD anemia patients both on dialysis and not on dialysis, and 3SBio Inc. has submitted a clinical trial application to the NMPA to initiate trials for their HIF-PH inhibitor. 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. 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. DaVita has a six-year sourcing and supply agreement with Amgen effective through 2022. Fresenius' contract with Amgen expired in 2015, following which Fresenius is providing Roche's ESA Mircera® to a significant portion of its U.S. dialysis patients. 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, Catabasis Pharmaceuticals ("Catabasis"), Santhera Pharmaceuticals ("Santhera") and Sarepta. Pfizer initiated a Phase 3 study with PF-06939926, its AAV9 mini-dystrophin gene therapy for DMD in February 2020. Catabasis' edasalonexent was reported to have preserved muscle function and slowed the progression of DMD compared to rates of change in the control period prior to treatment with edasalonexent in a Phase 2 study, and is currently undergoing Phase 3 development. Santhera's Puldysa® (idebenone) MAA for treatment of DMD was filed with the EMA in May 2019, and the opinion from the Committee for Medicinal Products for Human Use is expected in the third quarter of 2020. The FDA requested additional clinical data from the idebenone Phase 3 trial currently ongoing in the U.S. and Europe. Santhera offers compassionate use of idebenone in patients with DMD in U.S. and UK. Sarepta's SRP-9001 is an investigational gene therapy for DMD. Sarepta announced in December 2019 the licensing agreement with Roche that grants Roche the commercial rights to SRP-9001 outside the U.S.

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 /MACE 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, we or our partner 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 as a result of the current and potential future impacts on our commercialization efforts, supply chain, regulatory and clinical development activities, and other business operations, in addition to the impact of a global economic slowdown.*

Our business could be adversely affected by the effects of the COVID-19 pandemic, which has resulted in various and evolving government-mandated 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 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. Certain jurisdictions have begun re-opening only to return to restrictions in the face of increases in new COVID-19 cases. 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, our staff have returned to work in our offices, manufacturing plants, and are performing medical affairs out in the field.

Most of our, and our partners', commercial launch activities are continuing, and have resumed in China after the government shutdown during February and March. However, sales growth of roxadustat may be slowed due to continued social distancing measures, behaviors, or other restrictions. If there are any further COVID-19 outbreaks, we or our partners may need to re-institute or tighten restrictions on our operations.

While our clinical trials for MDS, CIA and locally advanced pancreatic cancer have continued to enroll, enrollment for IPF was paused at the beginning of the second quarter and has since 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 slowed or paused 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, we could face shortages in our global supply chains.

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.

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 with Astellas or AstraZeneca were terminated, if Astellas or AstraZeneca were to prioritize other initiatives over their collaborations with us, whether as a result of a change of control or otherwise, if conflicts arise between us and Astellas or AstraZeneca, or if Astellas or AstraZeneca becomes our competitor in the future, 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 fail to 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 we and our collaboration partners, Astellas and AstraZeneca, must reach consensus on our development programs and regulatory activities, including for the NDA in the U.S. and the MAA in Europe. 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.

We rely on third parties for the conduct of most of our preclinical and clinical trials for our product candidates, and if our third-party contractors do not properly and successfully perform their obligations under our agreements with them, 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 time period. 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 not perform satisfactorily.*

We do not have operating manufacturing facilities at this time other than our roxadustat manufacturing facility in China, and our current commercial manufacturing facility 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.

Other than for Catalent, our commercial third-party supplier of roxadustat drug product in the U.S. and Europe, most of our other third-party manufacturers may terminate their engagement with us at any time and we have not yet entered into any commercial supply agreements for the manufacture of drug substance, API, or drug products. 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 of the components of our product candidates are acquired from single-source suppliers and have been purchased without long-term supply agreements. The loss of any of these suppliers, or their failure to supply us with supplies of sufficient quantity and quality to complete our drug substance or finished drug product of acceptable quality and an acceptable price, 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 FibroGen 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 with third parties and competitors 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, we or our collaboration partners 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 U.K., 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 FibroGen, maintaining our intellectual property in all relevant scope.

On April 20, 2020, in response to an invalidation action brought against certain FibroGen UK patents by Akebia, the UK court handed down a decision invalidating UK designations of European Patent Nos. 1463823, 1633333, 2298301, 2322153, and 2322155. The UK 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 UK Court of Appeal. We note that narrowing or even 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.

We have an extensive worldwide patent portfolio. The cost of maintaining our patent protection is high and maintaining our patent protection requires continuous review and compliance in order to maintain worldwide patent protection. 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 the commercialization of 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 relationships with customers, physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

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 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 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 ("PPACA"), which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare and 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 penalties, including civil and criminal penalties, damages, fines, 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 develop, maintain, and implement 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.

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 Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, (collectively, 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. It is unclear how this decision, future decisions, subsequent appeals, 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 2020 contains further drug price control measures that could be enacted during the budget process or in other future legislation. In addition, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional 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. 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 us and our partners.*

Roxadustat is considered a Class 2 substance on the World Anti-Doping Agency ("WADA") 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 other improper activities, including noncompliance with regulatory standards and requirements, which could result in significant liability for us and 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 and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

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 are establishing international operations and seeking approval to commercialize our product candidates outside of the U.S., in particular in China, 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*" 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 are establishing a jointly owned Distribution 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 plan to use our own manufacturing facilities in China to produce roxadustat API and roxadustat drug product. As an organization, we have limited experience in the construction, licensure, and operation of a manufacturing plant, and accordingly we cannot assure you we will be able to continually meet regulatory requirements to operate our plant and to sell our products.*

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.

In addition to manufacturing, we are responsible for pharmacovigilance, medical affairs, and management of the third-party distribution logistics for roxadustat in China. We have no experience in these areas as a company, and accordingly we 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 the Distribution Entity) 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 control, including periodic downward adjustment, by Chinese government authorities.

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.

If our planned business activities in China fall within a restricted category under the China Catalog for Guidance for Foreign Investment, we will need to operate in China through a variable interest entity ("VIE") structure.

The China Catalog for Guidance for Foreign Investment sets forth the industries and sectors that the Chinese government encourages and restricts with respect to foreign investment and participation. The Catalog for Guidance for Foreign Investment is subject to revision from time to time by the China Ministry of Commerce. While we currently do not believe the development and marketing of roxadustat falls within a restricted category under the Catalog for Guidance for Foreign Investment, if roxadustat does fall under such a restricted category, we will need to operate in China through a VIE structure. A VIE structure involves a wholly foreign-owned enterprise that would control and receive the economic benefits of a domestic Chinese company through various contractual relationships. Such a structure would subject us to a number of risks that may have an adverse effect on our business, including that the Chinese government may determine that such contractual arrangements do not comply with applicable regulations, Chinese tax authorities may require us to pay additional taxes, shareholders of our VIEs may have potential conflicts of interest with us, and we may lose the ability to use and enjoy assets held by our VIEs that are important to the operations of our business if such entities go bankrupt or become subject to dissolution or liquidation proceedings. VIE structures in China have come under increasing scrutiny from accounting firms and the Securities and Exchange Commission ("SEC") staff. If we do attempt to use a VIE structure and are unsuccessful in structuring it so as to qualify as a VIE, we would not be able to consolidate the financial statements of the VIE with our financial statements, which could have a material adverse effect on our operating results and financial condition.

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.*

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 June 30, 2020, approximately $11.9 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 ("SAFE") by complying with certain procedural requirements. However, approval from SAFE 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, we and our foreign subsidiaries 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, political or social conditions or government policies could have a material adverse effect on our business and operations.

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 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 ability to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.*

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 be required to limit commercialization of our product candidates.

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 to operate our business and a cyber-attack or other breach of these systems could have a material adverse effect on our business.

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. The occurrence of an earthquake, fire or any other catastrophic event could disrupt our operations or the operations of third parties who provide vital support functions to us, which could have a material adverse effect on our business, results of operations and financial condition.*

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.

If securities or industry analysts do not continue to publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

As of July 31, 2020, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 40.03% 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 future acquisitions that could disrupt our business, cause dilution to our stockholders and harm our business, results of operations, financial condition and cash flows and future prospects.

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, even if an acquisition would be beneficial to our stockholders, 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, as well as rapidly changing trade relations, could have a material adverse effect on our business and results of operations.

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 amended and restated certificate of incorporation designates the state or federal courts located in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, 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 federal district courts of the United States of America 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.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain and you may never receive a return on your investment.

