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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017

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:

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐
		Emerging growth company	☐

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

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

The number of shares of common stock outstanding as of October 31, 2017 was 82,008,777.

FIBROGEN, INC.

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PART I—FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	September 30, 2017	December 31, 2016 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 651,373	$ 173,782
Short-term investments	78,599	79,397
Accounts receivable ($4,580 and $4,102 from a related party)	8,628	10,448
Prepaid expenses and other current assets	2,856	2,889
Total current assets	741,456	266,516
Restricted time deposits	6,217	6,217
Long-term investments	16,767	71,010
Property and equipment, net	126,643	123,657
Other assets	3,809	2,152
Total assets	$ 894,892	$ 469,552
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 6,407	$ 6,223
Accrued liabilities ($479 and $1,615 to related parties)	54,117	50,914
Deferred revenue	7,974	7,988
Total current liabilities	68,498	65,125
Long-term portion of lease financing obligations	97,370	97,352
Product development obligations	16,922	14,854
Deferred rent	3,799	4,212
Deferred revenue, net of current	110,844	106,709
Other long-term liabilities	6,690	6,191
Total liabilities	304,123	294,443
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 125,000 shares authorized at September 30, 2017 and December 31, 2016; no shares issued and outstanding at September 30, 2017 and December 31, 2016	—	—
Common stock, $0.01 par value; 225,000 shares authorized at September 30, 2017 and December 31, 2016; 81,814 and 63,665 shares issued and outstanding at September 30, 2017 and December 31, 2016	818	637
Additional paid-in capital	1,146,112	625,903
Accumulated other comprehensive loss	(1,609)	(960)
Accumulated deficit	(573,823)	(469,742)
Total stockholders' equity	571,498	155,838
Non-controlling interests	19,271	19,271
Total equity	590,769	175,109
Total liabilities, stockholders' equity and non-controlling interests	$ 894,892	$ 469,552

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

FIBROGEN, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue:				
License and milestone revenue (includes $4,125, $4,371, $11,652 and $20,727 from a related party)	$ 19,997	$ 20,867	$ 60,930	$ 113,802
Collaboration services and other revenue (includes $445, $436, $1,230 and $1,114 from a related party)	7,275	9,235	22,230	33,863
Total revenue	27,272	30,102	83,160	147,665
Operating expenses:				
Research and development	50,336	40,558	144,049	136,599
General and administrative	12,953	11,646	37,908	33,440
Total operating expenses	63,289	52,204	181,957	170,039
Loss from operations	(36,017)	(22,102)	(98,797)	(22,374)
Interest and other, net				
Interest expense	(2,769)	(2,760)	(7,901)	(7,975)
Interest income and other, net	1,106	866	2,783	2,411
Total interest and other, net	(1,663)	(1,894)	(5,118)	(5,564)
Loss before income taxes	(37,680)	(23,996)	(103,915)	(27,938)
Provision for (benefit from) income taxes	57	158	166	(260)
Net loss	$ (37,737)	$ (24,154)	$ (104,081)	$ (27,678)
Net loss per share - basic and diluted	$ (0.50)	$ (0.38)	$ (1.49)	$ (0.44)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	75,891	62,858	69,899	62,543

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

FIBROGEN, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net loss	$ (37,737)	$ (24,154)	$ (104,081)	$ (27,678)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(578)	(184)	(1,827)	(446)
Available-for-sale investments:				
Unrealized gain on investments, net of tax effect	403	(144)	1,250	745
Reclassification from accumulated other comprehensive loss	(47)	19	(72)	19
Net change in unrealized gain on available-for-sale investments	356	(125)	1,178	764
Other comprehensive income (loss), net of taxes	(222)	(309)	(649)	318
Comprehensive loss	$ (37,959)	$ (24,463)	$ (104,730)	$ (27,360)

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

FIBROGEN, INC.

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

	Nine Months Ended September 30,	
	2017	**2016**
Operating activities		
Net loss	$ (104,081)	$ (27,678)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	4,582	4,520
Amortization of premium on investments	1,503	2,080
Unrealized loss (gain) on short-term investments	3	(436)
Gain on disposal of property and equipment	3	—
Stock-based compensation	27,608	24,256
Tax benefit on unrealized gain on available-for-sale securities	—	(371)
Realized gain on sales of available-for-sale securities	(143)	(37)
Changes in operating assets and liabilities:		
Accounts receivable	1,820	7,713
Prepaid expenses and other current assets	33	23
Other assets	(1,657)	23
Accounts payable	184	(4,482)
Accrued liabilities	(114)	4,231
Deferred revenue	4,121	14,733
Lease financing liability	474	690
Other long-term liabilities	337	388
Net cash provided by (used in) operating activities	(65,327)	25,653
Investing activities		
Purchases of property and equipment	(4,992)	(1,106)
Proceeds from sale of property and equipment	5	—
Purchases of available-for-sale securities	(102)	(72)
Proceeds from sales of available-for-sale securities	21,109	4,298
Proceeds from maturities of available-for-sale securities	33,849	12,617
Net cash provided by investing activities	49,869	15,737
Financing activities		
Repayments of lease liability	(302)	(302)
Proceeds from follow-on offering, net of underwriting discounts and commission costs	471,205	—
Cash paid for payroll taxes on restricted stock unit releases	(5,970)	(2,242)
Proceeds from issuance of common stock	28,556	6,137
Payments of deferred offering costs	(430)	—
Net cash provided by financing activities	493,059	3,593
Effect of exchange rate change on cash and cash equivalents	(10)	(24)
Net increase in cash and cash equivalents	477,591	44,959
Total cash and cash equivalents at beginning of period	173,782	153,324
Total cash and cash equivalents at end of period	$ 651,373	$ 198,283

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 is a research-based biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics agents to treat serious unmet medical needs. The Company's focus in the areas of fibrosis and hypoxia-inducible factor ("HIF") biology has generated multiple programs targeting various therapeutic areas. The Company's most advanced product candidate, roxadustat, or FG-4592, is an oral small molecule inhibitor of HIF prolyl hydroxylases ("HIF-PHs") in Phase 3 clinical development for the treatment of anemia in chronic kidney disease ("CKD"). Pamrevlumab, or FG-3019, is the Company's monoclonal antibody in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer, Duchenne muscular dystrophy ("DMD") and liver fibrosis. The Company has taken a global approach with respect to the development and future commercialization of its product candidates, and this includes development and commercialization in the People's Republic of China ("China"). The Company is capitalizing on its extensive experience in fibrosis and hypoxia inducible factor ("HIF") biology and clinical development to advance a pipeline of innovative medicines for the treatment of anemia, fibrotic disease cancer, corneal blindness and other serious unmet medical needs.

On April 11, 2017, the Company closed the follow-on offering of its common stock. In this offering, the Company sold 5,228,750 shares of its common stock at a public offering price of $22.95 per share. Net proceeds from this offering were $115.1 million, after deducting underwriting discounts and commissions of $4.9 million. In addition, the offering expenses were approximately $0.6 million in total. On August 24, 2017, the Company completed another follow-on offering of its common stock. In this offering, the Company sold a total of 9,200,000 shares of its common stock at a public offering price of $40.75 per share. Net proceeds from this offering were $356.2 million, after deducting underwriting discounts and commissions of $18.7 million. In addition, the offering expenses were approximately $0.4 million in total.

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 China"). All inter-company transactions and balances have been eliminated in consolidation. The Company operates in 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 United States of America ("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 United States ("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 December 31, 2016 condensed consolidated balance sheet data contained within this Form 10-Q was derived from audited consolidated financial statements included in the Company's Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2016 ("2016 Form 10-K"), but does not include all disclosures required by U.S. GAAP.

The financial information included herein should be read in conjunction with the consolidated financial statements and related notes in the 2016 Form 10-K. 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 2016 Form 10-K.

Use of Estimates

The preparation of the 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, estimates of accruals related to clinical trial costs, valuation allowances for deferred tax assets, and valuation and recognition of stock-based compensation. 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 our opinion, the accompanying unaudited condensed consolidated financial statements include all normal recurring adjustments necessary for a fair statement of our financial position, results of operations and cash flows for the interim periods presented.

Recently Issued and Adopted Accounting Guidance

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-09, *Compensation - Stock Compensation (Topic 718)*. This guidance identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. This guidance was effective for the annual reporting period beginning after December 15, 2016, including interim periods within that reporting period. The Company adopted this guidance as of January 1, 2017 and has elected to continue with its existing policy to estimate forfeitures expected to occur when calculating stock compensation expense. Upon adoption, the Company recorded a retrospective increase of $19.5 million in deferred tax assets for previously unrecognized excess tax benefits that existed as of December 31, 2016, and a corresponding increase of $19.5 million in the valuation allowance against these deferred tax assets, as substantially all of the Company's U.S. and foreign deferred tax assets, net of deferred tax liabilities, are subject to a full valuation allowance. As such, the net impact from these retrospective adjustments was zero to the Company's accumulated deficit. The adoption of this guidance had no impact to the Company's consolidated financial statements for the three and nine months ended September 30, 2017.

Recently Issued Accounting Guidance Not Yet Adopted

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting*. This guidance provides guidance about which changes to the terms or conditions of a stock-based payment award require an entity to apply modification accounting in Topic 718. This guidance is effective for annual reporting period beginning after December 15, 2017, including interim periods, with early adoption permitted. The Company is currently evaluating the impact on its consolidated financial statements upon the adoption of this guidance.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. This guidance requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The measurement of expected credit losses is based on historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability. This guidance is effective for the annual reporting period beginning after December 15, 2019, including interim periods within that reporting period. The Company is currently evaluating the impact on its consolidated financial statements upon the adoption of this guidance.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. Under this guidance, an entity is required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. This guidance offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. This guidance is effective for the annual reporting period beginning after December 15, 2018, including interim periods within that reporting period, and requires a modified retrospective adoption, with early adoption permitted. The Company is currently evaluating the impact on its consolidated financial statements upon the adoption of this guidance.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments-Overall (Subtopic 825-10)*. This guidance requires equity investments that are not accounted for under the equity method of accounting to be measured at fair value with changes recognized in net income, simplifies the impairment assessment of certain equity investments, and updates certain presentation and disclosure requirements. This guidance is effective for the annual reporting period beginning after December 15, 2017 and interim periods within those annual periods. The Company is currently evaluating the impact on its consolidated financial statements upon the adoption of this guidance.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which supersedes the revenue recognition requirements in Accounting Standards Codification ("ASC") 605, *Revenue Recognition*. ASU 2014-09 is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. Subsequently, the FASB has issued the following standards related to ASU 2014-09: ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations* ("ASU 2016-08"); ASU No. 2016-10, *Revenue from Contracts with*

Customers (Topic 606): Identifying Performance Obligations and Licensing (“ASU 2016-10”); ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients* (“ASU 2016-12”); and ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers* (“ASU 2016-20”). The Company must adopt ASU 2016-08, ASU 2016-10, ASU 2016-12 and ASU 2016-20 with ASU 2014-09 (collectively, the “new revenue standards”). The amendments may be applied retrospectively to each prior period (full retrospective) or retrospectively with the cumulative effect recognized as of the date of initial application (modified retrospective). The Company has commenced its implementation activities related to the adoption of ASU 2014-09 and is in the process of applying the five-step model of the new standard to its various revenue related arrangements. The Company has completed step 1 (Identify the contract(s) with a customer) and concluded that its collaboration agreements with Astellas Pharma Inc. and AstraZeneca AB are the only material contracts which will be impacted by the adoption of the new revenue standards. The Company is in the process of completing step 2 (Identify the performance obligations in the contract) and has not yet reached a conclusion on whether the distinct criteria evaluated under ASC 605-25 for each performance obligation would result in a similar conclusion under the new revenue standards. With respect to milestones that were previously recognized under ASC 605-28, the milestone method is not applicable under the new revenue standards, and they are considered part of the overall arrangement consideration which will result in a deferral of revenue under the new revenue standards as part of the adoption. The Company will adopt the new revenue standards in the first quarter of 2018 and apply the full retrospective method to restate each prior reporting period presented in the consolidated financial statements. The new revenue standard is principle based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice, and guidance may evolve as companies and the accounting profession work to implement this new standard. As the Company completes its evaluation of this new standard, new information may arise that could change the Company's current understanding of the impact to revenues recognized and its views on the expected impact to the periods prior to adoption.

2. Collaboration Agreements

Astellas Agreements

Japan Agreement

In June 2005, the Company entered into a collaboration agreement with Astellas Pharma Inc. (“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). The Japan Agreement also provides for additional development and regulatory approval milestone payments up to $117.5 million, a commercial sales related milestone of $15.0 million and additional consideration based on net sales (as defined) in the low 20% range after commercial launch. A clinical milestone payment of $12.5 million was received in 2013. During the second quarter of 2016, the Company recognized $10.0 million of revenue as a result of the initiation by Astellas of the first Phase 3 clinical study in Japan of roxadustat for treatment of anemia associated with chronic kidney disease in patients on dialysis. The amount was received in early July 2016. The Company evaluated the criteria under ASC 605-28 and concluded that the aforementioned milestone was substantive.

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. Clinical milestone payments of $40.0 million and $50.0 million were received in 2010 and 2012, respectively. The Company evaluated the criteria under ASC 605-28 and concluded that each of those milestones was substantive. 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 product (as defined) in the low 20% range.

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 has agreed to pay upfront, non-contingent and time-based payments totaling $374.0 million, which were fully received in various amounts through June 2016. In addition, the U.S./RoW Agreement also provides for development and regulatory approval based milestone payments of up to $550.0 million, which include potential future indications which the companies choose to pursue, and commercial related milestone payments of up to $325.0 million. During 2015, the Company received a $15.0 million development milestone payment as a result of the finalization of its two audited pre-clinical carcinogenicity study reports. The Company evaluated the criteria under ASC 605-28 and concluded that the aforementioned milestone was substantive.

Under the U.S./RoW Agreement, the Company and AstraZeneca will share equally in the development costs of roxadustat not already paid for by Astellas, up to a total of $233.0 million (i.e. the Company's share of development costs is $116.5 million, which was reached during the fourth quarter of 2015). Any additional development costs incurred by FibroGen during the development period in excess of the $233.0 million (aggregated spend) will be fully reimbursed by AstraZeneca. AstraZeneca will pay the Company tiered royalty payments on AstraZeneca's future net sales (as defined in the agreement) of roxadustat in the low 20% range. In addition, the Company will receive a transfer price for delivery of commercial product based on a percentage of AstraZeneca's net sales (as defined in the agreement) in the low- to mid-single digit range.

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, which were fully received in 2014. In addition, the China Agreement provides for AstraZeneca to pay regulatory approval and other approval related milestones of up to $161.0 million. The China Agreement also provides for sales related milestone payments of up to $167.5 million and contingent payments of $20.0 million related to possible future compounds. 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.

In September 2016, AstraZeneca approved the protocol related to the development of roxadustat for the treatment of anemia in patients with myelodysplastic syndromes ("MDS"), for which the Company has received approval from the China Food and Drug Administration for its clinical trial application for a Phase 2/3 trial and acceptance of its investigational new drug application from the U.S. Food and Drug Administration for a Phase 3 trial. As a result, for revenue recognition purposes, during the third quarter of 2016, the Company extended the estimated joint development service period for the AstraZeneca agreements from the end of 2018 to the end of 2020, to allow for development of MDS.

In October 2017, the China Food and Drug Administration accepted the Company's recently submitted New Drug Application ("NDA") for registration of roxadustat for anemia in dialysis-dependent CKD and non-dialysis-dependent CKD (NDD-CKD) patients. This NDA submission triggers a $15.0 million milestone payment to the Company by AstraZeneca, which is expected to be received and fully recognized under the Company's current revenue recognition policy as license and milestone revenue in the fourth quarter of 2017.

Summary of Revenue Recognized Under the Collaboration Agreements

The table below summarizes the accounting treatment for the various deliverables pursuant to each of the Astellas and AstraZeneca agreements. License amounts identified below are included in the "License and milestone revenue" line item in the condensed consolidated statements of operations. All other elements identified below are included in the "Collaboration services 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):

Agreement	Deliverable	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Japan	License	$ 445	$ 3,041	$ 936	$ 3,159
	Milestones	—	—	—	10,000
	Total license and milestone revenue	445	$ 3,041	$ 936	$ 13,159
	Collaboration services revenue*	22	$ 144	$ 46	$ 151

* When and if available compounds, manufacturing — clinical supplies and committee services have each been identified as separate units of accounting with standalone value and amounts allocable to these elements have been recognized and classified within the Collaboration services revenue line item within the condensed consolidated statements of operations.

The total arrangement consideration has been allocated to each of the following deliverables under the Japan Agreement, along with any associated deferred revenue as follows (in thousands):

	Cumulative Revenue Through September 30, 2017	Deferred Revenue at September 30, 2017	Total Consideration Through September 30, 2017
License	$ 46,646	$ —	$ 46,646
When and if available compounds	24	24	48
Manufacturing--clinical supplies	2,164	—	2,164
Committee services	21	—	21
Total license and collaboration services revenue	$ 48,855	$ 24	$ 48,879

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

Agreement	Deliverable	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Europe	License	$ 3,680	$ 1,330	$ 10,716	$ 7,568
	Milestones	—	—	—	—
	Total license and milestone revenue	3,680	1,330	10,716	7,568
	Collaboration services revenue*	$ 423	$ 292	$ 1,184	$ 963

* When and if available compounds, manufacturing — clinical supplies, development services — in progress at the time of signing of the agreement, and committee services have each been identified as a separate unit of accounting with standalone value and amounts allocable to these units have been recognized in revenue as services are performed and classified within the Collaboration services revenue line item within the condensed consolidated statements of operations.

The total arrangement consideration has been allocated to each of the following deliverables under the Europe Agreement, along with any associated deferred revenue as follows (in thousands):

	Cumulative Revenue Through September 30, 2017	Deferred Revenue at September 30, 2017	Total Consideration Through September 30, 2017
License	$ 422,988	$ —	$ 422,988
When and if available compounds	434	394	828
Manufacturing--clinical supplies	10,132	—	10,132
Development services--in progress	33,892	—	33,892
Committee services	293	—	293
Total license and collaboration services revenue	$ 467,739	$ 394	$ 468,133

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

Agreement	Deliverable	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
U.S. / RoW and China	License	$ 15,872	$ 16,496	$ 49,278	$ 93,075
	Milestones	—	—	—	—
	Total license and milestone revenue	15,872	16,496	49,278	93,075
	Collaboration services revenue*	6,830	8,784	20,997	32,723
	China single unit of accounting**	$ —	$ —	$ —	$ —

* Co-development, information sharing, and committee services have been combined into a single unit of accounting because the requirements to share information and serve on committees are useful only in combination with the development services, and because all three items are delivered over the same period while manufacturing — clinical supplies has been identified as a separate unit of accounting with standalone value and amounts allocable to this unit of accounting have been recognized and classified within the Collaboration services revenue line item within the condensed consolidated statements of operations.

** All revenues attributable to the China unit of accounting are deferred until all deliverables are met. The China license and collaboration services elements have been combined into a single unit of accounting and consideration allocable to this unit is being deferred due to FibroGen's retention of manufacturing rights and lack of standalone value.

The total arrangement consideration has been allocated to each of the following deliverables under the U.S./RoW Agreement, along with any associated deferred revenue as follows (in thousands):

	Cumulative Revenue Through September 30, 2017	Deferred Revenue at September 30, 2017	Total Consideration Through September 30, 2017
License	$ 451,974	$ —	$ 451,974
Co-development, information sharing & committee services	111,693	25,723	137,416
Manufacturing--clinical supplies	436	34	470
China-single unit of accounting	—	92,643	92,643
Total license and collaboration services revenue	$ 564,103	$ 118,400	$ 682,503

Other Revenues

Other revenues consist of royalty payments received, which are recorded on a monthly basis as they are reported to the Company, and collagen feasibility sales. Other revenues were immaterial for all periods presented.

Deferred Revenue

Deferred revenue represents amounts 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 deliverables. 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 deliverables. The long term portion of deferred revenue also 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, which is not expected to occur within the next year.

3. Fair Value Measurements

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

	September 30, 2017			
	Level 1	Level 2	Level 3	Total
Corporate bonds	$ —	$ 75,872	$ —	$ 75,872
Bond and mutual funds	18,251	—	—	18,251
Equity investments	207	—	—	207
Money market funds	546,498	—	—	546,498
Certificate of deposits	—	1,036	—	1,036
Total	$ 564,956	$ 76,908	$ —	$ 641,864

	December 31, 2016			
	Level 1	Level 2	Level 3	Total
Corporate bonds	$ —	$ 126,683	$ —	$ 126,683
Bond and mutual funds	22,462	—	—	22,462
Equity investments	225	—	—	225
Money market funds	94,543	—	—	94,543
Certificate of deposits	—	1,037	—	1,037
Total	$ 117,230	$ 127,720	$ —	$ 244,950

Our 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 our financial liabilities that are carried at historical cost are as follows (in thousands):

	September 30, 2017			
	Level 1	Level 2	Level 3	Total
Lease financing obligations	$ —	$ —	$ 98,028	$ 98,028

	December 31, 2016			
	Level 1	Level 2	Level 3	Total
Lease financing obligations	$ —	$ —	$ 97,856	$ 97,856

The fair values of our 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. Balance Sheet Components

Cash and Cash Equivalents

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

	September 30, 2017	December 31, 2016
Cash	$ 104,875	$ 79,239
Money market funds	546,498	94,543
Total cash and cash equivalents	$ 651,373	$ 173,782

At September 30, 2017 and December 31, 2016, a total of $19.1 million and $24.3 million, respectively, of our cash and cash equivalents were held outside of the U.S. in our foreign subsidiaries to be used primarily for our China operations.

Investments

All investments are classified as available-for-sale. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's available-for-sale investments by major investments type are summarized in the tables below (in thousands):

	September 30, 2017			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Corporate bonds	$ 75,826	$ 62	$ (16)	$ 75,872
Certificate of deposits	1,036	—	—	1,036
Bond and mutual funds	17,182	1,069	—	18,251
Equity investments	126	81	—	207
Total investments	$ 94,170	$ 1,212	$ (16)	$ 95,366

	December 31, 2016			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Corporate bonds	$ 126,550	$ 182	$ (49)	$ 126,683
Certificate of deposits	1,037	—	—	1,037
Bond and mutual funds	22,305	157	—	22,462
Equity investments	125	100	—	225
Total investments	$ 150,017	$ 439	$ (49)	$ 150,407

At September 30, 2017, all of the available-for-sale investments had contractual maturities within two years. The Company periodically reviews its available-for-sale investments for other-than-temporary impairment. The Company considers factors such as the duration, severity and the reason for the decline in value, the potential recovery period and our intent to sell. For debt securities, the Company also considers whether (i) it is more likely than not that the Company will be required to sell the debt securities before recovery of their amortized cost basis, and (ii) the amortized cost basis cannot be recovered as a result of credit losses. During the three and nine months ended September 30, 2017 and 2016, the Company did not recognize any other-than-temporary impairment loss.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2017	December 31, 2016
Preclinical and clinical trial accruals	$ 26,989	$ 29,550
Payroll and related accruals	14,654	14,232
Professional services	2,144	1,252
Other	10,330	5,880
Total accrued liabilities	$ 54,117	$ 50,914

5. Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development	$ 5,538	$ 5,074	$ 16,060	$ 14,629
General and administrative	4,090	3,438	11,548	9,627
Total stock-based compensation expense	$ 9,628	$ 8,512	$ 27,608	$ 24,256

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Stock Options				
Expected term (in years)	5.3	5.3	5.7	5.3
Expected volatility	69.5 %	72.5 %	71.5 %	69.8 %
Risk-free interest rate	1.9	1.2	2.2	1.4
Expected dividend yield	—	—	—	—
Weighted average estimated fair value	$ 26.47	$ 10.73	$ 16.63	$ 11.46
ESPPs				
Expected term (in years)	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0
Expected volatility	52.8 - 76.0 %	63.7 - 80.7 %	52.8 - 77.2 %	61.9 - 80.7 %
Risk-free interest rate	0.6 - 1.3 %	0.4 - 0.9 %	0.5 - 1.3 %	0.2 - 0.9 %
Expected dividend yield	—	—	—	—
Weighted average estimated fair value	$ 9.67	$ 9.04	$ 9.15	$ 10.27

6. Income Taxes

The provisions for income taxes for the three and nine months ended September 30, 2017 were due to foreign taxes.

The provision for income taxes for the three months ended September 30, 2016 was due to the discrete tax effect arising from an unrealized loss in other comprehensive income (loss) related to available-for-sale securities, and foreign taxes. The benefit from income taxes for the nine months ended September 30, 2016 was due to the discrete tax effect arising from cumulative unrealized gains in other comprehensive income (loss) related to available-for-sale securities, partially offset by foreign taxes.

Based upon the weight of available evidence, which includes its historical operating performance, reported cumulative net losses since inception and expected continuing net loss, 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.

7. 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 $4.6 million and $4.8 million during the three months ended September 30, 2017 and 2016, respectively, and $12.9 million and $21.8 million during the nine months ended September 30, 2017 and 2016, respectively.

The Company recorded expense related to collaboration agreements with Astellas of $0.2 million and $1.8 million during the three months ended September 30, 2017 and 2016, respectively, and $0.8 million and $4.8 million during the nine months ended September 30, 2017 and 2016, respectively.

As of September 30, 2017 and December 31, 2016, accounts receivable from Astellas were $4.6 million and $4.1 million, respectively, and amounts due to Astellas were $0.5 million and $1.6 million, respectively.

Julian N. Stern, a director of the Company from November 1996 through June 2017, is currently serving as corporate secretary of the Company and is of counsel to the law firm of Goodwin Procter LLP, which he joined in 2008. He has received, and continues to receive, no compensation from Goodwin Procter LLP since joining as counsel. The Company retains Goodwin Procter LLP as legal counsel for various matters, primarily consisting of intellectual property matters. There was no payment to Goodwin Procter LLP during the three and nine months ended September 30, 2017. The Company's payments to Goodwin Procter LLP during the three and nine months ended September 30, 2016 were immaterial. As of September 30, 2017 and December 31, 2016, the balance of the accrued liability for Goodwin Proctor LLP was zero.

8. Subsequent Event

In October 2017, the China Food and Drug Administration accepted the Company's recently submitted NDA for registration of roxadustat for anemia in dialysis-dependent CKD and NDD-CKD patients. This NDA submission triggers a $15.0 million milestone payment to the Company by AstraZeneca, which is expected to be received and fully recognized under the Company's current revenue recognition policy as license and milestone revenue in the fourth quarter of 2017.

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, 2016 filed with the SEC on March 1, 2017.

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 a science-based biopharmaceutical company discovering and developing first-in-class therapeutics. Roxadustat (FG-4592), our most advanced product candidate, is an oral small molecule inhibitor of HIF prolyl hydroxylase ("HIF-PH") activity in Phase 3 clinical development for the treatment of anemia in chronic kidney disease ("CKD"). Pamrevlumab (FG-3019), a fully-human monoclonal antibody that inhibits the activity of connective tissue growth factor ("CTGF") is in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer, and Duchenne muscular dystrophy ("DMD"). We have taken a global approach to the development and future commercialization of our product candidates, and this includes development and commercialization in the People's Republic of China ("China"). We are capitalizing on our extensive experience in fibrosis and hypoxia inducible factor ("HIF") biology and clinical development to advance a pipeline of innovative medicines for the treatment of anemia, fibrotic disease cancer, corneal blindness and other serious unmet medical needs.

Financial Highlights

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(in thousands, except for per share data)			
Result of Operations				
Revenue	$ 27,272	$ 30,102	$ 83,160	$ 147,665
Operating expenses	$ 63,289	$ 52,204	$ 181,957	$ 170,039
Net loss	$ (37,737)	$ (24,154)	$ (104,081)	$ (27,678)
Net loss per share - basic and diluted	$ (0.50)	$ (0.38)	$ (1.49)	$ (0.44)

	September 30, 2017	December 31, 2016
	(in thousands)	
Balance Sheet		
Cash and cash equivalents	$ 651,373	$ 173,782
Short-term and long-term investments	$ 95,366	$ 150,407
Accounts receivable	$ 8,628	$ 10,448

Our revenue for the three and nine months ended September 30, 2017 decreased compared to the same periods a year ago primarily due to the impact of extension of the estimated joint development service period for the AstraZeneca agreements, for revenue recognition purposes, from the end of 2018 to the end of 2020. We made this extension in the third quarter of 2016 due to the approval of the development budget for roxadustat for the treatment of anemia in patients with myelodysplastic syndromes ("MDS"). Our revenue for the nine months ended September 30, 2017 decreased also due to that fact that, during the second quarter of 2016, we received an upfront payment of $62.0 million under our collaboration agreements with AstraZeneca and a $10.0 million development milestone revenue recorded under our collaboration agreements with Astellas, with no corresponding milestones in the current year periods.

Operating expenses for the three and nine months ended September 30, 2017 increased compared to the same period a year ago primarily due to higher drug development expenses associated with drug substance manufacturing activities related to pamrevlumab, higher clinical activities related to MDS, higher employee-related expenses, and higher stock-based compensation. The increases were partially offset by lower research and development outside services expense related to other HIF-PH inhibitors. Operating expenses for the nine months ended September 30, 2017 were also impacted by a $3.0 million reduction in assessed property tax resulted from the final assessment we obtained during the first quarter of 2017.

During the three and nine months ended September 30, 2017, we had a net loss of $37.7 million and $104.1 million, respectively, or net loss per basic and diluted share of $0.50 and $1.49, respectively, as compared to a net loss of $24.2 million and $27.7 million for the same periods a year ago, due to a decrease in revenue and an increase in operating expenses.

Cash and cash equivalents, investments and accounts receivable totaled $755.4 million at September 30, 2017, an increase of $420.8 million from December 31, 2016, primarily due to the net proceeds from the follow-on offerings of $115.1 million closed in April 2017 and $356.2 million closed in August 2017, partially offset by cash used in operations.

