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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

OR

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

For the transition period from _____ to _____

Commission file number: 001-36740

FIBROGEN, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

The number of shares of common stock outstanding as of October 31, 2018 was 84,978,056.

FIBROGEN, INC.

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PART I—FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	September 30, 2018	December 31, 2017 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 566,722	$ 673,658
Short-term investments	86,009	62,060
Accounts receivable ($19,434 and $4,004 from a related party)	23,187	8,452
Prepaid expenses and other current assets	2,865	4,800
Total current assets	678,783	748,970
Restricted time deposits	5,181	5,181
Long-term investments	40,602	10,506
Property and equipment, net	127,908	129,476
Other assets	3,167	4,517
Total assets	$ 855,641	$ 898,650
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 10,131	$ 5,509
Accrued liabilities ($353 and $272 to a related party)	52,598	63,781
Deferred revenue	37,697	16,670
Total current liabilities	100,426	85,960
Long-term portion of lease financing obligations	97,323	97,763
Product development obligations	16,948	17,244
Deferred rent	3,197	3,657
Deferred revenue, net of current	136,874	138,241
Other long-term liabilities	10,291	8,047
Total liabilities	365,059	350,912
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 125,000 shares authorized; no shares issued and outstanding at September 30, 2018 and December 31, 2017	—	—
Common stock, $0.01 par value; 225,000 shares authorized at September 30, 2018 and December 31, 2017; 84,847 and 82,498 shares issued and outstanding at September 30, 2018 and December 31, 2017	848	825
Additional paid-in capital	1,209,813	1,160,094
Accumulated other comprehensive loss	(2,570)	(1,795)
Accumulated deficit	(736,780)	(630,657)
Total stockholders' equity	471,311	528,467
Non-controlling interests	19,271	19,271
Total equity	490,582	547,738
Total liabilities, stockholders' equity and non-controlling interests	$ 855,641	$ 898,650

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

FIBROGEN, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017 (Note 1)	2018	2017 (Note 1)
Revenue:				
License revenue (includes $0, $0, $14,323 and $0 from a related party)	$ —	$ 9,933	$ 14,323	$ 9,933
Development and other revenue (includes $5,131, $5,322, $16,448 and $15,106 from a related party)	29,027	30,617	90,580	90,327
Total revenue	29,027	40,550	104,903	100,260
Operating expenses:				
Research and development	56,443	50,336	165,555	144,049
General and administrative	15,356	12,953	45,961	37,908
Total operating expenses	71,799	63,289	211,516	181,957
Loss from operations	(42,772)	(22,739)	(106,613)	(81,697)
Interest and other, net				
Interest expense	(2,739)	(2,769)	(8,257)	(7,901)
Interest income and other, net	3,079	1,106	7,796	2,783
Total interest and other, net	340	(1,663)	(461)	(5,118)
Loss before income taxes	(42,432)	(24,402)	(107,074)	(86,815)
Provision for income taxes	124	57	299	166
Net loss	$ (42,556)	$ (24,459)	$ (107,373)	$ (86,981)
Net loss per share - basic and diluted	$ (0.50)	$ (0.32)	$ (1.28)	$ (1.24)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	84,508	75,891	83,713	69,899

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

FIBROGEN, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017 (Note 1)	2018	2017 (Note 1)
Net loss	$ (42,556)	$ (24,459)	$ (107,373)	$ (86,981)
Other comprehensive income (loss):				
Foreign currency translation adjustments	72	(578)	503	(1,827)
Available-for-sale investments:				
Unrealized gain on investments, net of tax effect	(31)	403	(28)	1,250
Reclassification from accumulated other comprehensive loss	—	(47)	—	(72)
Net change in unrealized gain on available-for-sale investments	(31)	356	(28)	1,178
Other comprehensive income (loss), net of taxes	41	(222)	475	(649)
Comprehensive loss	$ (42,515)	$ (24,681)	$ (106,898)	$ (87,630)

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

FIBROGEN, INC.

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

	Nine Months Ended September 30,	
	2018	2017 (Note 1)
Operating activities		
Net loss	$ (107,373)	$ (86,981)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	4,693	4,582
Amortization of premium on investments	584	1,503
Unrealized loss (gain) on short-term investments	1,103	3
Loss (gain) on disposal of property and equipment	53	3
Stock-based compensation	38,432	27,608
Realized foreign currency gain	(1,074)	—
Realized gain on sales of available-for-sale securities	(87)	(143)
Changes in operating assets and liabilities:		
Accounts receivable	(14,735)	(13,180)
Prepaid expenses and other current assets	1,935	33
Other assets	1,350	(1,657)
Accounts payable	4,622	184
Accrued liabilities	(9,885)	(114)
Deferred revenue	19,660	2,021
Lease financing liability	35	474
Other long-term liabilities	2,008	337
Net cash used in operating activities	(58,679)	(65,327)
Investing activities		
Purchases of property and equipment	(4,852)	(4,992)
Proceeds from sale of property and equipment	184	5
Purchases of available-for-sale securities	(110,156)	(102)
Proceeds from sales of available-for-sale securities	8,167	21,109
Proceeds from maturities of available-for-sale securities	47,390	33,849
Net cash provided by investing activities	(59,267)	49,869
Financing activities		
Borrowings under capital lease obligations	49	—
Repayments of lease liability	(302)	(302)
Proceeds from follow-on offerings, net of underwriting discounts and commission costs	—	471,205
Cash paid for payroll taxes on restricted stock unit releases	(13,288)	(5,970)
Proceeds from issuance of common stock	24,598	28,556
Payments of deferred offering costs	—	(430)
Net cash provided by financing activities	11,057	493,059
Effect of exchange rate change on cash and cash equivalents	(47)	(10)
Net decrease in cash and cash equivalents	(106,936)	477,591
Total cash and cash equivalents at beginning of period	673,658	173,782
Total cash and cash equivalents at end of period	$ 566,722	$ 651,373

