FIBROGEN INC
Form 10-Q
May 09, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

þ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2016

OR

o 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 þ No o

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 þ No o

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

Large accelerated filer þ Accelerated filer o

Non-accelerated filer o (Do not check if a smaller reporting company) Smaller reporting company ¨

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

The number of shares of common stock outstanding as of April 30, 2016 was 62,450,875.

FIBROGEN, INC.

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FIBROGEN, INC.

PART I—FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share amounts)

(Unaudited)

	March 31, 2016	December 31, 2015 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$140,959	$153,324
Short-term investments	32,454	27,847
Accounts receivable ($3,662 and $4,455 from a related party)	5,937	15,405
Prepaid expenses and other current assets	4,651	3,988
Total current assets	184,001	200,564
Restricted cash	7,254	7,254
Long-term investments	122,009	131,720
Property and equipment, net	127,613	129,020
Other assets	1,658	2,016
Total assets	$442,535	$470,574
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$1,543	$6,521
Accrued liabilities ($1,639 and $2,045 to related parties)	44,038	47,932
Deferred revenue	12,722	12,728
Total current liabilities	58,303	67,181
Long-term portion of lease financing obligations	97,077	97,042
Product development obligations	15,786	15,085
Deferred rent	4,581	4,702
Deferred revenue, net of current	85,328	85,132
Other long-term liabilities	5,237	4,607
Total liabilities	266,312	273,749
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 125,000 shares authorized at March 31, 2016 and	—	—

December 31, 2015; no shares issued and outstanding at March 31, 2016 and December 31, 2015		
Common stock, $0.01 par value; 225,000 shares authorized at March 31, 2016 and December 31, 2015; 62,425 and 61,985 shares issued and outstanding at March 31, 2016 and December 31, 2015	624	620
Additional paid-in capital	593,935	586,647
Accumulated other comprehensive loss	(1,704)	(1,651)
Accumulated deficit	(435,903)	(408,062)
Total stockholders' equity	156,952	177,554
Non-controlling interests	19,271	19,271
Total equity	176,223	196,825
Total liabilities, stockholders' equity and non-controlling interests	$442,535	$470,574

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

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FIBROGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenue:		
License and milestone revenue (includes $3,313 and $4,692 from a related party)	$19,738	$11,506
Collaboration services and other revenue (includes $352 and $634 from a related party)	8,544	4,792
Total revenue	28,282	16,298
Operating expenses:		
Research and development	43,650	50,539
General and administrative	11,417	10,482
Total operating expenses	55,067	61,021
Loss from operations	(26,785)	(44,723)
Interest and other, net		
Interest expense	(2,777)	(2,758)
Interest income and other, net	1,416	843
Total interest and other, net	(1,361)	(1,915)
Loss before income taxes	(28,146)	(46,638)
Benefit from income taxes	(305)	(271)
Net loss	$(27,841)	$(46,367)
Net loss per share - basic and diluted	$(0.45)	$(0.78)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	62,184	59,197

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

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FIBROGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Net loss	$(27,841)	$(46,367)
Other comprehensive income (loss):		
Foreign currency translation adjustments	(642)	1,705
Available-for-sale investments:		
Unrealized gain on investments, net of tax effect	589	711
Reclassification from accumulated other comprehensive loss	—	(5)
Net change in unrealized loss on available-for-sale investments	589	706
Other comprehensive income, net of taxes	(53)	2,411
Comprehensive loss	$(27,894)	$(43,956)

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

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FIBROGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Operating activities		
Net loss	$(27,841)	$(46,367)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,502	1,388
Amortization of premium on investments	695	768
Unrealized foreign exchange gain on short-term investments	(620)	-
Stock-based compensation	7,340	6,446
Tax benefit on unrealized gain on available-for-sale securities	(339)	(271)
Changes in operating assets and liabilities:		
Accounts receivable	9,468	6,490
Prepaid expenses and other current assets	(663)	(780)
Other assets	358	(112)
Accounts payable	(4,978)	(2,118)
Accrued liabilities	(3,214)	(7,048)
Deferred revenue	190	(822)
Lease financing liability	136	156
Other long-term liabilities	708	80
Net cash used in operating activities	(17,258)	(42,190)
Investing activities		
Purchases of property and equipment	(898)	(448)
Purchases of available-for-sale securities	(19)	—
Proceeds from maturities of available-for-sale securities	5,976	5,000
Net cash provided by investing activities	5,059	4,552
Financing activities		
Repayments of lease liability	(101)	(101)
Cash paid for payroll taxes on restricted stock unit releases	(1,261)	—
Proceeds from issuance of common stock	1,213	721
Net cash provided by (used in) financing activities	(149)	620
Effect of exchange rate change on cash and cash equivalents	(17)	(68)
Net decrease in cash and cash equivalents	(12,365)	(37,086)
Cash and cash equivalents at beginning of period	153,324	165,455
Cash and cash equivalents at end of period	$140,959	$128,369

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

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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 in Phase 3 clinical development for the treatment of anemia in chronic kidney disease. FG-3019 is the Company's monoclonal antibody in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis, pancreatic cancer, Duchenne muscular dystrophy and liver fibrosis. We have taken a global approach with respect to the development and future commercialization of our product candidates, and this includes development and commercialization in the People's Republic of China ("China").

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, 2015 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, 2015 (the "2015 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 2015 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 2015 Form 10-K.

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. 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 presentation of our financial position, results of operations and cash flows for the interim periods presented.

Recently Issued Accounting Guidance Not Yet Adopted

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 is effective for the annual reporting period beginning after December 15, 2016, including interim periods within that reporting period, with early adoption permitted. The Company is currently evaluating the impact on its consolidated financial statements upon the adoption of this guidance.

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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), 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 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 August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern. This guidance requires management to evaluate, at each interim and annual reporting period, whether there are conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date the financial statements are issued, and provide related disclosures. This guidance will be effective for annual period ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. The Company does not expect a material 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. ASU 2014-09 can be adopted either retrospectively to each prior reporting period presented, or retrospectively with a cumulative-effect adjustment recognized as of the date of adoption. In April 2016, the FASB issued ASU 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing (“ASU 2016-10”), which clarifies the implementation guidance on identifying performance obligations in a contract and determining whether an entity’s promise to grant a license provides a customer with either a right to use the entity’s intellectual property (which is satisfied at a point in time) or a right to access the entity’s intellectual property (which is satisfied over time). The effective date and transition requirements for ASU 2016-10 are the same as those for ASU 2014-09. The original effective date of ASU 2014-09 for public entities was for the annual reporting period beginning after December 15, 2016. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606), to defer the effective date of ASU 2014-09 by one year, to the annual reporting period beginning after December 15, 2017, including interim periods within that reporting period. A reporting entity may choose to early adopt the guidance as of the original effective date. The Company does not anticipate an early adoption, and is currently evaluating the impact on its consolidated financial statements upon the adoption of ASU 2014-09 and ASU 2016-10.