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*+	Offer Letter, by and between FibroGen, Inc. and Thane Wettig, dated as of May 7, 2020.	—	—	—	—
10.2*†	Amendment No. 1 to Master Supply Agreement by and among FibroGen, Inc., Shanghai SynTheAll Pharmaceutical Co., Ltd. and STA Pharmaceutical Hong Kong Limited, effective as of May 11, 2020.	—	—	—	—
10.3*†	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.	—	—	—	—
10.4*†	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.	—	—	—	—
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
\+ Indicates a management contract or compensatory plan
† 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: August 6, 2020

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

Dated: August 6, 2020

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

Exhibit 10.1

May 7, 2020

Thane Wettig
[PRIVATE ADDRESS]

Dear Thane,

FibroGen, Inc. is pleased to offer you the position of Chief Commercial Officer reporting to Enrique Conterno, Chief Executive Officer. The effective date ("**Effective Date**") of your employment will be set, as mutually agreed upon in advance with FibroGen, Inc. ("**FibroGen**") and confirmed with Human Resources.

This offer of employment is made contingent upon successful completion of FibroGen's background check or upon completion of all required documentation that will be made available to you on the Effective Date or by your intended start date. This includes verification of the information provided online and your employment application. If necessary, you will be contacted to resolve any discrepancies in the verification of information. Your employment hire date will be determined after the completion of the background check process and your signed acceptance of this offer.

The terms of this offer of employment are as follows:

1. Compensation. FibroGen will pay you a starting annual salary of $500,000, payable in semi-monthly installments on our regular paydays in accordance with FibroGen's standard payroll policies. Your salary will begin as of the Effective Date. The position is classified as exempt and therefore not eligible for overtime pay. The first and last payment by FibroGen to you will be adjusted, if necessary, to reflect a commencement or termination date other than the first or last working day of a pay period.

2. Signing Bonus. FibroGen will pay you a sign-on bonus in the amount of $150,000 (subject to applicable payroll taxes and withholdings) paid out after you have completed 60 days of employment.

3. Stock Options and Restricted Stock Units. Pending approval by the FibroGen Compensation Committee, you will be granted the following equity incentive grant(s) pursuant to the terms and conditions of the Equity Plan effective on the date of acceptance of this letter (the "**Equity Plan**"), as may be amended or modified from time to time:

   - a stock option to purchase 90,000 shares of FibroGen's Common Stock with an exercise price set at the fair market value on the date of grant ("**Stock Options**"); and
   - a grant of 30,000 restricted stock units relating to shares of FibroGen's Common Stock ("**RSUs**").

   The actual number of shares subject to the grant hereunder may be adjusted, if required, for events such as stock splits, stock dividends, etc. pursuant to the Equity Plan. The Stock Options and RSUs will vest according to the schedule set forth in the Equity Plan.

4. Bonus Plan. You will be eligible to participate in FibroGen's Incentive Compensation Plan (the "**Bonus Plan**") adopted by FibroGen for its employees on such terms as FibroGen's Board of Directors (the "Board") may determine in its discretion.

   The target bonus for your level is 50%. Under the terms of the Plan, both corporate and individual performance is assessed annually and subject to final approval by the Company's Board of Directors. Employees hired during the course of a year will have a pro-rated bonus provided they commence their employment on or before September 30th of a calendar year. To remain eligible, employees must maintain satisfactory performance and be in an active status on the day of payment. Payments are expected to occur no later than the 15th of March in the year following the performance cycle.

5. Relocation. FibroGen will offer you Relocation assistance in the amount of $75,000 (subject to applicable payroll taxes and withholdings) once you acknowledge the services being provided to you via our third-party vendor NuCompass.

6. Benefits. During the term of your employment, you will be eligible to participate in FibroGen's benefits program, which may include FibroGen's standard vacation benefits and other employee benefits such as medical, vision and dental health insurance, covering employees and officers. These benefits may be modified or subject to change from time to time. A copy of FibroGen's current benefits summary has been provided to you.

7. Employment Eligibility. You will also be required to sign the Employment Eligibility Verification (Form I- 9). (You will need to complete and return Section One of Form I-9 along with your signed offer letter). On your first day of employment, please bring the necessary original documents that establish your identity and employment eligibility to work in the United States. Acceptable documents are listed on the reverse side of Form I-9. Such documentation must be provided to us within three (3) business days of your date of hire, or our employment relationship with you may be terminated.

8. Proprietary Information. You will abide by FibroGen's strict company policy that prohibits any new employee from using or bringing with them from any prior employer any proprietary information, trade secrets, proprietary materials or processes of such former employers. Moreover, because FibroGen's proprietary information is extremely important, this offer of employment is expressly subject to your execution of the enclosed Confidential Information, Secrecy and Invention Agreement for Employees.

9. At Will Employment. You should be aware that your employment with FibroGen is for no specified period and constitutes "at-will" employment. As a result, both FibroGen and you are free to terminate the employment relationship at any time, for any reason or for no reason, and with or without advance notice. The changing needs of FibroGen could also result in changes to certain aspects of your employment, such as compensation, responsibilities, location, etc. These provisions expressly supersede any previous representations, oral or written. Your at-will employment cannot be modified or amended except by written agreement signed by both you and the Chief Executive Officer of FibroGen.

10. Arbitration. Any dispute or claim, including all contract, tort, discrimination, and statutory claims, arising under or relating to your employment or termination of your employment with FibroGen ("Arbitrable Claim(s)") shall be resolved by arbitration. "Arbitrable Claims" shall not include: (1) claims under applicable workers' compensation law, (2) unemployment insurance claims, and (3) any disputes or claims relating to or arising out of the misuse or misappropriation of trade secrets. You and FibroGen hereby waive any rights each may have to a jury trial in regard to Arbitrable Claims. Arbitration for Arbitrable Claims will be conducted by the American Arbitration Association ("AAA") in San Francisco (or other mutually agreed upon city) under the Employment Arbitration Rules and Mediation Procedures ("AAARules").TheAAARulesareavailableat https://www.adr.org/sites/default/files/EmploymentRules_Web_0.pdf, or can be obtained by contacting the FibroGen Human Resources department or by calling AAA at 800-778-7879. FibroGen will pay the fees and costs of the arbitrator. The arbitrator shall have the same authority as a court to award equitable relief, damages, costs, and fees (excluding the costs and fees for the arbitrator) as provided by law for the particular claims asserted. The arbitrator shall also have exclusive authority to rule on his or her own jurisdiction, including any objections with respect to the existence, scope, enforceability or validity of the arbitration agreement. Such arbitration shall be final and binding on the parties and shall be the exclusive remedy for Arbitrable Claims.

Unless otherwise notified by FibroGen, this offer of employment is effective for five business days from the date of this letter. However, if you have any questions regarding the above provisions including the arbitration provision, please do not hesitate to contact us.

In the event of conflict between the terms contained in this offer letter and any other document, the terms of this offer letter (including any amendment to this letter) shall control. FibroGen reserves the right to amend the terms contained in this offer letter from time to time.

We look forward to your joining our team at FibroGen. Sincerely,

/s/ Richard Farley
Richard Farley
Vice President, Human Resources

/s/ Thane Wettig
Thane Wettig

June 22, 2020
Intended Start Date

Enclosures: Benefits Overview

[*] = 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

Confidential

AMENDMENT NO. 1 TO MASTER SUPPLY AGREEMENT

THIS AMENDMENT NO. 1 (the "First Amendment") is effective as of May 11, 2020 (the "First Amendment Effective Date") by and among: FibroGen, Inc. and its Affiliates (collectively, "**FibroGen**"); and Shanghai SynTheAll Pharmaceutical Co., Ltd (d/b/a "上海合全药业有限公司") ("**Shanghai STA**"); and STA Pharmaceutical Hong Kong Limited (d/b/a "合全药业香港有限公司") ("**STA Hong Kong**") (STA Hong Kong, Shanghai STA, and each of their Affiliates are collectively referred to as "**STA**"). This First Amendment amends the Master Supply Agreement entered into by and between STA and FibroGen on March 2, 2020 (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 First Amendment are collectively, "the Agreement".

WHEREAS, the Parties desire to amend the Master Supply Agreement to allow for the Parties' agreement on Work Orders for Other Services (both terms defined hereunder), including development related work hereunder; and

WHEREAS, as further set forth in Sect. 5.1.4, the Parties agree that if any Product resulting from such Work Orders for Other Services can be used commercially or converted into another Product at a later date, FibroGen will be given an applicable rebate or credit based on that Product that is the result of the conversion to be used later; and

WHEREAS, the Parties desire to continue the relationship as set forth under the Master Supply Agreement as amended by this First 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 First Amendment shall have the meaning ascribed to them in the Master Supply Agreement.