Programs

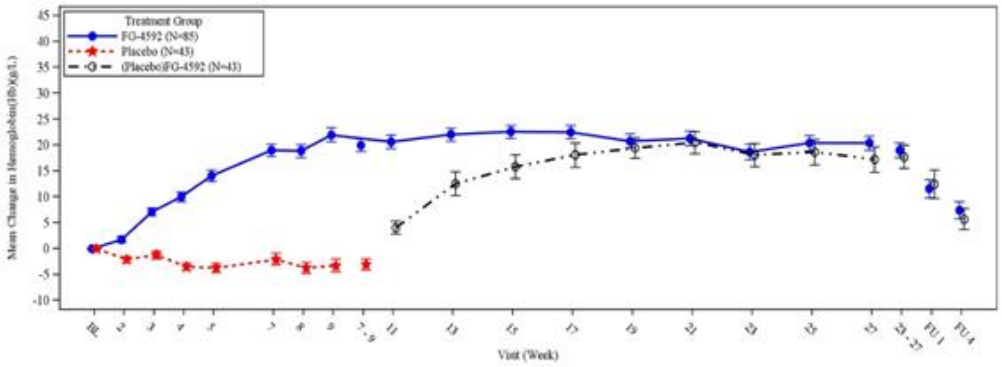
Roxadustat for the Treatment of Anemia in Chronic Kidney Disease

Roxadustat, the most advanced HIF-PH inhibitor in clinical development, acts by stimulating the body's natural pathway of erythropoiesis, or red blood cell production. We, along with our collaboration partners, Astellas Pharma Inc. ("Astellas") and AstraZeneca AB ("AstraZeneca"), continue to advance roxadustat through a global Phase 3 program to support regulatory approvals in the United States, Europe, Japan, and China in both dialysis-dependent CKD patients and CKD patients who are not dialysis-dependent. We are currently targeting a New Drug Application ("NDA") filing for roxadustat in the U.S. in 2018, subject to accrual of sufficient major adverse cardiac events ("MACE") for pooled analyses.

In January 2017, we reported topline results from our two China Phase 3 studies of roxadustat in CKD anemia. In October 2017, the China Food and Drug Administration ("CFDA") accepted for review our new drug application for the registration of roxadustat to treat anemia in dialysis-dependent and non-dialysis-dependent CKD patients.

In the double-blind, placebo-controlled non-dialysis Phase 3 trial in China, 151 anemia patients were randomized 2:1 to receive roxadustat (n=101) or placebo (n=50) for 8 weeks. As reported in January 2017, roxadustat met its primary efficacy endpoint of correcting anemia, by achieving a statistically significant increase in hemoglobin levels compared to placebo over eight weeks. After week 8, placebo patients were converted to roxadustat treatment and patients originally in the roxadustat arm continued treatment through week 26. Anemia correction and hemoglobin maintenance were observed up to week 27.

FGCL-4592-808: Mean Change in Hemoglobin Over Time in Phase 3 China Non-Dialysis CKD Patients (26 Weeks) Including Placebo Crossover to Roxadustat



In the 26-week portion of this China Phase 3 non-dialysis study, 97.6 % of patients who received up to 26 weeks of roxadustat achieved anemia correction with Hb ≥10.0g/dL. For patients who crossed over from placebo to roxadustat, there was an increase in mean hemoglobin levels over 18 weeks of roxadustat treatment, with mean hemoglobin increasing from 8.6 g/dL (averaged over weeks 7 to 9) to 10.8 g/dL (averaged over weeks 23 to 27); a statistically significant increase ($p < 0.0001$). Hemoglobin levels declined after week 27 when patients were no longer receiving roxadustat, as illustrated by the figure above.

In the 26-week portion of this non-dialysis study, roxadustat was shown to increase hemoglobin regardless of baseline inflammation status: both in patients with inflammation (CRP >4.9 mg/L) and patients without inflammation (CRP ≤4.9 mg/L). In addition, in the 8-week portion of this non-dialysis study, roxadustat led to significant reduction in serum hepcidin levels (-56.1 ng/mL for roxadustat patients vs -15.1 ng/mL for placebo, p=0.00000005). Anemia treatment with roxadustat was effective without the use of IV iron and there was no iron parameter (ferritin or TSAT) requirement for patients at study entry.

The durability of roxadustat's effect on hemoglobin levels was further supported by data from the subset of patients (n=23) who participated in the 52-week safety extension of this non-dialysis China Phase 3 study. Approximately 95% of the non-dialysis patients who completed the 52-week safety extension period maintained Hb ≥10.0g/dL at the end of treatment.

In our Phase 3 dialysis study in China, 304 patients previously on epoetin alfa were randomized to and treated with roxadustat (n=204) or epoetin alfa (n=100) for 26 weeks. 112 roxadustat patients continued treatment in a safety extension study for a total of 52 weeks. Approximately 96% of the dialysis patients who completed the 52-week safety extension period maintained Hb ≥10.0 g/dL at the end of treatment.

Roxadustat was generally well tolerated and there were no safety signals observed in the China Phase 3 clinical trials, including through the 52-week safety extension periods. There were no study drug-related deaths. The AEs and SAEs reported in the Phase 3 studies were generally representative of the underlying patient population and associated co-morbidities. Treatment of anemia with roxadustat in these Phase 3 clinical trials did not lead to an increase in blood pressure.

In Japan, Astellas completed the first of six roxadustat Phase 3 trials in Japan, evaluating roxadustat for the treatment of anemia in CKD patients on peritoneal dialysis (PD), with or without previous treatment with erythropoiesis-stimulating agents (ESAs). The study enrolled a total of 56 PD patients, of whom 43 patients had previously received ESAs (ESA-conversion patients), and 13 patients who had not previously received ESAs (ESA-naïve patients). Roxadustat was well tolerated and shown to correct hemoglobin levels in ESA-naïve patients and maintain hemoglobin (Hb) levels within the target range in both ESA-conversion patients and ESA-naïve patients.

The Hb maintenance rate, as measured by the proportion of subjects with average Hb levels within the target Hb range of 10.0 to 12.0 g/dL for weeks 18 to 24, was 92% in ESA-naïve patients who were corrected from baseline hemoglobin levels and 74% in ESA-conversion patients. The preliminary safety analysis for this trial is consistent with the safety profile of roxadustat in previous clinical trials.

Roxadustat for the Treatment of Anemia in Myelodysplastic Syndromes (MDS)

We plan to initiate a Phase 3 clinical trial to evaluate the safety and efficacy of roxadustat for treatment of anemia in MDS patients in the United States in the fourth quarter of 2017. We also plan on initiating a Phase 2/3 MDS clinical trial in China in the fourth quarter of 2017 or the first quarter of 2018.

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

Pamrevlumab is our fully human monoclonal antibody that inhibits the activity of CTGF, a central mediator and critical common element of the progression of fibrosis and associated serious diseases. We are currently conducting Phase 2 trials in pancreatic cancer and DMD and recently concluded our Phase 2 double-blind trial in IPF.

In August 2017, we reported positive topline results from our randomized, double-blind, placebo-controlled Phase 2 clinical trial designed to evaluate the safety and efficacy of pamrevlumab in patients with mild-to-moderate IPF. We also reported topline results from two sub-studies that were added to evaluate the safety of combining pamrevlumab with recently approved IPF therapies.

Pamrevlumab met the primary efficacy endpoint of change of forced vital capacity (“FVC”) percent predicted, a measure of a patient’s lung volume as a percentage of what would be expected for such patient’s age, race, sex and height. The average decline (least squares mean) in FVC percent predicted from baseline to week 48 was 2.85 in the pamrevlumab arm (n=50) as compared to an average decline of 7.17 in the placebo arm (n=51), a statistically significant difference of 4.33 (p=0.0331, using a linear slope analysis in the Intent to Treat (“ITT”) population).

Pamrevlumab-treated patients had an average decrease (least squares mean) in FVC of 129 ml at week 48 compared to an average decrease of 308 ml in patients receiving placebo, a statistically significant difference of 178 ml (p=0.0249, using a linear slope analysis in the ITT population). In addition, the pamrevlumab-treated arm had a lower proportion of patients (10%) who experienced a decline in FVC percent predicted of greater than or equal to 10% or death than did the placebo arm (31.4%) at week 48 (p=0.0103). The percentage of pamrevlumab patients who experienced decline in lung function of FVC percent predicted of 10% or more and discontinued therapy was less than 15% of that in the placebo arm.

Pamrevlumab was well tolerated in the placebo-controlled study. The treatment emergent adverse events were comparable between the pamrevlumab and placebo arms and the adverse events in the pamrevlumab arm were consistent with the known safety profile of pamrevlumab.

The double-blind, active-controlled combination sub-studies were designed to assess the safety of combining pamrevlumab with standard of care medication in IPF patients. Study subjects were on stable doses of pirfenidone or nintedanib for at least three months and were randomized 2:1 to receive 30 mg/kg of pamrevlumab or placebo every three weeks for 24 weeks. Thirty-six patients were enrolled in the pirfenidone sub-study and 21 patients were enrolled in the nintedanib sub-study. Pamrevlumab appeared to be well tolerated when given in combination with either pirfenidone or nintedanib.

In pancreatic cancer, we continue to follow patients in our ongoing open-label, randomized (2:1) Phase 2 trial designed to determine if pamrevlumab in combination with gemcitabine and nab-paclitaxel, can convert stage 3 inoperable cancer to resectable, or operable, cancer. We expect to define a registrational strategy in the first half of 2018.

We continue to enroll patients in our Phase 2 open-label trial of pamrevlumab in up to 22 non-ambulatory DMD patients.

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 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 U.S. and the European Union ("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. During the second quarter of 2016, we recognized $10.0 million of revenue as a result of the initiation by Astellas of the first Phase 3 clinical study in Japan of roxadustat for treatment of anemia associated with CKD in patients on dialysis. The amount was received in early July 2016. The aggregate amount of such consideration received through September 30, 2017 totals $472.6 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.

In addition, as of September 30, 2017, 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.

Now that we have reached the $116.5 million cap on our initial funding obligations (during which time we shared 50% of the joint initial development costs), 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. 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. During the second quarter of 2016, we received an upfront payment of $62.0 million as a time based development milestone. The aggregate amount of such consideration received through September 30, 2017 totals $417.2 million.

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.

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 China”), the commercial collaboration is structured as a 50/50 profit share. AstraZeneca will conduct commercialization activities in China as well as serve as the master distributor for roxadustat and will fund roxadustat launch costs in China until FibroGen Beijing has achieved profitability. At that time, AstraZeneca will recoup 50% of their historical launch costs out of initial roxadustat profits in China.

In September 2016, AstraZeneca approved the protocol related to the development of roxadustat for the treatment of anemia in patients with MDS, for which we have received approval from the China Food and Drug Administration (“CFDA”) for our clinical trial application in China for a Phase 2/3 trial and acceptance of our investigational new drug application (“IND”) from the FDA for a Phase 3 trial in the U.S. As a result, for revenue recognition purposes, during the third quarter of 2016, we extended the estimated joint development service period for the AstraZeneca agreements from the end of 2018 to the end of 2020, to allow for development of MDS.

In October 2017, the China Food and Drug Administration accepted our recently submitted NDA for registration of roxadustat for anemia in dialysis-dependent CKD and NDD-CKD patients. This NDA submission triggers a $15.0 million milestone payment to FibroGen by AstraZeneca, which is expected to be received and fully recognized under our revenue recognition policy as license and milestone revenue in the fourth quarter of 2017.

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.

Additional Information Related to Collaboration Agreements

Total cash consideration received through September 30, 2017 and potential cash consideration, other than development cost reimbursement, transfer price payments, royalties and profit share, pursuant to our existing collaboration agreements are as follows:

	Cash Received Through September 30, 2017	Additional Potential Cash Payments	Total Potential Cash Payments
	(in thousands)		
Astellas--related-party:			
Japan Agreement	$ 62,593	$ 110,000	$ 172,593
Europe Agreement	410,000	335,000	745,000
Total Astellas	472,593	445,000	917,593
AstraZeneca:			
U.S. / RoW Agreement	389,000	860,000	1,249,000
China Agreement	28,200	348,500	376,700
Total AstraZeneca	417,200	1,208,500	1,625,700
Total revenue	$ 889,793	$ 1,653,500	$ 2,543,293

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

RESULTS OF OPERATIONS

Revenue

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2017	2016	$	%	2017	2016	$	%
	(dollars in thousands)							
Revenue:								
License and milestone revenue	$ 19,997	$ 20,867	$ (870)	(4) %	$ 60,930	$ 113,802	$ (52,872)	(46) %
Collaboration services and other revenue	7,275	9,235	(1,960)	(21) %	22,230	33,863	(11,633)	(34) %
Total revenue	$ 27,272	$ 30,102	$ (2,830)	(9) %	$ 83,160	$ 147,665	$ (64,505)	(44) %

Our revenue to date has been generated substantially from our collaboration agreements with Astellas and AstraZeneca.

Under our revenue recognition policy, license revenue includes amounts from upfront, non-refundable license payments and amounts allocated pursuant to the relative selling price method from other consideration received (other than substantive milestone payments) during the periods. This revenue is generally recognized as deliverables are met and services are performed. Milestone revenue includes payments from milestones which are deemed to be substantive in nature and is recognized in its entirety in the period in which the milestone is achieved. License and milestone revenues represented 73% and 69% of total revenue for the three months ended September 30, 2017 and 2016, respectively, and 73% and 77% of total revenue for the nine months ended September 30, 2017 and 2016, respectively.

Collaboration services include co-development services, manufacturing of clinical supplies, committee services and information sharing. Collaboration services revenues are recognized over the non-contingent performance period, ranging from 36 to 89 months. Other revenues consist of royalty payments received, which are recorded on a monthly basis as they are reported to us, and have been included with collaboration services and other revenue in the condensed consolidated statements of operations, as they have not been material for any of the years presented. Collaboration services and other revenues represented 27% and 31% of total revenue for the three months ended September 30, 2017 and 2016, respectively, and 27% and 23% of total revenue for the nine months ended September 30, 2017 and 2016, respectively.

We have not generated any revenues based on the sale of FDA or CFDA approved products. In the future, we may generate revenue from product sales and from collaboration agreements in the form of license fees, milestone payments, reimbursements for collaboration services and royalties on product sales. We expect that any revenues we generate will fluctuate from quarter to quarter as a result of the uncertain timing and amount of such payments and sales.

Total revenue decreased $2.8 million, or 9% for the three months ended September 30, 2017, and decreased $64.5 million, or 44% for the nine months ended September 30, 2017, compared to the same periods a year ago for the reasons discussed in the sections below.

License and Milestone Revenue

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2017	2016	$	%	2017	2016	$	%
	(dollars in thousands)							
License and milestone revenue:								
Astellas	$ 4,125	$ 4,371	$ (246)	(6) %	$ 11,652	$ 20,727	$ (9,075)	(44) %
AstraZeneca	15,872	16,496	(624)	(4) %	49,278	93,075	(43,797)	(47) %
Total license and milestone revenue	$ 19,997	$ 20,867	$ (870)	(4) %	$ 60,930	$ 113,802	$ (52,872)	(46) %

License and milestone revenue decreased $0.9 million, or 4% for the three months ended September 30, 2017, and decreased $52.9 million, or 46% for the nine months ended September 30, 2017, compared to the same periods a year ago due to decreases in the license and milestone revenue recognized under both of our collaboration agreements with AstraZeneca and with Astellas.

License and milestone revenue recognized under our collaboration agreements with AstraZeneca decreased due to the impact of the extension of the estimated joint development service period for the AstraZeneca agreements, for revenue recognition purposes, from the end of 2018 to the end of 2020. We made this extension in the third quarter of 2016 due to the approval of the development budget for the treatment of anemia in patients with MDS. License and milestone revenue for the nine months ended September 30, 2017 was also impacted by an upfront payment of $62.0 million received during the second quarter of 2016, with no corresponding milestones in the current year periods.

License and milestone revenue recognized under our collaboration agreements with Astellas decreased primarily due to a $10.0 million of development milestone revenue recorded during the second quarter of 2016, with no corresponding milestones in the current year periods.

Collaboration Services and Other Revenue

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2017	2016	$	%	2017	2016	$	%
	(dollars in thousands)							
Collaboration services revenue:								
Astellas	$ 445	$ 436	$ 9	2 %	$ 1,230	$ 1,114	$ 116	10 %
AstraZeneca	6,830	8,784	(1,954)	(22) %	20,997	32,723	(11,726)	(36) %
Total collaboration services revenue	7,275	9,220	(1,945)	(21) %	22,227	33,837	(11,610)	(34) %
Other revenue	—	15	(15)	(100) %	3	26	(23)	(88) %
Total collaboration services and other revenue	$ 7,275	$ 9,235	$ (1,960)	(21) %	$ 22,230	$ 33,863	$ (11,633)	(34) %

Collaboration services and other revenue decreased $2.0 million, or 21%, for the three months ended September 30, 2017, and decreased $11.6 million, or 34%, for the nine months ended September 30, 2017, compared to the same periods a year ago primarily due to a decrease in the collaboration services revenue recognized under our collaboration agreements with AstraZeneca from the impact of the extension of the estimated joint development service period for the AstraZeneca agreements, for revenue recognition purposes, from the end of 2018 to the end of 2020. We made this extension in the third quarter of 2016 due to the approval of the development budget for the treatment of anemia in patients with MDS. Collaboration services and other revenue for the nine months ended September 30, 2017 was also impacted by the allocation of the upfront payment of $62.0 million during the second quarter of 2016, with no corresponding milestones in the current year periods.

Collaboration services revenue recognized under our collaboration agreements with Astellas remained relatively flat for the three and nine months ended September 30, 2017, compared to the same periods a year ago.

Operating Expenses

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2017	2016	$	%	2017	2016	$	%
	(dollars in thousands)							
Operating expenses								
Research and development	$ 50,336	$ 40,558	$ 9,778	24 %	$ 144,049	$ 136,599	$ 7,450	5 %
General and administrative	12,953	11,646	1,307	11 %	37,908	33,440	4,468	13 %
Total operating expenses	$ 63,289	$ 52,204	$ 11,085	21 %	$ 181,957	$ 170,039	$ 11,918	7 %

Total operating expenses increased $11.1 million, or 21%, for the three months ended September 30, 2017, and $11.9 million, or 7%, for the nine months ended September 30, 2017, compared to the same periods a year ago, for the reasons discussed in the sections below.

Research and Development Expenses

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

The following table summarizes our research and development expenses incurred during the three and nine months ended September 30, 2017 and 2016:

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2017	2016	2017	2016
Product Candidate	Phase of Development	(in thousands)			
Roxadustat	Phase 3	$ 32,493	$ 30,880	$ 92,595	$ 94,953
Pamrevlumab	Phase 2	12,230	5,206	37,366	26,898
FG-6874	Phase 1	18	—	41	123
FG-5200	Preclinical	1,319	1,040	3,457	3,602
Other research and development expenses		4,276	3,432	10,590	11,023
Total research and development expenses		$ 50,336	$ 40,558	$ 144,049	$ 136,599

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 continue 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 $9.8 million, or 24%, for the three months ended September 30, 2017, compared to the same period a year ago. The increase was primarily due to increases in drug development expenses of $6.8 million, employee-related costs of $3.4 million, clinical trial costs of $0.7 million, and stock-based compensation expense of $0.5 million, partially offset by a decrease in outside services of $2.0 million. Drug development expenses increased primarily due to higher drug substance manufacturing activities related to pamrevlumab. Employee-related costs increased due to higher headcount and higher average compensation level. Clinical trial costs increased as a result of the progression of the MDS studies. Stock-based compensation expense increased due to cumulative impact of stock option grant activities. Outside services costs decreased due to lower scientific contract work related to other HIF-PH inhibitors.

Research and development expenses increased $7.5 million, or 5%, for the nine months ended September 30, 2017, compared to the same period a year ago. The increase was primarily due to increases in employee-related costs of $4.7 million, clinical trial costs of $4.2 million, drug development expenses of $4.0 million, and stock-based compensation of $1.4 million, partially offset by decreases in outside services of $4.9 million, and allocated facility related expense of $2.0 million. Employee-related costs increased due to higher headcount and higher average compensation level. Clinical trial costs increased as a result of the progression of the Phase 3 trials for roxadustat and MDS studies. Drug development expenses increased due to higher drug substance manufacturing activities related to pamrevlumab. Stock-based compensation increased due to cumulative impact of stock option grant activities. Outside services costs decreased due to lower scientific contract work related to other HIF-PH inhibitors. Facility related expenses, as part of the allocated overhead costs, decreased due to the final assessment we obtained during the first quarter of 2017, resulting in a total of $3.0 million reduction in assessed property tax.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses for executive, operational, finance, legal, compliance, and human resource functions. Other general and administrative expenses include facility-related costs and professional fees, accounting and legal services, other outside services, recruiting fees and expenses associated with obtaining and maintaining patents.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. We also anticipate increased expenses, including exchange listing and SEC requirements, director and officer insurance premiums, legal, audit and tax fees, regulatory compliance programs, and investor relations costs associated with being a public company and ceasing to be an emerging growth company. Additionally, if and when we believe the first regulatory approval of one of our product candidates appears likely, we anticipate an increase in payroll and related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

General and administrative expenses increased $1.3 million, or 11%, for the three months ended September 30, 2017, compared to the same period a year ago, primarily due to increases in employee-related costs of $1.2 million, stock-based compensation expense of $0.7 million, partially offset by a decrease in outside services expenses of $0.4 million. Employee-related costs increased due to higher average compensation level, higher headcount, and increased recruiting activities. Stock-based compensation expense increased due to cumulative impact of stock option grant activities. Outside services expenses decreased primarily due to the lower administrative consulting activities.

General and administrative expenses increased $4.5 million, or 13%, for the nine months ended September 30, 2017, compared to the same period a year ago, primarily due to increases in employee-related costs of $2.9 million and stock-based compensation expense of $1.9 million, partially offset by a decrease in facility related expense of $0.9 million. Employee-related costs increased due to higher average compensation level, higher headcount, and increased recruiting activities. Stock-based compensation expense increased due to cumulative impact of stock option grant activities. Facility related expenses decreased due to the final assessment we obtained during the first quarter of 2017, resulting in a total of $3.0 million reduction in assessed property tax.

Operating Expenses for Roxadustat Covered Under Collaboration Agreements

We share responsibility with AstraZeneca for clinical development activities required for U.S. regulatory approval of roxadustat. During the fourth quarter of 2015, the $116.5 million cap on our share of development costs for roxadustat was reached. As such, 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, our subsidiary FibroGen Beijing will conduct the development work for CKD anemia, will hold all of the regulatory licenses issued by China regulatory authorities, and be primarily responsible for regulatory, clinical and manufacturing. All development and commercialization costs for roxadustat in China will be shared equally with AstraZeneca.

Interest and Other Income (Expense), Net

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2017	2016	$	%	2017	2016	$	%
	(dollars in thousands)							
Interest and other, net:								
Interest expense	$ (2,769)	$ (2,760)	$ (9)	— %	$ (7,901)	$ (7,975)	$ 74	(1) %
Interest income and other, net	1,106	866	240	28 %	2,783	2,411	372	15 %
Total interest and other, net	$ (1,663)	$ (1,894)	$ 231	(12) %	$ (5,118)	$ (5,564)	$ 446	(8) %

Interest Expense

Interest expense includes payments made for imputed interest related to the facility lease financing obligations for our leased facilities in San Francisco and China, as well as interest related to the Technology Development Center of the Republic of Finland product development obligations. Interest expense remained relatively flat for the three and nine months ended September 30, 2017, compared to the same period a year ago, with no significant offsetting impacts.

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 increased $0.2 million, or 28%, increased $0.4 million, or 15%, for the three and nine months ended September 30, 2017, compared to the same periods a year ago primarily due to higher interest earned on our cash, cash equivalents and investments associated with the higher average balances, partially offset by the unrealized foreign currency translation gain on our monetary assets denominated in foreign currency as a result of U.S. Dollar weakening.

Provision for (Benefit from) Income Taxes

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(dollars in thousands)			
Loss before income taxes	$ (37,680)	$ (23,996)	$ (103,915)	$ (27,938)
Provision for (benefit from) income taxes	57	158	166	(260)
Effective tax rate	(0.2)%	(0.7)%	(0.2)%	0.9%

The provisions for income taxes for the three and nine months ended September 30, 2017 were due to foreign taxes.

The provision for income taxes for the three months ended September 30, 2016 was due to the discrete tax effect arising from an unrealized loss in other comprehensive income (loss) related to available-for-sale securities, and foreign taxes. The benefit from income taxes for the nine months ended September 30, 2016 was due to the discrete tax effect arising from cumulative unrealized gains in other comprehensive income (loss) related to available-for-sale securities, partially offset by foreign taxes.

Based upon the weight of available evidence, which includes our historical operating performance, reported cumulative net losses since inception and expected continuing net loss, 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 convertible preferred stock and common stock (including our public offering proceeds) and from the execution of certain collaboration agreements involving license payments, milestones and reimbursement for development services.

On April 11, 2017, we closed an offering of our common stock. In this offering, we sold 5,228,750 shares of our common stock at a public offering price of $22.95 per share. Net proceeds from this offering were $115.1 million, after deducting underwriting discounts and commissions of $4.9 million. In addition, the total offering expenses were approximately $0.6 million. On August 24, 2017, the Company completed another follow-on offering of its common stock. In this offering, the Company sold a total of 9,200,000 shares of its common stock at a public offering price of $40.75 per share. Net proceeds from this offering were $356.2 million, after deducting underwriting discounts and commissions of $18.7 million. In addition, the offering expenses were approximately $0.4 million in total

As of September 30, 2017, we had cash and cash equivalents of $651.4 million. Cash is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting principally of corporate and government debt securities and stated at fair value, are also available as a source of liquidity. As of September 30, 2017, we had short-term and long-term investments of $78.6 million and $16.8 million, respectively. As of September 30, 2017, a total of $19.1 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

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one or more of our current or future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase 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. 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. 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 Fact*ors" 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 expenses, which would impair our growth prospects and could otherwise negatively impact our business.

Cash Sources and Uses

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

	Nine Months Ended September 30,	
	2017	2016
Net cash provided by (used in):		
Operating activities	$ (65,327)	$ 25,653
Investing activities	49,869	15,737
Financing activities	493,059	3,593
Effect of exchange rate changes on cash and cash equivalents	(10)	(24)
Net increase in cash and cash equivalents	$ 477,591	$ 44,959

Operating Activities

Net cash used in operating activities was $65.3 million for the nine months ended September 30, 2017 and consisted primarily of net loss of $104.1 million adjusted for non-cash items of $33.6 million and a net increase in operating assets and liabilities of $5.2 million. The significant non-cash items included stock-based compensation expense of $27.6 million, depreciation expense of $4.6 million and amortization of premium on investments of $1.5 million. The significant items in the changes in operating assets and liabilities included increases resulted from deferred revenue of $4.1 million and accounts receivable of $1.8 million, partially offset by a decrease resulted from other assets of $1.7 million. The changes in deferred revenue and accounts receivable were related to the timing of the receipt of upfront payments and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca. The change in other assets was primarily driven by the payment during the current year period for the land use right fee for the commercial active pharmaceutical ingredients manufacturing facility that we are establishing in China.

Net cash provided by operating activities was $25.7 million for the nine months ended September 30, 2016 and consisted primarily of net loss of $27.7 million adjusted for non-cash items of $30.0 million and a net increase in operating assets and liabilities of $23.3 million. The significant non-cash items included stock-based compensation expense of $24.3 million, depreciation expense of $4.5 million and amortization of premium on investments of $2.1 million. The significant items in the changes in operating assets and liabilities included increases resulted from deferred revenue of $14.7 million, accounts receivable of $7.7 million and accrued liabilities of $4.2 million, partially offset by a decrease resulted from accounts payable of $4.5 million. The changes in deferred revenue and accounts receivable were related to the timing of the receipt of upfront payments and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca. The change in accounts payable and accrued liabilities were primarily driven by clinical trial activities and the timing of payments.

Investing Activities

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

Net cash provided by investing activities was $49.9 million for the nine months ended September 30, 2017 and consisted of proceeds from maturities of available-for-sale securities of $33.8 million and sales of available-for-sale securities of $21.1 million, partially offset by cash used in purchases of property and equipment of $5.0 million.

Net cash provided by investing activities was $15.7 million for the nine months ended September 30, 2016 and consisted of proceeds from maturities of available-for-sale securities of $12.6 million and sales of available-for-sale securities of $4.3 million, partially offset by cash used in purchases of fixed assets of $1.1 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, repayments of our lease liability.

Net cash provided by financing activities was $493.1 million for the three months ended September 30, 2017 and consisted primarily of $471.2 million of total proceeds from follow-on offerings in April and August of 2017, net of underwriting discounts and commission costs, $28.6 million of proceeds from the issuance of common stock upon exercise of stock options and purchases under ESPP, partially offset by $6.0 million of cash paid for payroll taxes on restricted stock unit releases.

Net cash provided by financing activities was $3.6 million for the nine months ended September 30, 2016 and consisted of $6.1 million of proceeds from the issuance of common stock upon exercise of stock options and purchases under ESPP, partially offset by $2.2 million of cash paid for payroll taxes on restricted stock unit releases and $0.3 million of repayments on our lease liability.

Off-Balance Sheet Arrangements

During the three and nine months ended September 30, 2017, 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

There have been no material changes in our contractual obligations compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

There have been no material changes in our critical accounting policies, estimates and judgments during the three and nine months ended September 30, 2017 compared with the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2016.

Recently Issued and Adopted Accounting Guidance

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-09, *Compensation - Stock Compensation (Topic 718)*. This guidance identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. This guidance was effective for the annual reporting period beginning after December 15, 2016, including interim periods within that reporting period. We adopted this guidance as of January 1, 2017 and have elected to continue with our existing policy to estimate forfeitures expected to occur when calculating stock compensation expense. Upon adoption, we recorded a retrospective increase of $19.5 million in deferred tax assets for previously unrecognized excess tax benefits that existed as of December 31, 2016, and a corresponding increase of $19.5 million in the valuation allowance against these deferred tax assets, as substantially all of our U.S. and foreign deferred tax assets, net of deferred tax liabilities, are subject to a full valuation allowance. As such, the net impact from these retrospective adjustments was zero to our accumulated deficit. The adoption of this guidance had no impact to our consolidated financial statements for the three and nine months ended September 30, 2017.