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. The Company evaluated the criteria under ASC 605-28 and concluded that the aforementioned milestone was substantive.

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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 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 the Company expects to receive in various amounts through June 2016, of which $312.0 million was received as of March 31, 2016. The remaining payment of $62.0 million is contingent upon the occurrence of a specified event and accordingly is also not considered fixed or determinable. 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 the second quarter of 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). 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 (such amounts were fully received as of March 31, 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.

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.

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

Agreement	Deliverable	Three Months Ended March 31, 2016	2015
Japan	License	$75	$437
	Milestones	—	—
	Total license and milestone revenue	$75	$437
	Collaboration services revenue*	$4	$58

* 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 March 31, 2016	Deferred Revenue at March 31, 2016	Total Consideration Through March 31, 2016
License	$ 42,320	$ —	$ 42,320
When and if available compounds	15	27	42
Manufacturing--clinical supplies	1,969	—	1,969
Committee services	17	—	17
Total license and collaboration services revenue	$ 44,321	$ 27	$ 44,348

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

Agreement	Deliverable	Three Months Ended March 31, 2016	2015
Europe	License	$3,238	$4,255
	Milestones	—	—
	Total license and milestone revenue	3,238	4,255
	Collaboration services revenue*	$348	$576

* 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 March 31, 2016	Deferred Revenue at March 31, 2016	Total Consideration Through March 31, 2016
License	$ 404,554	$ —	$ 404,554
When and if available compounds	343	427	770
Manufacturing--clinical supplies	9,690	—	9,690
Development services--in progress	32,413	—	32,413
Committee services	278	2	280
Total license and collaboration services revenue	$ 447,278	$ 429	$ 447,707

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

Agreement	Deliverable	Three Months Ended March 31, 2016	2015
U.S. / RoW and China	License	$16,425	$6,814
	Milestones	—	—
	Total license and milestone revenue	16,425	6,814
	Collaboration services revenue*	8,184	4,138
	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 March 31, 2016	Deferred Revenue at March 31, 2016	Total Consideration Through March 31, 2016
License	$ 306,191	$ —	$ 306,191
Co-development, information sharing & committee services	58,317	34,775	93,092
Manufacturing--clinical supplies	261	57	318
China-single unit of accounting	—	62,761	62,761
Total license and collaboration services revenue	$ 364,769	$ 97,593	$ 462,362

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.

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3. Fair Value Measurements

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

	March 31, 2016			
	Level 1	Level 2	Level 3	Total
Corporate bonds	$—	$126,279	$ —	$126,279
Bond and mutual funds	25,712	—	—	25,712
Equity investments	231	—	—	231
Money market funds	44,761	—	—	44,761
Certificate of deposits	—	2,241	—	2,241
Total	$70,704	$128,520	$ —	$199,224

	December 31, 2015			
	Level 1	Level 2	Level 3	Total
Corporate bonds	$—	$126,103	$ —	$126,103
Bond and mutual funds	25,052	—	—	25,052
Equity investments	197	—	—	197
Money market funds	77,639	—	—	77,639
Certificate of deposits	—	8,215	—	8,215
Total	$102,888	$134,318	$ —	$237,206

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):

	March 31, 2016			
	Level 1	Level 2	Level 3	Total
Lease financing obligations	$—	$ —	$97,480	$97,480

	December 31, 2015			
	Level 1	Level 2	Level 3	Total
Lease financing obligations	$—	$ —	$97,445	$97,445

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):

	March 31, 2016	December 31, 2015
Cash	$96,198	$75,685
Money market funds	44,761	77,639
Total cash and cash equivalents	$140,959	$153,324

At March 31, 2016, a total of $26.0 million 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.

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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):

	March 31, 2016			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Corporate bonds	$125,825	$ 529	$ (75)	$126,279
Certificate of deposits	2,241	—	—	2,241
Bond and mutual funds	25,712	—	—	25,712
Equity investments	126	105	—	231
Total investments	$153,904	$ 634	$ (75)	$154,463

	December 31, 2015			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Corporate bonds	$126,522	$ 54	$ (473)	$126,103
Certificate of deposits	8,217	—	(2)	8,215
Bond and mutual funds	25,052	—	—	25,052
Equity investments	126	71	—	197
Total investments	$159,917	$ 125	$ (475)	$159,567

At March 31, 2016, all of the available-for-sale investments had contractual maturities within three 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 months ended March 31, 2016 and 2015, the Company did not recognize any other-than-temporary impairment loss.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2016	December 31, 2015
Preclinical and clinical trial accruals	$ 29,023	$ 27,973
Payroll and related accruals	9,511	13,535
Professional services	1,338	1,662
Other	4,166	4,762
Total accrued liabilities	$ 44,038	$ 47,932

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 March 31,	
	2016	2015
Research and development	$4,496	$4,222
General and administrative	2,844	2,224
Total stock-based compensation expense	$7,340	$6,446

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The assumptions used to estimate the fair value of stock options granted and ESPPs using the Black-Scholes option valuation model were as follows:

	Three Months Ended March 31,	
	2016	2015
Stock Options		
Expected term (in years)	5.3	5.2
Expected volatility	69%	70%
Risk-free interest rate	1.4	1.4
Expected dividend yield	—	—
Weighted average estimated fair value	$11.46	$17.49
ESPPs		
Expected term (in years)	0.4 - 2.0	0.4 - 2.0
Expected volatility	58.5 - 70.3%	58.5 - 68.3%
Risk-free interest rate	0.1 - 0.9%	0.1 - 0.4%
Expected dividend yield	—	—
Weighted average estimated fair value	$12.80	$13.27

6. Income Taxes

The benefit from income taxes for the three months ended March 31, 2016 was primarily due to the discrete tax effect arising from other comprehensive income related to available-for-sale securities. The benefit for income taxes for the three months ended March 31, 2015 was due to the discrete tax effect arising from other comprehensive income related to available-for-sale securities.

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.

7. Related Party Transactions

Astellas is an equity investor in the Company and considered a related party. During the quarter ended March 31, 2016 and 2015, the Company recorded revenue related to collaboration agreements with Astellas of $3.7 million and $5.3 million, respectively. During the quarter ended March 31, 2016 and 2015, the Company recorded expense related to collaboration agreements with Astellas of $1.6 million and $3.0 million, respectively.