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

FIBROGEN, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Significant Accounting Policies

Description of Operations

FibroGen, Inc. ("FibroGen" or the "Company") was incorporated in 1993 in Delaware and is a biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics agents to treat serious unmet medical needs. The Company's focus in the areas of fibrosis and hypoxia-inducible factor ("HIF") biology has generated multiple programs targeting various therapeutic areas. The Company's most advanced product candidate, roxadustat, or FG-4592, is an oral small molecule inhibitor of HIF prolyl hydroxylases ("HIF-PHs") in Phase 3 clinical development for the treatment of anemia in chronic kidney disease ("CKD") and myelodysplastic syndromes ("MDS"). Pamrevlumab, or FG-3019, is the Company's monoclonal antibody in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer and Duchenne muscular dystrophy ("DMD"). The Company is taking a global approach with respect to the development and future commercialization of its product candidates, and this includes development and commercialization in the People's Republic of China ("China"). The Company is capitalizing on its extensive experience in fibrosis and HIF biology and clinical development to advance a pipeline of innovative medicines for the treatment of anemia, fibrotic disease cancer, corneal blindness and other serious unmet medical needs.

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 Securities and Exchange Commission ("SEC") and, therefore, do not include all information and footnote disclosures normally included in the annual consolidated financial statements. The financial information included herein should be read in conjunction with the consolidated financial statements and related notes in the Company's Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2017 ("2017 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 2017 Form 10-K, except for the following:

Revenue Recognition

Substantially all of the Company's revenues to date have been generated from its collaboration agreements.

The Company's collaboration agreements include multiple performance obligations comprised of promised services, or bundles of services, that are distinct. Services that are not distinct are combined with other services in the agreement until they form a distinct bundle of services. The Company's process for identifying performance obligations and an enumeration of each obligation for each agreement is outlined in Note 2 "Collaboration Agreements." Determining the performance obligations within a collaboration agreement often involves significant judgment and is specific to the facts and circumstances contained in each agreement.

The Company has identified the following material promises under its collaboration agreements: (1) license of FibroGen technology, (2) the performance of co-development services, including manufacturing of clinical supplies and other services during the development period, and (3) manufacture of commercial supply. The evaluation as to whether these promises are distinct, and therefore represent separate performance obligations, is described in more details in Note 2 "Collaboration Agreements."

For revenue recognition purposes, the Company determines that the term of its collaboration agreements begin on the effective date and ends upon the completion of all performance obligations contained in the agreements. In each agreement, the contract term is defined as the period in which parties to the contract have present and enforceable rights and obligations. The Company believes that the existence of what it considers to be substantive termination penalties on the part of the counterparty create sufficient incentive for the counterparty to avoid exercising its right to terminate the agreement unless in exceptionally rare situations.

The transaction price for each collaboration agreement is determined based on the amount of consideration the Company expects to be entitled for satisfying all performance obligations within the agreement. The Company's collaboration agreements include payments to the Company of one or more of the following: non-refundable upfront license fees; co-development billings; development, regulatory, and commercial milestone payments; and royalties on net sales of licensed products.

Upfront license fees are non-contingent and non-refundable in nature and are included in the transaction price at the point when the license fees become due to the Company. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Co-development billings resulting from the Company's research and development efforts, which are reimbursable under its collaboration agreements, are considered variable consideration. Determining the amount of variable consideration from co-development billings requires the Company to make estimates of future research and development efforts, which involves significant judgment. Co-development billings are allocated entirely to the co-development services performance obligation when amounts are related specifically to research and development efforts necessary to satisfy the performance obligation, and such an allocation is consistent with the allocation objective.

Milestone payments are also considered variable consideration, which requires the Company to make estimates of when achievement of a particular milestone becomes probable. Similar to other forms of variable consideration, milestone payments are included in the transaction price when it becomes probable that such inclusion would not result in a significant revenue reversal. Milestone payments are therefore included in the transaction price when achievement of the milestone becomes probable.

For arrangements that include sales-based royalties and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from its collaboration arrangements.

The transaction price is allocated to performance obligations based on their relative standalone selling price ("SSP"), with the exception of co-development billings allocated entirely to co-development services performance obligations. The SSP is determined based on observable prices at which the Company separately sells the products and services. If an SSP is not directly observable, then the Company will estimate the SSP considering marketing conditions, entity-specific factors, and information about the customer or class of customer that is reasonably available. The process for determining SSP involves significant judgment and includes consideration of multiple factors, including assumptions related to the market opportunity and the time needed to commercialize a product candidate pursuant to the relevant license, estimated direct expenses and other costs, which include the rates normally charged by contract research and contract manufacturing organizations for development and manufacturing obligations, and rates that would be charged by qualified outsiders for committee services.

Significant judgment may be required in determining whether a performance obligation is distinct, determining the amount of variable consideration to be included in the transaction price, and estimating the SSP of each performance obligation. An enumeration of the Company's significant judgments is outlined in Note 2 "Collaboration Agreements."

For each performance obligation identified within an arrangement, the Company determines the period over which the promised services are transferred and the performance obligation is satisfied. Service revenue is recognized over time based on progress toward complete satisfaction of the performance obligation. The Company uses an input method to measure progress toward the satisfaction of co-development services and certain other related performance obligations, which is based on costs of labor hours or full time equivalents and out-of-pocket expenses incurred relative to total expected costs to be incurred. The Company believes this measure of progress provides a faithful depiction of the transfer of services because other measures do not measure as accurately how the Company transfers its performance obligations to its collaboration partners.