Recently Issued Accounting Guidance Not Yet Adopted

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting*. This guidance provides guidance about which changes to the terms or conditions of a stock-based payment award require an entity to apply modification accounting in Topic 718. This guidance is effective for annual reporting period beginning after December 15, 2017, including interim periods, with early adoption permitted. We are currently evaluating the impact on our consolidated financial statements upon the adoption of this guidance.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. This guidance requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The measurement of expected credit losses is based on historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability. This guidance is effective for the annual reporting period beginning after December 15, 2019, including interim periods within that reporting period. We are currently evaluating the impact on our consolidated financial statements upon the adoption of this guidance.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. Under this guidance, an entity is required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. This guidance offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. This guidance is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, and requires a modified retrospective adoption, with early adoption permitted. We are currently evaluating the impact on our consolidated financial statements upon the adoption of this guidance.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments-Overall (Subtopic 825-10)*, which requires equity investments that are not accounted for under the equity method of accounting to be measured at fair value with changes recognized in net income, simplifies the impairment assessment of certain equity investments, and updates certain presentation and disclosure requirements. This guidance is effective for annual reporting periods beginning after December 15, 2017 and interim periods within those annual periods. We are currently evaluating the impact on our consolidated financial statements upon the adoption of this guidance.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which supersedes the revenue recognition requirements in Accounting Standards Codification ("ASC") 605, *Revenue Recognition*. ASU 2014-09 is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. Subsequently, the FASB has issued the following standards related to ASU 2014-09: ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations* ("ASU 2016-08"); ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing* ("ASU 2016-10"); ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients* ("ASU 2016-12"); and ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers* ("ASU 2016-20"). We must adopt ASU 2016-08, ASU 2016-10, ASU 2016-12 and ASU 2016-20 with ASU 2014-09 (collectively, the "new revenue standards"). The amendments may be applied retrospectively to each prior period (full retrospective) or retrospectively with the cumulative effect recognized as of the date of initial application (modified retrospective). We have commenced our implementation activities related to the adoption of ASU 2014-09 and are in the process of applying the five-step model of the new standard to our various revenue related arrangements. We have completed step 1 (Identify the contract(s) with a customer) and concluded that our collaboration agreements with Astellas and AstraZeneca are the only material contracts which will be impacted by the adoption of the new revenue standards. We are in the process of completing step 2 (Identify the performance obligations in the contract) and have not yet reached a conclusion on whether the distinct criteria evaluated under ASC 605-25 for each performance obligation would result in a similar conclusion under the new revenue standards. With respect to milestones that were previously recognized under ASC 605-28, the milestone method is not applicable under the new revenue standards, and they are considered part of the overall arrangement consideration which will result in a deferral of revenue under the new revenue standards as part of the adoption. We will adopt the new revenue standards in the first quarter of 2018 and apply the full retrospective method to restate each prior reporting period presented in the consolidated financial statements. The new revenue standard is principle based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice, and guidance may evolve as companies and the accounting profession work to implement this new standard. As we complete our evaluation of this new standard, new information may arise that could change our current understanding of the impact to revenues recognized and our views on the expected impact to the periods prior to adoption.

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, 2016.

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 September 30, 2017 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 September 30, 2017 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, 2016.

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 clinical-stage biopharmaceutical company with two lead product candidates in clinical development, roxadustat in anemia in chronic kidney disease ("CKD") and pamrevlumab (FG-3019), in idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer, Duchenne muscular dystrophy ("DMD") and liver fibrosis. Pharmaceutical product development is a highly risky undertaking. To date, we have focused our efforts and most of our resources on hypoxia-inducible factor ("HIF"), and fibrosis biology research, as well as developing our lead product candidates. We are not profitable and, other than in 2006 and 2007 due to income received from our Astellas Pharma Inc. ("Astellas") collaboration, have incurred losses in each year since our inception. We have not generated any significant revenue based on 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 years ended December 31, 2016, 2015 and 2014 was approximately $61.7 million, $85.8 million and $59.5 million, respectively. As of September 30, 2017, we had an accumulated deficit of $573.8 million. As of September 30, 2017, we had capital resources consisting of cash, cash equivalents and short-term investments of $730.0 million plus $16.8 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, and the potential to receive milestone and other payments from these partners, we anticipate we will continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, and seek regulatory approval for our product candidates. If we do not successfully develop and obtain regulatory approval for our existing or any future product candidates and effectively manufacture, market and sell any product candidates that are approved, we may never generate product sales, and even if we do generate product sales, 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 the People's Republic of China ("China"), expand our clinical development efforts on pamrevlumab, seek regulatory approval, prepare for the 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. In particular, in our planned Phase 3 clinical trial program for roxadustat, which we believe will be the largest Phase 3 program ever conducted for an anemia product candidate, we are expecting to enroll over 8,000 patients for our U.S. and European programs alone. We are conducting this Phase 3 program in conjunction with Astellas and AstraZeneca, and we are substantially dependent on Astellas and AstraZeneca for the funding of this large program. 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, which are discussed in more detail below, 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.

Our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress in the development of our product candidates;
- the costs of development efforts for our product candidates, such as pamrevlumab, that are not subject to reimbursement from our collaboration partners;
- the costs necessary to obtain regulatory approvals, if any, for our product candidates in the United States ("U.S."), China and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where approval is obtained;
- the continuation of our existing collaborations and entry into new collaborations;
- the time and unreimbursed costs necessary to commercialize products in territories in which our product candidates are approved for sale;
- the revenues from any future sales of our products as well as revenue earned from profit share, royalties and milestones;
- the level of reimbursement or third party payor pricing available to our products;
- the costs of establishing and maintaining manufacturing operations and obtaining third party commercial supplies of our products, if any, manufactured in accordance with regulatory requirements;
- the costs we incur in maintaining domestic and foreign operations, including operations in China;
- regulatory compliance costs; and
- the costs we incur in the filing, prosecution, maintenance and defense of our extensive patent portfolio and other intellectual property rights.

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.

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

During the years ended December 2016, 2015 and 2014, substantially all of our revenues recognized were from our collaboration partners.

We will require substantial additional capital to achieve our development and commercialization goals, which for our lead product candidate, roxadustat, is currently contemplated to be provided under our existing third party collaborations with Astellas and AstraZeneca.

If either or both of these collaborations were to be terminated, we could require significant additional capital in order to proceed with development and commercialization of our product candidates, 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 research and development efforts or other operations.

If we are unable to continue to progress our development efforts and achieve milestones under our collaboration agreements, our revenues may decrease and our activities may fail to lead to commercial products.

Substantially all of our revenues to date have been, and a significant portion of our future revenues are expected to be, derived from our existing collaboration agreements. Revenues from research and development collaborations depend upon continuation of the collaborations, reimbursement of development costs, the achievement of milestones and royalties and profits from our product sales, if any, derived from future products developed from our research. If we are unable to successfully advance the development of our product candidates or achieve milestones, revenues under our collaboration agreements will be substantially less than expected.

Risks Related to the Development and Commercialization of Our Product Candidates

We are substantially dependent on the success of our lead product candidate, 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, which is currently our lead product candidate. Roxadustat is our only product candidate that has advanced into a potentially pivotal trial, and it may be years before the studies required for its approval are completed, if ever. Our other product candidates are less advanced in development and may never enter into pivotal studies. We have completed 26 Phase 1 and 2 clinical studies with roxadustat in North America, Europe and Asia, in which over 1,400 subjects have participated and for which we reported favorable primary and secondary safety and efficacy endpoint results. Based on our discussions with regulatory authorities, we believe that we have an acceptable plan for the conduct of our Phase 3 clinical programs to support NDA submissions in the U.S. and China. We have discussed our Phase 3 clinical development program with three national health authorities in the EU and obtained scientific advice from the European Medicines Agency. Our near-term prospects, including maintaining our existing collaborations with Astellas and AstraZeneca, will depend heavily on successful Phase 3 development and commercialization of roxadustat.

Our other lead product candidate, pamrevlumab, is currently in clinical development for IPF, pancreatic cancer, DMD, and liver fibrosis. Pamrevlumab requires substantial further development and investment. We do not have a collaboration partner for support of this compound, and, while we have promising open-label safety data and potential signals of efficacy, we would need to complete larger and more extensive controlled clinical trials to validate the results to date in order to continue further development of this product candidate. In addition, although there are many potentially promising indications beyond IPF, pancreatic cancer and liver fibrosis, we are still exploring indications for which further development of, and investment for, pamrevlumab may be appropriate. Accordingly, the costs and time to complete development and related risks are currently unknown. Moreover, pamrevlumab is a monoclonal antibody, which may require experience and expertise that we may not currently possess as well as financial resources that are potentially greater than those required for our small molecule lead compound, 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, continuation and completion of our Phase 3 clinical trials for roxadustat, which will depend substantially upon requirements for such trials imposed by the U.S. Food and Drug Administration (“FDA”) and other regulatory agencies and bodies and the continued commitment and coordinated and timely performance by our third party collaboration partners, AstraZeneca and Astellas;
- the timely initiation and completion of our Phase 2 clinical trials for pamrevlumab, including in IPF, pancreatic cancer, DMD, and liver fibrosis;
- our ability to demonstrate the safety and efficacy of our product candidates to the satisfaction of the relevant regulatory authorities;
- whether we are required by the 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 timely receipt of necessary marketing approvals from the FDA and foreign regulatory authorities, including pricing and reimbursement determinations;
- the ability to successfully commercialize our product candidates, if approved, for marketing and sale by the FDA or foreign regulatory authorities, whether alone or in collaboration with others;

- 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 and patients 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 our product candidates;
- the maintenance of an acceptable safety profile of our products following any approval;
- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competitive treatments;
- our ability to obtain and sustain an adequate level of pricing or reimbursement for our products by third party payors;
- our ability to enforce successfully our intellectual property rights for our product candidates and against the products of potential competitors; and
- our ability to avoid or succeed in third party patent interference or patent infringement claims.

Many of these factors are beyond our control. Accordingly, we cannot assure you that we will ever be able to achieve profitability through the sale of, or royalties from, our product candidates. If we or our collaboration partners are not successful in obtaining approval for and commercializing our product candidates, or are delayed in completing those efforts, our business and operations would be adversely affected.

We may be unable to obtain regulatory approval for our product candidates, 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 or pamrevlumab or any of our other product candidates.

We have not obtained regulatory approval for any of our product candidates and it is possible that roxadustat and pamrevlumab will never receive regulatory approval in any country. Regulatory authorities may take actions or impose requirements that delay, limit or deny approval of roxadustat or pamrevlumab 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 liver fibrosis;
- our failure to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- 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;
- collaboration partners may not perform or complete their clinical programs in a timely manner, or at all; or
- principal investigators may determine that one or more serious adverse events ("SAEs"), is related or possibly related to roxadustat, and any such determination may adversely affect our ability to obtain regulatory approval, whether or not the determination is correct.

Any of these factors, many of which are beyond our control, could jeopardize our or our collaboration partners' abilities to obtain regulatory approval for and successfully market roxadustat. Because our business and operations in the near-term are almost entirely dependent upon roxadustat, any significant delays or impediments to regulatory approval could have a material adverse effect on our business and prospects.

Furthermore, in both the U.S. and China, we also expect to be required to perform additional clinical trials in order to obtain approval or as a condition to maintaining approval due to post-marketing requirements. If the FDA requires a risk evaluation and mitigation strategy ("REMS"), for any of our product candidates if approved, the substantial cost and expense of complying with a REMS or other post-marketing requirements may limit our ability to successfully commercialize our product candidates.

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 early or small clinical trials may not be replicated or show as favorable an outcome, even if successful. For example, in the past we developed an earlier generation product candidate aimed at treating anemia in CKD that resulted in a clinical hold for a safety signal seen in that product in Phase 2 clinical trials. The clinical hold applied to that product candidate and roxadustat was lifted for both product candidates after submission of the requested data to the FDA. While we have not seen similar safety concerns involving roxadustat to date, our Phase 2 clinical trials have involved a relatively small number of patients exposed to roxadustat for a relatively short period of time compared to the Phase 3 clinical trials that we will be conducting, and only a fraction of the patients in the Phase 2 clinical trials were randomized to placebo. Accordingly, the Phase 2 clinical trials that we have conducted may not have uncovered safety issues, even if they exist. In addition, some of the safety concerns associated with the treatment of patients with anemia in CKD using Erythropoiesis Stimulating Agents ("ESAs") did not emerge for many years until placebo-controlled studies had been conducted in large numbers of patients. The biochemical pathways that we believe are affected by roxadustat are implicated in a variety of biological processes and disease conditions, and it is possible that the use of roxadustat to treat larger numbers of patients will demonstrate unanticipated adverse effects, including possible drug interactions, which may negatively impact the safety profile, use and market acceptance of roxadustat. We studied the potential interaction between roxadustat and three statins (atorvastatin, rosuvastatin and simvastatin), which are used to lower levels of lipids in the blood. An adverse effect associated with increased statin plasma concentration is myopathy, which typically presents in a form of myalgia. The studies indicated the potential for increased exposure to those statins when roxadustat is taken simultaneously with those statins and suggested the need for statin dose reductions for patients receiving higher statin doses. We performed additional clinical pharmacology studies to evaluate if the effect of any such interaction could be minimized or eliminated by a modification of the dosing schedule that would separate the administration of roxadustat and the statin, however, such studies showed no minimization of effect. It is possible that the potential for interaction between roxadustat and statins could lead to label provisions for statins or roxadustat relating, for example, to dose scheduling or recommended statin dose limitations. In CKD patients statin therapy is often initiated earlier than treatment for anemia, and risks of myopathy have been shown to decrease with increased time on drug. While we believe the prior statin treatment history of such patients at established doses may reduce the risk of adverse effects from any interaction with roxadustat and facilitate any appropriate dose adjustments, we cannot be sure that this will be the case.

The FDA has informed us that our Phase 3 trials must include, as a safety endpoint, a major adverse cardiac events ("MACE"), endpoint, which is a composite endpoint designed to identify major safety concerns, in particular relating to cardiovascular events such as cardiovascular death, myocardial infarction and stroke. In addition, we expect that our Phase 3 clinical trials supporting approval in Europe will be required to include MACE+ as a safety endpoint which, in addition to the MACE endpoints, also incorporates measurements of hospitalization rates due to heart failure or unstable angina. As a result, our ongoing and planned Phase 3 clinical trials may identify unanticipated safety concerns in the patient population under study. The FDA has also informed us that the MACE endpoint will need to be evaluated separately for our Phase 3 trials in non-dialysis dependent-CKD patients and our

Phase 3 trials in dialysis dependent-CKD patients. The MACE endpoint will be evaluated in pooled analysis across Phase 3 studies of similar study populations and requires demonstration of non-inferiority relative to comparator, which means that the MACE event rate in roxadustat-treated patients must have less than a specified probability of exceeding the rate in the comparator trial by a specified hazard ratio. The number of patients necessary in order to permit a statistical analysis with adequate ability to detect the relative risk of MACE or MACE+ events in different arms of the trial, referred to as statistical power, depends on a number of factors, including the rate at which MACE or MACE+ events occur per patient-year in the trial, treatment duration of the patients, the required hazard ratio, and the required statistical power and confidence intervals.

In addition, we cannot be sure that the potential advantages that we believe roxadustat may have for treatment of patients with anemia in CKD as compared to the use of ESAs will be substantiated by our Phase 3 clinical trials or that we will be able to include a discussion of such advantages in our labeling should we obtain approval. We believe that roxadustat may have certain benefits as compared to ESAs based on the data from our Phase 2 clinical trials conducted to date, including safety benefits, the absence of a hypertensive effect, the potential to lower cholesterol levels and the potential to correct anemia without the use of IV iron. However, our belief that roxadustat may offer those benefits is based on a limited amount of data from our Phase 2 clinical trials and our understanding of the likely mechanisms of action for roxadustat. Some of these benefits, such as those associated with the apparent effects on blood pressure and cholesterol, are not fully understood and, even if roxadustat receives marketing approval, we do not expect that it will be approved for the treatment of high blood pressure or high cholesterol based on the data from our Phase 3 trials, and we may not be able to refer to any such benefits in the labeling. While the data from our Phase 2 trials suggests roxadustat may reduce low-density lipoprotein (“LDL”), and reduce the ratio of LDL to high-density lipoprotein (“HDL”), the data show it may also reduce HDL, which may be a risk to patients. In addition, causes of the safety concerns associated with the use of ESAs to achieve specified target Hb levels have not been fully elucidated. While we believe that the issues giving rise to these concerns with ESAs are likely due to factors other than the Hb levels achieved, we cannot be certain that roxadustat will not be associated with similar, or more severe, safety concerns.

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. In addition, the CKD patient population has many afflictions that may cause severe illness or death, which may be attributed to roxadustat in a manner that negatively impacts the safety profile of our product candidate. If the results of our ongoing or future clinical trials for roxadustat are inconclusive with respect to efficacy, if we do not meet our clinical endpoints with statistical significance, or if there are unanticipated safety concerns or adverse events that emerge during clinical trials, we may be prevented from or delayed in obtaining marketing approval for roxadustat, and even if we obtain marketing approval, any sales of roxadustat may suffer.

Our preclinical and Phase 2 results to date for pamrevlumab may not be indicative of the results that may be obtained in larger, controlled Phase 2 clinical trials or Phase 3 clinical trials required for approval.*

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 early or small clinical trials may not be replicated or show as favorable an outcome, even if successful. We have conducted only a limited number of Phase 2 clinical trials with pamrevlumab. We have conducted a randomized placebo-controlled study in 103 IPF patients with substudies comparing pamrevlumab to 57 IPF patients receiving one of two standards of care, an open-label Phase 2 dose escalation study of pamrevlumab for IPF in 89 patients, a Phase 2 dose finding trial of pamrevlumab combined with gemcitabine plus erlotinib in 75 patients with pancreatic cancer and a randomized double-blind placebo controlled study for liver fibrosis in subjects with hepatitis B. We cannot be sure that the results of these trials will be substantiated in double-blinded trials with larger numbers of patients, that larger trials will demonstrate the efficacy of pamrevlumab for these or other indications or that safety issues will not be uncovered in further trials. In the Phase 2 clinical trial for IPF, we used quantitative high resolution computed tomography (“HRCT”), to measure the extent of lung fibrosis. While we believe that quantitative HRCT is an accurate measure of lung fibrosis, it is a novel technology that has not yet been accepted by the FDA as a primary endpoint in pivotal clinical trials. In addition, while we believe that the animal studies that we have conducted to date suggest that pamrevlumab has the potential to arrest or reverse fibrosis and reduce tumor mass, we cannot be sure that these results will be indicative of the effects of pamrevlumab in human trials. In addition, the IPF and pancreatic cancer patient populations are extremely ill and routinely experience SAEs, including death, which may be attributed to pamrevlumab in a manner that negatively impacts the safety profile of our product candidate. If the additional clinical trials that we are planning or are currently conducting for pamrevlumab do not show favorable efficacy results or result in safety concerns, or if we do not meet our clinical endpoints with statistical significance, or demonstrate an acceptable risk-benefit profile, we may be prevented from or delayed in obtaining marketing approval for pamrevlumab in one or both of these indications.

We do not know whether our ongoing or planned Phase 3 clinical trials in roxadustat or Phase 2 clinical trials in pamrevlumab will need to be redesigned based on interim results, be able to achieve sufficient enrollment or be completed on schedule, if at all.

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 ("IRB") 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;
- 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 addition, we could encounter delays if a clinical trial is suspended or terminated by us, by the relevant IRBs 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 and 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. Adverse events and SAEs that emerge during treatment with our product candidates or other compounds acting through similar biological pathways may be deemed to be related to our product candidate and 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 — Our Development Program for Roxadustat*" and "*Business — Pamrevlumab for the Treatment of Fibrosis and Cancer*" for a discussion of the adverse events and SAEs 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, may a more complete safety profile be 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 ESAs, that have been approved by the regulatory authorities but for which safety concerns have been uncovered following approval. Such safety concerns have led to labeling changes or withdrawal of ESAs products from the market, and any of our product

candidates may be subject to similar risks. For example, roxadustat for use in anemia in CKD is being developed to address a very diverse patient population expected to have many serious health conditions at the time of administration of roxadustat, including diabetes, high blood pressure and declining kidney function.

Although to date we have not seen evidence of significant safety concerns with our product candidates currently in clinical trials, 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.

We may fail to enroll a sufficient number of patients in our clinical trials in a timely manner, which could delay or prevent clinical trials of our product candidates.

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:

- 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;
- ongoing clinical trials of competitive agents;
- physicians' and patients' perceptions as to the potential advantages of our product candidates being studied in relation to available therapies or other products under development;
- our, 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.

Patients may be unwilling to participate in our clinical trials for roxadustat due to adverse events observed in other drug treatments of anemia in CKD, and patients currently controlling their disease with existing ESAs may be reluctant to participate in a clinical trial with an investigational drug. We may not be able to successfully initiate or continue clinical trials if we cannot rapidly enroll a sufficient number of eligible patients to participate in the clinical trials required by regulatory agencies. 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, any of which could have a material and adverse effect on our business and prospects.

If we or third party manufacturers on which we rely cannot manufacture sufficient quantities of our product candidates, or at sufficient quality, we may experience delays in development, regulatory approval, launch or commercialization.

Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture our product candidates at sufficient yields and at commercial scale. We have not yet entered into any commercial supply agreements with third-party manufacturers. 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 or coordinating forecasting supply for launch or commercialization, which is a complex process involving our third-party manufacturers and for roxadustat our collaboration partners. We may not be able to sufficiently forecast supplies for commercial launch, or do so in a timely manner and our efforts to establish these manufacturing capabilities may not meet our requirements as to quantities, scale-up, yield, cost, potency or quality in compliance with cGMP.

We have a limited amount of roxadustat and pamrevlumab in storage, limited capacity reserved at our third-party manufacturers, and there are long lead times required to manufacture and scale-up the manufacture of additional supply, as required for both late-stage clinical 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. For example, prior to agreement with regulatory authorities on the scope of our Phase 3 IPF trial design, there is uncertainty as to whether our supply plans will meet our clinical requirements in a timely manner. 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 clinical trials must be conducted with product produced under applicable cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We and even an experienced third party manufacturer may encounter difficulties in production, which 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;
- supply chain issues, including coordination of multiple contractors in our supply chain;
- the timely availability and shelf life requirements of raw materials and supplies;
- quality control and assurance;
- 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 floods, storms, earthquakes, tsunamis, and droughts, or accidents such as fire, that affect facilities, possibly limit or postpone production, and increase costs.

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, we expect that regulatory approvals, if obtained at all, will limit the approved indicated uses for which roxadustat may be marketed, as ESAs have been subject to significant safety limitations on usage as directed by the "Black Box" warnings included in their labels. Refer to "*Business — Roxadustat for the Treatment of Anemia in Chronic Kidney Disease — Limitations of the Current Standard of Care for Anemia in CKD*". In addition, in the past, an approved ESA was voluntarily withdrawn due to serious safety issues discovered after approval. 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 that limit the market opportunity for roxadustat. These warnings could include warnings against exceeding specified Hb targets and other warnings that derive from the lack of clarity regarding the basis for the safety issues associated with ESAs, even if our Phase 3 clinical trials do not themselves raise safety concerns.

As an organization, we have never completed a Phase 3 clinical trial or received approval for a New Drug Application ("NDA") before, and may be unable to do so efficiently or at all for roxadustat or any product candidate we are developing.

We are currently conducting Phase 2 clinical trials for pamrevlumab and plan on initiating Phase 3 clinical trials for pamrevlumab in the future. We have initiated Phase 3 clinical trials of roxadustat. The conduct of Phase 3 clinical trials and the submission of a successful NDA is a complicated process. As an organization, we have not completed a Phase 3 clinical trial before, have limited experience in preparing, submitting and prosecuting regulatory filings, and have not received approval for an NDA before. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to NDA submission and approval of roxadustat or for any other product candidate we are developing, even if our earlier stage clinical trials are successful. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials would prevent us from or delay us in commercializing roxadustat or any other product candidate we are developing.

In addition, in order for any Phase 3 clinical trial to support an NDA 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 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 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 and the FDA or other regulatory authorities may require us to exclude the use of patient data from our clinical trials not conducted in compliance with GCP or perform additional clinical trials before approving our marketing applications. They may even reject our application for approval or refuse to accept our future applications for an extended time period. For example in China, the China Food and Drug Administration ("CFDA") recently issued guidance related to its clinical trial data integrity regulations. While trial sites and CROs bear liability for the accuracy and authenticity of data they are directly responsible for, the sponsor ultimately bears full responsibility for submitted clinical data and the drug application dossier. Fraudulent clinical data could result in a ban in China of a sponsor's product-related NDA applications for three years and other NDA applications for one year. We have taken extensive steps to ensure the integrity of our China clinical data. However, we cannot assure you 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 will be deemed authentic or may be used in support of our regulatory submissions.

If we are unable to establish sales, marketing and distribution capabilities or enter into or maintain agreements with third parties to market and sell our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no 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.

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 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 (“KHK”), in Japan and China), darbepoetin (Amgen/KHK’s Aranesp ® and NESP ®) and Mircera ® marketed by Hoffmann-La Roche (“Roche”) outside of the U.S. and by Vifor Pharma (formerly a company of Galenica Group (“Vifor”)), 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 over 20 years, serving a significant majority of dialysis dependent CKD patients. While NDD-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 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 those patient segments not currently addressed by ESAs. Companies such as GlaxoSmithKline plc (“GSK”), Bayer Corporation (“Bayer”), Akebia Therapeutics, Inc. (“Akebia”), and Japan Tobacco, who are currently developing HIF prolyl hydroxylase (“HIF-PH”) inhibitors for anemia in CKD indications, may be in competition with roxadustat for patient recruitment and enrollment for clinical trials and may be in direct competition with roxadustat if and when it is approved and launched commercially. Akebia is currently conducting two Phase 3 studies in non-dialysis-dependent CKD patients primarily in the U.S., one started in December 2015 and the other in February 2016, and initiated two Phase 3 studies in DD-CKD, one in July 2016 and the other in August 2016, also primarily in the U.S. More recently, Akebia started a Phase 2 study with three-times-weekly 20-week dosing in dialysis patients in May 2017. In September 2017, Mitsubishi Tanabe Pharmaceutical Corporation, Akebia’s collaboration partner, announced topline results from a vadadustat Japan Phase 2 study in 51 NDD patients, and its plan to start a Japan Phase 3 development program, rather than including Japan sites in their global Phase 3 program. GSK started Phase 3 studies in NDD-CKD and DD-CKD in the U.S. in September 2016, and in Japan in June 2016. Bayer has completed global Phase 2 studies and recently announced its HIF-PH inhibitor is now in continued development in Japan only, currently in Phase 2. In September 2017, Japan Tobacco started two Phase 3 open label studies in Japan, one in 30 peritoneal dialysis patients and one in 26 ESA naïve hemodialysis patients. Some of these product candidates may enter the market prior to roxadustat.

In addition, there are other companies developing biologic therapies for the treatment of other anemia indications that we may also seek to pursue in the future, including anemia of myelodysplastic syndromes (“MDS”), for which we received approval from the CFDA for our Phase 2/3 clinical trial application in China and acceptance of our investigational new drug application (“IND”) and the Phase 3 pivotal study protocol from the FDA, and expected to start those studies in the second half of 2017. For example, Acceleron Pharma Inc., in partnership with Celgene Corporation, is in Phase 3 development of protein therapeutic candidates to treat anemia and associated complications in patients with ß-thalassemia and MDS, and has received orphan drug status from the EMA and FDA for these indications. 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, biosimilars of epoetin alfa are offered by Chinese pharmaceutical companies such as EPIAO marketed by 3SBio Inc. as well as over 15 other local manufacturers. We may also face competition by HIF-PH inhibitors from other companies such as Akebia, Bayer, and GSK who recently was authorized by the CFDA to conduct trials in China to support its ex-China regulatory filings. Akebia announced in December 2015 that it has 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 recently announced an expansion of their U.S. collaboration with Otsuka to add markets, including China. 3SBio Inc. also announced in 2016 its plan on beginning a Phase 1 clinical trial of a HIF-PH inhibitor for the China market.

The introduction of biosimilar ESAs into the market in the U.S. may occur by the time roxadustat enters the market and may alter the competitive and pricing landscape of anemia therapy in DD-CKD patients under the end stage renal disease bundle. The patents for Amgen's epoetin alfa, EPOGEN, expired in 2004 in the European Union ("EU"), 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 the EU, China and other territories. In the U.S., a few ESA biosimilars are currently under development or regulatory review, including Retacrit® (epoetin zeta), marketed by Pfizer in Europe and for which Pfizer resubmitted a Biologics License Application ("BLA") after receiving a complete response letter ("CRL") from the FDA denying approval of its BLA submitted in October 2015. While FDA's Advisory Committee recommended approving the BLA in May 2017, FDA issued another CRL on June 22, 2017. Sandoz, a division of Novartis, markets Binocrit ® (epoetin alfa) in Europe and plans to file a biosimilar BLA in 2017 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 approximately 70% of the U.S. dialysis patients, and therefore have historically won long-term contracts including rebate terms with Amgen. DaVita recently entered into a new 6-year sourcing and supply agreement with Amgen effective through 2022. Fresenius' contract with Amgen expired in 2015, and Fresenius is now administering Mircera ® in a significant portion of its U.S. dialysis patients since Mircera was made available by Vifor. Successful penetration of this market may require AstraZeneca to reach a significant agreement with Fresenius or DaVita on favorable terms and on a timely basis.

If pamrevlumab is approved and launched commercially to treat IPF, competing drugs are expected to include Roche's pirfenidone, which is approved for marketing in Europe, Canada, Japan and the U.S., and Boehringer Ingelheim's nintedanib which has been approved in the U.S. and EU. Nintedanib is also in development for non-small cell lung cancer and ovarian cancer. Other potential competitive product candidates in various stages of Phase 2 development for IPF include Promedior Inc.'s PRM-151, Biogen-Idec's STX-100, and Prometic Life Sciences Inc.'s PBI-4050.

If pamrevlumab is approved and launched commercially to treat pancreatic cancer, we expect it to be used in combination instead of as monotherapy, and, likely competition for pamrevlumab would be from other agents also seeking approval in combination with gemcitibine and nab-paclitaxel from companies such as NewLink Genetics Corporation, Merrimack Pharmaceuticals, Inc. ("Merrimack") and Halozyme Therapeutics, Inc. 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. In 2015, Merrimack received FDA approval for the use of ONIVYDE (irinotecan liposome injection) for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy.

If pamrevlumab is approved and launched commercially to treat DMD, pamrevlumab may face competition for some patients from Sarepta Therapeutics, Inc. ("Sarepta"), as well as PTC Therapeutics, Santhera Pharmaceuticals, Pfizer, Summit plc and Tivorsan Pharmaceuticals. Sarepta is researching and developing clinical candidates for many of the specific mutations in the dystrophin gene and recently received accelerated approval in the United States for its first drug Exondys 51 (eteplirsen). The approval is limited to patients who have a confirmed mutation in the DMD gene that is amenable to exon 51 skipping. This mutation represents a subset of approximately 13% of patients with DMD. Marathon Pharmaceuticals received approval for its drug Emflaza (deflazacort) on February 9, 2017 and on March 16, 2017 announced that it had sold the commercialization rights to Emflaza to PTC Therapeutics. PTC Therapeutics' product ataluren (Translarna ™) received conditional approval in Europe in 2014 and a complete response letter from the FDA in October of 2017 stating that the FDA is unable to approve the application in its current form. Translarna targets a different set of DMD patients from those being targeted by Sarepta's existing exon-skipping therapeutic candidate; however it is also limited to a subset of patients who carry a specific mutation.