As of March 31, 2016 and December 31, 2015, accounts receivable from Astellas were $3.7 million and $4.5 million, respectively, and amounts due to Astellas were $1.6 million and $2.0 million, respectively.

Julian N. Stern, a director of the Company since November 1996, 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 it as of counsel. The Company retains Goodwin Procter LLP as legal counsel for various matters, primarily consisting of intellectual property matters. During the three months ended March 31, 2016 and 2015, the Company made payments to Goodwin Procter LLP of less than $0.1 million, respectively. As of March 31, 2016 and December 31, 2015, the balance of accrued liability for Goodwin Proctor LLP was immaterial.

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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, 2015 filed with the SEC on February 29, 2016.

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 (the "Exchange Act"), Section 27A of the Securities Act of 1933, as amended (the "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 sim 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 research-based, biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics to treat serious unmet medical needs. We have capitalized on our extensive experience in fibrosis and hypoxia-inducible factor ("HIF") biology to generate multiple programs targeting various therapeutic areas. 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"). FG-3019 is our monoclonal antibody in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer, Duchenne muscular dystrophy ("DMD") and liver fibrosis. We have taken a global approach with respect to our product candidates, and this includes development and commercialization of product candidates in the People's Republic of China ("China").

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Financial Highlights

	Three Months Ended March 31,	
	2016	2015
	(in thousands, except for per share data)	
Result of Operations		
Revenue	$28,282	$16,298
Operating expenses	$55,067	$61,021
Net loss	$(27,841)	$(46,367)
Net loss per share - basic and diluted	$(0.45)	$(0.78)

	March 31, 2016	December 31, 2015
	(in thousands)	
Balance Sheet		
Cash and cash equivalents	$140,959	$153,324
Short-term and long-term investments	$154,463	$159,567
Accounts receivable	$5,937	$15,405

Our revenue for the three months ended March 31, 2016 increased compared to the same period a year ago primarily due to the fact that we had reached the cap with AstraZeneca AB (“AstraZeneca”) during the fourth quarter of 2015 on our initial funding obligations, therefore during the first quarter of 2016, we no longer shared 50% of the development costs compared to the prior periods, for roxadustat for the treatment of anemia in CKD in the U.S., Europe, Japan and all other markets outside of China. This increase in revenue was partially offset by decreased reimbursable co-development costs. Operating expenses decreased for the three months ended March 31, 2016 primarily due to lower research and development expenses, as we had reached the cap with AstraZeneca during the fourth quarter of 2015 as discussed above, and we no longer shared 50% of the development costs compared to the prior periods. During the three months ended March 31, 2016, we had a net loss of $27.8 million, or net loss per basic and diluted share of $0.45. The improvement in net loss and in net loss per basic and diluted share for the three months ended March 31, 2016 compared to the same period a year ago was due to an increase in revenue and a decrease in operating expenses.

Cash, cash equivalents, investments and accounts receivable, excluding restricted cash, totaled $301.4 million at March 31, 2016, a decrease of $26.9 million from December 31, 2015, primarily due to cash used in operations.

Programs

During the first three months of 2016, we continued to make progress in the development of our major programs.

Roxadustat, the first HIF-PH inhibitor to enter Phase 3 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, continue to advance roxadustat through our global Phase 3 program, conducting seven studies designed to support regulatory approval of roxadustat in both dialysis-dependent CKD patients and CKD patients who are not dialysis-dependent in multiple geographies. We have completed initial target enrollment in two of FibroGen’s three Phase 3 studies and we have enrolled approximately 80% of the third study’s initial target

enrollment. We are focusing on additional U.S. enrollment in this third study and expect to complete initial target enrollment in the third quarter of 2016. We are working with our partners to assess overall event rates to develop a view on expected study completion dates in the second half of 2016. We currently anticipate filing for New Drug Application ("NDA") approval for roxadustat in the U.S. in 2018.

Through our subsidiary, FibroGen (China) Medical Technology Development Co., Ltd. ("FibroGen Beijing"), we began enrolling patients in our China Phase 3 studies in December 2015. The primary efficacy endpoint is 26 weeks for the 300 subject dialysis study and we are over 80% enrolled and expect to complete enrollment in May 2016. The primary efficacy endpoint is 8 weeks for the 150 subject non-dialysis study and we are approximately one-third enrolled and expect to complete enrollment in the third quarter. We expect to report top-line data for these studies by year-end. We also believe we have enrolled sufficient subjects for the 52 week safety assessment study and expect to complete follow up with the last subjects in the second quarter of 2017.

We are operating within the context of a Class 1.1 drug approval pathway for Domestic innovative drugs, and we currently anticipate initiating the NDA process in China in the fourth quarter of 2016 after we have reached the primary efficacy endpoint for both studies. Given that there is little precedent in China for the approval pathway and the China Food and Drug Administration ("CFDA") is in the process of enacting regulatory reform, we continue to regularly consult with the CFDA with respect to the approval process.

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In Japan, Astellas has completed roxadustat Phase 2b studies in CKD dialysis and non-dialysis patients and currently expects to initiate Phase 3 clinical development in the second quarter of 2016, which would trigger a $10 million milestone followed by payment sometime in the second or third quarter of 2016.

Based on roxadustat's potential safety and efficacy profile and other potential advantages over Erythropoiesis Stimulating Agents, we believe that in addition to treating anemia in CKD, roxadustat has the potential to treat anemia associated with other conditions. We plan on submitting a clinical trial application in China in the second quarter of 2016 to study roxadustat in myelodysplastic syndrome. We also plan on submitting a clinical trial application in China to study roxadustat in chemotherapy induced anemia in 2016.

FG-3019 is our fully-human monoclonal antibody that inhibits the activity of connective tissue growth factor, a critical common element in the progression of fibrosis and associated serious diseases. We continue to expand the scope of our ongoing Phase 2, randomized, double-blind, placebo-controlled study (067) to evaluate the safety and efficacy of FG-3019 in IPF patients with mild to moderate disease. As with our open-label Phase 2 trial, Study 049, the primary efficacy endpoint for Study 067 is change in FVC from baseline. Secondary endpoints are extent of pulmonary fibrosis as measured by quantitative high resolution computed tomography, other pulmonary function assessments and measures of health-related quality of life. We have enrolled approximately 75 toward our goal of 90 patients in the placebo-controlled portion of this study, and intend to complete enrollment in mid-2016. We have also begun enrolling patients in a substudy targeting approximately 60 patients to test FG-3019 in combination with approved therapies. Hoffmann-La Roche's ("Roche's") pirfenidone is approved for marketing in Europe, Canada, Japan and the U.S. and Boehringer Ingelheim's nintedanib is approved for marketing in Europe and the U.S. We expect to report topline data from these studies in July of 2017.