Investments

The Company's investments consist of available-for-sale debt investments and marketable equity investments. Those investments with maturities less than 12 months are considered short-term investments. Those investments with maturities greater than 12 months are considered long-term investments. The Company's investments classified as available-for-sale are recorded at fair value based upon quoted market prices at period end. Unrealized gains and losses for available-for-sale debt investments that are deemed temporary in nature are recorded in accumulated other comprehensive income (loss) as a separate component of stockholder' equity. Marketable equity securities are equity securities with readily determinable fair value, and are measured and recorded at fair value. Realized and unrealized gains or losses resulting from changes in value and sale of the Company's marketable equity investments are recorded in other income (expenses) in the consolidated statement of operations.

A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the corresponding establishment of a new cost basis for the security. Premiums and discounts are amortized (accreted) over the life of the related security as an adjustment to its yield. Dividend and interest income are recognized when earned. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of investments sold.

Use of Estimates

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

Recently Issued and Adopted Accounting Guidance

New Revenue Standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which supersedes the revenue recognition requirements in Accounting Standards Codification ("ASC") 605, *Revenue Recognition*. ASU 2014-09 is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. Subsequently, the FASB has issued the following standards related to ASU 2014-09: ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations*; ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*; ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*; and ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers* (collectively, the "new revenue standards").

Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company adopted the new revenue standards as of January 1, 2018 using the full retrospective method, which required the Company to recast the prior reporting period presented in the condensed consolidated financial statements. The primary impact upon adoption of the new revenue standards relates to the manner in which revenue is recognized for co-development billings and milestone payments under the Company's collaboration arrangements. Under the new revenue standards, both of these elements of consideration are considered variable consideration which requires the Company to make estimates of when co-development billings become due or when achievement of a particular milestone becomes probable. Payments are included in the transaction price when it becomes probable that inclusion would not lead to a significant revenue reversal.

The Company has recast its condensed consolidated statement of operations and condensed balance sheet from amounts previously reported due to the adoption of the new revenue standards. The adoption of the new revenue standards had no impact to the Company's previously reported condensed consolidated statement of cash flows.

Select line items from the Company's condensed consolidated statement of operations and condensed balance sheet, which reflect the adoption of the new revenue standards are as follows (in thousands):

	Three Months Ended September 30, 2017			Nine Months Ended September 30, 2017		
	As Previously Reported	New Revenue Standards Adjustment	As Recast	As Previously Reported	New Revenue Standards Adjustment	As Recast
Statement of Operations						
License revenue	$ 19,997	$ (10,064)	$ 9,933	$ 60,930	$ (50,997)	$ 9,933
Development and other revenue	7,275	23,342	30,617	22,230	68,097	90,327
Total revenue	27,272	13,278	40,550	83,160	17,100	100,260
Net loss	(37,737)	13,278	(24,459)	(104,081)	17,100	(86,981)
Net loss per share - basic and diluted	$ (0.50)	$ 0.18	$ (0.32)	$ (1.49)	$ 0.25	$ (1.24)

	December 31, 2017		
	As Previously Reported	New Revenue Standards Adjustment	As Recast
Balance Sheet			
Deferred revenue, current	$ 7,968	$ 8,702	$ 16,670
Deferred revenue, net of current	112,231	26,010	138,241
Accumulated deficit	(595,945)	(34,712)	(630,657)

The adoption of the new revenue standards resulted in an increase in revenue of $5.3 million and $3.6 million for the years ended December 31, 2017 and 2016, respectively, and an increase in the opening accumulated deficit of $43.7 million as of January 1, 2016.

ASU 2016-01

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments-Overall (Subtopic 825-10)*. This guidance requires equity investments that are not accounted for under the equity method of accounting to be measured at fair value with changes recognized in net income, simplifies the impairment assessment of certain equity investments, and updates certain presentation and disclosure requirements. This guidance was effective for the annual reporting period beginning after December 15, 2017 and interim periods within those annual periods. The Company adopted this guidance as of January 1, 2018 using the modified retrospective approach. The impacts to the Company's accumulated other comprehensive loss and accumulated deficit upon adoption of this guidance are as follows (in thousands):

	Accumulated Other Comprehensive Loss	Accumulated Deficit
Balance at December 31, 2017	$ (1,795)	$ (630,657) *
Impact of change in accounting principle upon adoption of ASU 2016-01	(1,250)	1,250
Opening balance as of January 1, 2018	$ (3,045)	$ (629,407)

* Recast to reflect the adoption of the new revenue standards. See above.

The adoption of this guidance had no impact to the Company's condensed consolidated statement of operations or condensed consolidated statement of cash flows for the nine months ended September 30, 2018.

ASU 2017-09

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting*. This guidance provides guidance about which changes to the terms or conditions of a stock-based payment award require an entity to apply modification accounting in Topic 718. This guidance was effective for annual reporting period beginning after December 15, 2017, including interim periods. The Company adopted this guidance as of January 1, 2018, and the adoption of this guidance had no impact to the Company's condensed consolidated financial statements.

ASU 2016-16

In October 2016, the FASB issued ASU 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory*. This guidance requires companies to recognize the income tax effects of intercompany sales or transfer of assets, other than inventory, in the income statement as income tax expense (or benefit) in the period the sale or transfer occurs. The exception to recognizing the income tax effects of intercompany sales or transfer sales or transfer of assets remains in place for intercompany inventory sales and transfers. This guidance was effective for annual reporting period beginning after December 15, 2017, including interim periods. The Company adopted this guidance as of January 1, 2018 using the modified retrospective method. The adoption of this guidance did not result in any recognition of previously unrecognized deferred charges using a modified retrospective method, thus had no impact to the Company's condensed consolidated financial statements.