(2) Sect. 2.1.1 of the Master Supply Agreement is hereby deleted in its entirety and replaced with the following:

> "This Agreement establishes the general terms and conditions applicable to STA's manufacturing and supply of Products to FibroGen. This Agreement is intended to allow the Parties to contract for the (i) performance of manufacturing and supply of one or more Products through the execution of separate written orders or Forecasts, and (ii) performance of Other Services (defined in Sect. 2.1.2), in accordance with and consistent with this Agreement. Each Binding Forecast, Work Order or Stockpile Order shall become part of and incorporated by reference into this Agreement as a separate written order and each Binding Forecast, Work Order or Stockpile Order shall be subject to all of the terms and conditions of this Agreement. Any changes to a Binding Forecast, Work Order or Stockpile Order shall be agreed to in a signed writing by the Parties prior to any such changes being effective."

(3) All other references to "Binding Forecast or Stockpile Order", "Forecast or Stockpile Order", "Forecasts and Stockpile Orders" in the Master Supply Agreement shall be deemed to include "Work Order(s)" as the particular context requires.

(4) Sect. 2.1 of the Master Supply Agreement is hereby amended to include the following new provision, Section 2.1.2 (Other Services):

> "2.1.2 Other Services. On an as needed basis, through the mutual execution of Work Orders (defined in Sect 2.1.3 of this Agreement) by the Parties, STA shall provide other manufacturing services related to validation or qualification to ensure compliance with the Manufacturing Process of Product under this Agreement and supply of Products manufactured in such validation and qualification('**Other Services**'). Each Work Order for Other Services shall be governed by the terms and conditions of this Agreement (including the Draw-Down Prices set forth on **Exhibit C**), as also described on Sect. 5.1.4 hereof."

(5) Sect. 2.1 of the Master Supply Agreement is hereby further amended to include the following new provision, Section 2.1.3 (Work Orders):

> "2.1.3 Work Orders. Each Work Order for Other Services shall set forth the following as applicable: (a) Description of Other Services to be provided or description and quantity of Product ordered in metric tons (MT) or kilogram (kg) to be manufactured and supplied by STA; (b) Description of output, deliverables, or documentation to be delivered by STA as a result of such Other Services; (c) Date for completion of the Other Services by STA, and other relevant timeframes; (d) FibroGen Materials being provided by or on behalf of FibroGen, (e) Storage/handling; (f) Shipping terms; (g) STA Facility where Other Services will be performed; (h) STA and FibroGen contacts for Work Order, (i) Compensation, payment/payment schedule, and invoicing; and (j) any other details relevant to the Work Order."

(6) In order to expand the definition of "Manufacturing Services" to include "Other Services", the first sentence of Section 2.3.2 of the Master Supply Agreement is hereby deleted in its entirety and replaced with the following:

> "Such manufacture and supply of Product and such provision of other deliverables, such as the Batch Document Package, and Other Services (collectively, the "**Manufacturing Services**") shall be performed in a professional manner consistent with industry standards and in compliance with the terms and conditions of this Agreement, the Quality Agreement, the Specifications, and all Applicable Laws."

(7) Section 5.1 is hereby amended to include a new Section 5.1.4 (Draw-Down Prices and Credit for Work Orders) as follows:

> "5.1.4 Draw-Down Prices and Credit for Work Orders. The Parties agree that if any Product resulting from the Work Orders for Other Services executed under this Master Supply Agreement can be used commercially or converted into another Product at a later date, FibroGen will be given an applicable rebate or credit based on that Product that is the result of the conversion to be used later. For example, once STA produces Xkg of FG-[*] under a Work Order, and FibroGen pays for FG-[*] to be converted into FG-[*], FibroGen would not expect that FG-[*] be replenished and would therefore receive a reduction in price for the FG-[*].

For FG-6343 that are qualified on commercial scale that may be transferred into the normal ongoing manufacturing, the portion of the costs shall be deducted from normal delivery costs for FG-[*] or FG-[*], subject to the pricing and conversion costs set forth on **Exhibit C**, and as further described on **Exhibit C**. To further elaborate, once FibroGen pays for a separate Work Order for making FG-[*] (to qualify a new source of FG-[*]), FibroGen shall be deemed to have paid for FG-[*]. When the Parties move forward to [*], FibroGen shall only be responsible for paying [*]."

(8) Exhibit C is hereby amended to state the following: "If FibroGen provides FG-[*] and STA manufactures FG-[*], the cost to convert Product (once it is qualified) to FG-[*] or FG-[*] shall be the prices set forth on this **Exhibit C**."

(9) This First Amendment, together with the Master Supply Agreement, 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 First Amendment.

(10) This First 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 First Amendment to the Master Supply Agreement as of the First Amendment Effective Date.

STA PHARMACEUTICAL HONG KONG LIMITED

By: /s/ Fu Xiaoyong
Name: Fu Xiaoyong
Title: SVP
Date: 6/3/2020 6:04:49 PM PDT

FIBROGEN, INC.

By: /s/ Michael Martinelli
Name: Michael Martinelli
Title: SVP Tech Dev
Date: 6/3/2020 7:17:51 PM PDT

SHANGHAI SYNTHEALL PHARMACEUTICAL CO., LTD.

By: /s/ Fu Xiaoyong
Name: Fu Xiaoyong
Title: SVP
Date: 6/3/2020 6:04:49 PM PDT

Exhibit 10.3

Execution Version

CONFIDENTIAL

SECOND AMENDED AND RESTATED

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

(CHINA)

between

FIBROGEN CHINA ANEMIA HOLDINGS, LTD.; FIBROGEN (CHINA) MEDICAL TECHNOLOGY DEVELOPMENT CO., LTD.; FIBROGEN INTERNATIONAL (HONG KONG) LIMITED

and

ASTRAZENECA AB (PUBL)

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Exhibit D	–	Net Profit and Net Loss Calculations
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LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (CHINA)

This Second Amended and Restated License, Development and Commercialization Agreement (China) (the **"Agreement"**) 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 KY1-9009 ("**FibroGen Cayman**"), FibroGen (China) Medical Technology Development Co., Ltd., (formerly Beijing FibroGen Medical Technology Development Co., Ltd.) a wholly foreign owned limited liability company having its principal place of business at 101-601, Unit 2, Building 7, No. 88, 6th Ke Chuang Street, Beijing Economic Technological Development Area, Beijing, 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 whose registered office is at SE-151 85 Södertälje, Sweden ("**AstraZeneca**"), on the other hand, is effective as of July 1, 2020 (the "**Second A&R Agreement Effective Date**") and with effect on such date amends and restates in its entirety the Original A&R Agreement (as defined below)). 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 entered into the Amended and Restated License, Development and Commercialization Agreement (China) dated as of October 16, 2014 (the "**Original A&R Agreement**"), pursuant to which FibroGen China and AstraZeneca agreed to commercialize certain therapies developed by FibroGen WFOE. Under the Original A&R Agreement, FibroGen WFOE retained the rights to the technology, and was responsible for registration, clinical trials, manufacturing and physician education with respect to the Products. FibroGen China also granted certain co-exclusive license rights to AstraZeneca with respect to such technology under the terms of the Original A&R Agreement.

D. The Parties desire to amend and restate the Original A&R Agreement as of the Second A&R Agreement Effective Date, including by reflecting their agreement to (i) create JVCo (as defined below) to be appointed as the exclusive distributor of the First Product in the JV Territory (other than with respect to certain provinces) and (ii) share in the profit and losses generated by the JVCo from the Commercialization of the First Product in the JV Territory in accordance with the provisions of **Exhibit D**.

E. FibroGen, Inc. ("**FibroGen**") and AstraZeneca AB entered into a License, Development and Commercialization Agreement, effective as of July 30, 2013, and amended and restated on October 16, 2014, as further amended with effect on the Second A&R Agreement Effective Date, for development, 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. Certain additional terms are defined only in **Exhibit D** and have the meanings set forth therein. 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 **"ACA"** has the meaning set forth in **Exhibit D**.

1.2 **"Acquiror"** has the meaning set forth in Section 15.5.

1.3 [*]

1.4 **"Actual Annual Loss"** has the meaning set forth in **Exhibit D**.

1.5 **"Actual Annual Profit"** has the meaning set forth in **Exhibit D**.

1.6 **"Actual COGS"** has the meaning set forth in **Exhibit D**.

1.7 **"Actual Commercialization Costs"** has the meaning set forth in **Exhibit D**.

1.8 **"Actual Costs"** has the meaning set forth in **Exhibit D**.

1.9 **"Actual Volume"** has the meaning set forth in **Exhibit D**.

1.10 **"Adjusted Applicable COGS Cap"** has the meaning set forth in **Exhibit D**.

1.11 **"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. For clarity, for purposes of this Agreement, JVCo is considered an Affiliate of FibroGen China.

1.12 **"Agreed AZ Affiliate"** has the meaning set forth in **Exhibit D**.

1.13 **"Alliance Manager"** has the meaning set forth in Section 2.4.

1.14 "**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.

1.15 **"Applicable COGS Cap"** has the meaning set forth in **Exhibit D**.

1.16 **"Assumed Volume"** has the meaning set forth in **Exhibit D**.