We also continue to enroll an open-label Phase 2 trial in previously untreated patients with pancreatic cancer to determine whether FG-3019, in combination with gemcitabine and nab-paclitaxel, can convert stage 3 inoperable cancer to resectable, or operable, cancer. Target enrollment for this proof of concept study is approximately 42 patients, however, we won't necessarily have to complete the target enrollment before ending the study. There are 47,000 new cases of pancreatic cancer per year in U.S. In two thirds of new cases, the nature of the cancer precludes resection, in one third the tumors are potentially resectable. We reported on the first eight evaluable patients at the 2016 American Society of Clinical Oncology GastroIntestinal Cancer Meeting in January. Though we have only treated a limited number of patients, at present, of nine patients randomized to receive FG-3019 plus standard-of-care (gemcitabine and nab-paclitaxel), three patients continue on treatment, one discontinued treatment early due to a chemotherapy-related serious adverse event and five patients completed six months of treatment. All five who completed treatment were reassessed as eligible for resection based on standard scoring criteria set forth in the protocol; three having complete resection (R0) and one having an R1 resection (microscopic evidence of residual tumor cells at the resection margins), while the fifth patient's tumor was not resected due to the presence of metastatic disease observed during surgery. Of the seven patients randomized to the comparator arm of chemotherapy, three experienced disease progression, as defined in the protocol, prior to completing treatment and four completed the treatment regimen. Of the four who completed treatment, only one was reassessed as eligible for resection and that patient had a complete resection (R0). In addition, two of the seven randomized to the chemotherapy arm died.

In January 2016, we dosed the first patients in a two-year open-label trial of FG-3019 in approximately 22 non-ambulatory patients with DMD and expect to complete enrollment by the first quarter of 2017. The primary endpoint is change in pulmonary function compared to each individual subject's historical decline in lung function. Other endpoints include assessments of cardiac fibrosis and function assessed by magnetic resonance imaging ("MRI"), arm muscle fibrosis and fat assessed by MRI and upper body strength. We plan to conduct a preliminary assessment after all evaluable subjects have completed one year of dosing. In the third quarter of 2016, we expect to expand our IND and submit a protocol with the Food and Drug Administration ("FDA") to treat ambulatory DMD patients with FG-3019.

Intellectual Property Update

In March 2013, we obtained the grant of European Patent No. 1463823 (the ’823 patent), which is a method case relating to treatment of anemia using different chemical classes of HIF prolyl hydroxylase inhibitors. On December 5, 2013, Akebia Therapeutics, Inc. filed an opposition to the ’823 patent with the European Patent Office and in March 2016, the opposition division of the European Patent Office decided against FibroGen, revoking the ’823 patent as granted. FibroGen has appealed this decision, and the ’823 patent is currently valid and enforceable pending resolution on appeal. While we believe we will be successful on appeal, the ultimate outcome of the proceeding remains uncertain and ultimate resolution may take an additional 4-5 years. However, a narrowing of the scope of or even revocation of the ’823 patent would not affect our exclusivity for roxadustat or our freedom-to-operate with respect to use of roxadustat for the treatment of anemia in Europe. Akebia and other third parties may initiate additional or similar proceedings with the European Patent Office or in other similar foreign jurisdictions.

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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 a collaboration agreement with Astellas for roxadustat for the treatment of anemia in Europe, the Commonwealth of Independent States, the Middle East, and South Africa ("Europe Agreement"). Under these agreements, we provided Astellas the right to develop and commercialize roxadustat for anemia 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. The aggregate amount of such consideration received through March 31, 2016 totals $462.6 million. In Japan, Astellas has completed roxadustat Phase 2b studies in CKD dialysis and non-dialysis patients and currently expects to initiate Phase 3 clinical development in the second quarter of 2016, which would trigger a $10 million milestone followed by payment sometime in the second or third quarter of 2016.

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 March 31, 2016, Astellas had separate investment of $80.5 million in the equity of FibroGen, Inc.

AstraZeneca

In July 2013, we entered into 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 ("U.S./RoW Agreement"). In July 2013,

through our China subsidiary and related affiliates, we entered into a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in China ("China Agreement"). Under these agreements we provided 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 initial development costs), all future 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 will be paid by Astellas and AstraZeneca.

In China, FibroGen China will conduct the development work for CKD anemia and its subsidiary, FibroGen Beijing, will hold all of the regulatory licenses issued by China regulatory authorities, and FibroGen China 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.

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Under the AstraZeneca agreements, we will receive upfront and subsequent non-contingent payments totaling $402.2 million, a portion of which we have received and the remainder of which we expect to receive in various amounts through 2016, including a $62.0 million time based development milestone, which became non-contingent as of July 30, 2014. Potential milestone payments under the agreements total $1.2 billion, of which $571.0 million are development and regulatory milestones, and $652.5 million are commercial-based milestones. Total consideration under the agreements, excluding development cost reimbursement, transfer price payments, royalties and profit share, could reach $1.6 billion. The aggregate amount of such consideration received through March 31, 2016 totals $355.2 million.

During the second quarter of 2015, we received an upfront payment of $120.0 million and a development milestone payment of $15.0 million under the U.S./RoW Agreement. The development milestone payment resulted from the finalization of our two audited pre-clinical carcinogenicity study reports.

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, 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.

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 to pay 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 to pay 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 March 31, 2016 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 March 31, 2016	Additional Potential Cash Payments	Total Potential Cash Payments
	(in thousands)		
Astellas--related-party:			
Japan Agreement	$52,593	$ 120,000	$ 172,593
Europe Agreement	410,000	335,000	745,000
Total Astellas	462,593	455,000	917,593
AstraZeneca:			
U.S. / RoW Agreement	327,000	922,000	1,249,000
China Agreement	28,200	348,500	376,700
Total AstraZeneca	355,200	1,270,500	1,625,700
Total revenue	$817,793	$ 1,725,500	$ 2,543,293

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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 March 31,		Change	
	2016	2015	$	%
	(dollars in thousands)			
Revenue:				
License and milestone revenue	$19,738	$11,506	$8,232	72 %
Collaboration services and other revenue	8,544	4,792	3,752	78 %
Total revenue	$28,282	$16,298	$11,984	74 %

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 70% and 71% of total revenue for the three months ended March 31, 2016 and 2015, 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 65 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 periods presented. Collaboration services and other revenues represented 30% and 29% of total revenue for the three months ended March 31, 2016 and 2015, 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 increased by $12.0 million, or 74% for the three months ended March 31, 2016 compared to the same period a year ago for the reasons discussed in the sections below.