Recently Issued Accounting Guidance Not Yet Adopted

In August 2018, the FASB issued ASU 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.* This guidance requires capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). This guidance should be applied either retrospectively or prospectively, and is effective for annual reporting period beginning after December 15, 2019 including interim periods, with early adoption permitted. The Company is currently evaluating the impact on its consolidated financial statements upon the adoption of this guidance.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement.* This guidance amends existing fair value measurement disclosure requirements by adding, changing, or removing certain disclosures. This guidance is effective for annual reporting period beginning after December 15, 2019 including interim periods, with early adoption permitted. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The Company does not anticipate a material impact to its consolidated financial statements upon adoption of this guidance.

In June 2018, the FASB issued ASU 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.* This guidance expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance also specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. This guidance is effective for annual reporting period beginning after December 15, 2018, including interim periods. The Company will adopt this guidance on January 1, 2019 and does not anticipate a material impact to its consolidated financial statements upon adoption.

In February 2018, the FASB issued ASU 2018-02, *Income Statement - Reporting Comprehensive Income: Reclassification of Certain Tax effects from Accumulated Other Comprehensive Income*. This guidance allows for the reclassification from accumulated other comprehensive income to retained earnings for the stranded tax effects arising from the change in the reduction of the United States ("U.S.") federal statutory income tax rate from 35% to 21%. This guidance is effective for annual reporting period beginning after December 15, 2018, including interim periods, with early adoption permitted. The Company will adopt this guidance on January 1, 2019 and does not anticipate a material reclassification between its accumulated other comprehensive loss and accumulated deficit upon adoption.

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

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). 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. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements* ("ASU 2018-11"), which provides entities the option to initially apply ASU 2016-02 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. ASU 2016-02 and ASU 2018-11 are effective for the annual reporting period beginning after December 15, 2018, including interim periods within that reporting period. The Company will adopt this guidance as of January 1, 2019 and is currently in the stages of gathering data and assessing the impact of the new lease accounting standard. The Company anticipates that the adoption of this guidance will result in additional assets and liabilities being recorded on its consolidated balance sheet.

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, which amounts were fully received as of February 2009. Under the Japan Agreement, the Company is also eligible to receive from Astellas an aggregate of approximately $132.5 million in potential milestone payments, comprised of (i) up to $22.5 million in milestone payments upon achievement of specified clinical and development milestone events, which amounts were fully received as of July 2016, (ii) up to $95.0 million in milestone payments upon achievement of specified regulatory milestone events, and (iii) up to approximately $15.0 million in milestone payments upon the achievement of specified commercial sales milestone.

During the second quarter of 2018, Astellas reported positive results from the final phase 3 CKD-dialysis trial of roxadustat in Japan, indicating that Astellas is ready to make an NDA submission for the treatment of anemia with roxadustat in CKD-dialysis patients in 2018. The Company evaluated the regulatory milestone payment associated with NDA submission in Japan based on variable consideration requirements under the current revenue standards and concluded that this milestone became probable of being achieved in the second quarter of 2018. Accordingly, the consideration of $15.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the Japan Agreement in the second quarter of 2018, of which $14.9 million was recognized as revenue during the second quarter of 2018 from performance obligations satisfied or partially satisfied.

FibroGen and Astellas are currently negotiating an amendment to the Japan Agreement that will allow Astellas to manufacture roxadustat drug product for commercialization in Japan, and for which FibroGen would continue to manufacture and deliver to Astellas roxadustat active pharmaceutical ingredient ("API"). The commercial terms of the Japan Agreement would remain substantially the same. In the second quarter of 2018, FibroGen delivered roxadustat API to Astellas under a material transfer agreement for Astellas to conduct commercial scale manufacturing validation for roxadustat drug product in anticipation of commercial launch in Japan. The associated consideration of $20.9 million was recorded as deferred revenue because Astellas' right to use the material was limited as of September 30, 2018.

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). Under the Europe Agreement, the Company is also eligible to receive from Astellas an aggregate of approximately $425.0 million in potential milestone payments, comprised of (i) up to $90.0 million in milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $335.0 million in milestone payments upon achievement of specified regulatory milestone events. Clinical milestone payments of $40.0 million and $50.0 million were received in 2010 and 2012, respectively. Under the Europe Agreement, Astellas committed to fund 50% of joint development costs for Europe and North America, and all territory-specific costs. The Europe Agreement also provides for tiered payments based on net sales of product (as defined) in the low 20% range.

AstraZeneca Agreements

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

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

Under the U.S./RoW Agreement, the Company and AstraZeneca shared equally in the development costs of roxadustat not already paid for by Astellas, up to a total of $233.0 million (i.e. the Company's share of development costs is $116.5 million, which was reached during the fourth quarter of 2015). Development costs incurred by FibroGen during the development period in excess of the $233.0 million (aggregated spend) are 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 paid upfront, non-contingent and non-refundable payments totaling $28.2 million, which were fully received in 2014. Under the China Agreement, the Company is also eligible to receive from AstraZeneca an aggregate of approximately $348.5 million in potential milestone payments, comprised of (i) up to $15.0 million in milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $146.0 million in milestone payments upon achievement of specified regulatory milestone events, and (iii) up to approximately $187.5 million in milestone payments upon the achievement of specified commercial sales and other events. The China Agreement is structured as a 50/50 profit or loss share (as defined) and provides for joint development costs (including capital and equipment costs for construction of the manufacturing plant in China), to be shared equally during the development.

In October 2017, the State Drug Administration in China, now known as the National Medicine Products Administration, accepted the Company's submitted New Drug Application ("NDA") for registration of roxadustat for anemia in dialysis-dependent CKD and non-dialysis-dependent CKD ("NDD-CKD") patients. This NDA submission triggered a $15.0 million milestone payment to the Company by AstraZeneca. The Company evaluated this milestone based on variable consideration requirements under the new revenue standards and concluded that the milestone was probable of being achieved in the third quarter of 2017. Accordingly, consideration associated with this milestone was included in the transaction price and allocated to performance obligations under the China Agreement in the same period.