1.17 **"Astellas"** means Astellas Pharma, Inc.

1.18 **"Astellas Agreements"** means the Astellas EU Agreement and the Astellas Japan Agreement.

1.19 **"Astellas EU Agreement"** means the Anemia License and Collaboration Agreement between FibroGen and Astellas effective April 28, 2006, as amended from time to time.

1.20 **"Astellas Japan Agreement"** means the Collaboration Agreement between FibroGen and Astellas effective June 1, 2005, as amended from time to time.

1.21 **"AstraZeneca China"** means AstraZeneca Investment (China) Co., Ltd.

1.22 **"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.

1.23 **"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.

1.24 "**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.

1.25 **"AstraZeneca Technology"** means the AstraZeneca Patents, AstraZeneca Know-How, and AstraZeneca's and its Affiliates' interest in Joint Patents and Joint Inventions.

1.26 **"Audit"** has the meaning set forth in Section 10.4(e).

1.27 **"Auditor"** has the meaning set forth in Section 8.11(c).

1.28 **"AZ Profit/Loss Share"** has the meaning set forth in **Exhibit D**.

1.29 **"AZTC" means** AstraZeneca (Wuxi) Trading Co., Ltd..

1.30 **"Business Day"** means a day other than a Saturday, Sunday or bank or other public holiday in China, the Cayman Islands or Sweden.

1.31 **"Calendar Quarter"** means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1.

1.32 **"Calendar Year"** means each successive period of twelve (12) calendar months commencing on January 1.

1.33 **"CFDA"** means the China Food and Drug Administration or its successor.

1.34 **"Chargeable COGS"** has the meaning set forth in **Exhibit D**.

1.35 **"China Committee"** means the committee formed by the Parties as described in Section 2.2.

1.36 **"Clinical Trial"** means any human clinical trial of a Product.

1.37 **"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)).

1.38 **"Collaboration Inventions"** has the meaning set forth in Section 9.2.

1.39 **"Commercialization"** means 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.

1.40 **"Commercialization Budget"** has the meaning set forth in Section 5.2.

1.41 **"Commercialization License Agreement"** means the license agreement with respect to commercialization rights to be entered into between AstraZeneca China and JVCo. Once finalized, the Commercialization License Agreement shall be inserted as **Exhibit F-2** to this Agreement.

1.42 **"Commercialization Plan"** has the meaning set forth in Section 5.2.

1.43 **"Commercialization Services Agreement(s)"** has the meaning set forth in Section 5.1.

1.44 **"Commercially Reasonable Efforts"** means, with respect to a Party's obligations under this Agreement to Develop, Manufacture 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.

1.45 **"Committee"** means the China Committee, the Supply Committee or any other subcommittees established under Article 2, as applicable.

1.46 **"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).

1.47 **"Connected Dispute"** shall have the meaning set forth in Section 14.1.

1.48 **"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.

1.49 "**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.

1.50 "**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) [*].

1.51 **"CRO"** has the meaning set forth in Section 3.2(e)(i).

1.52 **"CSA Payment"** has the meaning set forth in **Exhibit D**.

1.53 **"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.

1.54 **"Cumulative Net Profit"** has the meaning set forth in **Exhibit D**.

1.55 **"Deferred Amount"** has the meaning set forth in **Exhibit D**.

1.56 **"Delivery Site"** has the meaning set forth in **Exhibit D**.

1.57 **"Detail"** means a face-to-face meeting, in an individual or group practice setting, between one or more physician prescribers and one or more representatives during which Product information is communicated in a manner consistent with the Commercialization Plan. When used as a verb, "Detail" or "Detailing" will mean to engage in a Detail.

1.58 **"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; (iii) Phase 4 Clinical Trials and Mandatory Post-Approval Safety Studies; and (iv) 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.

1.59 **"Development Budget"** means the budget associated with the activities conducted under a Development Plan for the Territory, detailing the anticipated Development Costs.

1.60 **"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 mark-up.

1.61 **"Development Plan"** has the meaning set forth in Section 3.2(a).

1.62 **"Dollar"** or **"$"** means United States dollar.

1.63 "**Drug Administration Law"** means the Drug Administration Law of the PRC and its implementing regulations, as amended from time to time.

1.64 "**Effective Date**" means the original effective date of this Agreement, being July 30, 2013.

1.65 **"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) [*].

1.66 **"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.

1.67 "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.

1.68 "FG-4592" means the molecule with the chemical structure set forth on **Exhibit A**.

1.69 "FG-6874" means the molecule in Development by FibroGen currently identified by FibroGen as "FG-6874".

1.70 "FGEN Commercialization Costs" has the meaning set forth in **Exhibit D**.

1.71 "FibroGen Contracting Parties" means FibroGen HK, FibroGen Cayman, and FibroGen WFOE.

1.72 "FGEN JVCo Operations Costs" has the meaning set forth in **Exhibit D**.

1.73 "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.

1.74 "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.

1.75 "FibroGen China Technology" means the FibroGen China Patents, FibroGen China Know-How, and FibroGen China's interest in Joint Patents and Joint Inventions.

1.76 **"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.

1.77 **"Final Statement"** has the meaning set forth in **Exhibit D**.

1.78 **"Finance Subcommittee"** has the meaning set forth in **Exhibit D**.

1.79 "**First Commercial Sale**" means, with respect to a Product, the first arm's length sale for monetary value by one of the Parties (or another entity designated by the Parties) to a Third Party in the Territory 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.

1.80 **"First Product"** means a Product containing FG-4592 as the sole active ingredient.

1.81 **"First Profitable Quarter"** has the meaning set forth in **Exhibit D**.

1.82 **"Fixed CSA Payment"** has the meaning set forth in **Exhibit D**.

1.83 **"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).

1.84 "**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.

1.85 **"HIF Compound"** means any compound that stabilizes hypoxia-inducible factor ("**HIF**") or that modulates HIF prolyl hydroxylase activity.

1.86 "**Indirect Taxes**" means VAT, sales taxes, consumption taxes and other similar taxes required by law to be disclosed on the invoice; provided that for purposes of **Exhibit D**, Indirect Taxes has the meaning set forth therein.

1.87 **"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.

1.88 **"Initial Development Plan"** has the meaning set forth in Section 3.2(b).

1.89 "**Initial Transfer Price**" has the meaning set forth in **Exhibit D**.

1.90 "**Innovation Indication**" has the meaning set forth in Section 3.2(a)(i).

1.91 **"Installment"** has the meaning set forth in **Exhibit D**.

1.92 "**Interim Period**" has the meaning set forth in **Exhibit D.**

1.93 **"Inventions"** has the meaning set forth in Section 9.2.

1.94 **"IP Committee"** has the meaning set forth in Section 9.1.

1.95 **"Joint Inventions"** has the meaning set forth in Section 9.2.

1.96 **"Joint Patent"** has the meaning set forth in Section 9.2.

1.97 **"JVCo"** means the limited liability company duly organized and validly existing under the laws of the PRC that shall be owned by AstraZeneca China and FibroGen WFOE, as more specifically described in Section 5.3.

1.98 **"JV Territory"** means the Territory other than Hong Kong SAR and Macau SAR.

1.99 **"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.

1.100 **"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.

1.101 **"Mandatory Post-Approval Safety Study Costs"** means the costs and expenses of conducting the Mandatory Post-Approval Safety Studies of a Product.

1.102 **"Manufacture" or "Manufacturing" or "Manufactured"** means all activities and operations involved in the manufacturing, filling and finishing, quality control testing, storage, releasing and packaging of the Products.

1.103 "**Manufacturing Approval**" means a Product License (yao pin sheng chan xu ke zheng 药品生产许可证) 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.

1.104 **"Manufacturing Plan**" has the meaning set forth in Section 6.2.

1.105 **"Marks"** has the meaning set forth in Section 9.11.

1.106 "**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.

1.107 **"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.

1.108 **"NDA"** means an application to the CFDA for Regulatory Approval in the Territory.

1.109 **"Net Loss"** has the meaning set forth in **Exhibit D.**

1.110 **"Net Profit"** has the meaning set forth in **Exhibit D.**

1.111 "**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, as applicable, (i) by AstraZeneca or its Affiliates (or Sublicensees), or (ii) with respect to the First Product, by JVCo as distributor within the JV Territory other than the WFOE Provinces (or, for WFOE Sales, FibroGen WFOE), (in each case as applicable, the "**Selling Party**") 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;

(b) amounts repaid or credited by reason of rejection, returns or recalls of goods, rebates or bona fide price reductions determined by AstraZeneca or its Affiliates 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 the Selling Party, as applicable, 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.

Net Sales will be calculated using the Selling Party'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.

With respect to Net Profit/Net Loss, "Net Sales" has the meaning set forth in **Exhibit D**.