License and Milestone Revenue

	Three Months Ended March 31,		Change	
	2016	2015	$	%
	(dollars in thousands)			
License and milestone revenue:				
Astellas	$3,313	$4,692	$(1,379)	(29)%
AstraZeneca	16,425	6,814	9,611	141 %
Total license and milestone revenue	$19,738	$11,506	$8,232	72 %

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License and milestone revenue increased by $8.2 million, or 72% for the three months ended March 31, 2016 compared to the same period a year ago due to an increase in the license and milestone revenue recognized under our collaboration agreements with AstraZeneca, partially offset by a decrease in the license and milestone revenue recognized under our collaboration agreements with Astellas. License and milestone revenue recognized under our collaboration agreements with AstraZeneca increased primarily due to the fact that we had reached the cap during fourth quarter of 2015 on our initial funding obligations, therefore during the first quarter of 2016, we no longer shared 50% of the development costs development and commercialization costs compared to the prior periods, for roxadustat for the treatment of anemia in CKD in the U.S., Europe, Japan and all other markets outside of China. The increase was partially offset by a decrease in reimbursable co-development costs allocated to license and milestone revenues. License and milestone revenue recognized under our collaboration agreements with Astellas decreased primarily due to a decrease in reimbursable co-development costs allocated to license and milestone revenues.

Collaboration Services and Other Revenue

	Three Months Ended March 31,		Change	
	2016	2015	$	%
	(dollars in thousands)			
Collaboration services revenue:				
Astellas	$352	$634	$(282)	(44)%
AstraZeneca	8,184	4,138	4,046	98 %
Total collaboration services revenue	8,536	4,772	3,764	79 %
Other revenue	8	20	(12)	(60)%
Total collaboration services and other revenue	$8,544	$4,792	$3,752	78 %

Collaboration services and other revenue increased $3.8 million, or 78%, for the three months ended March 31, 2016 compared to the same period a year ago due to an increase in the collaboration services revenue recognized under our collaboration agreements with AstraZeneca, partially offset by a decrease in the collaboration services revenue recognized under our collaboration agreements with Astellas. Collaboration services revenue recognized under our collaboration agreements with AstraZeneca increased primarily due to the fact that we had reached the cap during fourth quarter of 2015 on our initial funding obligations, therefore during the first quarter of 2016, we no longer shared 50% of the development costs development and commercialization costs compared to the prior periods, for roxadustat for the treatment of anemia in CKD in the U.S., Europe, Japan and all other markets outside of China. In addition, collaboration services revenue recognized under our collaboration agreements with AstraZeneca increased due to the amortization of a higher balance of deferred revenue resulting from the allocation of the upfront payment of $120.0 million received during the second quarter of 2015. The increases were partially offset by a decrease in reimbursable co-development costs allocated to collaboration services revenues. Collaboration services revenue recognized under our collaboration agreements with Astellas decreased due to a decrease in reimbursable co-development costs allocated to collaboration services.

Operating Expenses

	Three Months Ended March 31,		Change	
	2016	2015	$	%

	(dollars in thousands)			
Operating expenses				
Research and development	$43,650	$50,539	$(6,889)	(14)%
General and administrative	11,417	10,482	$935	9 %
Total operating expenses	$55,067	$61,021	$(5,954)	(10)%

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 (“CROs”), 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.

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The following table summarizes our research and development expenses incurred during the three months ended March 31, 2016 and 2015:

		Three Months Ended March 31,	
		2016	2015
Product Candidate	Phase of Development	(in thousands)	
Roxadustat	Phase 3	$27,475	$36,057
FG-3019	Phase 2	7,889	7,333
FG-6874	Phase 1	90	502
FG-5200	Preclinical	1,143	1,330
Other research and development expenses		7,053	5,317
Total research and development expenses		$43,650	$50,539

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 decreased by $6.9 million, or 14%, for the three months ended March 31, 2016 compared to the same period a year ago. The decrease was primarily due to a decrease in outside services of $9.8 million partially offset by increases in employee-related costs of $1.4 million and clinical trial costs of $1.3 million. Outside services costs decreased primarily due to the fact that we had reached the cap with AstraZeneca during the fourth quarter of 2015 on our initial funding obligations, therefore during the first quarter of 2016, we no longer shared 50% of the development costs compared to the prior periods, for roxadustat in the U.S., Europe, Japan and all other markets outside of China. Employee-related costs increased as a result of higher average compensation level. Clinical trial costs increased as a result of the progression of the Phase 3 trials for roxadustat and the ongoing Phase 2 trials for FG-3019.

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 $0.9 million, or 9%, for the three months ended March 31, 2016 compared to the same period a year ago. The increase was primarily due to increases in stock-based compensation

expense of $0.6 million and facility expenses of $0.5 million, partially offset by a decrease in legal fees of $0.6 million. Stock-based compensation expense increased primarily due to increased stock option grants during the current quarter. Facility expenses increased primarily due to the higher assessed property tax. Legal fees decreased due to the incremental maintenance costs associated with our intellectual property portfolio during prior year period.

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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 has been reached. As such, all future 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 will be paid by Astellas and AstraZeneca. In China, our subsidiary FibroGen China will conduct the development work for CKD anemia and will hold all of the regulatory licenses issued by China regulatory authorities, through its subsidiary FibroGen Beijing, 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 March 31,		Change	
	2016	2015	$	%
	(dollars in thousands)			
Interest and other, net:				
Interest expense	$(2,777)	$(2,758)	$(19)	1 %
Interest income and other, net	1,416	843	573	68 %
Total interest and other, net	$(1,361)	$(1,915)	$554	(29)%

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 TEKES product development obligations. Interest expense remained at the same level as compared to the same period a year ago.

Interest and Other Income, Net

Interest and other income, net increased $0.6 million, or 68%, primarily due to unrealized foreign currency translation gains on our monetary assets denominated in foreign currency as a result of USD weakening during the current quarter.

Benefit from Income Taxes

	Three Months Ended March 31,	
	2016	2015
	(dollars in thousands)	
Loss before income taxes	$(28,146)	$(46,638)
Benefit from income taxes	(305)	(271)
Effective tax rate	1.1 %	0.6 %

The benefit from income taxes for the three months ended March 31, 2016 was primarily due to the discrete tax effect arising from other comprehensive income related to available-for-sale securities. The benefit for income taxes for the three months ended March 31, 2015 was due to the discrete tax effect arising from other comprehensive income

related to available-for-sale securities.