Accounting for the Astellas Agreements

For each of the Astellas agreements, the Company has evaluated the promised services within the respective arrangements and has identified performance obligations representing those services and bundles of services that are distinct.

Promised services that were not distinct have been combined with other promised services to form a distinct bundle of promised services, with revenue being recognized on the bundle of services rather than the individual services. There are no right-of-return provisions for the delivered items in the Astellas agreements.

As of September 30, 2018, the transaction price for the Japan Agreement included $40.1 million of non-contingent upfront payments, $37.5 million of variable consideration related to payments for milestones considered probable of being achieved, and $12.6 million of variable consideration related to co-development billings. The transaction price for the Europe Agreement included $320.0 million of non-contingent upfront payments, $90.0 million of variable consideration related to payments for milestones considered probable of being achieved, and $183.0 million of variable consideration related to co-development billings.

For revenue recognition purposes, the Company determined that the term of each collaboration agreement with Astellas begins on the effective date and ends upon the completion of all performance obligations contained in the agreement. The contract term is defined as the period in which parties to the contract have present and enforceable rights and obligations. The Company believes that the requirement to continue funding development for a substantive period of time and loss of product rights, along with non-refundable upfront payments already remitted by Astellas, create significant disincentive for Astellas to exercise its right to terminate the agreements.

For the Astellas agreements, the Company allocated the transaction price to the various performance obligations based on the relative SSP of each performance obligation, with the exception of co-development billings allocated entirely to co-development services performance obligations.

For the technology license under the Japan Agreement and Europe Agreement, SSP was determined primarily by using the discounted cash flow ("DCF") method, which aggregates the present value of future cash flows to determine the valuation as of the effective date of each of the agreements. The DCF method involves the following key steps: 1) the determination of cash flow forecasts and 2) the selection of a range of comparative risk-adjusted discount rates to apply against the cash flow forecasts. The discount rates selected were based on expectations of the total rate of return, the rate at which capital would be attracted to the Company and the level of risk inherent within the Company. The discounts applied in the DCF analysis ranged from 17.5% to 20.0%. The Company's cash flow forecasts were derived from probability-adjusted revenue and expense projections by territory. Such projections included consideration of taxes and cash flow adjustments. The probability adjustments were made after considering the likelihood of technical success at various stages of clinical trials and regulatory approval phases. SSP also considered certain future royalty payments associated with commercial performance of the Company's compounds, transfer prices and expected gross margins.

The promised services that were analyzed, along with their general timing of satisfaction and recognition as revenue, are as follows:

(1) *License to the Company's technology existing at the effective date of the agreements.* For both of the Astellas agreements, the license was delivered at the beginning of the agreement term. In both cases, the Company concluded at the time of the agreement that its collaboration partner, Astellas, would have the knowledge and capabilities to fully exploit the licenses without the Company's further involvement. However, the Japan Agreement has contractual limitations that might affect Astellas' ability to fully exploit the license and therefore, potentially, the conclusion as to whether the license is capable of being distinct. In the Japan Agreement, Astellas does not have the right to manufacture commercial supplies of the drug. In order to determine whether this characteristic of the agreement should lead to a conclusion that the license was not distinct in the context of the agreement, the Company considered the ability of Astellas to benefit from the license together with other resources readily available to Astellas. Finally, the Company considered the fact that at the time of delivery of the license, the development services were beyond the preclinical development phase and any remaining development work in either agreement would not be expected to result in any significant modification or customization to the licensed technology. As such, the development services are separately identifiable from the licensed technology, indicating that the license is a distinct performance obligation.

Manufacturing rights. In the case of the Japan Agreement, the Company retained manufacturing rights largely because of the way the parties chose for FibroGen to be compensated under the agreement. At the time the agreement was signed, the Company believed that it was more advantageous upon commercialization to have a transfer price revenue model in place as opposed to a traditional sales-based model. The manufacturing process does not require specialized knowledge or expertise uniquely held by FibroGen, and notwithstanding contractual restrictions, Astellas could employ manufacturing services from readily available third parties in order to benefit from the license. Therefore, along with the foregoing paragraph, the Company determined that the license in Japan is a distinct performance obligation despite the retention of manufacturing rights by the Company.

In summary, the Company concludes that item (1) represents a performance obligation. The portion of the transaction price allocated to this performance obligation based on a relative SSP basis is recognized as revenue in its entirety at the point in time the license transfers to Astellas.

(2) *Co-development services (Europe Agreement).* This promise relates to co-development services that were reasonably expected to be performed by the Company at the time the collaboration agreement was signed and is considered distinct. Co-development billings are allocated entirely to the co-development services performance obligation as amounts are related specifically to research and development efforts necessary to satisfy the performance obligation, and such an allocation is consistent with the allocation objective. Revenue is recognized over time based on progress toward complete satisfaction of the performance obligation. The Company uses an input method to measure progress toward the satisfaction of the performance obligation, which is based on costs of labor hours and out-of-pocket expenses incurred relative to total expected costs to be incurred. The measure of progress is updated each reporting period. Co-development services are expected to continue over the development period which is currently estimated to continue through the end of 2019. There was no provision for co-development services in the Japan Agreement.

(3) *License to the Company's technology developed during the term of the agreement and development (referred to as "when and if available") and information sharing services.* These promises are generally satisfied throughout the term of the agreements.

(4) *Manufacturing of clinical supplies of products.* This promise is satisfied as supplies for clinical product are delivered for use in the Company's clinical trial programs during the development period, or pre-commercialization period.

(5) *Committee service*. This promise is satisfied throughout the course of the agreements as meetings are attended.

Items (3)-(5) are bundled into a single performance obligation which is distinct given the fact that all are highly interrelated during the development period (pre-commercial phase of development) such that satisfying them independently is not practicable. Revenue is recognized over time based on progress toward complete satisfaction of the performance obligation. The Company uses an input method to measure progress toward the satisfaction of the performance obligation, which is based on costs of labor hours or full time equivalents and out-of-pocket expenses incurred relative to total expected costs to be incurred. The measure of progress is updated each reporting period.