1.112 **"Net Sales Price"** has the meaning set forth in **Exhibit D**.

1.113 "**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.

1.114 "**NRDL**" means National Reimbursement Drug List or its equivalent.

1.115 **"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.

1.116 **"Paid Transfer Price"** has the meaning set forth in **Exhibit D**.

1.117 **"Payable Transfer Price"** has the meaning set forth in **Exhibit D**.

1.118 **"Permitted Overages"** has the meaning set forth in **Exhibit D.**

1.119 **"Pharmacovigilance Agreement"** has the meaning set forth in Section 4.3.

1.120 **"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.

1.121 **"Phase 4 Clinical Costs"** means the costs and expenses of conducting the Phase 4 Clinical Trials of a Product.

1.122 **"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.

1.123 **"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.

1.124 **"Product Infringement"** has the meaning set forth in Section 9.6(a).

1.125 **"Product Liability Losses"** has the meaning set forth in **Exhibit D**.

1.126 "**Product Reimbursement**" means first inclusion of a Product into the NRDL or any Provincial Reimbursement Drug List in the Territory.

1.127 "**Product Revenues**" has the meaning set forth in **Exhibit D**.

1.128 **"Promote"** means to perform 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.

1.129 **"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.

1.130 **"Publication"** has the meaning set forth in Section 12.4(b).

1.131 **"Quarterly Net Profit/Loss"** has the meaning set forth in **Exhibit D**.

1.132 **"Quarterly Report"** has the meaning set forth in **Exhibit D**.

1.133 **"Quarterly Statement"** has the meaning set forth in **Exhibit D**.

1.134 **"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.

1.135 **"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.

1.136 "**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.

1.137 **"Remaining Transfer Price"** has the meaning set forth in **Exhibit D**.

1.138 "**RMB**" means Renminbi, the legal currency of the PRC.

1.139 "Shareholders' Agreement" or "SHA" means the shareholders' agreement by and among AstraZeneca China and FibroGen WFOE to be substantially on the terms set forth in **Exhibit J** and to be finalized and entered into following the Second A&R Agreement Effective Date.

1.140 "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.

1.141 "Supply Agreement" means the supply agreement to be entered into between FibroGen China and JVCo, as set forth in Section 5.3. Once finalized, the Supply Agreement will be inserted as **Exhibit F-1** to this Agreement.

1.142 "Supply Committee" has the meaning set forth in Section 6.9.

1.143 "**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, by expedited resolution in accordance with Section 14.8; or (b) a Regulatory Authority action or decision [*].

1.144 "Term" has the meaning set forth in Section 13.1.

1.145 "Territory" or "**China**" or "**PRC**" means the People's Republic of China (including Hong Kong SAR and Macau SAR, but excluding Taiwan region).

1.146 "Third Party" means any entity other than FibroGen China or AstraZeneca or an Affiliate of either of them.

1.147 "**Third Party Logistics Costs**" has the meaning set forth in **Exhibit D**.

1.148 "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.

1.149 "**Transaction Agreements**" means, collectively, this Agreement, Commercialization License Agreement, Trademark License Agreement, Supply Agreement, Commercialization Services Agreement(s), and the Shareholders' Agreement.

1.150 "Trademark License Agreement" means the trademark license agreement to be entered into between AstraZeneca China and JVCo. Once finalized, the Trademark License Agreement shall be inserted as **Exhibit F-3** to this Agreement.

1.151 **"Transfer Price"** has the meaning set forth in **Exhibit D**.

1.152 **"U.S."** means the United States of America (including all possessions and territories thereof).

1.153 **"Volume Increase Difference"** has the meaning set forth in **Exhibit D**.

1.154 **"WFOE Provinces"** has the meaning set forth in **Exhibit D**.

1.155 **"WFOE Sales"** has the meaning set forth in **Exhibit D**.

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 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. 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;

(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 Commercialization Plan or Commercialization Services Agreement(s);

(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 Supply Committee.

(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), (2) conduct of the Mandatory Post-Approval Safety Studies, including the Mandatory Post-Approval Safety Study Costs included in the Development Budget, (3) governmental pricing negotiations to establish the maximum allowable retail price, and (4) Manufacturing of Products (including the Manufacturing Plan); and

(ii) the Executive Officer of AstraZeneca will have final say with respect to Commercialization of Products in China (including (x) the Commercialization Plan and the Commercialization Budget therein, (y) except to the extent set forth in Section 2.2(e)(i)(3) with respect to governmental pricing negotiations, all pricing of Products, including for provincial tendering, and (z) the management of commercial discounting process), subject to Article 6; and

(iii) disputes with respect to whether a Technical Product Failure as defined in Section 1.143(a) has occurred will be resolved pursuant to Section 14.8 if the Executive Officers fail to reach consensus.

For clarity, the Executive Officers of each Party may not use their final say under this Agreement or the U.S. and RoW Agreement with respect to any failure of the China Committee to come to consensus on the approval of Actual Costs or any costs or expenses in excess of Permitted Overages.

(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 or its designated Affiliate 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 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 Global Franchise Head, Roxadustat (or an individual with an equivalent position for the Territory at AstraZeneca China) 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 (through its Affiliate, AstraZeneca China). 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 (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.

(iv) The Mandatory Post-Approval Safety Study Costs in the Development Budget shall be reasonably determined by FibroGen WFOE in light of the applicable requirements for the Mandatory Post-Approval Safety Studies.

(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 FGEN 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 [*] as provided in Section 8.5, including costs for supply of Collaboration Compound or Product as provided in Section 6.7. 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 [*] 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 [*] 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 [*] percent ([*]%) for the Calendar Quarter or [*] 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 [*]. The Parties shall negotiate and agree on a commercialization arrangement in relation to such Probe Compound. [*], 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 or other payment arrangement for Development Costs under Section 8.5 (as may be amended to include such Collaboration Compound) 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 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 (through its Affiliate, AstraZeneca China) 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. The Parties have defined and finalized 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, Manufactured, 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, effective July 8, 2014, between AstraZeneca on the one hand and FibroGen WFOE and FibroGen, Inc. on the other hand (such agreement, as amended to date, 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 (through its Affiliate, AstraZeneca China), 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. FibroGen WFOE and AstraZeneca (through its Affiliate, AstraZeneca China or AZTC) shall Promote, Detail, and perform other Commercialization activities and medical affairs activities with respect to the Products in the Field in the Territory as provided in this Article 5 and the terms set forth on **Exhibit C-1**, under the direction of the China Committee, and pursuant to the Commercialization Plan applicable to each Product. For clarity, the Parties agree that JVCo shall be the distributor of the First Product in the JV Territory, and that JVCo (or in the WFOE Provinces, FibroGen WFOE) shall engage AstraZeneca China's local Affiliate AZTC (or such other Affiliate as may be appointed in accordance with **Exhibit D**) to perform the Commercialization activities assigned to AstraZeneca in the Commercialization Plan initially pursuant to a commercial services agreement to be entered into between (i) AZTC on the one hand and (ii) JVCo and FibroGen WFOE on the other hand, or if the Parties so determine a separate commercial services agreement between AZTC and FibroGen WFOE (the "**Commercialization Services Agreement(s)**"); and *provided* that (a) AstraZeneca shall remain liable for AZTC's performance of or failure to perform Commercialization activities to the same extent as if it had performed such Commercialization activities itself and (b) AZTC shall undertake in writing obligations of confidentiality and non-use regarding Confidential Information, that are substantially the same as those undertaken by AstraZeneca pursuant to Article 12 hereof. When finalized, the Commercialization Services Agreement(s) shall be inserted as **Exhibit C-2** to this Agreement.

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"**). 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 Formation, Functions and Ownership of JVCo.

(a) Formation and Functions of JVCo. The Parties have agreed that, following the Second A&R Agreement Effective Date, FibroGen China and AstraZeneca (through its Affiliate, AstraZeneca China) shall pursue the transactions [*] where the Target [*] will serve as the JVCo and be the distribution entity for the First Product in the JV Territory other than the WFOE Provinces. In connection with the foregoing, [*]. To the extent permissible under applicable laws and regulations, the Parties shall include dispute resolution provisions in the SHA, Supply Agreement, Commercialization License Agreement, Trademark License Agreement, and/or Commercialization Services Agreement(s) that are consistent with the provisions of Section 14.1 relating to the treatment of Connected Disputes.

(b) Ownership of JVCo. The capitalization obligations and operational governance of JVCo will be set forth in the JVCo's Articles of Association and SHA. The ownership of JVCo will consist of FibroGen WFOE holding [*] of the equity interests in the registered capital of JVCo and AstraZeneca China holding the remaining [*] of the equity interests in the registered capital of JVCo.