Conversely, pamrevlumab and some other potential competitors are intended to treat DMD patients regardless of the specific mutation. For example, Santhera Pharmaceuticals recently reported positive Phase 3 data with its drug idebenone (Raxone ®/Catena ®) in a trial measuring changes in lung function for DMD patients, however the FDA has asked for additional data from an ongoing trial prior to considering Raxone for approval. Previously we had expected this additional trial to be confirmatory rather than necessary for submission. Idebenone is a synthetic short-chain benzoquinone and a cofactor for the enzyme NAD(P)H:quinone oxidoreductase (NQO1). Pfizer's product candidate, which is in Phase 2 development to treat DMD, is an antibody targeting myostatin which is a protein that regulates muscle growth. The goal of the program is to increase muscle growth and muscle strength in patients with DMD. Summit plc and Tivorsan Pharmaceuticals are both working on drugs involving the utrophin pathway. Utrophin is a protein similar to dystrophin that is potentially implicated in all DMD patients. Summit is conducting a Phase 2 trial and Tivorsan intends to submit an IND and start Phase 1 in 2017. In October 2016, Summit and Sarepta announced a collaboration in which the companies have agreed to collaborate on Summit's utrophin modulator pipeline including its lead candidate ezutromid. The companies will co-develop the pipeline and Sarepta will receive the rights to the compounds in Europe, Turkey, and the Commonwealth of Independent States. Sarepta also has an option on the rights to the program for Latin America. Summit will retain commercialization rights in all other countries including the U.S.

If FG-5200 is approved and launched to treat corneal blindness resulting from partial thickness corneal damage without active inflammation and infection in China, it is likely to compete with other products designed to treat corneal damage. For example, in April 2015, a subsidiary of China Regenerative Medicine International Limited received approval for their acellular porcine cornea stroma medical device to treat patients in China with corneal ulcers and in April 2016, Guangzhou Yourvision Biotech Co. Ltd, a subsidiary of Guanhao Biotech, received approval for their acellular porcine cornea medical device to treat patients in China with infectious keratitis that does not respond to drug treatment.

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 comparators, whether placebo or active, 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 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. These competitors have in the past successfully prevented new and competing products from entering into the anemia market, and we expect that their resources will represent challenges for us and our collaboration partners, AstraZeneca and Astellas. 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.

Our future commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, third party payors and others in the health care community.

Even if we obtain marketing approval for roxadustat, pamrevlumab or any other product candidates that we may develop or acquire in the future, these product candidates may not gain market acceptance among physicians, third party payors, patients and others in the health care community. Market acceptance of any approved product depends on a number of other factors, including:

- 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;
- acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new therapies and of physicians to prescribe new therapies;
- the cost, safety, efficacy and convenience of treatment in relation to alternative treatments;
- the restrictions on the use of our products together with other medications, if any;
- the availability of adequate coverage and reimbursement or pricing by third party payors and government authorities;

- the ability of treatment providers, such as dialysis clinics, to enter into relationships with us without violating their existing agreement; and
- the effectiveness of our sales and marketing efforts.

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 third party payors and may be affected by existing and future healthcare reform measures or the prices of related products for which third party reimbursement applies. Coverage and reimbursement by a third party payor may depend upon a number of factors, including the third party payor's determination that use of a product is:

- a covered benefit under its 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. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our products.

Price controls may limit the price at which products such as roxadustat, if approved, are sold. For example, reference pricing is used by various EU 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 Our Reliance on Third Parties

If our collaborations with Astellas or AstraZeneca were terminated, or 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, our ability to successfully develop and commercialize our lead product candidate, roxadustat, 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.

Conflicts with our collaboration partners could jeopardize our collaboration agreements and our ability to commercialize product candidates.

Our collaboration partners 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, 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 a novel drug such as roxadustat in the dialysis market.

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 Phase 3 development program. 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 planned Phase 3 clinical studies.

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, and we should be precluded from such internal activities. Moreover, disagreements with our collaboration partners could develop over rights to our intellectual property. 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.

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 Phase 3 development program for 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 you 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 clinical studies and product manufacturing, and these third parties may not perform satisfactorily.*

We do not have any operating manufacturing facilities at this time other than our roxadustat and FG-5200 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. 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 for all aspects of manufacturing activities, including regulatory compliance and quality control and assurance;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that 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 or suppliers unrelated to our product, including the bankruptcy of the manufacturer or supplier or a catastrophic event affecting our manufacturers 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.

Any of our 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 active pharmaceutical ingredients ("APIs") 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 our Phase 3 clinical trials or, if roxadustat is approved and marketed, a failure to satisfy patient demand.

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. To date, we have used purchase orders for the supply of materials that we use in our product candidates. We may be unable to enter into long-term commercial supply arrangements with our vendors, 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. Moreover, we currently do not have any agreements for the commercial production of those materials.

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 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 ("AIA"), 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 assign their inventions to us, 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 intend, if necessary, to vigorously enforce our intellectual property in order to protect the proprietary position of our product candidates, including roxadustat and pamrevlumab. Active efforts to enforce our patents 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. We previously prevailed in an administrative challenge initiated by a major biopharmaceutical company regarding our intellectual property rights, maintaining our intellectual property in all relevant scope, and will continue to protect and enforce our intellectual property rights. Moreover, third parties may continue to initiate new proceedings in the U.S. and foreign jurisdictions to challenge our patents from time to time.

We may consider administrative proceedings and other means for challenging third party patents and patent applications. 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 other comparable proceedings, such as oppositions or invalidation proceedings, before foreign patent offices. 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. Even if we are successful, participation in administrative proceedings before the USPTO or a foreign patent office may result in substantial costs and time on the part of our management and other employees. For example, oppositions have been filed against four FibroGen European patents within our HIF Anemia-related Technologies Patent Portfolio. (An opposition is a European Patent Office mechanism providing for a third-party challenge to a granted European patent.) In three of these proceedings, for FibroGen European Patent Nos. 1463823, 1633333 and 2322155, the European Patent Office has handed down decisions unfavorable to FibroGen. These decisions are currently under appeal, and these three patents are valid and enforceable pending resolution of the appeals. In the fourth of the challenged cases, the European Patent Office issued a decision favorable to FibroGen, maintaining FibroGen European Patent No. 2322153. An appeal of this decision may be filed by one or more parties to the opposition. The ultimate outcomes of these proceedings remain uncertain, and ultimate resolution of each of the appeal proceedings may take two to four years or longer. While we believe these FibroGen patents will be upheld in relevant part, we note that narrowing or even revocation of any of these patents would not affect our exclusivity for roxadustat or our freedom-to-operate with respect to use of roxadustat for the treatment of anemia.

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, particularly certain developing countries such as China, 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. 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, often are of lower cost, often are of lower quality (having different ingredients or formulations, for example), and have the potential to damage the reputation for quality and effectiveness of the genuine product. 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. 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 ever obtain regulatory approval.

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, 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 current or planned 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.

If our product candidates obtain marketing approval, we will be subject to more extensive healthcare laws, regulation and enforcement and our failure to comply with those laws could have a material adverse effect on our results of operations and financial condition.

If we obtain approval 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 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 United States Government must be manufactured in the United States or in TAA approved and designated countries. Drugs manufactured in countries not approved under the TAA, may not be sold to the United States 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 United States 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 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.

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, if any, 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 which 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 Centers for Medicare and Medicaid Services ("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, 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. If roxadustat is reimbursed outside of the bundle, it may potentially limit or delay market penetration of roxadustat.

More recently, the PPACA was enacted in 2010 with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers. The PPACA, among other things, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. In addition, other legislative changes have been proposed and adopted in the U.S. since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013.

It is likely that federal and state legislatures within the U.S. and foreign governments will continue to consider changes to existing healthcare legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any products that may be approved for sale;
- the price and profitability of our products;
- pricing, coverage and reimbursement applicable to our products;
- the ability to successfully position and market any approved product; and
- the taxes applicable to our pharmaceutical product revenues.

Some of the provisions of the PPACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, that while not a law, is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the PPACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the Affordable Care Act that are repealed. Given these possibilities and others we may not anticipate, the full extent to which our business, results of operations and financial condition could be adversely affected by the recent proposed legislation and the Executive Order is uncertain. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

Furthermore, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent regulatory approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We may not be able to conduct, or contract others to conduct, animal testing in the future, which could harm our research and development activities.

Certain laws and regulations relating to drug development require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted or delayed.

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 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 foreign 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;
- unexpected 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;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating 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, including war and terrorism, or natural disasters.

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. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our product candidates in China. Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry, in some cases launching industry-wide investigations, oftentimes appearing to focus on foreign companies. The costs and time necessary to respond to an investigation can be material. 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.

Patients' use of traditional Chinese medicine in violation of study protocols in our China studies may lead the China Food and Drug Administration ("CFDA") and regulators in other jurisdictions in which we are seeking approval to suspend our studies, reject our study data and withhold approval for roxadustat.

A common issue encountered in conducting clinical studies in China is patients' use of traditional Chinese medicine in violation of study protocols. We believe that many patients with anemia in CKD are currently being treated with traditional Chinese medicine, and it is possible that such patients may continue their use of traditional Chinese medicine after enrollment in our studies and in violation of study protocols. If the patients participating in our China clinical studies do not comply with study protocols and continue to use traditional Chinese medicine, adverse events may emerge in our studies that are due to such traditional Chinese medicine or the interaction between such traditional Chinese medicine and roxadustat. In addition, the use of traditional Chinese medicine by patients in our studies may confound our study results. The occurrence of such adverse events or the confounding of our study results may lead the CFDA and regulators in other jurisdictions in which we are seeking approval to, among other things, suspend our studies, reject our study data and withhold approval for roxadustat.

We are planning on using our own manufacturing facilities in China to produce roxadustat drug product, FG-5200 corneal implants, and possibly roxadustat API. As an organization, we have limited experience in the construction, licensure, or operation of a manufacturing plant, and, accordingly we cannot assure you we will be able to meet regulatory requirements to operate our plant and to sell our products.*

In 2014, we received a Pharmaceutical Production Permit ("PPP") for our facility in Beijing, China, and are currently building a manufacturing facility in Cangzhou, Hebei, in which we intend to manufacture roxadustat for commercial sale. The PPP allowed us to produce the NDA registration campaign of roxadustat according to cGMP. However, we have not yet received a license for commercial manufacture of roxadustat. As an organization, we have limited experience building and licensing manufacturing facilities which must be constructed, licensed and operated in conformity with applicable cGMP requirements. We will be obligated to comply with continuing cGMP requirements and there can be no assurance that we will receive and 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 succeed for licensure or continue to be successful in meeting these requirements.

We would require separate approval for the manufacture of FG-5200. In addition, we may convert our existing manufacturing process of FG-5200 to a semi-automated process which may require us to show that implants from our new manufacturing process are comparable to the implants from our existing manufacturing process. There can be no assurance that we will successfully receive licensure and maintain approval for the manufacture of either or both of roxadustat or FG-5200, either of which would be expected to delay or preclude our ability to develop and commercialize those product candidates in China and may materially adversely affect our business and operations and prospects in China.

Manufacturing facilities in China are subject to periodic unannounced inspections by the CFDA 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, 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.

Our decision to seek approval in China for roxadustat prior to approval in the U.S. or Europe is largely unprecedented and could be subject to significant risk, delay and expense.*

Our subsidiary FibroGen (China) Medical Technology Development Co., Ltd. ("FibroGen Beijing"), plans to seek approval for roxadustat in China as a Domestic Class 1 Drug, which we believe, if approved, would be the first CFDA approval of a first in class drug candidate while Phase 3 trials are ongoing in the U.S. and Europe. Because of this largely novel regulatory pathway, the CFDA approval process may take longer than we currently expect, or the CFDA may require us to submit additional data including data from the U.S. or European Phase 3 trials. In addition, negative data from the U.S. or European Phase 3 trials could impact the CFDA approval process. Any such development delays would result in significant delay in our commercialization plans for roxadustat in China. Elements of our plan for approval of roxadustat and other product candidates in China are based on communications with the CFDA, some of which are not reflected in formal written communications, regulations, findings or determinations. Accordingly, while we believe we have understandings with the CFDA regarding the domestic drug approval process and the clinical and manufacturing

(including bio-equivalency) data currently required for approval and the timing and process of a potential approval, the regulatory authorities may later determine that changes are required in the drug approval process, or that additional or different clinical or manufacturing data must be generated, any of which could significantly delay approval of roxadustat or any of our other product candidates, and materially and adversely affect our plans and operations in China. It is possible that other unforeseen delays in the China regulatory process could have a material adverse effect on our development and commercialization of roxadustat in China.

For example, prior to enrolling our Phase 3 studies, the Ministry of Science and Technology established a new approval process to obtain routine blood and urine samples that contain genetic information. Our Phase 3 CKD clinical trial sites have received such approval, but applications are reviewed only on a quarterly basis, thus new studies or work at additional clinical trial sites could be delayed until they receive such approval.

In addition, there are new and evolving environmental and manufacturing regulations in China. The application thereof may impact our API manufacturing location or strategy. In order to prevent or mitigate any delay in commercialization, we are establishing a 5,500 square meter commercial API manufacturing facility in Cangzhou, Hebei, with the intention of being operational shortly after NDA approval. Any delays related to these regulations or our new manufacturing facility could adversely affect the cost timing of our commercialization in China.

In May 2016, China announced implementation of a three-year pilot program for the Marketing Authorization Holder System ("MAH") in certain piloted regions. We are considering applying to participate in this program, and if accepted, we may be able to outsource drug product or API manufacturing to third parties while retaining the manufacturing license. However, we cannot know if we will be accepted into the MAH program, or how long such program will be available.

Even if roxadustat is approved 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. Even if roxadustat is approved for sale in China, we and AstraZeneca may experience difficulties in our marketing, commercialization and sales efforts in China, and our business and operations could be adversely affected. In particular, sales of roxadustat in China may be limited due to the complex nature of the healthcare system, low average personal income, lack of patient cost reimbursement, pricing controls, poorly developed infrastructure and potentially rapid competition from other products.

The market for treatments of anemia in CKD in China is highly competitive.

Even if roxadustat is approved in China, it will face intense competition in the market for treatments of anemia in CKD. Roxadustat would compete with ESAs, which are offered by established multinational pharmaceutical companies such as Kyowa Hakko Kirin China Pharmaceutical Co., Ltd. and Roche and Chinese pharmaceutical companies such as 3SBio Inc. and Di'ao Group Chengdu Diao Jiuhong Pharmaceutical Factory. Many of these competitors have substantially greater name recognition, scientific, financial and marketing resources as well as established distribution capabilities than we do. Many of our competitors have more resources to develop or acquire, and more experience in developing or acquiring, new products and in creating market awareness for those products. Many of these competitors have significantly more experience than we have in navigating the Chinese regulatory framework regarding the development, manufacturing and marketing of drugs in China, as well as in marketing and selling anemia products in China. Additionally, we believe that most patients with anemia in CKD in China are currently being treated with traditional Chinese medicine, which is widely accepted and highly prevalent in China. Traditional Chinese medicine treatments are often oral and thus convenient and low-cost, and practitioners of traditional Chinese medicine are numerous and accessible in China. As a result, it may be difficult to persuade patients with anemia in CKD to switch from traditional Chinese medicine to roxadustat.

There is no assurance that roxadustat will be included in the Medical Insurance Catalogs.

Eligible participants in the national basic medical insurance program in China, which consists of mostly urban residents, are entitled to reimbursement from the social medical insurance fund for up to the entire cost of medicines that are included in the Medical Insurance Catalogs. Refer to "*Business — Government Regulation — Regulation in China*." We believe that the inclusion of a drug in the Medical Insurance Catalogs can substantially improve the sales of a drug. The Ministry of Labor and Social Security in China ("MLSS") together with other government authorities, select medicines to be included in the Medical Insurance Catalogs based on a variety of factors, including treatment requirements, frequency of use, effectiveness and price. The MLSS also occasionally removes medicines from such catalogs. There can be no assurance that roxadustat will be included, and once included, remain in the Medical Insurance Catalogs. The exclusion or removal of roxadustat from the Medical Insurance Catalogs may materially and adversely affect sales of roxadustat.

We may not be successful in the tender processes for the purchase of medicines by state-owned and state-controlled hospitals.

Most hospitals in China participate in collective tender processes for the purchase of medicines listed in the Medical Insurance Catalogs and medicines that are consumed in large volumes and commonly prescribed for clinical uses. During a collective tender process, the hospitals will establish a committee consisting of recognized pharmaceutical experts. The committee will assess the bids submitted by the various participating pharmaceutical manufacturers, taking into consideration, among other things, the quality and price of the drug product and the service and reputation of the manufacturer. Only drug products that have been selected in the collective tender processes may be purchased by participating hospitals. If we are unable to win purchase contracts through the collective tender processes in which we decide to participate, there will be limited demand for roxadustat, and sales revenues from roxadustat will be materially and adversely affected.

Even if FG-5200 can be manufactured successfully and achieve regulatory approval, we may not achieve commercial success.

We have not yet received a license to manufacture FG-5200 in our Beijing manufacturing facility or at scale, and we will have to show that FG-5200 from our China manufacturing facility meets the applicable regulatory requirements. There can be no assurance that we can meet these requirements or that FG-5200 can be approved for development, manufacture and sale in China.

Even if we are able to manufacture and develop FG-5200 as a medical device in China, the size and length of any potential clinical trials required for approval are uncertain and we are unable to predict the time and investment required to obtain regulatory approval. Moreover, even if FG-5200 can be successfully developed for approval in China, our product candidate would require extensive training and investment in assisting physicians in the use of FG-5200.

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 which 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 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 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 expenses. The payment of dividends by FibroGen Beijing is subject to limitations. Regulations in China currently permit payment of dividends only out of accumulated profits as determined in accordance with accounting standards and regulations in China. FibroGen Beijing is not permitted to distribute any profits until losses from prior fiscal years have been recouped and in any event must maintain certain minimum capital requirements. FibroGen Beijing is also required to set aside at least 10.0% of its after-tax profit based on Chinese accounting standards each year to its statutory reserve fund until the cumulative amount of such reserves reaches 50.0% of its registered capital. Statutory reserves are not distributable as cash dividends. In addition, if FibroGen Beijing incurs debt on its own behalf in the future, the agreements governing such debt may restrict its ability to pay dividends or make other distributions to us. As of September 30, 2017, approximately $2.4 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.

If roxadustat is approved for sale in China, 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 the U.S., comprehensive tax reform has been announced as a priority by the new President's administration and the U.S. Congress. Various proposals are under evaluation and consideration but it is not possible to accurately ascertain at this time the overall impact of such proposals on our future effective tax rate and corporate structure.

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 of the tax treaties, we could be subject to additional taxes, which could adversely affect our financial condition and results of operations.

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.

We are subject to laws and regulations governing corruption, which will require us to develop 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 creation and implementation of international business practices compliance programs is costly and such programs are 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.

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.

The Chinese economy and Chinese society continue to undergo significant change. Adverse changes in the political 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 structure of foreign investment in this industry. We are unable to predict the frequency and scope of such policy changes, any of which could materially and adversely affect FibroGen Beijing's 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.

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.

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

The United Kingdom held a referendum on June 23, 2016 in which a majority voted for the United Kingdom's withdrawal from the EU, commonly referred to as "Brexit". As a result of this vote, negotiations are expected to commence to determine the terms of the United Kingdom's withdrawal from the EU as well as its relationship with the EU going forward, including the terms of trade between the United Kingdom and the EU. The effects of the United Kingdom's withdrawal from the EU, 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 EU could also have the effect of disrupting the free movement of goods, services and people between the United Kingdom and the EU and could also lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which EU 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. However, the full effects of such withdrawal are uncertain and will depend on any agreements the United Kingdom may make to retain access to EU markets. Lastly, as a result of the United Kingdom's withdrawal from the EU, other European countries may seek to conduct referenda with respect to their continuing membership with the EU. Given these possibilities and others we may not anticipate, as well as the lack of comparable precedent, the full extent to which our business, results of operations and financial condition could be adversely affected by the United Kingdom's withdrawal from the EU is uncertain.

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 our company.

If we fail to attract and keep senior management and key personnel, in particular our chief executive officer, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

We are highly dependent on our chief executive officer, Thomas B. Neff, and other members of our senior management team. The loss of the services of Mr. Neff or any of these other individuals would be expected to significantly negatively impact the development and commercialization of our product candidates, our existing collaborative relationships 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. 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 have recently upgraded our disaster data recovery program, 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 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 and data storage facilities 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, such as data storage, 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.

We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations, 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. 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 publication of research reports by securities analysts about us or our competitors or our industry or negative recommendations or withdrawal of research coverage by securities analysts;
- 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;
- the ineffectiveness of our internal controls;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- announced strategic decisions by us or our competitors;
- 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;
- sales of our common stock by us, our insiders or our other stockholders;
- speculation in the press or investment community;
- announcement or expectation of additional financing efforts;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- changes in accounting principles;
- 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;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters such as earthquakes and other calamities;
- changes in market conditions for biopharmaceutical stocks;
- changes in general market and economic conditions; 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.

We have broad discretion in the use of the net proceeds from our underwritten public offerings of common stock completed on April 11, 2017 (the "April 2017 Offering")and completed on August 24, 2017 (the "August 2017 Offering") and may not use them effectively.*

The net proceeds from the April 2017 Offering is intended to be used to fund the expansion of product development in China, including developing roxadustat in additional indications beyond CKD, manufacturing and commercialization activities, as well as for general corporate purposes. The net proceeds from the August 2017 Offering is intended to be used to fund the expansion of product development, including our development of pamrevlumab beyond current Phase 2 programs, manufacturing and commercialization activities, as well as for general corporate purposes. These general corporate purposes, may include, among other things, funding research and development, clinical trials, vendor payables, potential regulatory submissions, hiring additional personnel and capital expenditures. However, we have no current commitments or obligations to use the net proceeds in the manner described above. Our management has broad discretion in the application of the balance of the net proceeds from the April 2017 Offering and the August 2017 Offering, and could spend the proceeds in ways our stockholders may not agree with or that fails to improve our business or enhance the value of our common stock. The failure by our management to use these funds effectively could result in financial losses that could harm our business, cause the price of our common stock to decline and delay the development of our product candidates.

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 our company 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 October 31, 2017, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 21.21% 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 July 31, 2017. 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.

Additional remedial measures that may be imposed in the proceedings instituted by the SEC against five China based accounting firms, including the Chinese affiliate of our independent registered public accounting firm, could result in our consolidated financial statements being determined to not be in compliance with the requirements of the Exchange Act.

In late 2012, the SEC commenced administrative proceedings under Rule 102(e) of its Rules of Practice and also under the Sarbanes-Oxley Act of 2002 against the Chinese affiliates of the "big four" accounting firms, including PricewaterhouseCoopers Zhong Tian CPAs Limited, the Chinese affiliate of our independent registered public accounting firm. The Rule 102(e) proceedings initiated by the SEC relate to these firms' failure to produce documents, including audit work papers, in response to the request of the SEC pursuant to Section 106 of the Sarbanes-Oxley Act of 2002, as the auditors located in China are not in a position lawfully to produce documents directly to the SEC because of restrictions under Chinese law and specific directives issued by the China Securities Regulatory Commission ("CSRC"). The issues raised by the proceedings are not specific to our auditors or to us.

In January 2014, an administrative law judge reached an initial decision that the Chinese affiliates of the "big four" accounting firms should be barred from practicing before the SEC for a period of six months. In February 2015, the Chinese affiliates of the "big four" accounting firms each agreed to a censure and to pay a fine to the SEC to settle the dispute and avoid suspension of their ability to practice before the SEC and audit U.S.-listed companies. The settlement required the firms to follow detailed procedures and to seek to provide the SEC with access to Chinese firms' audit documents via the CSRC. If future document productions fail to meet specified criteria, the SEC retains authority to impose a variety of additional remedial measures on the firms depending on the nature of the failure.

We cannot predict if the SEC will further review the four firms' compliance with specified criteria or if such further review would result in the SEC imposing additional penalties such as suspensions or commencing any further administrative proceedings. Although it does not play a substantial role (as defined under PCAOB standards) in the audit of our consolidated financial statements, if PricewaterhouseCoopers Zhong Tian CPAs Limited were denied, temporarily, the ability to practice before the SEC, our ability to produce audited consolidated financial statements for our company could be affected and we could be determined not to be in compliance with the requirements of the Exchange Act. Such a determination could ultimately lead to the delisting of our shares from the NASDAQ Global Select Market or deregistration from the SEC, or both, which would substantially reduce or effectively terminate the trading of our 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.

While we currently have no specific plans to acquire any other businesses, 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 our company. 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.

Our ability to use net operating losses ("NOLs") to offset future taxable income may be subject to certain limitations.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended ("Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOL or tax credits ("credits"), to offset future taxable income. Our existing NOLs or credits may be subject to substantial limitations arising from previous ownership changes, and if we undergo an ownership change our ability to utilize NOLs or credits could be further limited by Section 382 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. As described above under "— *Risks Related to Our Financial Condition and History of Operating Losses*," we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOLs or credits. A full valuation allowance has been provided for all of our NOLs and credits.

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. In the U.S., comprehensive tax reform has been announced as a priority by the new President's administration and the U.S. Congress. Various proposals are under evaluation and consideration but it is not possible to accurately ascertain at this time the overall impact of such proposals on our future tax liabilities, profitability, and financial condition.

We are also subject to non-income taxes, such as payroll, sales, use, value-added, net worth, property, gross receipts, and goods and services taxes in the U.S, state and local, or 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.

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 (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. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. 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. Alternatively, 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	Investor Rights Agreement by and among FibroGen, Inc. and certain of its stockholders, dated as of December 1995.	S-1	333-199069	4.2	10/01/2014
4.3	Investor Rights Agreement by and among FibroGen, Inc. and certain of its warrant holders, dated as of February 8, 2000.	S-1	333-199069	4.7	10/01/2014
4.4	Warrant to Purchase 11,076 Shares of Common Stock issued to Bristow Investments, L.P, dated as of February 8, 2000.	S-1	333-199069	4.12	10/01/2014
4.5	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
4.6*	Shareholders' Agreement by and among FibroGen International (Cayman) Limited and certain of its shareholders, dated as of September 8, 2017.	—	—	—	—
10.9*	Collaboration Agreement, by and between FibroGen, Inc. and Astellas Pharma Inc., effective as of June 1, 2005.	—	—	—	—
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*	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended September 30, 2017, formatted in XBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations (iii) the Condensed Consolidated Statement of Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash Flows and (v) the Notes to the Condensed Consolidated Financial Statements.	—	—	—	—

* Filed herewith

SIGNATURES

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

FibroGen, Inc.

Dated: November 8, 2017

By: /s/ Thomas B. Neff
Thomas B. Neff
Chairman of the Board and Chief Executive Officer
(Principal Executive Officer)

Dated: November 8, 2017

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

Exhibit 4.6

FIBROGEN INTERNATIONAL (CAYMAN LIMITED)

SHAREHOLDERS' AGREEMENT

DATED September 8, 2017

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SHAREHOLDERS' AGREEMENT

THIS SHAREHOLDERS' AGREEMENT (this "**Agreement**") is made as of the 8th day of September, 2017 (the "**Effective Date**"), by and among FibroGen International (Cayman) Limited, a Cayman Islands exempted company limited by shares (the "**Company**") and each of the holders of Series A Preference Shares (including FibroGen, Inc.) listed on Schedule I hereto (each of which is referred to in this Agreement as a "**Holder**" and collectively as the "**Holders**") and any other Person that becomes a party to this Agreement in accordance with Section 8.8 hereof.

RECITALS

WHEREAS, the Holders were previously holders of Series A Preference Shares (the "**Cayman II Series A Shares**") of FibroGen China Anemia Holdings, Ltd. ("**Cayman II**"), a wholly owned subsidiary of the Company;

WHEREAS, pursuant to the terms of that certain offer letter (the "**Offer Letter**"), dated July 29, 2017, of the Company and Cayman II, the Holders (other than FibroGen who was not a shareholder in Cayman II) agreed to the Exchange (as defined in the Offer Letter) of all of their Cayman II Series A Shares held for Series A Preference Shares of the Company;

WHEREAS, pursuant to the terms of the Exchange, this Agreement is contemplated to be executed by the Company and each of the Holders in their capacity assshareholders of the Company; and

WHEREAS, the parties hereto desire to enter into this Agreement to provide for certain matters regarding the Holders' ownership of the Series A Preference Shares.

NOW, THEREFORE, the parties hereby agree as follows:

1. Definitions. For purposes of this Agreement:

1.1. "**Affiliate**" means, with respect to any specified Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including without limitation any general partner, managing member, officer or director of such Person or any venture capital fund now or hereafter existing that is controlled by one or more general partners or managing members of, or shares the same management company with, such Person. As used in this definition, "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct the management and policies of a Person, whether through the ownership of voting securities, contract, or otherwise.

1.2. "**Capital Shares**" means (a) Common Shares and Series A Preference Shares, in each case, whether now outstanding or hereafter issued in any context (including, without limitation, in connection with any share division, sub-division, consolidation, dividend, recapitalization, reorganization, or the like), (b) Common Shares issued or issuable upon conversion of Series A Preference Shares and (c) Common Shares issued or issuable upon exercise or conversion, as applicable, of stock options, warrants or other convertible securities of the Company, in each case now owned or subsequently acquired by any Holder or their respective successors or permitted transferees or assigns. For purposes of the number of shares of Capital Shares held by a Holder (or any other calculation based thereon), all shares of Series A Preference Shares shall be deemed to have been converted into Common Shares at the then-applicable conversion ratio.

1.3. "**Closing"** means the closing of the Exchange.

1.4. "**Common Shares**" means the Company's common shares, par value $0.0001 per share.

1.5. "**Company Notice**" means written notice from the Company notifying the selling Holder(s) that the Company intends to exercise its Right of First Refusal as to a specific number of, or all of, the Transfer Shares with respect to any Proposed Holder Transfer.

1.6. "**Competitor**" means a Person engaged, directly or indirectly (including through any partnership, limited liability company, corporation, joint venture or similar arrangement (whether now existing or formed hereafter)), in the pharmaceutical industry in China for the treatment of anemia, hepatitis C treatment induced anemia, or Myelodysplastic Syndrome, but shall not include any financial investment firm or collective investment vehicle that, together with its Affiliates, holds less than 10% of the outstanding equity of any Competitor and does not, nor do any of its Affiliates, have a right to designate any members of the Board of Directors of any Competitor.

1.7. "**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

1.8. "**Excluded Registration**" means (i) a registration relating to the sale of securities to employees of the Company or a subsidiary pursuant to a share option, share purchase, or similar plan; (ii) a registration relating to an SEC Rule 145 transaction; (iii) a registration on any form that does not include substantially the same information as would be required to be included in a Registration Statement covering the sale of the Registrable Securities; or (iv) a registration in which the only Common Shares being registered are Common Shares issuable upon conversion of debt securities that are also being registered.

1.9. "**Immediate Family Member**" means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, of a natural person referred to herein.

1.10. "**Initiating Holders**" means, collectively, Holders who properly initiate a registration request under this Agreement.

1.11. "**IPO**" means the Company's first underwritten public offering of its Common Shares pursuant to a Registration Statement.

1.12. "**Person**" means any individual, corporation, partnership, trust, limited liability company, association or other entity.

1.1. "**Proposed Holder Transfer**" means any assignment, sale, offer to sell, pledge, mortgage, hypothecation, encumbrance, disposition of or any other like transfer or encumbering of any Transfer Shares (or any interest therein) proposed by any of the Holders.