(6) *Manufacturing commercial supplies of products.* This promised service is distinct as services are not interrelated with any of the other performance obligations. Payments received for commercial supplies of products represent sales-based payments related predominately to the license of intellectual property under both Astellas agreements. Revenue is recognized as supplies are shipped for commercial use during the commercialization period. To date, no such revenue has been recognized.

Accounting for the AstraZeneca Agreements

The Company evaluated whether the U.S./RoW Agreement and China Agreement should be accounted for as a single or separate arrangements and concluded that the agreements should be accounted for as a single arrangement with the presumption that two or more agreements executed with a single customer at or around the same time should be presumed to be a single arrangement. The key points the Company considered in reaching this conclusion are as follows:

1. While the two agreements were largely negotiated separately, those negotiations proceeded concurrently, and were intended to be completed contemporaneously, presuming AstraZeneca decided to proceed with licenses in all regions available.

2. Throughout negotiations for both agreements, the Company and the counterparties understood and considered the possibility that one arrangement may be executed without the execution of the other arrangement. However, the preference for the Company and the counterparties during the negotiations was to execute both arrangements concurrently.

3. The two agreements were executed as separate agreements because different development, regulatory and commercial approaches required certain terms of the agreements to be structured differently, rather than because the Company or the counterparties considered the agreements to be fundamentally separate negotiations.

Accordingly, as the agreements are being accounted for as a single arrangement, upfront and other non-contingent consideration received and to be received has been and will be pooled together and allocated to each of the performance obligations in both the U.S./RoW Agreement and China Agreement based on their relative SSPs.

For each of the AstraZeneca agreements, the Company has evaluated the promised services within the respective arrangements and has identified performance obligations representing those services and bundled services that are distinct.

Promised services that were not distinct have been combined with other promised services to form a distinct bundle of promised services, with revenue being recognized on the bundle of services rather than the individual promised services. There are no right-of-return provisions for the delivered items in the AstraZeneca agreements.

As of September 30, 2018, the transaction price for the U.S./RoW Agreement and China Agreement included $402.2 million of non-contingent upfront payments, $30.0 million of variable consideration related to payments for milestones considered probable of being achieved, and $669.7 million of variable consideration related to co-development billings.

For the AstraZeneca agreements, the Company allocated the transaction price to the various performance obligations based on the relative SSP of each performance obligation, with the exception of co-development billings. Co-development billings under the U.S./RoW Agreement were allocated entirely to the U.S./RoW co-development services performance obligation, and co-development billings under the China Agreement were allocated entirely to the combined performance obligation under the China Agreement.

For revenue recognition purposes, the Company determined that the term of its collaboration agreements with AstraZeneca begin on the effective date and ends upon the completion of all performance obligations contained in the agreements. The contract term is defined as the period in which parties to the contract have present and enforceable rights and obligations. The Company believes that the requirement to continue funding development for a substantive period of time and the loss of product rights, along with non-refundable upfront payments already remitted by AstraZeneca, represent substantive termination penalties that create significant disincentive for AstraZeneca to exercise its right to terminate the agreement.

For the technology license under the AstraZeneca U.S./RoW Agreement, SSP was determined based on a two-step process. The first step involved determining an implied royalty rate that would result in the net present value of future cash flows to equal to zero (i.e. where the implied royalty rate on the transaction would equal the target return for the investment). This results in an upper bound estimation of the magnitude of royalties that a hypothetical acquirer would reasonably pay for the forecasted cash flow stream. The Company's cash flow forecasts were derived from probability-adjusted revenue and expense projections. Such projections included consideration of taxes and cash flow adjustments. The probability adjustments were made after considering the likelihood of technical success at various stages of clinical trials and regulatory approval phases. The second step involved applying the implied royalty rate, which was determined to be 40%, against the probability-adjusted projected net revenues by territory and determining the value of the license as the net present value of future cash flows after adjusting for taxes. The discount rate utilized was 17.5%.

U.S./RoW Agreement:

The promised services that were analyzed, along with their general timing of satisfaction and recognition as revenue, are as follows:

(1) *License to the Company's technology existing at the effective date of the agreements.* For the U.S./RoW Agreement, the license was delivered at the beginning of the agreement term. The Company concluded that AstraZeneca has the knowledge and capabilities to fully exploit the license under the U.S./RoW Agreement without the Company's further involvement. Finally, the Company considered the fact that at the time of delivery of the license, the development services were beyond the preclinical development phase and any remaining development work would not be expected to result in any significant modification or customization to the licensed technology. As such, the development services are separately identifiable from the licensed technology, indicating that the license is a distinct performance obligation. Therefore, the Company has concluded that the license is distinct and represents a performance obligation. The portion of the transaction price allocated to this performance obligation based on a relative SSP basis is recognized as revenue in its entirety at the point in time the license transfers to AstraZeneca.

(2) *Co-development services.* This promise relates to co-development services that were reasonably expected to be performed by the Company at the time the collaboration agreement was signed and is distinct. Co-development billings are allocated entirely to the co-development services performance obligation as amounts are related specifically to research and development efforts necessary to satisfy the performance obligation, and such an allocation is consistent with the allocation objective. Revenue is recognized over time based on progress toward complete satisfaction of the performance obligation. The Company uses an input method to measure progress toward the satisfaction of the performance obligation, which is based on costs of labor hours or full time equivalents and out-of-pocket expenses incurred relative to total expected costs to be incurred Co-development services are expected to continue over the development period which is estimated to continue through the end of 2020.

(3) *Manufacturing of clinical supplies of products.* This promise is satisfied as supplies for clinical product are delivered for use in the Company's clinical trial programs during the development period, or pre-commercialization period.