(c) Mutual Covenants. The Parties hereby agree that they shall, or shall cause their relevant Affiliates to, exercise their respective voting rights and other rights as a shareholder of JVCo:

(i) in order (insofar as it is able to do so through the exercise of such rights) to give full effect to the terms of this Agreement and the rights and obligations of the Parties as set out in this Agreement; and

(ii) to procure that any director appointed by it to the board of directors of JVCo from time to time shall (subject to their fiduciary duties to JVCo and other applicable laws and regulations) exercise their voting rights and other powers and authorities in order (insofar as they are able to do so through the exercise of such rights, powers and authorities) to give full effect to the terms of this Agreement and the rights and obligations of the Parties as set out in this Agreement, [*], and that all operational matters of JVCo will be decided in accordance with the China Committee's specific responsibilities and the SHA.

(d) Arrangements During the Interim Period and Within the WFOE Provinces. The Parties agree that during the Interim Period and following the Interim Period within the WFOE Provinces, FibroGen WFOE shall perform its obligations in accordance with **Exhibit D** and this Agreement, including the reporting obligations in Section 5.5, the regulatory compliance obligations in Section 5.8, the cross-territorial restrictions in Section 7.6, and the recording keeping obligations in Section 8.11, with respect to the First Product in the JV Territory, and the Parties shall, if applicable, include reasonably equivalent obligations in the Shareholders' Agreement to the extent applicable to the activities that JVCo is to perform.

(e) Arrangements Following Termination of SHA. If, at any time during the term of this Agreement, JVCo is dissolved or sold to a Third Party, then the period of time from the date of the first such event until the termination of the last Transaction Agreement shall also be deemed an "Interim Period" and the provisions of this Agreement and **Exhibit D** shall be applied in accordance with the Interim Period arrangements set forth herein and therein.

5.4 Responsibilities. Except as otherwise described in the Commercialization Plan, AstraZeneca (through its Affiliate, AstraZeneca China) or its other designated Affiliate shall have the sole right and responsibility for distribution of Products in the Territory; provided that with respect to the First Product, within the JV Territory, AstraZeneca has agreed that it shall procure that AstraZeneca China (or its other designated Affiliate) agrees that: (a) during the Interim Period, FibroGen WFOE shall sell the First Product directly to Third Party distributors; (b) following the Interim Period, JVCo will be appointed as the exclusive distributor in the JV Territory (other than the WFOE Provinces and FibroGen WFOE shall sell the First Product directly to Third Party distributors within the WFOE Provinces) and AstraZeneca China shall grant JVCo commercialization rights in connection with such appointment pursuant to the Commercialization License between AstraZeneca China and JVCo**.** The Parties acknowledge that, under this Agreement and through AstraZeneca's participation in the development of the First Product since the Effective Date, AstraZeneca has rights to Commercialize and benefit from the Commercialization of the First Product. AstraZeneca will assign, license or delegate its contractual rights and obligations and its accrued rights with respect to Commercialization to AstraZeneca China or other designated Affiliate; provided that AstraZeneca shall remain liable for, Commercialization activities delegated to any AstraZeneca Affiliate including any such activities provided pursuant to the terms of the Commercialization Services Agreement(s). The Supply Agreement and the Commercialization Services Agreement will contain representations, warranties and covenants 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 any First Product 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.

5.5 Commercialization Reports. FibroGen China and AstraZeneca (through its Affiliate, AstraZeneca China) 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)).

5.6 Samples. Neither Party shall distribute any samples of Products without the prior written consent of the other Party.

5.7 Diligence; Subcontracts. Each Party shall use Commercially Reasonable Efforts to carry out the tasks assigned to it and its Affiliates under the Commercialization Plan and the Commercialization Services Agreement(s) in a timely and effective manner and in compliance with all applicable laws and regulations. Without limiting Section 5.1, 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.

5.8 Regulatory Compliance.

(a) Each of FibroGen China and AstraZeneca (through its Affiliate, AstraZeneca China) 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 5.8(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.

(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 5.8 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 5.8. In the event that the Parties have different understandings or interpretations of this Section 5.8 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 5.8 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;

(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 5.8; 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.

5.9 **Other Transaction Agreements**. The Parties shall finalize and enter into, or cause JVCo or AstraZeneca China (as applicable) to enter into, one or more Commercialization Services Agreements, the Supply Agreement, the Commercialization License Agreement, and the Trademark License Agreement within thirty (30) days following the Second A&R Agreement Effective Date or with respect to the SHA as soon as reasonably practical following such date. In addition, the Parties will amend the U.S. and ROW Agreement to be consistent with the amendments to final decision making with respect to the Territory as set forth in Section 2.2(e)(i) and (ii) of this Agreement.

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 Affiliates and Sublicensees requirements of Product for Development and Commercialization in the Territory under the terms of this Article 6 and in accordance with this Agreement; *provided* that with respect to a First Product, FibroGen WFOE shall supply JVCo with its requirements of the First Product for distribution in the JV Territory other than the WFOE Provinces in accordance with this Agreement the Manufacturing Plan, and the Supply Agreement. All Product supplied to AstraZeneca or is Affiliates (or Sublicensees) or JVCo by or on behalf of FibroGen WFOE under this Agreement will be supplied as finished product.

6.2 Manufacturing Plan. The manufacturing strategy for Manufacture of the First Product in the JV Territory shall be described in a reasonably detailed plan that describes [*] (each such plan, a **"Manufacturing Plan"**). All Manufacture and supply of the First Product pursuant to this Agreement for the JV Territory shall be conducted in accordance with the Manufacturing Plan and the Supply Agreement. All Manufacturing Plans with respect to the First Product in the JV Territory and subsequent revisions thereto will contain such information as the China Committee reasonably believes necessary for the successful Manufacture of the First Product in the JV Territory. [*], the Parties shall agree on an initial First Product Manufacturing Plan for review and approval by the China Committee, which initial Manufacturing Plan shall be based on FibroGen China's then-existing manufacturing plan for the First Product in the JV Territory.

6.3 Covenant. Except as expressly set forth in this Article 6 or the U.S. and RoW Agreement, AstraZeneca shall not have the right to Manufacture any Product anywhere in the world.

6.4 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.

6.5 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 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 JVCo 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 6.5, 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 6.5 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.

6.6 Quality Agreement. FibroGen WFOE and JVCo will negotiate in good faith and enter into a quality agreement at the same time as entering into the Supply Agreement. In the event of any inconsistency between the Supply Agreement and Article 6 of this Agreement with regard to matters relating to quality control and quality assurance, the terms of the quality agreement shall prevail.

6.7 Product Price. With respect to Products other than the First Product, the Parties will agree on pricing mechanisms for determining the price per unit of Product for the supply of such Products to AstraZeneca based on the then-current Commercialization Plan, [*].

6.8 Potential Cost Reductions. Through the Supply Committee, the Parties shall identify, discuss, and agree upon [*], and FibroGen WFOE shall use its Commercially Reasonable Endeavors to implement any steps or actions in accordance with the Manufacturing Plan agreed by the Supply Committee to effect cost reduction and efficiency improvements, [*].

6.9 Supply Committee. The Parties shall, within thirty (30) days following the Second A&R Agreement Effective Date, establish a Supply Committee (the "**Supply Committee**") with equal representation from each Party to oversee the establishment and operation of the commercial supply chain for the Products in the Territory. The Supply Committee shall meet each Calendar Quarter, or as otherwise agreed between the Parties. Decision making shall be by consensus and the team members from each shall jointly have one (1) vote. Disputes at the Supply Committee shall be handled by the China Committee. The Supply Committee shall have a chair selected by FibroGen China. The role of the chair shall be to convene and preside at meetings of the Supply Committee, to prepare and circulate agendas and to ensure the preparation of minutes. The Supply Committee' responsibilities shall include:

(a) Overseeing the construction and qualification of the FibroGen WFOE Beijing plant;

(b) Identifying any additional resource or capabilities needed to deliver the plant;

(c) Discussing and agreeing on the process for Manufacture of the Product in the Territory;

(d) Defining a China supply strategy for the Products in the Territory;

(e) Carrying out the supplier selection process and recommending suitable CMOs to the China Committee;

(f) Overseeing supply chain performance for the Products in the Territory;

(g) Identifying, discussing, and agreeing, in good faith, upon cost reduction and efficiency improvement opportunities as described in **Exhibit D**;

(h) Discussing, preparing, and approving for submission to the China Committee for approval, annual and interim amendments to the Manufacturing Plan for each Product for the Territory;

(i) Overseeing the implementation of the Manufacturing Plan;

(j) Monitoring logistical strategies, capacity planning, inventory levels for each Product for consistency with the forecasts or each Product in the Territory;

(k) Developing and agreeing to terms for the receiving, accepting and filling of orders and the delivery of the First Product to Third Parties by JVCo in the JV Territory; and

(l) Engaging in any other activities or assuming any other responsibilities delegated to it by the China Committee or as set forth in this Agreement or in the Supply Agreement.