1.2. "**Proposed Transfer Notice**" means written notice from a Holder setting forth the terms and conditions of a Proposed Holder Transfer.

1.13. **"Prospective Transferee**" means any Person to whom a Holder proposes to make a Proposed Holder Transfer.

1.14. "**Registrable Securities**" means (i) the Common Shares issuable or issued upon conversion of the Series A Preference Shares and (ii) any Common Shares issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as) a dividend or other distribution with respect to the Series A Preference Shares; excluding in all cases, however, any such Common Shares issued or issuable, or any security issued as a dividend, in each case, with respect to Series A Preference Shares sold in a transaction in which the applicable rights under this Agreement are not assigned pursuant to Subsection 8.1, and excluding for purposes of Section 2 any shares for which registration rights have terminated pursuant to Subsection 2.9 of this Agreement.

1.15. "**Registrable Securities then outstanding**" means the number of shares of Registrable Securities determined by adding the number of outstanding Common Shares that are Registrable Securities and the number of Common Shares issuable (directly or indirectly) pursuant to then exercisable and/or convertible securities that are exercisable or convertible into Registrable Securities.

1.16. "**Registration Statement**" means a form S-1 under the Securities Act as in effect on the date hereof, or any successor registration form under the Securities Act subsequently adopted by the SEC, or any similar registration form on a U.S., Hong Kong, China or other exchange on which the Company decides to list.

1.17. **"Reorganization"** means a merger or consolidation of the Company with or into any other corporation or corporations (other than the merger of a wholly or majority owned subsidiary into the Company), or a sale, lease or other conveyance of all or substantially all of the assets, key technology or shares of capital stock of the Company in a transaction or series of transactions.

1.18. **"Restated Articles"** means the Amended and Restated Memorandum and Articles of Association of the Company.

1.19. "**Restricted Securities**" means the securities of the Company required to bear the legend set forth in Subsection 3.1(b) hereof.

1.20. "**Right of First Refusal**" means the right, but not an obligation, of the Company, or its permitted transferees or assigns, to purchase some or all of the Transfer Shares with respect to a Proposed Holder Transfer, on the terms and conditions specified in the Proposed Transfer Notice.

1.21. "**SEC**" means the Securities and Exchange Commission.

1.22. "**SEC Rule 144**" means Rule 144 promulgated by the SEC under the Securities Act.

1.23. "**SEC Rule 145**" means Rule 145 promulgated by the SEC under the Securities Act.

1.24. "**Securities Act**" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

1.25. "**Selling Expenses**" means all underwriting discounts, selling commissions, and stock transfer taxes applicable to the sale of Registrable Securities, and fees and disbursements of counsel for any Holder, except for the fees and disbursements of the Selling Holder Counsel borne and paid by the Company as provided in Subsection 2.6.

1.26. "**Series A Preference Shares**" means the Company's Series A Preference Shares, par value $0.0001 per share.

2. Registration Rights. The Company covenants and agrees as follows:

2.1. Demand Registration.

(a) Demand. If at any time after the earlier of (i) twelve (12) months after approval of the Company's anemia product in the People's Republic of China by the State Food and Drug Administration or (ii) one hundred eighty (180) days after the effective date of the Registration Statement for the IPO, the Company receives a request from Holders of fifty percent (50%) of the Registrable Securities then outstanding that the Company file a Registration Statement with respect to at least forty percent (40%) of the Registrable Securities then outstanding (or a lesser percent if the anticipated aggregate offering price, net of Selling Expenses, would exceed USD$10 million), then the Company shall (i) within thirty (30) days after the date such request is given, give notice thereof (the "**Demand Notice**") to all Holders other than the Initiating Holders; and (ii) as soon as practicable, file a Registration Statement under the Securities Act covering all Registrable Securities that the Initiating Holders requested to be registered and any additional Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within twenty (20) days of the date the Demand Notice is given, and in each case, subject to the limitations of Subsections 2.1(c) and 2.1(d) and Subsection 2.3.

(b) Form S-3 Demand. If at any time when it is eligible to use a Form S-3 Registration Statement in the United States, the Company receives a request from Holders of at least twenty percent (20%) of the Registrable Securities then outstanding that the Company file a Form S-3 Registration Statement with respect to outstanding Registrable Securities of such Holders having an anticipated aggregate offering price, net of Selling Expenses, of at least USD$5 million, then the Company shall (i) within ten (10) days after the date such request is given, give a Demand Notice to all Holders other than the Initiating Holders; and (ii) as soon as practicable after the date such request is given by the Initiating Holders, file a Form S-3 Registration Statement under the Securities Act covering all Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within twenty (20) days of the date the Demand Notice is given, and in each case, subject to the limitations of Subsection 2.1(d) and Subsection 2.3.

(c) Deferred Registration. Notwithstanding the foregoing obligations, if the Company furnishes to Holders requesting a registration pursuant to Subsection 2.1, a certificate signed by the Company's chief executive officer stating that in the good faith judgment of the Company, it would be materially detrimental to the Company and its shareholders for such Registration Statement to either become effective or remain effective for as long as such Registration Statement otherwise would be required to remain effective, then the Company shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, for a period of not more than one hundred eighty (180) days after the request of the Initiating Holders is given; provided, however, that the Company may not invoke this right more than once in any twelve (12) month period.

(d) Limitations on Registration; Effectiveness. The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Subsection 2.1(a): (i) during the period that is ninety (90) days before the Company's good faith estimate of the date of filing of, and ending on a date that is one hundred eighty (180) days after the effective date of, a Company-initiated registration; (ii) after the Company has effected one registration pursuant to Subsection 2.1(a); or (iii) if the Initiating Holders propose to dispose of shares of Registrable Securities that may be immediately registered on Form S-3 pursuant to a request made pursuant to Subsection 2.1(b). The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Subsection 2.1(b) (i) during the period that is sixty (60) days before the Company's good faith estimate of the date of filing of, and ending on a date that is ninety (90) days after the effective date of, a Company-initiated registration;

or (ii) if the Company has effected two registrations pursuant to Subsection 2.1(b) within the eighteen (18) month period immediately preceding the date of such request. A registration shall not be counted as "effected" for purposes of this Subsection 2.1(d) until such time as the applicable Registration Statement has been declared effective by the SEC, unless the Initiating Holders withdraw their request for such registration, elect not to pay the registration expenses therefor, and forfeit their right to one demand Registration Statement pursuant to Subsection 2.6, in which case such withdrawn Registration Statement shall be counted as "effected" for purposes of this Subsection 2.1(d).

2.2. Company Registration. If the Company proposes to register (including, for this purpose, a registration effected by the Company for shareholders other than the Holders) any of its Common Shares under the Securities Act (or other applicable securities laws outside the United States) in connection with the public offering of such securities solely for cash (other than in an Excluded Registration), the Company shall, at such time, promptly give each Holder notice of such registration. Upon the request of each Holder given within twenty (20) days after such notice is given by the Company, the Company shall, subject to the provisions of Subsection 2.3, cause to be registered all of the Registrable Securities that each such Holder has requested to be included in such registration. The Company shall have the right to terminate or withdraw any registration initiated by it under this Subsection 2.2 before the effective date of such registration, whether or not any Holder has elected to include Registrable Securities in such registration. The expenses (other than Selling Expenses) of such withdrawn registration shall be borne by the Company in accordance with Subsection 2.6. The rights of the Holders set forth in this Subsection 2.2 shall not apply to an IPO.

2.3. Underwriting Requirements.

(a) If, pursuant to Subsection 2.1(a), the Initiating Holders intend to distribute the Registrable Securities covered by their request by means of an underwriting, they shall so advise the Company as a part of their request made pursuant to Subsection 2.1, and the Company shall include such information in the Demand Notice. The underwriter(s) will be selected by the Company and shall be reasonably acceptable to a majority in interest of the Initiating Holders. In such event, the right of any Holder to include such Holder's Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided herein. All Holders proposing to distribute their securities through such underwriting shall (together with the Company as provided in Subsection 2.4(e)) enter into an underwriting agreement in customary form with the underwriter(s) selected for such underwriting. Notwithstanding any other provision of Subsection 2.3, if the managing underwriter(s) advise(s) the Initiating Holders in writing that marketing factors require a limitation on the number of shares to be underwritten, then the Company shall so advise all Holders of Registrable Securities that otherwise would be underwritten pursuant hereto, and the number of Registrable Securities that may be included in the underwriting shall be allocated among such Holders of Registrable Securities, including the Initiating Holders, in proportion (as nearly as practicable) to the number of Registrable Securities owned by each Holder; provided, however, that the number of Registrable Securities held by the Holders to be included in such underwriting shall not be reduced unless all other securities are first entirely excluded from the underwriting. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest one hundred (100) shares.

(b) In connection with any offering involving an underwriting of shares of the Company's Capital Shares pursuant to Subsection 2.2, the Company shall not be required to include any of the Holders' Registrable Securities in such underwriting unless the Holders accept the terms of the underwriting as agreed upon between the Company and its underwriters, and then only in such quantity as the underwriters determine will not jeopardize the success of the offering by the Company. If the total number of securities, including Registrable Securities, requested by Company shareholders to be included in such offering exceeds the number of securities to be sold (other than by the Company) that the

underwriters in their reasonable discretion determine is compatible with the success of the offering, then the Company shall be required to include in the offering only that number of such securities, including Registrable Securities, which the underwriters and the Company in their sole discretion determine will not jeopardize the success of the offering. If the underwriters determine that less than all of the Registrable Securities requested to be registered can be included in such offering, then the Registrable Securities that are included in such offering shall be allocated among the selling Holders in proportion (as nearly as practicable to) the number of Registrable Securities owned by each selling Holder. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest one hundred (100) shares. For purposes of the provision in this Subsection 2.3(b) concerning apportionment, for any selling Holder that is a partnership, limited liability company, or corporation, the partners, members, retired partners, retired members, stockholders, and Affiliates of such Holder, or the estates and Immediate Family Members of any such partners, retired partners, members, and retired members and any trusts for the benefit of any of the foregoing Persons, shall be deemed to be a single "selling Holder," and any pro rata reduction with respect to such "selling Holder" shall be based upon the aggregate number of Registrable Securities owned by all Persons included in such "selling Holder," as defined in this sentence.

2.4. Obligations of the Company. Whenever required under Section 2 to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:

(a) prepare and file with the applicable governmental authority a Registration Statement with respect to such Registrable Securities and use its commercially reasonable efforts to cause such Registration Statement to become effective and, upon the request of the Holders of a majority of the Registrable Securities registered thereunder, keep such Registration Statement effective for a period of up to one hundred twenty (120) days or, if earlier, until the distribution contemplated in the Registration Statement has been completed; provided, however, that (i) such one hundred twenty (120) day period shall be extended for a period of time equal to the period the Holder refrains, at the request of an underwriter of Common Shares (or other securities) of the Company, from selling any securities included in such registration, and (ii) in the case of any registration of Registrable Securities on Form S-3 that are intended to be offered on a continuous or delayed basis, subject to compliance with applicable SEC rules, such one hundred twenty (120) day period shall be extended for up to 180 days, if necessary, to keep the Registration Statement effective until all such Registrable Securities are sold;

(b) prepare and file with the applicable governmental authority such amendments and supplements to such Registration Statement, and the prospectus used in connection with such Registration Statement, as may be necessary to comply with the Securities Act (or other applicable securities laws outside the United States) in order to enable the disposition of all securities covered by such Registration Statement;

(c) furnish to the selling Holders such numbers of copies of a prospectus, including a preliminary prospectus, as required by the Securities Act (or other applicable securities laws outside the United States), and such other documents as the Holders may reasonably request in order to facilitate their disposition of their Registrable Securities;

(d) use its commercially reasonable efforts to register and qualify the securities covered by such Registration Statement under such other securities or blue-sky laws of such jurisdictions as shall be reasonably requested by the selling Holders; provided that the Company shall not be required to qualify to do business or to file a general consent to service of process in any such states or jurisdictions, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act (or other applicable securities laws outside the United States);

(e) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the underwriter(s) of such offering;

(f) use its commercially reasonable efforts to cause all such Registrable Securities covered by such Registration Statement to be listed on a national securities exchange or trading system;

(g) provide a transfer agent and registrar for all Registrable Securities registered pursuant to this Agreement and provide a CUSIP (or equivalent) number for all such Registrable Securities, in each case not later than the effective date of such registration;

(h) notify each selling Holder, promptly after the Company receives notice thereof, of the time when such Registration Statement has been declared effective or a supplement to any prospectus forming a part of such Registration Statement has been filed; and

(i) after such Registration Statement becomes effective, notify each selling Holder of any request by the applicable governmental authority that the Company amend or supplement such Registration Statement or prospectus.

2.5. Furnish Information. It shall be a condition precedent to the obligations of the Company to take any action pursuant to Section 2 with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself, the Registrable Securities held by it, and the intended method of disposition of such securities as is reasonably required to effect the registration of such Holder's Registrable Securities.

2.6. Expenses of Registration. All expenses (other than Selling Expenses) incurred in connection with registrations, filings, or qualifications pursuant to Section 2, including all registration, filing, and qualification fees; printers' and accounting fees; fees and disbursements of counsel for the Company; and the reasonable fees and disbursements, not to exceed ten thousand dollars ($10,000), of one counsel for the selling Holders ("**Selling Holder Counsel**"), shall be borne and paid by the Company; provided, however, that the Company shall not be required to pay for any expenses of any registration proceeding begun pursuant to Subsection 2.1 if the registration request is subsequently withdrawn at the request of the Holders of a majority of the Registrable Securities to be registered (in which case all selling Holders shall bear such expenses pro rata based upon the number of Registrable Securities that were to be included in the withdrawn registration), unless the Holders of a majority of the Registrable Securities agree to forfeit their right to one registration pursuant to Subsection 2.1(a). All Selling Expenses relating to Registrable Securities registered pursuant to Section 2 shall be borne and paid by the Holders pro rata on the basis of the number of Registrable Securities registered on their behalf.

2.7. Delay of Registration. No Holder shall have any right to obtain or seek an injunction restraining or otherwise delaying any registration pursuant to this Agreement as the result of any controversy that might arise with respect to the interpretation or implementation of Section 2.

2.8. "Market Stand-off" Agreement. Each Holder hereby agrees that it will not, without the prior written consent of the managing underwriter, during the period commencing on the date of the final prospectus relating to the registration by the Company of Common Shares or any other equity securities under a Registration Statement, and ending on the date specified by the Company and the managing underwriter (such period not to exceed one hundred eighty (180) days in the case of the IPO, or such other period as may be requested by the Company or an underwriter to accommodate regulatory restrictions on (1) the publication or other distribution of research reports and (2) analyst recommendations and opinions, including, but not limited to, the restrictions contained in FINRA Rule

2711(f)(4) or NYSE Rule 472(f)(4), or any successor provisions or amendments thereto), (i) lend; offer; pledge; sell; contract to sell; sell any option or contract to purchase; purchase any option or contract to sell; grant any option, right, or warrant to purchase; or otherwise transfer or dispose of, directly or indirectly, any Common Shares or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Shares (whether such shares or any such securities are then owned by the Holder or are thereafter acquired) or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Common Shares or other securities, in cash, or otherwise. The foregoing provisions of this Subsection 2.8 shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement. The underwriters in connection with such registration are intended third-party beneficiaries of this Subsection 2.8 and shall have the right, power, and authority to enforce the provisions hereof as though they were a party hereto. Each Holder further agrees to execute such agreements as may be reasonably requested by the underwriters in connection with such registration that are consistent with this Subsection 2.8 or that are necessary to give further effect thereto.

2.9. Termination of Registration Rights. The right of any Holder to request registration or inclusion of Registrable Securities in any registration pursuant to Subsection 2.1 or Subsection 2.2 shall terminate upon the earliest to occur of:

(a) the closing of a Reorganization, as such term is defined in the Company's Restated Articles;

(b) such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such Holder's Capital Shares without limitation during a three-month period without registration; and

(c) the second anniversary of the IPO.

3. Restrictions on Transfer.

3.1. General.

(a) The Capital Shares held by any Holder shall not be sold, pledged, or otherwise transferred, and the Company shall not recognize and shall issue stop-transfer instructions to its transfer agent with respect to any such sale, pledge, or transfer, except upon the conditions specified in this Agreement. A transferring Holder will cause any proposed purchaser, pledgee, or transferee of the Capital Shares held by such Holder to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Agreement (any such Capital Shares transferred or proposed to be transferred, the "**Transfer Shares**"). Any successor or permitted assignee of any Holder, including any Prospective Transferee who purchases Transfer Shares in accordance with the terms hereof, shall deliver to the Company, as a condition to any transfer or assignment, a counterpart signature page hereto pursuant to which such successor or permitted assignee shall confirm their agreement to be subject to and bound by all of the provisions set forth in this Agreement that were applicable to the predecessor or assignor of such successor or permitted assignee.

(b) Each certificate or instrument, if any, representing (i) Capital Shares and any other securities issued in respect thereof upon any share division, subdivision, share dividend, recapitalization, merger, consolidation, or similar event, shall (unless otherwise permitted by the provisions of Subsection 3.1(c)) be stamped or otherwise imprinted with a legend substantially in the following form:

> THE SECURITIES REPRESENTED HEREBY HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER ANY SECURITIES ACT, INCLUDING THE SECURITIES ACT OF 1933. SUCH SHARES MAY NOT BE SOLD, PLEDGED, OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR A VALID EXEMPTION FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SAID ACT.
>
> THE SECURITIES REPRESENTED HEREBY MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE SHAREHOLDERS, A COPY OF WHICH IS AVAILABLE ON REQUEST FROM THE COMPANY, AND WHICH INCLUDES, AMONG OTHER PROVISIONS, A RIGHT OF FIRST REFUSAL IN FAVOR OF THE COMPANY ON ALL TRANSFERS OF THE SECURITIES REPRESENTED BY THIS CERTIFICATE.

The Holders consent to the Company making a notation in its records and giving instructions to any transfer agent of the Restricted Securities in order to implement the restrictions on transfer set forth in Subsection 3.1.

(c) Each Holder of Restricted Securities, whether or not represented by a certificate or other instrument, by acceptance thereof, agrees to comply in all respects with the provisions of Section 3. Before any proposed sale, pledge, or transfer of any Restricted Securities, unless there is in effect a Registration Statement covering the proposed transaction, the Holder thereof shall give notice to the Company of such Holder's intention to effect such sale, pledge, or transfer in accordance with Subsection 3.2(b). Each such notice shall describe the manner and circumstances of the proposed sale, pledge, or transfer in sufficient detail and, if reasonably requested by the Company, shall be accompanied at such Holder's expense by either (i) a written opinion of legal counsel who shall, and whose legal opinion shall, be reasonably satisfactory to the Company, addressed to the Company, to the effect that the proposed transaction may be effected without registration under applicable securities laws; (ii) a "no action" letter from the SEC (or equivalent governmental authority) to the effect that the proposed sale, pledge, or transfer of such Restricted Securities without registration will not result in a recommendation by the staff of the SEC (or equivalent governmental authority) that action be taken with respect thereto; or (iii) any other evidence reasonably satisfactory to counsel to the Company to the effect that the proposed sale, pledge, or transfer of the Restricted Securities may be effected without registration under applicable securities laws, whereupon, subject to compliance with the terms of Section 3, including, without limitation, Section 3.2, the Holder of such Restricted Securities shall be entitled to sell, pledge, or transfer such Restricted Securities in accordance with the terms of the notice given by the Holder to the Company. Each certificate or instrument evidencing the Restricted Securities transferred as above provided shall bear the appropriate restrictive legend set forth in Subsection 3.1(b), except that such certificate shall not bear such restrictive legend if, in the opinion of counsel for such Holder and the Company, such legend is not required in order to establish compliance with any provisions of applicable securities laws.

3.2. Right of First Refusal.

(a) Grant. Subject to the terms of Section 3.2(e) below, each Holder hereby unconditionally and irrevocably grants to the Company a Right of First Refusal to purchase all or any portion of any Transfer Shares that such Holder may propose to transfer in a Proposed Holder Transfer, at the same price and on the same terms and conditions as those offered to the Prospective Transferee. The Right of First Refusal herby granted to the Company shall be assignable, in whole or in party, by the Company to any Person, in the Company's sole discretion.

(b) Notice. Each Holder proposing to make a Proposed Holder Transfer must deliver a Proposed Transfer Notice to the Company not later than forty-five (45) days prior to the consummation of such Proposed Holder Transfer. Such Proposed Transfer Notice shall contain the material terms and conditions (including price and form of consideration) of the Proposed Holder Transfer and the identity of the Prospective Transferee. To exercise its Right of First Refusal under Section 3.2, the Company must deliver a Company Notice to the selling Holder within thirty (30) days after delivery of the Proposed Transfer Notice.

(c) Forfeiture of Rights. Notwithstanding the foregoing, if the total number of Transfer Shares that the Company has agreed to purchase in the Company Notice is less than the total number of Transfer Shares proposed to be transferred, then the Company shall be deemed to have forfeited any right to purchase such remaining Transfer Shares, and the selling Holder shall be free to sell such Transfer Shares not purchased by the Company to the Prospective Transferee on terms and conditions substantially similar to (and in no event more favorable to the Prospective Transferee than) the terms and conditions set forth in the Proposed Transfer Notice, it being understood and agreed that (i) any such sale or transfer shall be subject to the other terms and restrictions of this Agreement; (ii) any future Proposed Holder Transfer shall remain subject to the terms and conditions of this Agreement, including Section 3; and (iii) such sale shall be consummated within seventy-five (75) days after receipt of the Proposed Transfer Notice by the Company and, if such sale is not consummated within such seventy-five (75) day period, such sale shall again become subject to the Right of First Refusal on the terms set forth herein.

(d) Consideration; Closing. If the consideration proposed to be paid for the Transfer Shares is in property, services or other non-cash consideration, the fair market value of the consideration shall be as determined in good faith by the Company and as set forth in the Company Notice. If the Company cannot for any reason pay for the Transfer Shares in the same form of non-cash consideration, the Company may pay the cash value equivalent thereof, as determined in good faith by the Company and as set forth in the Company Notice. The closing of the purchase of Transfer Shares by the Company shall take place, and all payments from the Company shall have been delivered to the selling Holder, by the later of (i) the date specified in the Proposed Transfer Notice as the intended date of the Proposed Holder Transfer and (ii) thirty (30) days after delivery of the Proposed Transfer Notice.

(e) Violation of First Refusal Right. If any Holder becomes obligated to sell any Transfer Shares to the Company under this Agreement and fails to deliver such Transfer Shares in accordance with the terms of this Agreement, the Company may, at its option, in addition to all other remedies it may have, send to such Holder the purchase price for such Transfer Shares as is herein specified and thereby purchase such Transfer Shares and cancel such shares in accordance with the Restated Articles.

(f) Exempted Transfers. Notwithstanding the foregoing or anything to the contrary herein, the provisions of this Subsection 3.2 shall not apply: (a) in the case of a Holder that is an entity, upon a transfer by such Holder to its stockholders, members, partners or other equity holders, or (b) in the case of a Holder that is a natural person, upon a transfer by such Holder, either during his or her lifetime or on death by will or intestacy to his or her Immediate Family Member or any other relative approved by the Company, or any custodian or trustee of any trust, partnership or limited liability company for the benefit of, or the ownership interests of which are owned wholly by, such Holder or any such Immediate Family Members; provided that in the case of clauses (a**)** or (b), the Holder shall deliver prior written notice to the Company of such pledge, gift or transfer and such shares of Transfer Shares shall at all times remain subject to the terms and restrictions set forth in this Agreement and such transferee shall, as a condition to such issuance, deliver a counterpart signature page to this Agreement as confirmation that such transferee shall be bound by all the terms and conditions of this Agreement as a Holder (but only with respect to the securities so transferred to the transferee).

(g) Termination of Right of First Refusal. The Right of First Refusal set forth in Section 3 shall terminate upon the earliest to occur of:

i. the effectiveness of a public offering by the Company; and

ii. the sale or other transfer in a transaction or series of transactions, other than to an Affiliate, of greater than fifty percent (50%) of the Capital Shares of the Company held by FibroGen International (Cayman) Limited as of the final Closing of the Series A Preference shares.

3.3. Prohibited Transferees. No Holder shall transfer any Transfer Shares to (a) any Person which, in the determination of the Company is a Competitor, or (b) any customer, distributor or supplier of the Company, if the Company should determine that such transfer would result in such customer, distributor or supplier receiving information that would place the Company at a competitive disadvantage with respect to such customer, distributor or supplier.

3.4. Transfer Void. Any Proposed Holder Transfer not made in compliance with the requirements of this Agreement shall be null and void *ab initio*, shall not be recorded on the books of the Company or its transfer agent and shall not be recognized by the Company.

3.5. Exempted Offerings. Notwithstanding the foregoing or anything to the contrary herein, the provisions of Section 3 shall not apply to any sale, pledge or other transfer of any Capital Shares (a) to the public in an offering pursuant to an effective Registration Statement, (b) pursuant to a Reorganization (as defined in the Company's Restated Articles), or (c) by FibroGen, Inc., FibroGen International (Cayman) Limited or its Affiliates.

4. Drag-Along Right.

4.1. Definitions. A "**Sale of the Company**" shall mean either: (a) a transaction or series of related transactions (excluding an IPO or other registered offering by the Company) in which a Person, or a group of related Persons, acquires from shareholders of the Company shares representing at least fifty percent (50%) of the outstanding voting power of the Company (a "**Share Sale**"); or (b) a transaction that qualifies as a "**Reorganization**" as defined in the Restated Articles.

4.2. Actions to be Taken. In the event that (a) holders representing at least fifty percent (50%) of the Common Shares (i) then issued and outstanding and (ii) issuable upon conversion of the shares of Series A Preference Shares, voting together as a single class, and (b) holders representing at least fifty percent (50%) of the Series A Preference Shares then issued and outstanding voting as a separate class (collectively, the "**Selling Holders**"), approve a Sale of the Company in writing, specifying that Section 4 shall apply to such transaction, then each Holder and the Company hereby agrees:

(a) if such transaction requires shareholder approval, with respect to all Capital Shares that such Holder owns or over which such Holder otherwise exercises voting power, to vote (in person, by proxy or by action by written consent, as applicable) all Series A Preference Shares in favor of, and adopt, such Sale of the Company (together with any related amendment to the Restated Articles required in order to implement such Sale of the Company) and to vote in opposition to any and all other proposals that could delay or impair the ability of the Company to consummate such Sale of the Company;

(b) if such transaction is a Share Sale, to sell the same proportion of Capital Shares of the Company beneficially held by such Holder as is being sold by the Selling Holders to the Person to whom the Selling Holders propose to sell their Capital Shares, and, except as permitted in Subsection 4.3 below, on the same terms and conditions as the Selling Holders;

(c) to execute and deliver all related documentation and take such other action in support of the Sale of the Company as shall reasonably be requested by the Company or the Selling Holders in order to carry out the terms and provision of Section 4, including without limitation executing and delivering instruments of conveyance and transfer, and any purchase agreement, merger agreement, indemnity agreement, escrow agreement, consent, waiver, governmental filing, share certificates duly endorsed for transfer (free and clear of impermissible liens, claims and encumbrances) and any similar or related documents;

(d) not to deposit, and to cause their Affiliates not to deposit, except as provided in this Agreement, any Capital Shares of the Company owned by such party or Affiliate in a voting trust or subject any Capital Shares to any arrangement or agreement with respect to the voting of such Capital Shares, unless specifically requested to do so by the acquiror in connection with the Sale of the Company;

(e) to irrevocably waive any dissenters' rights or rights of appraisal under applicable law at any time with respect to such Sale of the Company;

(f) if the consideration to be paid in exchange for the Capital Shares pursuant to Section 4 includes any securities and due receipt thereof by any Holder would require under applicable law (x) the registration or qualification of such securities or of any person as a broker or dealer or agent with respect to such securities or (y) the provision to any Holder of any information other than such information as a prudent issuer would generally furnish in an offering made solely to "accredited investors" as defined in Regulation D promulgated under the Securities Act of 1933, as amended, the Company may cause to be paid to any such Holder in lieu thereof, against surrender of the Capital Shares which would have otherwise been sold by such Holder, an amount in cash equal to the fair value (as determined in good faith by the Company) of the securities which such Holder would otherwise receive as of the date of the issuance of such securities in exchange for the Capital Shares; and

(g) in the event that the Selling Holders, in connection with such Sale of the Company, appoint a shareholder representative (the "**Shareholder Representative**") with respect to matters affecting the under the applicable definitive transaction agreements following consummation of such Sale of the Company, (x) to consent to (i) the appointment of such Shareholder Representative, (ii) the establishment of any applicable escrow, expense or similar fund in connection with any indemnification or similar obligations, and (iii) the payment of such Holder's pro rata portion (from the applicable escrow or expense fund or otherwise) of any and all reasonable fees and expenses to such Shareholder Representative in connection with such Shareholder Representative's services and duties in connection with such Sale of the Company and its related service as the representative of the, and (y) not to assert any claim or commence any suit against the Shareholder Representative or any other Holder with respect to any action or inaction taken or failed to be taken by the Shareholder Representative in connection with its service as the Shareholder Representative, absent fraud or willful misconduct.

4.3. Exceptions. Notwithstanding the foregoing, a Holder will not be required to comply with Subsection 4.2 above in connection with any proposed sale of the Company unless, upon the consummation of the proposed sale, (i) each Holder, with respect to each class or series of Company securities held thereby, will receive the same form and amount of consideration per share for its shares of such class or series as is received by the Selling Holders in respect of shares of such same class or series held by such Selling Holders, and (ii) unless Holders representing at least fifty percent (50%) of the Series A Preference Shares elect to receive a lesser amount by written notice given to the Company at least fifteen (15) days prior to the effective date of any such proposed sale, the aggregate consideration receivable by all shareholders of the Company shall be allocated among the such shareholders on the basis of the relative liquidation preferences to which the holders of each such class or series of Company securities are entitled in a Reorganization (assuming for this purpose that the proposed sale is a Reorganization) in accordance with the Company's Restated Articles in effect immediately prior to the proposed sale.

5. Vote to Increase Authorized Common Shares. Each Holder agrees to vote or cause to be voted all Capital Shares owned by such Holder, or over which such Holder has voting control, from time to time and at all times, in whatever manner as shall be necessary to increase the number of authorized shares of Common Shares from time to time to ensure that there will be sufficient Common Shares available for conversion of all of the preference shares issued and outstanding by the Company at any given time.

6. Information Rights.

6.1. Delivery of Financial Statements. The Company shall deliver to each Holder (provided that the Company has not reasonably determined that such Holder is a Competitor), as soon as practicable following the end of each fiscal year, (a) a balance sheet as of the end of such fiscal year, (ii) statements of income and of cash flows for such fiscal year, and (iii) a statement of shareholders' equity as of the end of such fiscal year.