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

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

During the second quarter of 2015, we received a $120.0 million upfront payment and a $15.0 million development milestone payment under the U.S./RoW Agreement. The development milestone payment was related to the finalization of our two audited pre-clinical carcinogenicity study reports.

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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. 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. As a newly public company, we expect to incur additional costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

As of March 31, 2016, we had cash and cash equivalents of approximately $141.0 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 March 31, 2016 we had short-term and long-term investments of approximately $32.5 million and $122.0 million, respectively. As of March 31, 2016, a total of $26.0 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.

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 future capital requirements and the adequacy of available funds will depend on many factors, including those set forth under Part II, Item 1A “Risk Factors” in this Quarterly Report on Form 10-Q. We may not be able to secure additional financing to meet our operating requirements on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, the ownership of our existing stockholders will be diluted. If we raise additional financing by the incurrence of indebtedness, we will be subject to increased fixed payment obligations and could also be subject to restrictive covenants, such as limitations on our ability to incur additional debt, and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to obtain needed additional funds, we will have to reduce our operating 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 for each of the periods set forth below:

	Three Months Ended March 31,	
	2016	2015
Net cash provided by (used in):		
Operating activities	$(17,258)	$(42,190)
Investing activities	5,059	4,552
Financing activities	(149)	620
Effect of exchange rate changes on cash and cash	(17)	(68)

equivalents		
Net change in cash and cash equivalents	$(12,365)	$(37,086)

Operating Activities

Net cash used in operating activities was $17.3 million for the three months ended March 31, 2016 and consisted primarily of net loss of $27.8 million adjusted for non-cash items of $8.6 million and a net increase in operating assets and liabilities of $2.0 million. The significant non-cash items included stock-based compensation expense of $7.3 million and depreciation expense of $1.5 million. The significant items in the changes in operating assets and liabilities included an increase resulted accounts receivable of $9.5 million, partially offset by decreases resulted from accounts payable of $5.0 million and accrued liabilities of $3.2 million. The changes in accounts receivable was related to the recognition of revenues under our collaboration agreements with Astellas and AstraZeneca. The changes in accounts payable and accrued liabilities were primarily driven by clinical trial activities and the timing of payments.

Net cash used in operating activities was $42.2 million for the three months ended March 31, 2015 and consisted primarily of a net loss of $46.4 million adjusted for non-cash items of $8.3 million and a net decrease in operating assets and liabilities of $4.2 million.

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The significant non-cash items included stock-based compensation expense of $6.4 million, depreciation expense of $1.4 million and amortization of the premium on investments of $0.8 million. The significant items in the change in operating assets and liabilities included a decrease in accrued liabilities of $7.0 million, a decrease in accounts payable of $2.1 million, a decrease in prepaid expenses and other current assets of $0.8 million and a decrease in deferred revenue of $0.8 million, partially offset by an increase in accounts receivable of $6.5 million. The changes in deferred revenue and accounts receivable were related to the timing of upfront payments and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca. The changes 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 fixed assets, purchases of investments, and proceeds from the maturity and sale of investments.

Net cash provided by investing activities was $5.1 million for the three months ended March 31, 2016 and consisted of proceeds from maturities of available-for-sale securities of $6.0 million, partially offset by cash used in purchases of fixed assets of $0.9 million.

Net cash provided by investing activities was $4.6 million for the three months ended March 31, 2015 and consisted of proceeds from maturities of available-for-sale securities of $5.0 million, offset by cash used in purchases of fixed assets of $0.4 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 used in financing activities was $0.1 million for the three months ended March 31, 2016 and consisted of $1.3 million of cash paid for payroll taxes on restricted stock unit releases and $0.1 million of repayments on our lease liability, offset by $1.2 million of proceeds from the issuance of common stock upon exercise of stock options.

Net cash provided by financing activities was $0.6 million for the three months ended March 31, 2015 and consisted of $0.7 million of proceeds from the issuance of common stock upon exercise of stock options, offset by $0.1 million of repayments on our lease liability.

Off-Balance Sheet Arrangements

During the three months ended March 31, 2016, 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, 2015.

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 U.S. generally accepted accounting principles. 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 months ended March 31, 2016 compared with the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2015.

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Recently Issued Accounting Guidance Not Yet Adopted

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 is effective for the annual reporting period beginning after December 15, 2016, including interim periods within that reporting period, with early adoption permitted. 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 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. 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 the annual reporting period 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 August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. This guidance requires management to evaluate, at each interim and annual reporting period, whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date the financial statements are issued, and provide related disclosures. This guidance will be effective for annual period ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. We do not expect a material 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 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. ASU 2014-09 can be adopted either retrospectively to each prior reporting period presented, or retrospectively with a cumulative-effect adjustment recognized as of the date of adoption. In April 2016, the FASB issued ASU 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing ("ASU 2016-10"), which clarifies the implementation guidance on identifying performance obligations in a contract and determining whether an entity's promise to grant a license provides a customer with either a right to use the entity's intellectual property (which is satisfied at a point in time) or a right to access the entity's intellectual property (which is satisfied over time).

The effective date and transition requirements for ASU 2016-10 are the same as those for ASU 2014-09. The original effective date of ASU 2014-09 for public entities was for the annual reporting period beginning after December 15, 2016. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606), to defer the effective date of ASU 2014-09 by one year, to the annual reporting period beginning after December 15, 2017, including interim periods within that reporting period. A reporting entity may choose to early adopt the guidance as of the original effective date. We do not anticipate an early adoption, and are currently evaluating the impact on our consolidated financial statements upon the adoption of ASU 2014-09 and ASU 2016-10.

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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, 2015.

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 U.S. 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 March 31, 2016 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 March 31, 2016 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.

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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, 2015.

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 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, 2015, 2014 and 2013 was approximately $85.8 million, $59.5 million and $14.9 million, respectively. As of March 31, 2016, we had an accumulated deficit of $435.9 million. As of March 31, 2016, we had capital resources consisting of cash, cash equivalents and short-term investments of $173.4 million plus $122.0 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.

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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 FG-3019, 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 approximately 7,000 to 8,000 patients worldwide. 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 initial public offering ("IPO"), our existing cash, cash equivalents and short-term investments 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 FG-3019, 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 2015, 2014 and 2013, 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.

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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, FG-3019.*

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 US 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, FG-3019, is currently in clinical development for IPF, pancreatic cancer, DMD, and liver fibrosis. FG-3019 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, FG-3019 may be appropriate. Accordingly, the costs and time to complete development and related risks are currently unknown. Moreover, FG-3019 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 FG-3019 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 FG-3019.*

The clinical and commercial success of roxadustat and FG-3019 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 FG-3019, 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;

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- 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 FG-3019 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 FG-3019 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 FG-3019 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 FG-3019 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 FG-3019, 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;

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- 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.