ARTICLE 7

LICENSES AND EXCLUSIVITY

7.1 License to AstraZeneca. Subject to the terms and conditions of this Agreement, FibroGen China 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 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 does hereby grant to 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. The foregoing license shall not extend to or be sublicensed by FibroGen Cayman or any Affiliate of FibroGen Cayman to JVCo and, for clarity, any and all license grants to JVCo to perform its activities as contemplated hereunder shall be granted by AstraZeneca China pursuant to a Commercialization License Agreement entered into by JVCo.

7.3 Sublicensing. For clarity, the license granted by FibroGen Cayman to AstraZeneca in Section 7.1 may be sublicensed by AstraZeneca to: (i) AstraZeneca China or any other Affiliate of AstraZeneca or, directly or through an Affiliate, to JVCo in the Commercialization License Agreement, in each case, without any requirement of consent; provided that any 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 Promotion. Except for the promotion rights expressly granted to the Parties under this Agreement and except as otherwise permitted under an applicable Commercialization Plan or the Commercialization Services Agreement(s), neither Party shall be permitted to 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 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 or, if for the First Product in the JV Territory other than the WFOE Provinces, JVCo. 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 or JVCo's rights within the Territory, provided that any such exercise of rights by AstraZeneca or JVCo 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. The Parties acknowledge that, prior to the Second A&R Agreement Effective Date, AstraZeneca paid in full to FibroGen Cayman each of the following non-refundable, non-creditable license fees on or before the applicable date set forth below.

License Fees. Number	Due Date	Payment
[*]	[*]	[*]
[*]	[*]	[*]

8.2 Upfront Development Reimbursement. [*]

8.3 Development Milestone Payments.

(a) Development Milestone Payments. AstraZeneca has made or 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
[*]	[*]	[*]

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. FibroGen China acknowledges that, prior to the Second A&R Agreement Effective Date, payment for milestone events 1 through 6 above have been paid in full.

[*]

(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 non-creditable 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 or its designated Affiliate (where applicable based on information provided by JVCo) shall notify FibroGen Cayman and AstraZeneca 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, (i) prior to July 1, 2020, FibroGen China and AstraZeneca and (ii) on or after July 1, 2020, FibroGen China and AstraZeneca China, 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, which the Parties acknowledge has been paid in full by AstraZeneca as of the Second A&R Agreement Effective Date). AstraZeneca shall cause AstraZeneca China to share any costs and expenses arising under clause (ii) of this Section 8.5(a).

(b) Payments and Reports. All amounts payable to FibroGen China or AstraZeneca pursuant to this Section 8.5 shall be paid in Dollars prior to July 1, 2020, or after July 1, 2020 in RMB (which in the case of amounts payable by AstraZeneca, shall be paid by AstraZeneca China) unless otherwise agreed by the Parties, on a Calendar Quarter basis. Within fifteen (15) days if reasonably possible for AstraZeneca using reasonable endeavors to meet such timeline and in no event later than twenty (20) days after the end of each Calendar Quarter after the Second A&R Agreement 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 1.165).

8.6 Net Profit and Net Loss Share.

(a) General. For each Product, the Parties shall each be entitled to fifty percent (50%) of any Net Profits, and bear fifty percent (50%) of any Net Losses as described in Exhibit D. Notwithstanding anything to the contrary herein, the Parties acknowledge and agree that [*] AstraZeneca China and FibroGen WFOE shall each be entitled to receive fifty percent (50%) of any Net Profit, and bear fifty percent (50%) of any Net Loss, as applicable, for the First Product in the JV 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 milestone payments made by AstraZeneca under Section 8.3 and Section 8.4, which shall be paid in Dollars, all amounts payable and all calculations under this Agreement shall be made in RMB. Sales or costs and expenses shall be converted into Dollars or RMB, as applicable, in a manner consistent with FibroGen China's and AstraZeneca's (or if applicable, AstraZeneca China'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 or the Commercialization Services Agreement(s), with respect to Development Costs or Actual 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 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 Actual Costs are based on estimates or accruals with respect to the Products in the Territory, FibroGen China shall notify AstraZeneca or its designated Affiliate 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 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 hereby grants to FibroGen Cayman a non-exclusive, worldwide, sublicenseable license to such inventions and intellectual property rights for any and all purposes 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 1.220, 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).

(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 shared by the Parties equally under this Agreement (50%/50%); [*]. If such Party recovers monetary damages from such Third Party in such suit or action, such recovery shall be first allocated 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 shared by the Parties equally (50%/50%).

(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 shared by the Parties equally (50%/50%) under this Agreement; [*]. 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 shared by the Parties equally (50%/50%) 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. 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 shared by the Parties shared by the Parties equally (50%/50%) under this Agreement; [*]. 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 and any rights to use any such trademarks in connection with the First Product shall be as set forth in a trademark license agreement. 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 and Second A&R Agreement 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.

(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 China 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 China 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 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.

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.

(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.

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 (or its Affiliates) pursuant to this Agreement or any other Transaction Agreements 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 any other Transaction 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;

(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 or distributors (including JVCo), 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 made a joint public announcement of the execution of this Agreement and the U.S. and RoW Agreement on or promptly after the Effective Date.

(b) 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 AstraZeneca 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) Termination of the SHA. The SHA (or any equivalent agreement governs the rights and obligations of JVCo's shareholders) shall be terminated in accordance with the terms and conditions thereof.

(b) Licenses. The licenses granted in Article 7 shall terminate. Notwithstanding the foregoing, AstraZeneca shall, and if applicable shall cause AstraZeneca China to, grant 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

(c) 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.

(d) Transition Assistance. AstraZeneca shall, or shall cause its designated Affiliate to, 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 or its designated Affiliate 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 or its designated Affiliate is manufacturing bulk or finished Product under an agreement entered into pursuant to Section 6.5, then AstraZeneca shall, or shall cause its designated Affiliate to, 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 or its designated Affiliate 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 or its designated Affiliate a price equal to AstraZeneca's (or its designated Affiliate'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 (or its designated Affiliate's) actual cost to manufacture or acquire such supplies plus a mark-up of [*] of such actual cost.

(e) Ongoing Clinical Trials. As soon as practicable and subject to applicable law, including GCP, AstraZeneca shall or shall cause AstraZeneca China to 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.

(f) Remaining Inventories. FibroGen China shall have the right to purchase from AstraZeneca any or all of the inventory of Products held by AstraZeneca (or its Affiliate) 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 (or its Affiliate'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 does not elect to exercise such right AstraZeneca and its Affiliates 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.

(g) Effect of Termination by AstraZeneca at Will. If AstraZeneca terminates this Agreement under Section 1.243 (but not in the event of any other termination), AstraZeneca shall remain responsible for all Development Costs and all FGEN Commercialization Costs incurred by FibroGen China under the respective Development Plans and Commercialization Plans during the [*]. If AstraZeneca terminates this Agreement under Section 1.243 (but not in the event of any other termination), then (i) AstraZeneca shall cause AstraZeneca China to additionally pay to FibroGen Cayman or FibroGen WFOE, as applicable, all reasonable costs to transition any then-ongoing Clinical Trials of Products in the Territory being conducted by AstraZeneca at such time (if any) and (ii) AstraZeneca shall pay to FibroGen Cayman a payment of ten million Dollars ($10,000,000).

(h) 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.

(i) 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 5.8 (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 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 5.8.

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 Articles 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. It is also the expectation of the Parties that any disputes that arise under the SHA, Supply Agreement, Commercialization License Agreement, Trademark License Agreement, and/or Commercialization Services Agreement(s) are likely to be related to (or the source of) a dispute or disagreement under this Agreement, or raise issues or facts that are substantially the same as or connected with issues or facts raised in a dispute under this Agreement (a "**Connected Dispute**"). Accordingly, the Parties undertake to each other that they shall not, and shall procure that their respective relevant Affiliates that are parties to the SHA, Supply Agreement, Commercialization License Agreement, Trademark License Agreement, and/or Commercialization Services Agreement(s) shall not, initiate or otherwise commence any legal proceedings under the SHA, Supply Agreement, Commercialization License Agreement, Trademark License Agreement, and/or Commercialization Services Agreement(s) and shall, instead, seek to resolve the Connected Dispute in accordance with the provisions of this Section 14.1.

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 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 Articles 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 Articles 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 1.143(a), or resolved by the Parties, in the case of a Technical Product Failure as defined in Section 1.143(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 or its designated Affiliate 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.