6.2. If, for any period, the Company has any subsidiary whose accounts are consolidated with those of the Company, then in respect of such period, the financial statements delivered pursuant to Subsection 6.1 shall be the consolidated and consolidating financial statements of the Company and all such consolidated subsidiaries.

6.3. Notwithstanding anything else in Section 6 to the contrary, the Company may cease providing the information described herein during the period starting with the date ninety (90) days before the Company's good-faith estimate of the date of filing of a Registration Statement if it reasonably concludes it must do so to comply with the applicable regulations or exchange rules; provided that the Company's covenants under Section 6 shall be reinstated at such time as the Company is no longer actively employing its commercially reasonable efforts to cause such Registration Statement to become effective.

6.4. Termination of Information Rights. The covenants set forth in Subsections 6.1 and 6.2 shall terminate and be of no further force or effect: (i) immediately before the consummation of the IPO, or (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act (or substantially equivalent requirements in any non-U.S. jurisdiction), or (iii) upon a Reorganization, as such term is defined in the Restated Articles, whichever event occurs first.

6.5. Confidentiality. Each Holder agrees that such Holder will keep confidential and will not disclose, divulge, or use for any purpose (other than to monitor its investment in the Company) any confidential information obtained from the Company (pursuant to the terms of this Agreement or otherwise, and including notice of the Company's intention to file a Registration Statement), unless such confidential information (a) is known or becomes known to the public in general (other than as a result of

a breach of this Subsection 6.5 by such Holder), (b) is or has been independently developed or conceived by the Holder without use of the Company's confidential information, or (c) is or has been made known or disclosed to the Holder by a third party without a breach of any obligation of confidentiality such third party may have to the Company; provided, however, that a Holder may disclose confidential information (i) to its attorneys, accountants, consultants, and other professionals to the extent necessary to obtain their services in connection with monitoring its investment in the Company; (ii) to any prospective purchaser of any Registrable Securities (other than to a Competitor), if such prospective purchaser agrees to be bound by the provisions of this Subsection 6.5; (iii) to any existing Affiliate, partner, member, stockholder, or wholly owned subsidiary of such Holder in the ordinary course of business, provided that such Holder informs such Person that such information is confidential and directs such Person to maintain the confidentiality of such information; or (iv) as may otherwise be required by law, provided that the Holder promptly notifies the Company of such disclosure and takes reasonable steps to minimize the extent of any such required disclosure.

7. Term. This Agreement shall be effective as of the Effective Date hereof and shall terminate upon the earliest to occur of (a) the consummation of the Company's IPO (other than pursuant to a Registration Statement relating either to the sale of securities to employees of the Company pursuant to its share option, share purchase or similar plan or an SEC Rule 145 transaction); (b) the consummation of a Sale of the Company and distribution of proceeds to or escrow for the benefit of the Holders in accordance with the Restated Articles, provided that the provisions of Section 4 hereof will continue after the closing of any Sale of the Company to the extent necessary to enforce the provisions of Section 4 with respect to such Sale of the Company; (c) termination of this Agreement in accordance with Subsection 8.6. Notwithstanding the foregoing, the terms and provisions of Section 2, all related definitions as set forth in Section 1, and the terms and provisions of Section 8, shall survive in accordance with the terms of Subsection 2.9.

8. Miscellaneous.

8.1. Successors and Assigns.

(a) The terms and conditions of this Agreement shall inure to the benefit of and be binding upon the respective successors and permitted assigns of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.

(b) Any successor or permitted assignee of any Holder, including any Prospective Transferee who purchases shares of Transfer Shares in accordance with the terms hereof, shall deliver to the Company, as a condition to any transfer or assignment, a counterpart signature page hereto pursuant to which such successor or permitted assignee shall confirm their agreement to be subject to and bound by all of the provisions set forth in this Agreement that were applicable to the predecessor or assignor of such successor or permitted assignee.

(a) The rights of the Holders hereunder are not assignable without the Company's written consent (which shall not be unreasonably withheld, delayed or conditioned), except by a Holder to any Affiliate, it being acknowledged and agreed that any such assignment be subject to and conditioned upon any such assignee's delivery to the Company of a counterpart signature page hereto pursuant to which such assignee shall confirm their agreement to be subject to and bound by all of the provisions set forth in this Agreement that were applicable to the assignor of such assignee.

(b) Except in connection with a merger, acquisition or sale of assets, the rights and obligations of the Company hereunder may not be assigned under any circumstances.

8.2. Governing Law. This Agreement shall be governed by the internal law of the State of Delaware without giving effect to any choice of law or conflict of law rules or provisions (of the State of Delaware or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of Delaware.

8.3. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes**.**

8.4. Titles and Subtitles. The titles and subtitles used in this Agreement are for convenience only and are not to be considered in construing or interpreting this Agreement.

8.5. Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt or: (i) personal delivery to the party to be notified; (ii) when sent, if sent by electronic mail or facsimile during the recipient's normal business hours, and if not sent during normal business hours, then on the recipient's next business day; (iii) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (iv) one (1) business day after the business day of deposit with a nationally recognized overnight courier, freight prepaid, specifying next-day delivery, with written verification of receipt. All communications shall be sent to the respective parties at their addresses as set forth on Schedule I hereto, or to the principal office of the Company, and to the attention of the Chief Executive Officer, in the case of the Company, or to such email address, facsimile number, or address as subsequently modified by written notice given in accordance with this Subsection 8.5. If notice is given to the Company, a copy shall also be sent to FibroGen, Inc., Corporate Legal Department, 409 Illinois St., San Francisco, CA 94158, USA.

8.6. Amendments and Waivers. This Agreement may be amended or terminated, and the observance of any term hereof may be waived (either generally or in a particular instance and either retroactively or prospectively) only by a written instrument executed by the Company and Holders representing not less than fifty percent (50%) of Registrable Securities held by the Holders (voting as a single class and on an as-converted basis). Notwithstanding the foregoing:

(a) this Agreement may not be amended or terminated and the observance of any term of this Agreement may not be waived with respect to any Holder without the written consent of such Holder unless such amendment, termination or waiver applies to all Holders in the same fashion;

(b) the consent of the Holder shall not be required for any amendment or waiver if such amendment or waiver either (i) is not directly applicable to the rights of the Holder hereunder or (ii) does not adversely affect the rights of the Holder in a manner that is different than the effect on the rights of the other Holders party hereto;

(c) Schedule I hereto may be amended by the Company from time to time in accordance with Subsection 8.8 of this Agreement to add information regarding additional Holders without the consent of the other parties hereto; and

(d) any provision hereof may be waived by the waiving party on such party's own behalf, without the consent of any other party.

The Company shall give prompt written notice of any amendment, termination or waiver hereunder to any party that did not consent in writing thereto. Any amendment, termination or waiver effected in accordance with this Subsection 8.6 shall be binding on each party and all of such party's successors and permitted assigns, whether or not any such party, successor or assignee entered into or approved such amendment or waiver. For purposes of this Subsection 8.6, the requirement of a written instrument may be satisfied in the form of an action by written consent circulated by the Company and executed by the Investor parties specified, whether or not such action by written consent makes explicit reference to the terms of this Agreement.

8.7. Severability. In case any one or more of the provisions contained in this Agreement is for any reason held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement, and such invalid, illegal, or unenforceable provision shall be reformed and construed so that it will be valid, legal, and enforceable to the maximum extent permitted by law.

8.8. Additional Holders. Notwithstanding anything to the contrary contained herein, if the Company issues additional shares of the Series A Preference Shares after the date hereof, whether pursuant to the Offer Letter or otherwise, any purchaser of such shares of Series A Preference Shares shall become a party to this Agreement by executing and delivering a Joinder to this Agreement substantially in the form of Exhibit A, and thereafter shall be deemed a "Holder" for all purposes hereunder. No action or consent by the Holders shall be required for such Joinder to this Agreement by such additional Holder, so long as such additional Holder has agreed in writing to be bound by all of the obligations as an "Holder" hereunder.

8.9. Entire Agreement. This Agreement (including any Schedules and Exhibits hereto) constitutes the full and entire understanding and agreement among the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the parties is expressly canceled.

8.10. Dispute Resolution.

(a) Any unresolved controversy or claim arising out of or relating to this Agreement, except as otherwise provided in this Agreement, shall be submitted to arbitration by one arbitrator mutually agreed upon by the parties, and if no agreement can be reached within thirty (30) days after names of potential arbitrators have been proposed by JAMS, Inc. ("**JAMS**"), then by one arbitrator having reasonable experience in transactions of the type provided for in this Agreement and who is chosen by JAMS. The arbitration shall take place in San Francisco, California, in accordance with JAMS' Comprehensive Arbitration Rules and Procedures rules then in effect, and judgment upon any award rendered in such arbitration will be binding and may be entered in any court having jurisdiction thereof. There shall be limited discovery prior to the arbitration hearing as follows: (a) exchange of witness lists and copies of documentary evidence and documents relating to or arising out of the issues to be arbitrated, (b) depositions of all party witnesses and (c) such other depositions as may be allowed by the arbitrators upon a showing of good cause. Depositions shall be conducted in accordance with the California Code of Civil Procedure, the arbitrator shall be required to provide in writing to the parties the basis for the award or order of such arbitrator, and a court reporter shall record all hearings, with such record constituting the official transcript of such proceedings.

(b) Each party will bear its own costs in respect of any disputes arising under this Agreement, provided that the prevailing party shall be entitled to reasonable attorney's fees, costs, and necessary disbursements in addition to any other relief to which such party may be entitled. Each of the parties to this Agreement consents to personal jurisdiction for any equitable action sought in the U.S. District Court for the District of Northern California or any court of the State of California having subject matter jurisdiction.

8.11. Delays or Omissions. No delay or omission to exercise any right, power, or remedy accruing to any party under this Agreement, upon any breach or default of any other party under this Agreement, shall impair any such right, power, or remedy of such nonbreaching or nondefaulting party, nor shall it be construed to be a waiver of or acquiescence to any such breach or default, or to any similar breach or default thereafter occurring, nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. All remedies, whether under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

8.12. Share Splits, Share Dividends, etc. In the event of any issuance of Series A Preference Shares of the Company's voting securities hereafter to any of the Holders (including, without limitation, in connection with any share split, share dividend, recapitalization, reorganization, or the like), such Series A Preference Shares shall become subject to this Agreement and shall be endorsed with the legend set forth in Subsection 3.1(b).

8.13. Manner of Voting. The voting of Series A Preference Shares pursuant to this Agreement may be effected in person, by proxy, by written consent or in any other manner permitted by applicable law. For the avoidance of doubt, voting of the Shares pursuant to the Agreement need not make explicit reference to the terms of this Agreement.

8.14. Aggregation of Shares. All Capital Shares held or acquired by a Holder and/or its Affiliates shall be aggregated together for the purpose of determining the availability of any rights under this Agreement, and such Affiliated persons may apportion such rights as among themselves in any manner they deem appropriate.

8.15. Further Assurances. At any time or from time to time after the date hereof, the parties agree to cooperate with each other, and at the request of any other party, to execute and deliver any further instruments or documents and to take all such further action as the other party may reasonably request in order to evidence or effectuate the consummation of the transactions contemplated hereby and to otherwise carry out the intent of the parties hereunder.

8.16. Specific Enforcement; Remedies Cumulative. Each party hereto acknowledges and agrees that each party hereto will be irreparably damaged in the event any of the provisions of this Agreement are not performed by the parties in accordance with their specific terms or are otherwise breached. Accordingly, it is agreed that each of the Company and each Holder shall be entitled, without the posting of a bond, to an injunction to prevent breaches of this Agreement, and to specific enforcement of this Agreement and its terms and provisions in any action instituted in any court of the United States or any state having subject matter jurisdiction. All remedies, either under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative

8.17. Passive Foreign Investment Company.

(a) The Company shall make due inquiry with its U.S. tax advisors at least annually regarding the Company's status as a passive foreign investment company (a "**PFIC**"), as defined in Section 1297 of the United States Internal Revenue Code of 1986, as amended. If the Company becomes a PFIC, the Company shall (i) notify the Holders of such status and (ii) within 75 days following the end of each taxable year, provide the Holders with a PFIC Annual Information Statement in the form required pursuant to the Code. The Company will permit the Holders to inspect and copy the Company's permanent books of account, records, and such other Company documents as are necessary to establish that the Company's ordinary earnings and net capital gain are computed in accordance with U.S. income tax principles.

(b) If the Holders are subject to U.S. information and reporting requirements that require the disclosure of information about the Company not readily available to the Holders, the Company agrees to use commercially reasonable efforts to provide such information to the Holders as may be necessary to allow the Holders to fulfill their U.S. tax filing and reporting obligations.

8.18. Termination of FibroGen China Anemia Holdings, Ltd. Shareholder's Agreement. As of the Effective Date, the parties hereto agree that that certain Shareholders' Agreement, dated of as July 11, 2012, by and among FibroGen China Anemia Holdings, Ltd. And each of the holders of the Series A Preference Shares of FibroGen China Anemia Holdings, Ltd. listed on Schedule I thereto shall be terminated in its entirety, and shall be null, void and of no further effect.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

FIBROGEN INTERNATIONAL (CAYMAN) LIMITED

By:	/s/ Graham MacDonald
Name:	Graham MacDonald
Title:	General Manager

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By: /s/ Gary Harmon Anderson
Name: Gary Harmon Anderson
Entity (if applicable):
Title (if applicable):

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Charles Antell
Name:	Charles Antell
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By: /s/ Maria Teresa Arnal

Name: Maria Teresa Arnal

Entity (if applicable):

Title (if applicable):

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Bradford Thomas Beeson
Name:	Bradford Thomas Beeson
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Matthew S. Beeson
Name:	Matthew S. Beeson
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ William H. Beeson
Name:	William H. Beeson
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By: /s/ Balbir Singh Bindra
Name: Balbir Singh Bindra
Entity (if applicable):
Title (if applicable):

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By: /s/ Patricio Miguel Madero Blasquez
Name: Patricio Miguel Madero Blasquez
Entity (if applicable):
Title (if applicable):

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Dan Drecher
Name:	Dan Drecher
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Sabin Wyatt Carr Jr.
Name:	Sabin Wyatt Carr Jr.
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Winston Cutshall
Name:	Winston Cutshall
Entity (if applicable):	Curious Gems, LLC
Title (if applicable):	Manager

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Robert E. Howard
Name:	Robert E. Howard
Entity (if applicable):	Dallas Mineral Partners LLC
Title (if applicable):	Manager

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Steven Gold
Name:	Steven Gold
Entity (if applicable):	Eli Investments, Inc.
Title (if applicable):	President

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Toni A. Evans
Name:	Toni A. Evans
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Steven C. Finegan
Name:	Steven C. Finegan
Entity (if applicable):	Estate of Robert J. Finegan
Title (if applicable):	Executor

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Frederick C. Goggans, M.D.
Name:	Frederick C. Goggans, M.D.
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By: /s/ Mark Gold & Janice Gold

Name: Mark Gold & Janice Gold

Entity (if applicable):

Title (if applicable):

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Gabriela Kalb Gout
Name:	Gabriela Kalb Gout
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Jaime Kalb Gout
Name:	Jaime Kalb Gout
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Roberto Rosenkranz
Name:	Roberto Rosenkranz
Entity (if applicable):	Grama Ventures, LLC
Title (if applicable):	President

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Dahlia W. Grant
Name:	Dahlia W. Grant
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Laurie Sands Harrison
Name:	Laurie Sands Harrison
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Harvey A. Herman
Name:	Harvey A. Herman
Entity (if applicable):	Harvey A. Herman Living Trust
Title (if applicable):	Trustee

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ T.E. Nelson
Name:	T.E. Nelson
Entity (if applicable):	Lyda Hunt-Herbert Trusts – Lyda Bunker Hunt
Title (if applicable):	Trustee

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Winton A. Jackson, Jr.
Name:	Winton A. Jackson, Jr.
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Joe O. Neuhoff Jr.
Name:	Joe O. Neuhoff Jr.
Entity (if applicable):	Joscar Investment, Ltd.
Title (if applicable):	General Partner

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Thomas F. C. Kennedy
Name:	Thomas F. C. Kennedy
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Michael F. Solomon
Name:	Michael F. Solomon
Entity (if applicable):	Kesef Investment, LLC
Title (if applicable):	Managing Member

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ George Lai
Name:	George Lai
Entity (if applicable):	Lai Family Trust dated 12/14/1993
Title (if applicable):	Trustee

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Schuyler B. Marshall
Name:	Schuyler B. Marshall
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Dennis Mensch
Name:	Dennis Mensch
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ David Merrylees
Name:	David Merrylees
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Ken D. Mindell
Name:	Ken D. Mindell
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Adam C. Wagner
Name:	Adam C. Wagner
Entity (if applicable):	Neo Ventures, LLC
Title (if applicable):	Sole Member

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ James Silverman
Name:	James Silverman
Entity (if applicable):	Opaleye, LP
Title (if applicable):	President

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ André Perold and Suellen Perold
Name:	André Perold and Suellen Perold
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Matthew J. and Julia R. Pickett
Name:	Matthew J. and Julia R. Pickett
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Matthew S. Beeson
Name:	Matthew S. Beeson
Entity (if applicable):	Primrose Partners, Ltd.
Title (if applicable):	General Partner

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Mauricio Reynaud
Name:	Mauricio Reynaud
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ James Silverman
Name:	James Silverman
Entity (if applicable):	RJS Virginia LLC
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By: /s/ Benjamin Salinaro
Name: Benjamin Salinaro
Entity (if applicable):
Title (if applicable):

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Jill Salinaro Custodian for Tess Salinaro
Name:	Jill Salinaro Custodian for Tess Salinaro
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By: /s/ Michael Salinaro
Name: Michael Salinaro
Entity (if applicable):
Title (if applicable):

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Nicholas Salinaro
Name:	Nicholas Salinaro
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Patrick B. Sands
Name:	Patrick B. Sands
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ R. Randolph Scott
Name:	R. Randolph Scott
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ David J. Shorma
Name:	David J. Shorma
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Anthony F. Sinclair
Name:	Anthony F. Sinclair
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Richard A. Smith
Name:	Richard A. Smith
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Julian N. Stern
Name:	Julian N. Stern
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Peter & Mary Jane Suzman JTWRS
Name:	Peter & Mary Jane Suzman JTWRS
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ W. Duncan Kennedy
Name:	W. Duncan Kennedy
Entity (if applicable):	The Ninety-Six Corporation
Title (if applicable):	President

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ C. Thomas & Carole L. Tull JT TEN
Name:	C. Thomas & Carole L. Tull JT TEN
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Dr. Peter A. Wish
Name:	Dr. Peter A. Wish
Entity (if applicable):	Peter A. Wish Revocable Trust dated 11/21/94
Title (if applicable):	Trustee

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Dominik E. Zehnder
Name:	Dominik E. Zehnder
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

HOLDER:

By:	/s/ Eric Zwisler
Name:	Eric Zwisler
Entity (if applicable):	
Title (if applicable):	

SIGNATURE PAGE TO SHAREHOLDERS' AGREEMENT

SCHEDULE I

SCHEDULE OF HOLDERS

Anderson, Gary Harmon
Antell, Charles
Arnal, Maria Teresa
Beeson, Bradford T.
Beeson, Matthew S.
Beeson, William H.
Bindra, Balbir Singh
Blasquez, Patricio Miguel Madero
Brecher, Dan
Carr, Jr., Sabin Wyatt
Curious Gems, LLC
Dallas Mineral Partners
Eli Investments, Inc.
Evans, Toni A.
Finegan, Robert J.
Goggans, Frederick Crawford
Gold, Mark & Janice
Gout, Gabriela Kalb
Gout, Jaime Kalb
Grama Ventures, LLC
Grant IRA, Dahlia W.
Harrison, Laurie Sands
Herman Living Trust, Harvey A.
Hunt, Lyda Hunt-Herbert Trusts - Lyda Bunker Hunt
Jackson, Jr., Winton A.
Joscar Investment, Ltd.
Kennedy, Fred C.
Kesef Investment, LLC - Class V
Lai Family Trust dated December 14, 1993
Marshall, Schuyler B.
Mensch, Dennis
Merrylees, David
Mindell, Ken D.
Neo Ventures, LLC
Opaleye, L.P.
Perold, André F. And Suellen S.
Pickett, Matthew J. & Julia R.
Primrose Partners, Ltd.
Reynaud de la Lama, Mauricio
RJS Virginia LLC
Salinaro, Benjamin
Salinaro, Jill as Custodian for Tess Salinaro
Salinaro, Michael
Salinaro, Nicholas
Sands, Patrick B.
Scott, R. Randolph
Shorma, David J.
Sinclair, Anthony F.
Smith, Richard A.
Stern Family Trust
Suzman JTWRS, Peter & Mary Jane
The Ninety-Six Corporation
Tull JT TEN, C. Thomas & Carole L.
Wish Revocable Trust dated 11/21/94, Peter A.
Zehnder, Dominik E.
Zwisler, Eric

EXHIBIT A

JOINDER AGREEMENT

This Joinder Agreement ("**Joinder Agreement**") is executed on _____, by the undersigned (the "**Holder**") pursuant to the terms of that certain Shareholders' Agreement dated as of _____ __, 2017 (the "**Agreement**"), by and among **FibroGen International (Cayman) Limited** (the "**Company**") and certain of its shareholders, as such Agreement may be amended or amended and restated hereafter. Capitalized terms used but not defined in this Joinder Agreement shall have the respective meanings ascribed to such terms in the Agreement. By the execution of this Joinder Agreement, the Holder agrees as follows:

1.1 Acknowledgement. Holder acknowledges that Holder is acquiring certain shares of the capital shares of the Company (the "**Shares**"), for one of the following reasons (Check the correct box):

☐ as a transferee of Shares from a party in such party's capacity as an "Holder" bound by the Agreement, and after such transfer, Holder shall be considered an "Holder" for all purposes of the Agreement.

☐ as a new investor, in which case Holder will be an "Holder" for all purposes of the Agreement.

1.2 Agreement. Holder hereby (a) agrees that the Shares, and any other shares of capital shares or securities required by the Agreement to be bound thereby, shall be bound by and subject to the terms of the Agreement and (b) adopts the Agreement with the same force and effect as if Holder were originally a party thereto.

1.3 Notice. Any notice required or permitted by the Agreement shall be given to Holder at the address or facsimile number listed below Holder's signature hereto.

HOLDER: _____

By: _____

Name and Title of Signatory:

_____

Address: _____

_____

ACCEPTED AND AGREED:
COMPANY

By: _____

Title: CEO

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

Exhibit 10.9

CONFIDENTIAL EXECUTION COPY

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(continued)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

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(continued)

TABLE OF CONTENTS
(continued)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

COLLABORATION AGREEMENT

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

BACKGROUND

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

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

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

ARTICLE 1
DEFINITIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1.37 "HIF" shall mean hypoxia inducible factor.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1.55 "Phase III" shall mean human clinical trials, the principal purpose of which is to establish safety and efficacy of one or more particular doses in patients with the Indication being studied as required in 21 C.F.R. §312.21, or similar clinical study in a country other than the United States. For purposes of this Section 1.55, and Sections 1.53 and 1.54 above, a particular trial that (i) is intended to overlap two phases of trials, (ii) combines the elements of two phases of trials, or (iii) is treated by the FDA or comparable foreign agency as two phases of trials, such as a Phase I/II trial or a Phase II/III trial, shall be deemed a trial of the later, as well as the earlier, phase (*i.e.*, a Phase II and a Phase III, respectively).

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

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

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

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

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

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

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

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

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

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

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

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

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

ARTICLE 2
JOINT DEVELOPMENT COMMITTEE

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

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

2.3 JDC Meetings. The JDC shall meet no fewer than [*] times each calendar year, or as otherwise agreed by the parties, with the understanding that [*] meetings are to be held at mutually agreed locations alternating among Japan, California, Hawaii, or at such other locations as the parties agree, and the other [*] meetings are to be held by means of telecommunication,

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

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

ARTICLE 3
DEVELOPMENT PLANS

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

3.2 Annual Review

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

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

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

ARTICLE 4
DEVELOPMENT PROGRAM

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

4.2 Global Harmonization

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

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

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

4.4 Regulatory Matters

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

4.4.2 Reporting Adverse Experiences

(a) With respect to adverse drug experiences relating to any Lead Compound, the parties shall promptly report such experiences to the appropriate regulatory authorities in the countries in which such Lead Compound is being developed or

commercialized, in accordance with the appropriate laws and regulations of the relevant countries and authorities, and each party shall ensure that its Affiliates and Sublicensees comply with such reporting obligations. In addition, in order that each party may be fully informed of these experiences, each party shall report to the other party all "adverse events" involving such Lead Compound. "Serious adverse events" for all fatal and life-threatening adverse events shall be reported to the designated safety contact person of the other party by e-mail within five (5) calendar days of a party's and/or its agent's becoming aware of such an event (a "reporting party"), and all other serious adverse events shall be forwarded to the other party within seven (7) calendar days of the reporting party's and/or its agent's becoming aware of such an event. To the extent legally possible, FG and Astellas shall report to the other all serious adverse events with respect to a Lead Compound in the Field at least twenty-four (24) hours prior to reporting the same to a regulatory authority, and shall report adverse events which may constitute a dose limiting toxicity in a reasonably prompt time after the occurrence of such event. The reporting party shall report all non-serious adverse events on a monthly basis; provided that, non-serious adverse event data arising from a clinical trial will be included in the clinical trial report which shall be prepared and sent to the other party as soon as practicable following completion of the final clinical report.

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

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

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

Astellas. FG shall prepare the periodic safety reports for clinical studies requested by European and U.S. authorities and provide Astellas with the copy of such reports at the time of submission to the regulatory authorities in the FG Territory. Astellas will provide FG with the data needed for making such periodic safety reports.

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

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

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

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

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

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

ARTICLE 5
RECORDKEEPING; PUBLICATION

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

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

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

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

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

of scientific data resulting from the Development Program, such disclosures and publications shall also be subject to review by the reviewing party under this Section 5.2.

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

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

ARTICLE 6
DEVELOPMENT PROGRAM FUNDING

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

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

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

EVENT	AMOUNT
4.Upon the first [*].	U.S. $[*]

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

EVENT	AMOUNT
1.Upon the first [*] for the [*]; provided, that in the event Astellas chooses the Bridging Strategy, such payment shall be increased by an additional U.S. $[*] for a total of U.S. $[*]	U.S. $[*]
2.Upon the first [*] in the Astellas Territory for the [*]**;** provided, that in the event Astellas chooses the Bridging Strategy, such payment shall be increased by an additional U.S. $[*] for a total of U.S. $[*].	U.S. $[*]
3.Upon the first [*] in the Astellas Territory for the [*]; provided, that in the event Astellas chooses the Bridging Strategy, such payment shall be increased by an additional U.S. $[*] for a total of U.S. $[*].	U.S. $[*]
4.Upon the first [*] in the Astellas Territory for the first indication within [*] (see Exhibit B); provided, that in the event Astellas chooses the Bridging Strategy, such payment shall be increased by an additional U.S. $[*] for a total of U.S. $[*].	U.S. $[*]
5.Upon [*] in the Astellas Territory for each of up to [*] indications listed on Exhibit B, including separate indications within [*] up to a total of U.S. $[*].	U.S. $[*]

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

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

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

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

ARTICLE 7
USE OF PRECLINICAL AND CLINICAL DATA

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

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

(b) Astellas shall have access to and the right to use solely for the purpose of this Agreement, any Data developed by or on behalf of FG or its Affiliates or Sublicensees with respect to Lead Compounds in connection with the Field (i) to the extent necessary to support the application to the regulatory authority in the Astellas Territory or to fulfill other Japanese Ministry of Health, Labor and Welfare regulatory requirements, or (ii) if not necessary to support such application or to fulfill such Japanese Ministry of Health, Labor and Welfare regulatory requirements, to the extent FG is permitted subject to FG's third party obligations; provided that FG shall [*] negotiate the availability of such Data to Astellas from such Sublicensee, and provided, further, that Astellas agrees not to use or disclose to third parties any such data for purposes outside the Field except as authorized under this Agreement.

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

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

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

ARTICLE 8
MARKETING RIGHTS

8.1 Astellas. Astellas shall have the exclusive right to market, sell and distribute the Lead Compounds supplied by FG for use in the Astellas Territory within the Field under the license granted in Article 13. Astellas may exercise its rights under this Section 8.1 through one or more Sublicensees; provided, that any such Sublicensee agrees to terms identical in all material respects to those contained in this Agreement, and, provided, further, that any arrangement between Astellas and an Astellas Sublicensee with respect to a Lead Compound shall be subject to the requirements of Section 13.2.

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

8.3 Covenants

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

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

8.3.3 Use of FG Technology by Astellas. Astellas shall use the FG Technology only to exercise the rights granted under Section 13.1 of this Agreement and as expressly authorized under the Development Program, and shall not under any circumstances use or apply any FG Technology, including without limitation any FG know-how and/or any other FG materials, confidential information, intellectual property or other related information

provided by FG to Astellas under this Agreement or any other agreement between FG and Astellas relating to the subject matter hereof, for any use outside the Field at any time or within the Field after the expiration or termination of this Agreement.

8.3.4 Activities Outside Field by Astellas. Without limiting the foregoing, Astellas agrees that during the term of this Agreement it will not (and will not authorize any third party, including, without limitation, any Affiliates or Sublicensees, to) (i) Commercialize any Lead Compound within the Field in the Astellas Territory, except a Lead Compound that has been designated a Lead Compound by the JDC and that has received Marketing Approval in the Astellas Territory for use in the Field, (ii) Commercialize any Lead Compound for use outside the Field or outside the Astellas Territory, (iii) provide any supplies of any Lead Compound to any third party, including, without limitation, any Affiliates or Sublicensees, which Astellas knows or has reason to know is being marketed, sold or distributed for use outside the Field or outside the Astellas Territory, (iv) conduct or sponsor, or provide any supplies of any Lead Compound for use in, any clinical trial designed to demonstrate that a Lead Compound can be used outside the Field, or (v) seek regulatory approval of, or use labeling for a Lead Compound stating that such Lead Compound is for use outside the Field.

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

ARTICLE 9
TRANSFER PRICING

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

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

(a) For any quantities of Lead Compound shipped by FG to Astellas prior to the issuance of the national health insurance price as determined by the Japanese Ministry of Health, Labour and Welfare (the "Listed Price"), Astellas shall pay for such quantities at a price equal to [*] of the estimate of the Listed Price as determined in good faith by FG and Astellas, subject to adjustment upon the issuance of the actual Listed Price. Upon the issuance of such Listed Price by the Japanese Ministry of Health, Labour and Welfare, Astellas shall pay to FG, or FG shall reimburse Astellas, as the case may be, the amount of any difference between the payment made for such Lead Compound at the estimated Listed Price and the payment required based upon the actual Listed Price.