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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.

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Our preclinical and Phase 2 results to date for FG-3019 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 FG-3019. We have conducted an open-label Phase 2 dose escalation study of FG-3019 for IPF in 89 patients, a Phase 2 dose finding trial of FG-3019 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 FG-3019 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 FG-3019 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 FG-3019 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 FG-3019 in a manner that negatively impacts the safety profile of our product candidate. If the additional Phase 2 clinical trials that we are planning for FG-3019 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 FG-3019 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 FG-3019 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.

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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 — FG-3019 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 FG-3019.

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;

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- 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 our product candidates and/or products at sufficient yields or quality, we may experience delays in development, regulatory approval and 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 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. Our efforts to establish these capabilities may not meet our requirements as to scale-up, yield, cost, potency or quality in compliance with cGMP. 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. 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 FG-3019, which is a monoclonal antibody;
- supply chain issues, including 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 limitations and scheduling availability in contracted facilities; and
- natural disasters that affect facilities and possibly limit production.

For example, we have a limited amount of FG-3019 in storage and there are long lead times required to manufacture and scale-up the manufacture of additional supply. If we are unable to manufacture sufficient quantities of FG-3019 on a timely basis, it may limit our ability to replenish inventory or delay our development of FG-3019 in some or all indications. Any delay or interruption in the supply of our product candidates or products could have a material adverse effect on our business and operations.

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.

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As an organization, we have never completed a Phase 3 clinical trial or submitted 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 FG-3019 and we may need to conduct additional Phase 2 clinical trials before initiating our Phase 3 clinical trials for FG-3019. We have initiated Phase 3 clinical trials of roxadustat, and if our Phase 2 clinical trials are successful for FG-3019, we intend to conduct Phase 3 clinical trials for FG-3019. 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 submitted 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. 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 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.

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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®, commercialized by Amgen Inc. in the U.S., Procrit® and Erypo®/Eprex®, commercialized by Johnson & Johnson Inc.), darbepoetin (Amgen/Kyowa Hakko Kirin's Aranesp® and NESP®) and Mircera ® commercialized by Hoffmann-La Roche ("Roche") outside of the U.S., and by Galenica, 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 on Medicare. It may be difficult to encourage treatment providers and patients to switch from products with which they have become familiar to roxadustat.

We may also face competition from potential new anemia therapies currently in clinical development for the treatment of anemia in CKD patients, 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, 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 recently announced that it has initiated its first Phase 3 study in non-dialysis dependent CKD patients in December 2015, and has reached agreement with the FDA regarding its dialysis dependent CKD program. GSK and Bayer are currently in Phase 2 development globally, and Japan Tobacco is in Phase 2b in Japan. Some of these product candidates may enter the market prior to roxadustat. There may 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 addition, there are other companies developing biologic therapies for treatment of other anemia indications that we may also seek to pursue in the future, including myelodysplastic syndrome, for which we plan to submit a Clinical Trial Application in China in the first half of 2016 and may pursue in broader markets.

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 dialysis patients under the end stage renal disease bundle. A biosimilar product is a follow-on version of an existing, branded biologic product. Under current laws, an application for a biosimilar product should not be approved by the FDA until 12 years after the existing, patent-protected product was approved under a Biologics License Application ("BLA"). The patents for the existing, branded product must expire in a given market before biosimilars may enter that market with limited or no risk of being sued for patent infringement. The patents for epoetin alfa, a version of EPOGEN, expired in 2004 in the European Union ("EU"), and the final material patents expired in May 2015 in the U.S. 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™, an EPOGEN and Procrit biosimilar that is being marketed by Pfizer in Europe and for which Pfizer has said it plans to resubmit a BLA for after receiving a complete response letter from the FDA denying approval of its BLA in October 2015, as well as Binocrit®, an epoetin alfa biosimilar being marketed in Europe by Sandoz (Novartis) and in Phase 3 development 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’s contract with Amgen that began in January 2012 includes an exclusive relationship through 2018. Fresenius’ contract with Amgen is non-exclusive and expired in 2015. Fresenius is now administering Mircera ® in a significant portion of its U.S. dialysis patients since Mircera was made available by Galenica. Successful penetration of this market may require AstraZeneca to reach a significant agreement with Fresenius or DaVita, the two largest dialysis clinics in the U.S., on favorable terms and on a timely basis.

If FG-3019 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 Bristol-Myers Squibb’s BMS-986020 and Biogen-Idec’s STX-100.

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If FG-3019 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 FG-3019 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., Momenta Pharmaceuticals Inc., Gilead Sciences Inc., 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. On October 22, 2015, Merrimack Pharmaceuticals Inc., announced that it had 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 FG-3019 is approved and launched commercially to treat DMD, FG-3019 may face competition for some patients from Sarepta Therapeutics, Inc, as well as BioMarin, and PTC Therapeutics, Santhera Pharmaceuticals, Pfizer, Summit plc and Tivorsan Pharmaceuticals. BioMarin along with Sarepta, have entered clinical development with therapeutics based on exon-skipping technology which seeks to help patients produce functioning forms of the dystrophin protein. As there are multiple distinct mutations of the dystrophin gene that cause DMD, each exon skipping therapy targets only one specific mutation, treating only a subset of DMD patients (for example, exon-51 targets approximately 13% of DMD patients). BioMarin and Sarepta are researching and developing clinical candidates for many of the specific mutations in the dystrophin gene. PTC Therapeutics' product ataluren (Translarna ™) received conditional approval in Europe in 2014 and a Refuse to File letter from the FDA in March 2016. Translarna targets a different set of DMD patients from those being targeted by BioMarin's and Sarepta's existing exon-skipping therapeutics; however it is also limited to a subset of patients who carry a specific mutation. Conversely, FG-3019 is intended to treat DMD patients without limitation to type of mutation. 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. 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, 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. Summit has completed a Phase 1b trial and started a Phase 2 study in the United Kingdom. Tivorsan is conducting preclinical work on their compound.

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 FG-3019. In addition, any competitive products that are on the market or in development may compete with FG-3019 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 FG-3019 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, these companies have greater experience and expertise 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 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.

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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, FG-3019 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.

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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.

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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, and our current manufacturing facility plans in China are not expected to satisfy the requirements necessary to support roxadustat 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.

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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., acquired IRIX.

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.

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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.

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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 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. The effects of this change and other elements of the AIA are currently unclear, as the U.S. Patent and Trademark Office (“USPTO”), is still implementing associated regulations, and the applicability of the AIA and associated regulations to our patents and patent applications have not been fully determined. This new system also includes new 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 a 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 FG-3019. 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.