(a) This Agreement specifically amends and restates the Original A&R Agreement as of the Second A&R Agreement Effective Date. Without limitation of the foregoing, this Agreement, including the Exhibits hereto, and the agreements referred to in this Agreement, 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 and the Second A&R Agreement 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/or Manufacturing 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 China:	FibroGen China Anemia Holdings, Ltd. FibroGen Medical Technology Development Co., Ltd. FibroGen International (Hong Kong Limited) c/o FibroGen, Inc. 499 Illinois St. 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
If to AstraZeneca:	AstraZeneca AB SE-151 85 Södertälje, Sweden Attention: Chief Financial Officer
With a copy to:	AstraZeneca UK Limited 1 Francis Crick Avenue Cambridge Biomedical Campus Cambridge CB2 0AA, England Email: legalnotices@astrazeneca.com Attention: Legal Department

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 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.

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. 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 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.

(a) 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.

(b) The Parties agree that the execution of this Agreement by industry standard electronic signature software or by exchanging PDF signatures will have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Agreement, each Party hereby waives any right to raise any defense or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

[Signature Page Follows]

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

FibroGen (China) Medical Technology Development Co., Ltd.

Chop:

FibroGen International (Hong Kong) Limited

By: /s/Christine Chung

Name: Christine Chung

Title: Director

In Witness Whereof, the Parties have executed this Agreement in duplicate originals by their duly authorized officers as of the Execution Date.

ASTRAZENECA AB

By: /s/ Elizabeth Bjork

Name: Elizabeth Bjork

Title: SVP, CVRM, BioPharma RD, AstraZeneca

[Signature Page to the Second Amended and Restated License, Development and Commercialization Agreement]

EXHIBITS

Exhibit A	–	Structure of FG-4592
Exhibit B	–	[Reserved]
Exhibit C-1	–	Certain Commercialization Terms
Exhibit C-2	–	Commercialization Services Agreement(s)
Exhibit D	–	Net Profit and Net Loss Calculations
Exhibit E	–	Initial Development Plan
Exhibit F-1	–	Supply Agreement
Exhibit F-2	–	Commercialization License Agreement
Exhibit F-3	–	Trademark License Agreement
Exhibit G	–	Listed Patents
Exhibit H	–	AstraZeneca's Anti-Corruption Rules and Policies
Exhibit I	–	Invoicing Requirements
Exhibit J	–	Terms for SHA

Exhibit A
Structure of FG-4592

[*]
[*]

Exhibit B

[RESERVED]

Exhibit C-1

Certain Commercialization Terms

Teams and responsibilities	The Parties agree that all activities allocated to AstraZeneca under this **Exhibit C-1** will be performed by, and all rights granted to AstraZeneca under this **Exhibit C-1** will be exercised by, AstraZeneca China. 1. AstraZeneca will have principal responsibility for promotion and Detailing activities. 2. AstraZeneca will hire, train, and manage the marketing team in accordance with budget and activities set forth in the Commercialization Plan. 3. 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 or FibroGen China 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. 4. 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.

	5. 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. 6. 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.
Pricing.	The Parties are committed to making first-in-class novel therapies available to Chinese patients on a cost-effective basis. [*] 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.
Commercialization Costs Fee	[*]

Exhibit C-2

Commercialization Services Agreement(s)

[To be inserted upon finalization]

Exhibit D

Net Profit and Net Loss Calculations of the First Product

[*]

* * *

EXHIBIT D-1

FINANCE SUBCOMMITTEE

Formation and Purpose. FibroGen China and AstraZeneca China (either itself or via its designated Affiliate) have established as of the Second A&R Agreement Effective Date a Finance Subcommittee (the "**FSC**"), which at all times 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 First Product 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) of this Agreement.

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 China. 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.

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 WFOE, 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, and any adjustment proposed to implement equal profit sharing in accordance with this Exhibit D.
- Review the Quarterly Statement to be prepared by FibroGen WFOE.
- Recommend minor amendments to implement the profit/loss sharing required by this 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, without escalation to the Executive Officers. 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.
- Agree on a process to invoice taking into account Indirect Taxes requirements.
- Establish the process for financial detail discussions between the Parties regarding the costs and expenses charged to the profit and loss calculations for the First Product.

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.

* * *

Schedule 1 and Schedule 2

[*]

Exhibit E

Initial Development Plan

[*]

Exhibit F-1

Supply Agreement

[To be inserted when finalized]

Exhibit F-2

Form of Commercialization License Agreement

[To be inserted when finalized]

Exhibit F-3

Form of Trademark License Agreement

[To be inserted when finalized]

Exhibit G

Listed Patents

[*Note: To be updated as applicable***]**

DOCKET NO.	COUNTRY	STATUS	APPLICATION NO.	FILING DATE	PATENT NO.	GRANT DATE
[*]	[*]	[*]	[*]	[*]	[*]	[*]

Exhibit H

AstraZeneca's Anti-Corruption Rules and Policies

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 to AstraZeneca 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: To be advised from time to time
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.

Exhibit J
Terms for SHA

[*]

[*] = 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 10.4

Execution Version

CONFIDENTIAL

AMENDMENT NO. 1 TO THE AMENDED AND RESTATED LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (FOR THE US AND CERTAIN OTHER TERRITORIES)

This Amendment No. 1 to the Amended and Restated License, Development and Commercialization Agreement (this "Amendment") is 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 a registered office at SE-151 85 Södertälje, Sweden ("AstraZeneca"), is effective as of July 1, 2020 (the "Effective Date"). Each of FibroGen and AstraZeneca may be referred to in this Amendment individually as a "Party" and collectively as the "Parties".

WHEREAS, FibroGen and AstraZeneca are parties to that certain Amended and Restated License, Development and Commercialization Agreement (for the US and Certain Other Territories) effective as of July 30, 2013 and entered into as of October 16, 2014 (the "Existing Agreement");

WHEREAS, on the Effective Date, that certain Second Amended and Restated License, Development and Commercialization Agreement (China) with respect to the Parties or their Affiliates' collaboration in China become effective and the Parties have agreed to certain amendments to the Existing Agreement so as to align with such amendments; and

WHEREAS, in accordance with Section 15.1 (*Entire Agreement; Amendment*) of the Existing Agreement, the Parties desire to memorialize such amendments in this Amendment.

NOW, **THEREFORE**, in consideration of the foregoing premises, the mutual promises and covenants of the Parties contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

1. Amendment to the Recitals

(a) Recital E of the Existing Agreement is hereby amended and restated in its entirety to read as follows:

"With respect to the collaboration between the Parties (or their Affiliates)_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., FibroGen Medical Technology Development Co., Ltd., and FibroGen International (Hong Kong) Limited, Affiliates of FibroGen, and AstraZeneca, effective as of even date herewith and amended and restated with effect on July 1, 2020 (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.

2. Amendments to Section 2.6 (*Resolutions of Committee Disputes*).

(a) Clause (i) of Section 2.6(c) (*Referral to Executive Officers*) of the Existing Agreement is hereby amended and restated in its entirety to read as follows:

"(i) **[*]**

(b) Clause (ii) of Section 2.6(c) (*Referral to Executive Officers*) of the Existing Agreement is hereby amended and restated in its entirety to read as follows:

"(ii) **[*]**

(c) The following new clause (iii) is hereby added to Section 2.6(c) (*Referral to Executive Officers*) of the Existing Agreement as the final clause of such Section:

[*]

3. Miscellaneous.

(a) Each Party hereby represents and warrants to the other Party that the Existing Agreement, as hereby amended, constitutes the legal, valid and binding obligation of such Party and is enforceable against such Party in accordance with its terms, subject, as to enforceability, to equitable principles of general application (regardless of whether enforcement is sought in a proceeding in equity or at law). The Parties agree that the Existing Agreement, as specifically amended by this Amendment, continues to remain in full force and effect.

(b) This Amendment may be amended only by a written instrument executed by FibroGen and AstraZeneca.

(c) The Parties agree that the execution of this Amendment by industry standard electronic signature software or by exchanging PDF signatures will have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Amendment, each Party hereby waives any right to raise any defense or waiver based upon execution of this Amendment by means of such electronic signatures or maintenance of the executed agreement electronically.

(d) Article 14 (Dispute and Governing Law) of the Existing Agreement applies to this Amendment.

[*Signature Page Follows*]

IN WITNESS WHEREOF, each of the Parties has caused this Amendment to be executed by a duly authorized corporate officer.

FIBROGEN, INC.

By: /s/ Enrique Conterno
Name: Enrique Conterno
Title: Chief Executive Officer

IN WITNESS WHEREOF, each of the Parties has caused this Amendment to be executed by a duly authorized corporate officer.

AstraZeneca AB

By: /s/ Elisabeth Bjork
Name: Elisabeth Bjork
Title: SVP, CVRM, RD BioPharma

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: August 6, 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: August 6, 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 June 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: August 6, 2020

In Witness Whereof, the undersigned have set their hands hereto as of the 6th day of August, 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.