(4) *Information sharing and committee service.* These promises are satisfied throughout the course of the agreement as services are provided.

Items (3)-(4) are bundled into a single performance obligation which is distinct given the fact that all are highly interrelated during the development period (pre-commercial phase of development) such that delivering them independently is not practicable. Revenue is recognized over time based on progress toward complete satisfaction of the performance obligation. The Company uses an input method to measure progress toward the satisfaction of the performance obligation, which is based on costs of labor hours or full time equivalents and out-of-pocket expenses incurred relative to total expected costs to be incurred. The measure of progress is updated each reporting period.

(5) *Manufacturing commercial supplies of products.* This promise is distinct as services are not interrelated with any of the other performance obligations. Payments received for commercial supplies of products represent sales-based royalties related predominately to the license of intellectual property under the agreement. Revenue is recognized as supplies are shipped for commercial use during the commercialization period. To date, no such revenue has been recognized.

China Agreement:

The performance obligation that were analyzed, along with their general timing of satisfaction and recognition as revenue, are as follows:

- *License to the Company's technology existing at the effective date of the agreement.* The license was delivered at the beginning of the agreement term. However, the China Agreement with AstraZeneca has contractual limitations that might affect AstraZeneca's ability to fully exploit the license and therefore, potentially, the conclusion as to whether the license is distinct in the context of the agreement. In the China Agreement, AstraZeneca does not have the right to manufacture commercial supplies of the drug. In order to determine whether this characteristic of the arrangement should lead to a conclusion that the license was not distinct in the context of the agreement, the Company considered the ability of AstraZeneca to benefit from the license on its own or together with other resources readily available to AstraZeneca.

For the China Agreement, the Company retained manufacturing rights as an essential part of a strategy to pursue domestic regulatory pathway for product approval which requires the regulatory licensure of the manufacturing facility in order to commence commercial shipment. The prospects for the collaboration as a whole would have been substantially different had manufacturing rights been provided to AstraZeneca. Due to certain regulatory restrictions in China, manufacturing services of commercial drug product in China are not readily available to AstraZeneca or any other parties. Therefore, AstraZeneca cannot benefit from the license on its own or together with other readily available resources. Accordingly, all the promises identified, including co-development services, under the China Agreement have been bundled into a single performance obligation and amounts of the transaction price allocable to this performance obligation are deferred until control of the manufactured commercial drug product has begun to transfer to AstraZeneca. Upon commencement of the transfer of control to commercial drug product, revenue would be recognized in a pattern consistent with estimated deliveries of the commercial drug product.

Summary of Revenue Recognized Under the Collaboration Agreements

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

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

		Three Months Ended September 30,		Nine Months Ended September 30,	
Agreement	Performance Obligation	2018	2017 *	2018	2017 *
Japan	License revenue	$ —	$ —	$ 14,323	$ —
	Development revenue	$ 474	$ 517	$ 2,065	$ 1,130

* Recast to reflect the adoption of the new revenue standards. See Note 1.

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

Japan Agreement	Cumulative Revenue Through September 30, 2018	Deferred Revenue at September 30, 2018	Total Consideration Through September 30, 2018
License	$ 74,089	$ —	$ 74,089
Development revenue	13,572	386	13,958
Total license and development revenue	$ 87,661	$ 386	$ 88,047

The true-up relating to prior periods resulting from changes to estimated variable consideration was immaterial in the quarter ended September 30, 2018. The remainder of the transaction price related to the Japan Agreement includes $2.1 million of variable consideration from estimated future co-development billing and is expected to be recognized over the remaining development service period.

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

		Three Months Ended September 30,		Nine Months Ended September 30,	
Agreement	Performance Obligation	2018	2017 *	2018	2017 *
Europe	License revenue	$ —	$ —	$ —	$ —
	Development revenue	$ 4,658	$ 4,805	$ 14,384	$ 13,976

* Recast to reflect the adoption of the new revenue standards. See Note 1.

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

Europe Agreement	Cumulative Revenue Through September 30, 2018	Deferred Revenue at September 30, 2018	Total Consideration Through September 30, 2018
License	$ 370,481	$ —	$ 370,481
Development revenue	198,717	4,350	203,067
Total license and development revenue	$ 569,198	$ 4,350	$ 573,548

The revenue recognized under the Europe Agreement in the quarter ended September 30, 2018 included a decrease in revenue of $0.1 million as true-up relating to prior periods resulting from changes to estimated variable consideration in the current period. The remainder of the transaction price related to the Europe Agreement includes $19.4 million of variable consideration from estimated future co-development billing and is expected to be recognized over the remaining development service period.

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

		Three Months Ended September 30,		Nine Months Ended September 30,	
Agreement	**Performance Obligation**	**2018**	**2017 ***	**2018**	**2017 ***
U.S. / RoW and China	License revenue	$ —	$ 9,933	$ —	$ 9,933
	Development revenue	23,895	25,295	74,096	75,218
	China performance obligation	$ —	$ —	$ —	$ —

* Recast to reflect the adoption of the new revenue standards. See Note 1.

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

U.S. / RoW and China Agreements	**Cumulative Revenue Through September 30, 2018**	**Deferred Revenue at September 30, 2018**	**Total Consideration Through September 30, 2018**
License	$ 286,216	$ —	$ 286,216
Co-development, information sharing & committee services	377,765	29,163	406,928
China performance obligation	—	119,744	119,744
Total license and development revenue	$ 663,981	$ 148,907	$ 812,888

The revenue recognized under the U.S./RoW Agreement in the quarter ended September 30, 2018 included a decrease in revenue of $0.1 million as true-up relating to prior periods resulting from changes to estimated variable consideration in the current period. The remainder of the transaction price related to the U.S./RoW Agreement and China Agreement includes $223.7 million of variable consideration from estimated future co-development billing and is expected to be recognized over the remaining development service period, except for amounts allocated to the China performance obligation, which are expected to be recognized in a pattern consistent with estimated deliveries of the commercial drug product.