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We intend, if necessary, to vigorously enforce our intellectual property in order to protect the proprietary position of our product candidates, including roxadustat and FG-3019. 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 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, on December 5, 2013, Akebia filed an opposition to our European Patent No. 1463823 (the "'823 patent"), with the European Patent Office, and Akebia and other third parties may initiate or pursue similar proceedings with the European Patent Office or other corresponding foreign jurisdictions. The granted claims of the '823 patent encompass the use of roxadustat for the treatment of anemia. In March 2016, the opposition division of the European Patent Office decided against FibroGen, revoking the patent as granted. FibroGen has appealed this decision, and the '823 patent is currently valid and enforceable pending resolution on appeal. While we believe we will be successful on appeal, and while loss of the '823 patent would not affect our exclusivity for roxadustat or our freedom-to-operate with respect to use of roxadustat for the treatment of anemia, the ultimate outcome of the proceeding remains uncertain and ultimate resolution may take an additional 4 to 5 years and result in substantial costs to us.

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.

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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.

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The existence of counterfeit pharmaceutical products in pharmaceutical markets may damage 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 FG-3019, 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.

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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; and
- 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.

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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 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;

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- 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.

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.

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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.

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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 facility in China to produce roxadustat drug product, and possibly API, and corneal implants. 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 recently received a Pharmaceutical Production Permit ("PPP") for our facility in China in which we intend to manufacture roxadustat. 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 a manufacturing facility in the past and our facility 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 facility 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 facility, and wars, could significantly impair our ability to operate our manufacturing facility. 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.

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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 subsidiaries, FibroGen China Anemia Holdings, Ltd. and FibroGen (China) Medical Technology Development Co., Ltd. (individually or collectively referred to as "FibroGen China"), plan to seek approval for roxadustat in China as a Domestic Class 1.1 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, some of our clinical trial sites recently received permission from the Ministry of Science and Technology, under a new approval process, to obtain routine blood and urine samples that contain genetic information. Such applications are reviewed only on a quarterly basis, thus studies to be performed at additional clinical trial sites could be delayed until they receive approval.

In addition, there are evolving environmental and manufacturing regulations in China. Final regulations and the application thereof, and any further changes to these regulations may impact our API manufacturing location or strategy. It is possible that we may be able to produce API at contract manufacturers or we may be required to move our API manufacturing to another facility that we must build outside of Beijing. The exact impact of these regulations are yet to be determined, however, it is possible that they could adversely affect the cost or, potentially, the timeline of our commercial manufacturing plan and timing of our commercialization in China.

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 Brewery 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.

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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 China 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.

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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 (China) Medical Technology Development Co., Ltd. ("FibroGen Beijing") would be subject to restrictions on paying dividends or making other payments to us, which may restrict our ability to satisfy our liquidity requirements.

We plan to conduct all of our business in China through FibroGen 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 March 31, 2016, approximately $6.6 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.

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

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

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

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

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

In addition, we and our foreign subsidiaries have various intercompany transactions. We may not be able to obtain certain benefits under relevant tax treaties to avoid double taxation on certain transactions among our subsidiaries. If we are not able to avail ourselves 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 currently have at least 5 granted patents relating to roxadustat in China. Refer to "Business — Intellectual Property." 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 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 Chinese 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 Chinese 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.

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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 company 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.

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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 became effective in 2008 and provides stronger protections for employees and imposes more 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.

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.

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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. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption 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. To the extent that any disruption or security breach 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 the further

development of our product candidates could be delayed.

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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, such as our data storage facilities, enterprise financial systems or manufacturing resource planning and enterprise quality systems, 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 currently are limited and are unlikely to prove adequate 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 FG-3019;
- 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;

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- 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.

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 April 30, 2016, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 25.61% 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 April 30, 2016. 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.

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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 are incurring significant compliance costs as a result of operating as a public company and our management is required to devote substantial resources to public company compliance programs.*

As a newly public company, we are incurring significant legal, insurance, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the listing requirements of The NASDAQ Stock Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We are currently and intend to continue to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from product development activities, particularly now that we are no longer an "emerging growth company". If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. In the future, it may be more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

Specifically, in order to comply with the requirements of being a public company, we may need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our ordinary shares could decline. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on The NASDAQ Stock Market.

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We are required to comply with the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act ("Section 404"), which include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. In addition, we are required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting. To achieve compliance with Section 404, we need to continue to dedicate internal resources, outside consultants and continue to execute a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements and we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls in the future.

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.

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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.

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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.

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

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.

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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.

The exhibits listed on the accompanying Exhibit Index are filed or incorporated by reference (as stated therein) as part of this Quarterly Report on From 10-Q.

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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: May 9, 2016 By: /s/ Thomas B. Neff
Thomas B. Neff
Chairman of the Board and Chief Executive Officer
(Principal Executive Officer)

Dated: May 9, 2016 By: /s/ Pat Cotroneo
Pat Cotroneo
Vice President, Finance and Chief Financial Officer
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

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 stockholders, dated as of February 20, 1998.	S-1	333-199069	4.3	10/01/2014
4.4	Investor Rights Agreement by and among FibroGen, Inc. and certain of its warrant holders, dated as of June 3, 1999.	S-1	333-199069	4.6	10/01/2014
4.5	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
4.6	Warrant to Purchase 4,000 Shares of Common Stock issued to Laurence S. Shushan and Magdalena Shushan, Trustees of The Laurence and Magdalena Shushan Family Trust, dated as of June 3, 1999.	S-1	333-199069	4.10	10/01/2014
4.7	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
4.8	Warrant to Purchase 2,769 Shares of Common Stock issued to Laurence S. Shushan and Magdalena Shushan, Trustees of The Laurence and Magdalena Shushan Family Trust, dated as of February 8, 2000.	S-1	333-199069	4.13	10/01/2014
4.9	Shareholders' Agreement by and among FibroGen China Anemia Holdings, Ltd. and certain of its shareholders, dated as of July 11, 2012.	S-1	333-199069	4.15	10/01/2014
4.10	Share Purchase Agreement by and among FibroGen China Anemia Holdings, Ltd. and the purchasers party thereto, dated as of July 11, 2012.	S-1	333-199069	4.16	10/01/2014
4.11		S-1/A	333-199069	4.17	10/24/2014

	Common Stock Purchase Agreement by and between FibroGen, Inc. and AstraZeneca AB, dated as of October 20, 2014.				
10.4*	FibroGen, Inc. Non-Employee Director Compensation Plan, as amended	—	—	—	—
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 March 31, 2016, 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.