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

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

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

9.3 Payment. Any payments to be made with respect to the transfer of any Lead Compound in accordance with Section 9.1 or 9.2 above shall be immediately due to FG upon shipment, which shall be paid by Astellas to FG no later than [*] of the date of invoice, which invoice FG shall deliver to Astellas upon Delivery of Lead Compound to Astellas pursuant to Section 9.2(a), (b) or (c), and shall be made in U.S. dollars. For transfer of any Lead Compound in accordance with Section 9.1 or 9.2(c) above, FG shall deliver to Astellas, within ten (10) days of receipt of a firm commitment order from Astellas, an invoice for the estimated Fully Burdened Costs of the Lead Compound to be transferred to Astellas. Within [*] after the transfer of the Lead Compound to Astellas, FG shall provide a revised final invoice to Astellas that shall indicate the actual Fully Burdened Costs of the Lead Compound. If the actual Fully Burdened Costs are less than the estimated Fully Burdened Costs, FG shall include a reimbursement payment to Astellas for the difference between the initial estimated Fully Burdened Costs and the actual Fully Burdened Costs. If the actual Fully Burdened Costs are greater than the estimated Fully Burdened Costs, Astellas shall pay such difference within [*] of receipt of an invoice from FG for such amounts. For payments for the transfer of Lead Compound under Section 9.2(d) hereof, FG's invoice to Astellas shall be calculated based on the current Listed Price as set by the Japanese Ministry of Health, Labour and Welfare. Upon calculation of the Sales Price, Astellas shall submit, for any amounts actually sold, the Sales Price to FG, and FG shall credit Astellas for the difference between the invoice cost, cost calculated based on the Listed Price and the cost calculated based on the Sales Price.

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

ARTICLE 10
ADDITIONAL PAYMENTS; BOOKS AND RECORDS

10.1 Quarterly Reports. Astellas shall make quarterly reports to FG within sixty (60) days after the end of each calendar quarter (April 1 though June 30, July 1 through September 30, October 1 though December 31, January 1 through March 31), which reports shall include, (a) the Net Sales, unit shipments and other distributions, including samples, by Astellas, and its Affiliates and Sublicensees, in such calendar quarter and (b) such other information as may be reasonably requested by FG to ensure either proper payment by Astellas of amounts required under this Agreement or to calculate payments with respect to FG's Third Party Agreements. Concurrently with making such report, Astellas shall remit payment to FG for any payments due under this Agreement.

10.2 Payment Method. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the payee. All such payments made by or on behalf of Astellas hereunder shall be made by a Japanese entity. All dollar amounts specified in this Agreement, and, except as specifically authorized under Section

10.3 hereof, all payments made hereunder, are and shall be made in U.S. dollars. Any payments due under this Agreement which are not paid by the date such payments are due under this Agreement shall bear interest to the extent permitted by applicable law at the U.S. prime rate per annum quoted in the "Money Rates" column of The Wall Street Journal (U.S., Western Edition) on the first business day after such payment is due, plus an additional [*], calculated on the number of days such payment is delinquent. This Section 10.2 shall in no way limit any other remedies available to either party.

10.3 Currency Conversion. In the event that the amount of an Astellas payment obligation in U.S. dollars must be determined by the calculation of an underlying amount received by Astellas in Japanese Yen utilizing the U.S. dollar-Japanese Yen exchange rate (i.e., a transfer payment under Section 9.2(a), (b) or (d) hereof), currency conversion from Japanese Yen to U.S. dollars shall be made using the closing exchange rate reported in the Wall Street Journal (U.S. Western Edition) for the date on which the Lead Compound is Delivered to Astellas. If any such payment is not made by the due date, the exchange rate utilized for determination of such payment obligation shall be the exchange rate [*] reported in the Wall Street Journal (U.S. Western Edition) during the period from the date of invoice through the due date, not including any additional amounts owed under Section 10.2 hereof.

10.4 Taxes

10.4.1 Generally. Each party shall bear and, except as otherwise expressly provided in this Section 10.4, pay any and all taxes, duties, levies, and other similar charges (and any related interest and penalties), however designated, imposed on that party as a result of the existence or operation of this Agreement. If laws or regulations require that taxes be withheld, the paying party will (i) timely pay the taxes to the proper taxing authority, and (ii) send proof of payment to the other party within [*] following that payment.

10.4.2 Certain Payments. Notwithstanding Section 10.4.1, all payments by Astellas required under this Agreement above, including under Section 6.1.1 are expressed as net amounts and shall be made free and clear of, and without reduction for, any withholding taxes, provided, however, that in the event that any withholding taxes are due on the payments Astellas shall make to FG under Sections 6.1.2 and 6.1.3, Astellas shall make such payments directly to the Japanese Tax Authority and shall be entitled to reduce the amount paid to FG by [*] of the amount of the withholding taxes paid to Japanese Tax Authority in respect of such payment, unless the amount of such withholding taxes is reduced by a decision of the Japanese tax authority, or is subsequently adjusted downward as result of appeal, in which event the next payment due hereunder, including, without limitation, a transfer payment or a payment upon termination, shall be increased by such amount. Any such taxes which are otherwise imposed on payments to FG shall be the sole responsibility of Astellas. Astellas shall provide FG with official receipts issued by the appropriate taxing authority or such other evidence as is reasonably requested by FG to establish that such taxes have been paid. Astellas and FG shall cooperate to minimize the withholding taxes due on the amounts payable by Astellas to FG hereunder to the extent permissible under law, including, but not limited to, making appropriate application(s) to

the tax authorities within the Astellas Territory. If possible, FG shall use its reasonable efforts to apply for the tax refund from U.S. tax authorities for the withholding taxes paid to the Japanese Tax Authority on the payment U.S. $[*] payment made by Astellas to FG on January 13, 2004 as set forth in Section 6.1 when such application for the tax refund becomes possible, and if FG has received any such tax refund, FG shall reimburse to Astellas for the amounts corresponding to the withholding taxes paid in Astellas' accounts as set forth above.

10.5 Records; Inspections. Astellas shall keep, and require its Affiliates and Sublicensees to keep, complete, true and accurate books of accounts and records for the purpose of determining payments due pursuant to this Agreement. Such books and records shall be kept for at least [*] following the end of the calendar quarter to which they pertain. FG shall keep, and require its Sublicensee(s) to keep, complete, true and accurate books of accounts and records for the purpose of verifying the accuracy of the [*] Percentage and Fully Burdened Costs. Such records will be open for inspection at the principal place of business of each party (the "Inspected Party") during such [*] period by an independent auditor chosen by the other party (the "Inspecting Party") and reasonably acceptable to the Inspected Party for the purpose of verifying the amounts payable by Astellas to FG hereunder or the accuracy of the [*] Percentage and/or Fully Burdened Costs. Such inspections may be made no more than once each calendar year, at reasonable times and on reasonable notice. Any books of accounts or records shall not be inspected more than once. The independent auditor retained by the Inspecting Party shall be obligated to execute a reasonable confidentiality agreement with the Inspected Party prior to commencing any such inspection, which, among other customary clauses, contains the provisions to the effect that such auditor shall not disclose to the Inspecting Party any information other than as necessary to accomplish the purpose of the inspection. Inspections conducted under this Section 10.5 shall be at the expense of the Inspecting Party. Any underpaid or overcharged amounts that are discovered will be paid by the Inspected Party, and with interest on such underpaid or overcharged amounts at the rate set forth in Section 10.2 above. The parties will endeavor to minimize disruption of the Inspected Party's normal business activities to the extent reasonably practicable.

ARTICLE 11
DUE DILIGENCE

11.1 Astellas' Due Diligence. Astellas shall use its commercially reasonable efforts (i) to conduct any development work undertaken under the Development Program, and any and all clinical trials (including without limitation Phase III) required to obtain, and thereafter to take such other actions as are necessary to obtain, Marketing Approvals for any Lead Compound in the Astellas Territory as soon as practicable, and (ii) to launch each such Lead Compound in the Astellas Territory as soon as practicable after receiving Marketing Approval in the Astellas Territory for such Lead Compound.

11.2 FG's Due Diligence. FG shall use its commercially reasonable efforts to conduct, and to the extent possible taking into account safety and other applicable issues, complete a Phase II clinical trial with FG-2216 or another Lead Compound in the FG Territory.

11.3 Development Diligence

11.3.1 Astellas shall pursue development of Indications according to the following terms: (i) Astellas shall pursue Commercialization in "Treatment of anemia in patients with chronic kidney disease undergoing dialysis" and "Treatment of anemia in patients with chronic kidney disease not undergoing dialysis"; (ii) Astellas shall notify FG within six (6) months of the execution of this Agreement whether it shall pursue Commercialization in [*]; (iii) Astellas shall notify FG within six (6) months of the date FG notifies Astellas that it has demonstrated Proof of Concept whether it will pursue Commercialization in [*]; (iv) Astellas shall notify FG within six (6) months of the date FG notifies Astellas that it has demonstrated Proof of Concept whether it will pursue Commercialization in [*]; and (v) Astellas shall notify FG, upon Marketing Approval for any Lead Compound in each of the following Indications, whether it will pursue Commercialization of such Indication: [*], and any other indications to be added hereafter to the definition of the Indication by mutual agreement; and (vi) if FG is pursuing Commercialization of [*], Astellas shall notify FG after Marketing Approval whether it shall pursue Commercialization of such Indication. Should Astellas inform FG that it does not wish to pursue Commercialization of any Indication, or should Astellas fail to meet the due diligence obligations under Section 11.3.2 for any Indication as set forth in Section 11.3.1(iv) or under Section 11.3.3 for any Indication as set forth in Section 11.3.1(v), such Indication shall no longer be considered an Indication for the purposes of this Agreement, and Astellas shall have no right or shall lose any right with respect to such Indication under this Agreement including, without limitation, the licenses granted under Sections 8.1 and 13.1 hereof. Each Indication for which Astellas is obligated to pursue Commercialization under Section 11.3.1(i) or for which it decides to pursue Commercialization under Sections 11.3.1(ii), (iii) or (iv) shall be a "Major Indication".

11.3.2 In addition to the obligations set forth in Section 11.1 and 11.3, for each Major Indication, until such time as Astellas obtains Marketing Approval in the Astellas Territory for such Major Indication, with respect to each Lead Compound for each Major Indication, Astellas shall:

(a) If required for development of a Lead Compound in an Indication, Initiate Phase I clinical trials within [*] after the later of (i) the Effective Date, for Indications for which FG has commenced clinical trials prior to the execution of this Agreement, and (ii) FG's or its Sublicensees Initiation of a Phase I clinical trial for other such Indications.

(b) Initiate Phase II clinical trials within the later of (i) [*] after FG's, or its Sublicensee's, Initiation of Phase II, (ii) [*] after Astellas' Completion of its Phase I clinical trial(s), (iii) if Astellas' obligations under this Subsection 11.3.2(b) are triggered upon FG's notification of demonstration of Proof of Concept in an Indication, [*] after the date

Astellas notifies FG that it will pursue Commercialization in such Indication, and (iv) in the event Astellas' obligations under this Section 11.3.2(b) are triggered by the designation of a secondary Lead Compound as a primary Lead Compound, [*] after such designation.

(c) Either notify FG of its intent to employ the Bridging Strategy, if applicable, or Initiate Phase III clinical trials within [*] of the later of (i) FG's, or its Sublicensee's Initiation of a Phase III clinical trial and (ii) Astellas' Completion of its Phase II clinical trial(s).

11.3.3 For each of the Indications set forth in Section 11.3.1(v), Astellas shall Initiate Phase II clinical studies within [*] of its notification to FG that it will pursue Commercialization in such Indication.

11.3.4 Astellas' diligence obligations set forth in Section 11.3.2 shall apply to all Lead Compounds designated by FG, provided, that for each Indication for which such diligence obligations apply, the diligence obligations shall only apply to the primary Lead Compound designated by FG, and for the secondary Lead Compound, Astellas' diligence obligations shall be limited to those set forth in Section 11.3.2(a) until the designation of the secondary Lead Compound as the primary Lead Compound, provided, further, upon such designation, that such diligence obligation shall be expanded to include the requirement that Astellas complete the Phase I clinical studies required to Initiate Phase II clinical studies in the Indication with such secondary Lead Compound.

ARTICLE 12
MANUFACTURING RIGHTS

12.1 Procedures. FG shall have the exclusive right to determine the methods and procedures for the manufacture of all Lead Compounds. If FG intends to make any change in the methods or procedures, including, without limitation, manufacturing process, analyzing process and/or site change for manufacture of the Lead Compounds, FG shall notify Astellas in writing of such intended change; provided, that if in Astellas' reasonable opinion, such change may lead to any amendment to the relevant Marketing Approval or Marketing Approval Application, Astellas shall use best efforts to (i) as soon as possible petition the Japanese Ministry of Health, Labor and Welfare to make the change without an amendment to the Marketing Approval or MAA and shall concurrently prepare an application for amendment to the Marketing Approval or MAA, and (ii) if the Japanese Ministry of Health, Labor and Welfare determines such an amendment is required, shall notify FG and submit the application for amendment immediately following notice of such requirement, and FG shall not make the intended change without a prior written consent from Astellas, such consent not to be unreasonably withheld or delayed, provided, further, that consent shall be deemed granted upon notice that an amendment is not required or approval of an amendment from the Japanese Ministry of Health, Labor and Welfare. FG shall provide Astellas with all the data and information necessary for Astellas to amend the Marketing Approval or MAA in Astellas Territory and shall continue to supply Astellas with the

Lead Compound as manufactured with the manufacturing methods and procedures or at the manufacturing site described in Astellas' (or its Affiliate's or Sublicensee's) then current Marketing Approval or MAA until Astellas will have finished the necessary amendment to the relevant Marketing Approval or MAA or received notice that an amendment is not required.

12.2 FG Right. FG shall have the worldwide exclusive right (itself or through third party vendors) to manufacture (or have manufactured) Lead Compounds. Astellas and its Affiliates and Sublicensees shall not directly or indirectly make, produce or manufacture any Lead Compounds.

12.3 Manufacture and Supply. FG shall have the exclusive right and obligation to supply the Lead Compounds to Astellas and its Affiliates and Sublicensees for all development and commercial purposes, and Astellas and its Affiliates and Sublicensees shall purchase such Lead Compounds exclusively from FG. It is understood that FG may engage subcontractors with respect to the manufacture of such Lead Compounds to fulfill its supply obligations to Astellas hereunder. In all cases, supply by FG of Lead Compounds hereunder shall be Ex Works (Incoterms 2000) the manufacturing facility. Subject to Section 8.3.5 hereof, nothing herein is intended to preclude FG from granting rights to supply or supplying (a) any Lead Compound outside of the Astellas Territory to any third party for use within or outside the Field, or (b) any compound Controlled by FG within the Astellas Territory except for a Lead Compound for the duration of its designation in compliance with the terms and conditions of this Agreement.

12.4 Product Specifications. The Lead Compounds to be supplied by FG hereunder shall meet the Product Specifications. In addition to, but not in limitation of, the foregoing, FG and Astellas agree that upon Marketing Approval for any Lead Compound, FG's obligation to supply Astellas with Lead Compound shall be limited to, and all payment obligations set forth in Section 9.2 shall be based on, the supply of Bulk Product, unless otherwise agreed by the parties. The packaging for the Lead Compound to be distributed commercially by Astellas shall contain a clearly visible acknowledgment that the Lead Compound was manufactured by FG, and shall contain a registered trademark of the FG logo or other trademark approved by FG.

12.5 Orders Forecast

12.5.1 Orders for Non-Commercial Use. In connection with the supply of any Lead Compound for non-commercial use in the Territory, Astellas shall provide FG with a firm purchase order as early as possible prior to its requirements, and in no event less than [*] prior to the shipment or other release date(s) requested by Astellas for such Lead Compound. FG shall provide such Lead Compound to Astellas as soon as practicable within such time period, subject, prior to Marketing Approval, to the reasonable lead time requirements of third party contract manufacturers. All forecasts shall be prepared in good faith in order to facilitate FG's manufacture and shipment of the Lead Compound in compliance with this Agreement.

12.5.2 Forecast and Order for Commercial Use. In connection with the supply of any Lead Compound for commercial use in the Astellas Territory upon FG's request, Astellas and FG shall negotiate in good faith appropriate forecasting and firm purchase order lead times, taking into consideration the reasonable notice requirements of FG and its third party manufacturers. All forecasts shall be prepared in good faith in order to facilitate FG's manufacture and shipment of the Lead Compound in compliance with this Agreement.

12.6 Shipment. Astellas, or FG at Astellas' request if specified in a purchase order by Astellas, shall arrange for shipment of the Lead Compound as specified in each purchase order by Astellas, Ex Works (Incoterms 2000) the manufacturing facility. For purposes of this Agreement, and notwithstanding anything to the contrary contained within the term "Ex Works", it is hereby acknowledged and agreed that title and risk of loss shall transfer to Astellas from receipt by Astellas at the manufacturing facility. Astellas shall bear the costs of such carrier, including the costs of insurance of the shipment, and all customs, duties, sales taxes and other governmental charges related to the importation and sales of the Lead Compound.

12.7 Inspection of Shipment/Right to Reject. Each shipment of Lead Compound from FG to Astellas shall contain such laboratory and quality control certificate as are necessary to show that the Lead Compound is in conformity with the Product Specifications. Astellas shall promptly inspect each shipment. In the event that any portion of the shipment fails to conform to the Product Specifications, Astellas shall notify FG within [*] of Astellas' receipt of such shipment. Such notice shall specify the manner in which the Lead Compound fails to meet the Product Specifications. In the absence of such notification, Astellas shall be deemed to have accepted the shipment. FG and Astellas agree to consult with each other to resolve any discrepancy between each other's determinations regarding any possible nonconformity of the Lead Compound. If such consultation does not resolve the discrepancy, the parties agree to nominate a reputable independent laboratory or other independent third party, in each case acceptable to both parties, to carry out tests on representative samples taken from such shipment, and the results of such tests shall be binding on both parties. If the results of such tests demonstrate that the Lead Compound does not meet the Product Specifications, then FG shall pay the costs of such tests; otherwise, Astellas shall pay for the costs of such tests. FG shall, at its expense, promptly replace any Lead Compound to the extent that, in accordance with this Section 12.7, it is determined that it does not conform to the Product Specifications. Unless

otherwise instructed by FG, all non-conforming Lead Compound shall be returned to FG at the place of manufacture at FG's direction and at FG's expense. If Astellas detects at any time any defect in the Lead Compound which has not been found through Astellas' inspection, it shall notify FG to that effect within [*] of the discovery of such defect, and the procedures set forth above in this Section 12.7 shall be applied to such defective Lead Compound, provided, that FG shall only be responsible to pay for costs of defects that are the result of FG's gross negligence or willful misconduct.

12.8 Inspection of Facilities. Astellas shall have the right, upon reasonable advance notice and during regular business hours, to inspect and audit, either by itself or through its Affiliates or consultants, the facilities (including any facilities of sub-contractors) being used by FG for production of the Lead Compound to assure compliance with applicable laws, rules and regulations, including, without limitation, Japanese regulatory standards and FG quality control procedures ("Relevant Standards"). FG shall also reasonably comply with inspection requests of the Japanese Ministry of Health, Labor & Welfare. Such inspection and audit shall be conducted at Astellas' sole cost and expense in a manner so as to minimize disruption of FG's, or its subcontractor's or Sublicensee's, business operations. FG shall, within [*] after FG's receipt of written notice from Astellas detailing any deficiencies which may be noted in any such audit which relate to the Relevant Standards use good faith efforts to remedy such deficiencies, and submit a plan to the Astellas outlining steps proposed to be taken.

12.9 Recall. In the event that Astellas deems it necessary to recall any Lead Compound from the market, it may do so in its sole discretion, after notification to the FG. The costs and expenses for such recall shall be borne by Astellas unless caused by a failure for which FG is required to indemnify Astellas pursuant to Section 17.3, or by FG's gross negligence or willful misconduct, in which event it shall be borne by FG.

12.10 Warranty. FG represents and warrants that the Lead Compounds to be supplied to Astellas under this Agreement shall conform to the Product Specifications and shall, as appropriate, be manufactured in compliance with GMP Guidelines. Subject to Sections 12.9 and 17.3 hereof, FG's sole obligation and Astellas' sole remedy with respect to Lead Compound which does not meet the warranty contained herein is limited to replacement of such Lead Compound and reimbursement of Astellas' out of pocket expenses for shipping to FG at the address designated by FG.

12.11 Interruption in Supply. For any particular Lead Compound, in order to minimize any interruptions in supply hereunder, FG and Astellas agree that within [*], FG shall maintain two separate, validated manufacturing sites (which may either be its own manufacturing facilities or facilities of a contract manufacturer) for such Lead Compound.

12.12 Reference and Standard Materials. For any Lead Compound provided to Astellas hereunder, upon Astellas' request and pursuant to Section 9.4 hereof, FG shall provide to Astellas reasonable quantities of reference materials, including analogs, metabolites, impurities, degradates and radio-labeled compounds ("Reference Materials") and standard materials, i.e.

defined, highly purified Lead Compound ("Standard Materials") for such Lead Compound for the purposes of conducting analytical, release, stability and other studies as may be authorized by the JDC under the Development Program.

ARTICLE 13
LICENSE GRANTS

13.1 Grant to Astellas. Subject to the terms and conditions of this Agreement including Article 12 above, FG hereby grants to Astellas an exclusive license under the FG Technology to: use, package, sell, have sold, import, market and otherwise distribute the Lead Compounds for use solely in the Field in the Astellas Territory

13.2 Sublicenses. The licenses granted under Section 13.1 above include the right to grant and authorize sublicenses, subject to the requirements of this Agreement and Section 7.2. Notwithstanding the foregoing, Astellas shall not have the right to authorize a Sublicensee to market, sell or distribute Lead Compounds without FG's prior written consent (which consent shall not be unreasonably withheld). For the purposes of the foregoing, and without limitation, it shall be deemed reasonable for FG to withhold consent for competitive concerns.

13.3 No Rights Beyond Lead Compounds. Except as expressly provided herein, nothing in this Agreement shall be deemed to grant to Astellas rights in FG Technology other than the rights granted hereunder to the Lead Compounds, or for applications outside the Field or outside the Astellas Territory, or to manufacture Lead Compounds; nor shall any provision of this Agreement be deemed to restrict FG's right to exploit any FG Technology and/or the Lead Compounds outside the Astellas Territory.

13.4 Expanded Field Negotiation. Following the signing of this Agreement, FG agrees to negotiate in good faith with Astellas for a license to develop compounds for the Expanded Field in the Astellas Territory, exclusively for a period of [*] following such date, and non-exclusively thereafter until the execution of a license agreement with a third party to develop compounds for the Expanded Field. FG and Astellas hereby agree that FG's obligation to negotiate non-exclusively for the Expanded Field shall not constitute a right of first offer, right of first refusal, right of first negotiation or any obligation to enter into any agreement with Astellas at any time, and the failure of such negotiations to result in an agreement between FG and Astellas with respect to the Expanded Field shall not constitute a breach of this Agreement.

ARTICLE 14
INTELLECTUAL PROPERTY

14.1 Ownership of Inventions. Subject to Section 14.1.1, title to all inventions and other intellectual property made related to (i) the Development Program, (ii) the Lead Compounds, (iii) FG Technology or FG Confidential Information, (iv) the Field, or (v) the

Expanded Field (subsections 14.1(i)-(v), collectively, the "Protected Field") shall be owned by or is hereby assigned to FG; provided, however that Astellas shall own inventions of general applicability relating solely to drug delivery systems created exclusively by Astellas under subsection 14.1(i), excluding inventions related to or based on subsections 14.1(ii), (iii), (iv), or (v), and provided, further, that Astellas hereby grants to FG a worldwide, fully paid non-exclusive license with the right to sublicense to practice such inventions with respect to the FG Technology. Astellas agrees to execute any and all assignments and other documents necessary to effectuate the foregoing.

14.1.1 Notwithstanding Section 14.1, in the event that Astellas develops, completely independently from any FG Technology and/or any other FG materials, confidential information, intellectual property or other related information provided by or on behalf of FG to Astellas under this Agreement or any other agreement between FG and Astellas relating to the subject matter hereof, any inventions or intellectual property rights related to the Field or the Expanded Field, [*], Astellas shall own such intellectual property and hereby grants to FG and its Sublicensees a non-exclusive, royalty-free, irrevocable license to such intellectual property for the FG Territory. Astellas agrees to execute any and all assignments and other documents necessary to effectuate the foregoing.

14.2 Patent Prosecution

14.2.1 FG Inventions. FG shall control all Prosecution and Interference Activities pertaining to FG Patents and patent applications and patents related to its, its Affiliate's or its Sublicensee's inventions in the Protected Field worldwide using counsel of its choice and shall bear the costs of such Prosecution and Interference Activities, provided, however, that; and Astellas shall reimburse to FG, within [*] of receipt by Astellas of invoice therefor, any such costs to the extent incurred in connection with or reasonably allocable to the FG Patents registered and/or to be registered in the Astellas Territory and related to the Field and the Lead Compounds, provided, further, that, with respect to patents or patent applications excluding those covering composition of matter claims and all patents listed on Exhibit A hereto as of the Effective Date, Astellas may postpone such reimbursement until the respective FG Patent will have been registered in the Astellas Territory if [*], on condition that once the respective FG Patent has been registered in the Astellas Territory, Astellas shall pay to FG such costs, plus interest to the extent permitted by applicable law at the U.S. prime rate per annum quoted in the "Money Rates" column of The Wall Street Journal (U.S., Western Edition), calculated in each case from the date such costs were incurred, plus an additional [*] thereof.

14.2.2 Astellas Inventions. Astellas shall not file for or otherwise seek to obtain (directly or indirectly) patent or other intellectual property protection for inventions that are related to the Protected Field, without the prior written consent of FG, which may be withheld at FG's sole discretion, subject to Section 14.1.1, and provided also that Astellas may file for or otherwise seek to obtain patent protection for inventions related to drug delivery systems as described in Section 14.1. To the extent that FG consents to the filing of any patent application or other intellectual property protection related to the foregoing, such patent application or other intellectual property protection shall be subject to Section 14.1, unless otherwise agreed in writing.

14.2.3 Cooperation. Astellas shall cooperate with and assist FG in connection with Prosecution and Interference Activities and shall use best efforts to consult with FG regarding the prosecution and maintenance of the FG Patents for the FG Territory and the Astellas Territory for those FG Patents for which Astellas or its Affiliates, Sublicensees or investigators are inventors, except solely for inventions (i) of general applicability relating solely to drug delivery systems created by Astellas under subsection 14.1(i), or (ii) created in compliance with Section 14.1.1 as determined solely by FG in good faith.

14.3 Defense of Third Party Infringement Claims. If the development, manufacture, sale or use of any Lead Compound pursuant to this Agreement results in a claim, suit or proceeding (collectively, "Actions") alleging patent infringement against FG or Astellas (or their respective Affiliates or Sublicensees), such party shall promptly notify the other party hereto in writing. The party subject to such Action (for purposes of this Section 14.3, the "Controlling Party") shall have the exclusive right to defend and control the defense of any such Action using counsel of its own choice; provided, however, that if such Action is directed to the subject matter of a patent of the other party (*i.e.*, for Astellas, a FG Patent), such other party may participate in the defense and/or settlement thereof at its own expense with counsel of its choice. Except as agreed in writing by Astellas and FG, Astellas shall not enter into any settlement relating to a Lead Compound, if such settlement admits the invalidity or unenforceability, or limits any claim, of any patent within the FG Technology. The Controlling Party agrees to keep the other party hereto reasonably informed of all material developments in connection with any such Action. Any cost, liability or expense associated with such action (including amounts paid in settlement) (together, "Expenses") shall be borne by the Controlling Party; provided, that if Astellas is the Controlling Party, and the Action is related to Future Third Party Intellectual Property, with respect to Expenses related solely to such Future Third Party Intellectual Property, it shall be entitled to deduct up to [*] of the Expenses incurred on an annual basis from [*] in such year under this Agreement, provided, however, that (i) the total amount deducted shall not exceed [*] thereunder, and (ii) notwithstanding (i) above, Astellas' right to deduct Expenses incurred shall be further limited such that in no event shall the sum of (a) the Expenses deducted by Astellas under this Section 14.3, and (b) the consideration FG contributes for the acquisition of intellectual property from Third Party Licensors for the Astellas Territory as set forth in Section 14.5, exceed [*] hereunder, and, provided further, that if FG is the Controlling Party, it shall be entitled to reimbursement by Astellas of [*] of such Expenses, as incurred. Notwithstanding the foregoing, Astellas shall be solely responsible (without right of deduction) for all Expenses related to any Action relating to Preexisting Third Party Intellectual Property.

14.4 Enforcement. Subject to the provisions of this Section 14.4, in the event that FG or Astellas reasonably believes that any FG Technology necessary for the development, manufacture, use or sale of a Lead Compound is infringed or misappropriated by a third party or is subject to a declaratory judgment action arising from such infringement, in each case with respect to the development, manufacture, sale or use of a product within the Field and within the Astellas Territory, Astellas or FG (respectively) shall promptly notify the other party hereto. Promptly after such notice the parties shall meet to discuss the course of action to be taken with

respect to an Enforcement Action (as defined below) with respect to such infringement or misappropriation, including the control thereof and sharing of costs and expenses related thereto, for the purposes of entering into a litigation agreement setting forth the same ("Litigation Agreement"). If the parties do not enter such Litigation Agreement, FG shall have the initial right (but not the obligation) to enforce the intellectual property rights with respect to the FG Technology, or defend any declaratory judgment action with respect thereto (such action, for purposes of this Section 14.4, an "Enforcement Action").

14.4.1 Information. Absent a Litigation Agreement, the party initiating or defending any such Enforcement Action within the Field shall keep the other party hereto reasonably informed of the progress of any such Enforcement Action, and such other party shall have the right to participate with counsel of its own choice at its own expense.

14.4.2 Enforcement Costs; Recoveries. Absent a Litigation Agreement, FG shall have the initial right to initiate such an Enforcement Action**,** and shall notify Astellas within a reasonable time whether it elects to exercise such right. In the event that FG elects to initiate or defend such Enforcement Action, FG shall be responsible for [*] of the costs and expenses while Astellas shall be responsible for [*] of the costs and expenses, and all amounts recovered shall first be applied to reimbursement of each party's costs and expenses with the remainder to be allocated to FG and Astellas at the ratio of [*] and [*]. In the event that FG elects not to initiate or defend such Enforcement Action, Astellas shall have the right to initiate or defend such Enforcement Action in its own name, and to the extent permitted under Third Party Agreements, in the name of FG or in the names of both FG and Astellas, in which case, Astellas shall be responsible for [*] of the costs and expenses while FG shall be responsible for [*] of the costs and expenses, and all amounts recovered shall first be applied to reimbursement of each party's costs and expenses with the remainder to be allocated to Astellas and FG at the ratio of [*] and [*].

14.4.3 Cooperation in Enforcement Action. Absent a Litigation Agreement, at the request of the party which has the right to initiate or defend an Enforcement Action, the other party shall reasonably cooperate in the Enforcement Action, such cooperation to include, without limitation, furnishing records, information and testimony, and attending conferences, discovery proceedings, hearings, trials and appeals; provided, that the requesting party shall reimburse to the cooperating party for the out-of-pocket expenses incurred for such cooperation pursuant to the reimbursement regime set forth in Section 14.4.2.

14.5 Third Party Agreements

14.5.1 Future Agreements. It is understood that FG may find it necessary to utilize in connection with a Lead Compound intellectual property that is controlled by a non-Affiliate third party (such party, a "Third Party Licensor"), in addition to or in lieu of the FG Technology existing as of the Effective Date. FG shall have the right to obtain (by purchase, license, or otherwise) rights to such intellectual property with the right to sublicense to Astellas. In the event that FG determines that it must obtain such rights, it shall provide notice and submit

a description of such rights to Astellas, and shall discuss with Astellas the need to obtain such rights. Astellas shall inform FG within [*] of receipt of such notice whether it believes it is necessary to obtain such rights for the Astellas Territory and wishes to obtain such rights. In the event Astellas determines to obtain such rights, FG shall obtain a worldwide license for the rights under such terms and conditions as are [*], and such intellectual property of the Third Party Licensor shall be deemed to be the part of FG Technology, provided, however, that, notwithstanding anything contained in this Agreement (i) for Preexisting Third Party Intellectual Property, [*] shall pay [*] of all consideration due in connection with the acquisition of such rights for the Astellas Territory, and (ii) for Future Third Party Intellectual Property, [*] shall [*] pay [*] of all consideration due in connection with the acquisition of such rights for the Astellas Territory, provided, however, notwithstanding FG's obligation to contribute to the consideration due for Future Third Party Intellectual Property under (ii) above, FG's obligation to contribute shall be limited such that in no event shall the sum of (a) the consideration FG contributes for the acquisition of intellectual property from Third Party Licensors for the Astellas Territory, and (b) the Expenses for which Astellas has the right to deduct under Section 14.3 exceed [*] hereunder, and Astellas shall be responsible for all consideration related to the acquisition of rights from Third Party Licensors in excess of such amount. In the event Astellas determines not to obtain such rights for the Astellas Territory, FG shall obtain a license for the FG Territory but not the Astellas Territory, and Astellas shall be solely responsible for the defense of any infringement Action, for all Expenses related to any such Action, and any right of Astellas to deduct Expenses under this Agreement against payments required to be made to FG hereunder shall not apply to any action brought with respect to such rights.

14.5.2 Payment; Reports. If FG is obligated to pay amounts to a Third Party Licensor, FG shall notify Astellas [*] in advance of the due date of such payment obligation (or such later date as FG may determine), and Astellas shall reimburse its share of such payments within [*] after receipt of notice therefor.

14.5.3 Limitation. To the extent that FG Patents includes any intellectual property licensed under FG's License Agreement with Imigen, Inc. relating to HIF stabilization technology dated as of October 30, 2003, and amended as from time to time of which a redacted copy shall have been provided to Astellas prior to the Effective Date, Astellas shall be considered a sublicensee and be subject to the applicable requirements thereunder.

14.5.4 Compliance with Third Party Agreements. Notwithstanding anything to the contrary contained herein, Astellas agrees to comply with the requirements (upon sublicensees or otherwise) of FG's License Agreement with Imigen, Inc. relating to HIF stabilization technology dated as of October 30, 2003. In addition, Astellas agrees to comply with the requirements (upon sublicensees or otherwise) of any future Third Party Agreements for which Astellas obtains rights through an FG license pursuant to Section 14.5.1 hereof.

ARTICLE 15
REPRESENTATIONS AND WARRANTIES

15.1 FG Warranties. FG warrants and represents to Astellas, as of the execution of this Agreement, that (i) it is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware; (ii) the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action on the part of FG; (iii) there is no pending litigation which alleges or any communication alleging that Commercialization of any Lead Compound or any compound Controlled by FG for use in the Field has infringed or misappropriated the intellectual property rights of any Third Party or has been obtained by misappropriating any Third Party's intellectual property right; and (iv) subject to the terms and conditions of the agreements for the FG Acquired Patents, FG has complete title to and ownership of the FG Patents, free and clear from any mortgages, pledges, liens, security interests, conditional and installment sale agreements, encumbrances, charges or claims of any kind.

15.2 Astellas Warranties. Astellas warrants and represents to FG, as of the execution of this Agreement, that (i) it is a corporation duly organized, validly existing and in good standing under the laws of Japan; and (ii) the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action on the part of Astellas.

15.3 Disclaimer of Warranties. EXCEPT AS OTHERWISE SET FORTH HEREIN, FG AND ASTELLAS EXPRESSLY DISCLAIM ANY WARRANTIES OR CONDITIONS, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE DEVELOPMENT PROGRAM, OR THE FG TECHNOLOGY OR LEAD COMPOUNDS, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF FG TECHNOLOGY, PATENTED OR UNPATENTED, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 16
CONFIDENTIALITY

16.1 Confidential Information. Except as expressly provided herein, the parties agree that the receiving party shall not publish or otherwise disclose and shall not use for any purpose other than this Agreement any information furnished to it by the other party hereto pursuant to this Agreement which if disclosed in tangible form is marked "Confidential" or with other similar designation to indicate its confidential or proprietary nature or if disclosed orally is indicated orally to be confidential or proprietary by the party disclosing such information at the time of such disclosure and is confirmed in writing as confidential or proprietary by the disclosing party within a reasonable time after such disclosure (collectively, "Confidential Information"). Notwithstanding the foregoing, Confidential Information shall not include information that, in each case is demonstrated by written documentation:

(a) was already known to the receiving party, other than under an obligation of confidentiality directly or indirectly to the disclosing party at the time of disclosure hereunder;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving party hereunder;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving party in breach of this Agreement; or

(d) was subsequently lawfully disclosed to the receiving party by any third party without any confidentiality obligation directly or indirectly to the disclosing party or developed by the receiving party without reference to any information or materials disclosed by the disclosing party.

It is agreed and understood that all matters discussed and presented at the meetings of the JDC shall be considered Confidential Information hereunder, subject to the terms and conditions of this Agreement.

16.2 Permitted Disclosures. Notwithstanding the provisions of Section 16.1 above, each party hereto may disclose the other party's Confidential Information to the extent such disclosure is reasonably necessary to exercise the rights granted to it, or reserved by it, under this Agreement (including, without limitation, entering into and/or performing business or scientific relationships with respect to products outside the Field as permitted hereunder), in filing or prosecuting patent applications, prosecuting or defending litigation, complying with applicable governmental regulations, submitting information to tax or other governmental authorities (including regulatory authorities), or conducting clinical trials hereunder with respect to Lead Compounds, provided that if a party is required by law to make any such disclosure of the other party's Confidential Information, to the extent it may legally do so, it will give reasonable advance notice to the latter party of such disclosure and, save to the extent inappropriate in the case of patent applications or otherwise, will use its reasonable efforts to secure confidential treatment of such Confidential Information prior to its disclosure (whether through protective orders or otherwise).

16.3 Clinical Data. Except as expressly permitted under Sections 7.2 and 16.2, and for publications or disclosures in accordance with Section 5.2, neither party shall disclose to third parties pre-clinical data, clinical data or regulatory filings, comprising Confidential Information of the other party.

16.4 Press Releases. Except as may already be, or is agreed to be, publicly disclosed, in the event that either party proposes to release a press release with respect to this Agreement or the Development Program, such party shall obtain the prior written consent of the other party, which shall not be unreasonably withheld.

ARTICLE 17
INSURANCE; INDEMNIFICATION

17.1 Insurance. Each party shall secure and maintain in effect during the term of this Agreement and for a period of five (5) years thereafter insurance policy(ies) underwritten by a reputable insurance company and in a form and having limits standard and customary for entities in the biopharmaceutical industry for exposures related to the Lead Compounds. Such insurance shall include general liability, clinical trial liability and products liability coverage with respect to such party's performance of the Development Program and commercialization of Lead Compounds hereunder. Upon request by the other party hereto, certificates of insurance evidencing the coverage required above shall be provided to the other party.

17.2 Indemnification of FG. Astellas shall indemnify each of FG and its Affiliates and the directors, officers, and employees of FG and such Affiliates and the successors and assigns of any of the foregoing (the "FG Indemnitees"), and hold each FG Indemnitee harmless from and against any and all liabilities, damages, settlements, claims, actions, suits, penalties, fines, costs or expenses (including, without limitation, reasonable attorneys' fees and other expenses of litigation) incurred by any FG Indemnitee to the extent not otherwise covered by insurance, arising from or occurring as a result of any claim, action, suit, or other proceeding brought by third parties against a FG Indemnitee arising from or occurring as a result of any development, testing, manufacture, importation, use, offer for sale, sale or other distribution of any Lead Compound by or for the benefit of Astellas or its Affiliates or Sublicensees, distributors or agents (including, without limitation, product liability and infringement claims) except to the extent caused by failure of the Lead Compound supplied by FG to meet the Product Specifications in effect at the time of manufacture, or material deviation by FG or its sub-contractor from GMP Guidelines in manufacturing the Lead Compound, or FG's breach of this Agreement or willful misconduct.

17.3 Indemnification of Astellas. FG shall indemnify each of Astellas and its Affiliates and the directors, officers, and employees of Astellas and such Affiliates and the successors and assigns of any of the foregoing (the "Astellas Indemnitees"), and hold each Astellas Indemnitee harmless from and against any and all liabilities, damages, settlements, claims, actions, suits, penalties, fines, costs or expenses (including, without limitation, reasonable attorneys' fees and other expenses of litigation) incurred by any Astellas Indemnitee to the extent not otherwise covered by insurance, arising from or occurring as a result of any claim, action, suit, or other proceeding brought by third parties against an Astellas Indemnitee to the extent caused by failure of the Lead Compound supplied by FG to meet the Product Specifications in effect at the time of manufacture, or material deviation by FG or its sub-contractor from GMP Guidelines in manufacturing the Lead Compound, except in each case in this Section 17.3 to the extent caused by Astellas' breach of this Agreement or willful misconduct.

17.4 Procedure. A party (for purposes of this Section 17.4, the "Indemnitee") that intends to claim indemnification under any provision of this Agreement shall promptly notify the indemnifying party (the "Indemnitor") in writing of any claim, action, suit, or other proceeding

brought by third parties in respect of which the Indemnitee or any of its Affiliates, or their directors, officers, employees, successors or assigns intend to claim such indemnification hereunder. As between the parties hereto the Indemnitor shall have the right to control the defense and settlement of such claim, action, suit, or other proceeding; provided, that the Indemnitee shall have the right to participate in such defense or settlement with counsel of its own choosing at its expense. The Indemnitee shall not make any settlement of any loss, claim, damage, liability or action without the consent of the Indemnitor, to the extent such consent is not withheld unreasonably or delayed. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Article 17 but the omission so to deliver written notice to the Indemnitor shall not relieve the Indemnitor of any liability that it may have to any Indemnitee otherwise than under this Article 17. Without limiting the foregoing, the Indemnitee shall keep the Indemnitor fully informed of the progress of any claim, action, suit, or other proceeding for which it intends to claim indemnification under this Article 17.

ARTICLE 18
TERM AND TERMINATION

18.1 Term. This Agreement shall become effective as of the Effective Date and, shall continue in full force and effect until terminated pursuant to this Article 18.

18.2 Termination for Cause or Technical Product Failure

18.2.1 Material Breaches. FG may forthwith terminate this Agreement in the event Astellas fails to make any payment due under Articles 6, 9 or 14, within [*] following receipt of written notice of such default, or materially breaches its obligations under Articles 8 or 14, and fails to cure such breach within [*] following receipt of written notice of such default. Astellas may forthwith terminate this Agreement in the event FG materially breaches its obligations under Article 7 or Article 12, and fails to cure such breach within [*] following receipt of written notice of such default. Any termination shall become effective at the end of such [*] or [*] period unless the defaulting or breaching party (or any other party on its behalf) has cured any such default prior to the expiration of the [*] or [*] period, as the case may be.

18.2.2 Independent Activities. Notwithstanding anything contained in Section 8.3.2 or Section 14.1.1, in the event that Astellas Commercializes any molecules for the Field or the Expanded Field, except for actions taken within the Field in the course of the exercise of the licenses granted under Sections 8.1 and 13.1 hereof and expressly authorized under this Agreement, even if FG determines that Astellas' activities are completely independent of any FG Technology and/or any other FG materials, confidential information, intellectual property or other related information provided by FG to Astellas under this Agreement or any other agreement between FG and Astellas relating to the subject matter hereof, FG shall have the right at its sole discretion to terminate this Agreement upon [*] notice to Astellas.

18.2.3 Technical Product Failure. Astellas may terminate this Agreement upon [*] notice to FG upon Technical Product Failure.

18.2.4 Development Diligence Failure. FG may terminate this Agreement upon thirty (30) days notice to Astellas in the event Astellas fails to meet any of its development diligence requirements as set forth in Article 11 hereof, provided, however, that with respect to the development diligence obligations set forth in Section 11.3.2, such termination right on behalf of FG shall be triggered only upon Astellas' failure to meet such development diligence obligations for a Major Indication (except those Major Indications set forth in Section 11.3.1(iv)), and Astellas may terminate this Agreement upon thirty (30) days notice to FG in the event FG fails to meet the development diligence requirement as set forth in Section 11.2 hereof.

18.2.5 Other Material Non-Performance/Misrepresentation. Other than a breach giving rise to a termination right as set forth in Sections 18.2.1 or 18.2.4, or a termination pursuant to a Technical Product Failure as set forth in Section 18.2.3 in the event of (i) a party's breach or default in any other material respect in the performance or observance of any other material term, covenant or provision of this Agreement, or (ii) if any representation by a party contained in this Agreement shall prove to have been incorrect in any material respect when made, resulting in material adverse consequences for the other party, (any such default or material incorrect representation a "Material Non-Performance"), such Material Non-Performance shall be remedied only as provided in Section 18.7.4 below.

18.3 Termination in case of Generic Competition. In the event generic equivalents has captured the [*] of the quantity of Lead Compound sold by Astellas during the [*] preceding such termination calculated on a annual basis; or in the event, after the entry into the market of generic equivalents, that Astellas' annual sales fall below $[*] for all Lead Compounds, Astellas may terminate this Agreement upon [*] written notice to FG; provided, that Astellas does not Commercialize any Lead Compound after such termination until the expiration of the last to expire FG Patents applicable to such Lead Compound.

18.4 Negative Advice from Authorities. Astellas may terminate this Agreement upon [*] notice to FG in the event Astellas has commenced Phase III clinical studies in those of the following Indications that FG is developing: "Treatment of anemia in patients with chronic kidney disease undergoing dialysis", "Treatment of anemia in patients with chronic kidney disease not undergoing dialysis" and [*], and the Japanese Ministry of Health, Labor & Welfare has provided written notification that it will not approve the Lead Compounds in such Indications or the JDC determines, after the submission by Astellas of Marketing Approval Applications for such Indications, and the receipt of a response or request of the Japanese Ministry of Health, Labor & Welfare that contains development demands that are so onerous that it is not reasonable to continue with Development of the Lead Compounds in such Indications.

18.5 Admission of Invalidity or Unenforceability of FG Patent. Astellas may terminate this Agreement upon [*] notice to FG in the event that FG enters into a settlement under Section 14.3 that admits the invalidity or unenforceability of all patents within the FG Technology, including patents covering Lead Compounds.

18.6 Termination upon Notice. Subject to Section 18.7.2, Astellas may terminate this Agreement upon six (6) months notice to FG for any reason or no reason.

18.7 Effect of Termination

18.7.1 Accrued Obligations. Termination of this Agreement for any reason shall not release either party hereto from any liability which, at the time of such termination, has already accrued to the other party or which is attributable to a period prior to such termination nor preclude either party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement.

18.7.2 Termination. In the event of (a) a termination by Astellas under Section 18.6 during the period from the execution of this Agreement until the last to expire of the FG Patents, or (b) by FG under Section 18.2.1, 18.2.2, 18.2.4 or 18.2.5 hereof, Astellas shall, upon the effective date of such termination, pay to FG (i) a termination fee of $[*] U.S. dollars and (ii) any payments to which FG is otherwise entitled to receive hereunder in the period from the date of such termination notice until the [*].

18.7.3 Survival. Articles 1, 5, 14, 16, 17, 18, 19 and 20, and Sections 8.3.3 and 10.5, shall survive any termination of this Agreement, along with FG's rights and Astellas' obligations (but not Astellas' rights or FG's obligations, except to the extent required by the Japanese Ministry of Health, Labor and Welfare) under Section 5.1.1 and Article 7. In addition, the following provisions shall survive termination of this Agreement for any reason: Astellas shall assign or cause to be assigned to FG (or if not so assignable, Astellas shall take all reasonable actions to make available to FG) all regulatory filings and registrations (including MAAs and Marketing Approvals) with respect to the Lead Compounds that have been filed or made by or under authority of Astellas, and the rights in trademark with respect to each Lead Compound as provided for in Section 4.4.1, in each case such assignment (or availability) shall be made within [*] after the notice of termination. From and after the date of a notice of termination, FG shall have no further obligations under this Agreement beyond those obligations that survive termination in such events as specified in this Section 18.7.3.

18.7.4 Material Non-Performance. In the event of any Material Non-Performance by a party, the other party shall, without reasonable delay following discovery of such Material Non-Performance notify the defaulting party in writing, and the parties shall consult with each other in good faith to endeavor to agree upon the most effective means to cure such Material Non-Performance and, if necessary, to effect a remedy in favor of the non-defaulting party for the consequences of such Material Non-Performance by the defaulting party (collectively, the "Resolution"). In the event (i) the parties are unable to agree upon Resolution,

or (ii) the defaulting party, in the exercise of reasonable diligence shall have been unable to remedy such Material Non-Performance, then in either such event the remedy of the non-defaulting party with respect to the Material Non-Performance by the defaulting party shall be determined by arbitration pursuant to Section 19.2 hereof, and the arbitrators shall be authorized to fashion such remedy, including equitable relief, which may include termination of this Agreement in whole or in part, as the arbitrators shall determine appropriate, except that termination of this Agreement in whole shall only be the remedy of last resort.

18.7.5 License Upon Termination. In the event of a termination of this Agreement, FG shall have an irrevocable, exclusive, license, with the right to grant and authorize sublicenses, to any trademarks used by Astellas in association with the Lead Compounds hereunder to make, use, sell, import and otherwise exploit products within the Field in the Astellas Territory. Such license shall be royalty-free, provided, however, if such trademark is not a global trademark (i.e. materially different from the trademark used in the FG Territory) and either (i) if Astellas terminates this Agreement under Section 18.2.1 or 18.2.4, or (ii) if this Agreement is terminated in accordance with the procedure as provided for in Section 18.2.5 as a result of FG's Material Non-Performance, in which event FG and Astellas shall negotiate in good faith a reasonable fee for such license.

ARTICLE 19
DISPUTE RESOLUTION

19.1 Disputes. If the parties are unable to resolve any dispute between them regarding the breach, interpretation or enforcement of this Agreement, either party may, by written notice to the other, have such dispute referred to their Authorized Designees, provided that such individuals are not directly involved in the dispute (i.e., the dispute occurs at the JDC, such individuals shall not be members of the JDC), for good faith negotiations. If after [*] such executives are unable to resolve the issue, each of Astellas and FG shall have the right to refer the matter to mediation upon notice to the other party, and the parties shall choose a mediator within [*] of the receipt of such notice, and shall negotiate in good faith to resolve such matter through the mediator within [*] thereafter.

19.2 Full Arbitration. Any dispute, controversy or claim arising out of or relating to the breach, interpretation or enforcement of this Agreement, including disputes relating to termination of this Agreement, shall be settled by binding arbitration in the manner described in this Section 19.2. The arbitration shall be conducted pursuant to the rules of Arbitration of the International Chamber of Commerce then in effect. Notwithstanding those rules, the following provisions shall apply to the arbitration hereunder:

19.2.1 Arbitrators. The arbitration shall be conducted by a panel of three (3) arbitrators, with one (1) arbitrator chosen by each of FG and Astellas and the third appointed by the other two (2) arbitrators. If the parties are unable to agree upon a single arbitrator, or the third arbitrator in case of a panel of three (3), such third arbitrator (as the case may be) shall be appointed in accordance with the rules of the Arbitration of the International Chamber of Commerce.

19.2.2 Proceedings. Except as otherwise provided herein, the parties shall use their best efforts to complete the arbitration within [*] after the appointment of the Panel under Section 19.2.1 above, unless a party can demonstrate to the Panel that the complexity of the issues or other reasons warrant the extension of one or more of the time tables. In such case, the Panel may extend such time table as reasonably required. The Panel shall, in rendering its decision, apply the substantive law of the State of California, without regard to its conflicts of laws provisions, except that the interpretation of and enforcement of this Article 19 shall be governed by the U.S. Federal Arbitration Act. The proceeding shall be conducted in English and shall take place in the city of Vancouver, British Columbia, Canada. The judgment of the Panel shall be binding upon the parties and enforceable in any court of competent jurisdiction.

19.2.3 Interim Relief. Notwithstanding anything in this Article 19 to the contrary, FG and Astellas shall each have the right to apply to any court of competent jurisdiction for a temporary restraining order, preliminary injunction, or other similar interim or conservatory relief, as necessary, pending resolution under the above described arbitration procedures. Nothing in the preceding sentence shall be interpreted as limiting the powers of the arbitrators with respect to any dispute subject to arbitration under this Agreement.

ARTICLE 20
MISCELLANEOUS

20.1 Confidential Terms. Except as expressly provided herein, each party agrees not to disclose any terms of this Agreement to any third party without the consent of the other party, except (i) as required by securities or other applicable laws or (ii) to prospective and other investors and such party's accountants, attorneys and other professional advisors, or (iii) to others under reasonable conditions of confidentiality.

20.2 Governing Law. This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed and enforced in accordance with, the laws of the State of California, without reference to conflicts of laws principles.

20.3 Force Majeure. Nonperformance of any party (except for payment of amounts due hereunder) shall be excused to the extent that performance is rendered impossible by strike, fire, earthquake, flood, governmental acts or orders or restrictions, failure of suppliers, or any other reason where failure to perform is beyond the reasonable control of the non-performing party. In such event FG or Astellas, as the case may be, shall promptly notify the other party of such inability and of the period for which such inability is anticipated to continue. Without limiting the foregoing, the party subject to such inability shall use reasonable efforts to minimize the duration of any force majeure event.

20.4 No Implied Waivers; Rights Cumulative. No failure on the part of FG or Astellas to exercise and no delay in exercising any right under this Agreement, or provided by statute or at law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right,

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

nor shall any partial exercise of any such right preclude any other or further exercise thereof or the exercise of any other right.

20.5 Independent Contractors. Nothing contained in this Agreement is intended implicitly, or is to be construed, to constitute FG or Astellas as partners in the legal sense. No party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of any other party or to bind any other party to any contract, agreement or undertaking with any third party.

20.6 Notices. All notices, requests and other communications hereunder shall be in writing and shall be personally delivered or sent by registered or certified mail, return receipt requested, postage prepaid; facsimile transmission (receipt verified); or express courier service (signature required), in each case to the respective address specified below, or such other address or fax number as may be specified in writing to the other party hereto:

Astellas: Astellas Pharma Inc.
Attn: Director of Legal Department
[*]

with copy to: Astellas Pharma Inc.
Attn: Licensing, Corporate Strategy
[*]

FG: FibroGen, Inc.
Attn: Chief Executive Officer
225 Gateway Boulevard
San Francisco, California 94080
Fax: 1-650-866-7202

with a copy to: FibroGen, Inc.
Attn: Legal Department
225 Gateway Boulevard
San Francisco, California 94080
Fax: 1-650-866-7343

20.7 Assignment. This Agreement shall not be assignable by either party to any third party without the written consent of the other party hereto; except that either party may assign this Agreement without the other party's consent to an entity that acquires substantially all of the business or assets of the assigning party within the Field, in each case whether by merger, transfer of assets, or otherwise. Upon a permitted assignment of this Agreement, all references herein to the assigning party shall be deemed references to the party to whom the Agreement is so assigned.

20.8 Modification. No amendment or modification of any provision of this Agreement shall be effective unless in writing signed by all parties hereto. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by all parties.

20.9 Severability. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, the parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the parties and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

20.10 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which together, shall constitute one and the same instrument.

20.11 Headings. Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement.

20.12 Export Laws. Notwithstanding anything to the contrary contained herein, all obligations of FG and Astellas are subject to prior compliance with United States and foreign export regulations and such other United States and foreign laws and regulations as may be applicable, and to obtaining all necessary approvals required by the applicable agencies of the governments of the United States and foreign jurisdictions. FG and Astellas shall cooperate with each other and shall provide assistance to the other as reasonably necessary to obtain any required approvals.

20.13 Language. This Agreement is in the English language only, which language shall be controlling in all respects, and all versions hereof in any other language shall not be binding on the parties hereto. All communications and notices to be made or given pursuant to this Agreement shall be in the English language.

20.14 Entire Agreement. This Agreement (including the Exhibits hereto) constitutes the entire agreement, both written or oral, with respect to the subject matter hereof, and supersedes all prior or contemporaneous understandings or agreements, including the Binding Term Sheet, dated as of February 9, 2004 by and between FG and Astellas, as amended on January 25, 2005, whether written or oral, between FG and Astellas with respect to such subject matter.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed and delivered in duplicate originals as of the date first above written.

ASTELLAS PHARMA INC.

By: /s/ Toichi Takenaka
Toichi Takenaka
President and Chief Executive Officer

Date: 1.September.05

FIBROGEN, INC.

By: /s/ Thomas B. Neff
Thomas Neff
President and Chief Executive Officer

Date:23 August 05

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

EXHIBIT A
LIST OF PATENTS

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

EXHIBIT B
INDICATIONS

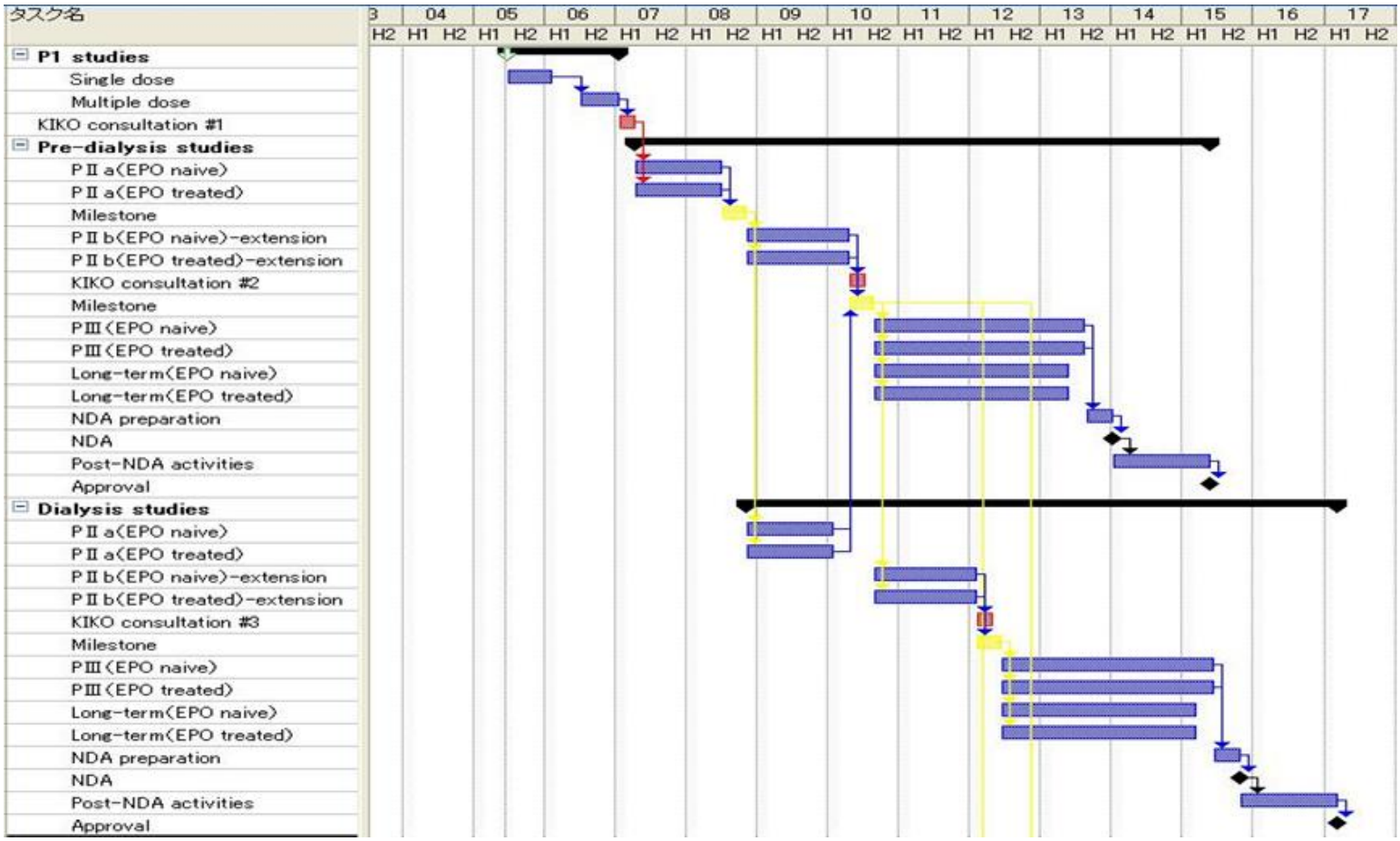
Included indications:

- Treatment of anemia in patients with chronic kidney disease undergoing dialysis
- Treatment of anemia in patients with chronic kidney disease not undergoing dialysis
- [*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

EXHIBIT C
INITIAL DEVELOPMENT PLAN

[



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[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

COLLABORATION AGREEMENT

BY AND BETWEEN

ASTELLAS PHARMA INC.

AND

FIBROGEN, INC.

June 1, 2005

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

Exhibit 31.1

CERTIFICATION

I, Thomas B. Neff, certify that;

1. I have reviewed this Form 10-Q of FibroGen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2017

/s/ Thomas B. Neff
Thomas B. Neff
Chairman of the Board and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Pat Cotroneo, certify that;

1. I have reviewed this Form 10-Q of FibroGen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2017

/s/ Pat Cotroneo

Pat Cotroneo
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), Thomas B. Neff, Chief Executive Officer of FibroGen, Inc. ("the Company"), and Pat Cotroneo, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2017, to which this Certification is attached as Exhibit 32.1 ("Quarterly 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 Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 8, 2017

In Witness Whereof, the undersigned have set their hands hereto as of the 8th day of November, 2017.

/s/ Thomas B. Neff
Thomas B. Neff
Chairman of the Board and Chief Executive Officer

/s/ Pat Cotroneo
Pat Cotroneo
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.