Other Revenues

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

Deferred Revenue

Deferred revenue represents amounts billed to the Company's collaboration partners for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met. The current portion of deferred revenue represents the amount to be recognized within one year from the balance sheet date based on the estimated performance period of the underlying performance obligations. The long term portion of deferred revenue represents amounts to be recognized after one year through the end of the non-contingent performance period of the underlying performance obligations. The long term portion of deferred revenue also includes amounts allocated to the China unit of accounting under the AstraZeneca arrangement as revenue recognition associated with this unit of accounting is tied to the commercial launch of the products within China, which is not expected to occur within the next year.

3. Fair Value Measurements

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

	September 30, 2018			
	Level 1	Level 2	Level 3	Total
Corporate bonds	$ —	$ 6,009	$ —	$ 6,009
Bond and mutual funds	10,446	—	—	10,446
Equity investments	223	—	—	223
Money market funds	495,131	—	—	495,131
Certificate of deposits	—	109,933	—	109,933
Total	$ 505,800	$ 115,942	$ —	$ 621,742

	December 31, 2017			
	Level 1	Level 2	Level 3	Total
Corporate bonds	$ —	$ 53,943	$ —	$ 53,943
Bond and mutual funds	18,402	—	—	18,402
Equity investments	221	—	—	221
Money market funds	569,942	—	—	569,942
Total	$ 588,565	$ 53,943	$ —	$ 642,508

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

	September 30, 2018			
	Level 1	Level 2	Level 3	Total
Lease financing obligations	$ —	$ —	$ 98,209	$ 98,209

	December 31, 2017			
	Level 1	Level 2	Level 3	Total
Lease financing obligations	$ —	$ —	$ 98,476	$ 98,476

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

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

4. Balance Sheet Components

Cash and Cash Equivalents

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

	September 30, 2018	December 31, 2017
Cash	$ 71,591	$ 103,716
Money market funds	495,131	569,942
Total cash and cash equivalents	$ 566,722	$ 673,658

At September 30, 2018 and December 31, 2017, a total of $25.5 million and $32.3 million, respectively, of the Company's cash and cash equivalents were held outside of the U.S. in its foreign subsidiaries to be used primarily for its China operations.

Investments

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

	September 30, 2018			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Corporate bonds	$ 6,011	$ —	$ (2)	$ 6,009
Certificate of deposits	110,000	—	(67)	109,933
Bond and mutual funds	10,399	47	—	10,446
Equity investments	125	98	—	223
Total investments	$ 126,535	$ 145	$ (69)	$ 126,611

	December 31, 2017			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Corporate bonds	$ 53,985	$ 4	$ (46)	$ 53,943
Bond and mutual funds	17,249	1,153	—	18,402
Equity investments	126	95	—	221
Total investments	$ 71,360	$ 1,252	$ (46)	$ 72,566

At September 30, 2018, all of the available-for-sale investments had contractual maturities within one year. 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 its intent to sell. For debt securities, the Company also considers whether (i) it is more likely than not that the Company will be required to sell the debt securities before recovery of their amortized cost basis, and (ii) the amortized cost basis cannot be recovered as a result of credit losses. During the three and nine months ended September 30, 2018 and 2017, the Company did not recognize any other-than-temporary impairment loss.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Preclinical and clinical trial accruals	$ 22,606	$ 32,321
Payroll and related accruals	16,626	18,810
Property taxes and other	1,900	4,201
Professional services	1,835	1,991
Other	9,631	6,458
Total accrued liabilities	$ 52,598	$ 63,781

5. Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$ 8,465	$ 5,538	$ 22,729	$ 16,060
General and administrative	5,858	4,090	15,703	11,548
Total stock-based compensation expense	$ 14,323	$ 9,628	$ 38,432	$ 27,608

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Stock Options				
Expected term (in years)	5.3	5.3	5.4	5.7
Expected volatility	68.1 %	69.5 %	67.8 %	71.5 %
Risk-free interest rate	2.9 %	1.9 %	2.7 %	2.2 %
Expected dividend yield	—	—	—	—
Weighted average estimated fair value	$ 35.99	$ 26.47	$ 32.37	$ 16.63
ESPPs				
Expected term (in years)	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0
Expected volatility	47.3 - 72.8 %	52.8 - 76.0 %	47.3 - 75.3 %	52.8 - 77.2 %
Risk-free interest rate	1.0 - 2.6 %	0.6 - 1.3 %	0.8 - 2.6 %	0.5 - 1.3 %
Expected dividend yield	—	—	—	—
Weighted average estimated fair value	$ 20.10	$ 9.67	$ 15.27	$ 9.15

6. Income Taxes

The provisions for income taxes for the three and nine months ended September 30, 2018 and 2017 were due to foreign taxes.

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

7. Related Party Transactions

Astellas is an equity investor in the Company and considered a related party. The Company recorded revenue related to collaboration agreements with Astellas of $5.1 million and $5.3 million during the three months ended September 30, 2018 and 2017, respectively, and $30.8 million and $15.1 million during the nine months ended September 30, 2018 and 2017, respectively. The related party revenue for the nine months ended September 30, 2018 included $14.9 million of a $15.0 million regulatory milestone under the Japan Agreement that was included in the transaction price during the second quarter of 2018. See Note 2 and below for details. The related party revenue was recast for the three and nine months ended September 30, 2017 as a result of adoption of the new revenue standards. See Note 1 for details.

The Company recorded expense related to collaboration agreements with Astellas of $0.4 million and $0.2 million during the three months ended September 30, 2018 and 2017, respectively, and $1.1 million and $0.8 million during the nine months ended September 30, 2018 and 2017, respectively.

As of September 30, 2018 and December 31, 2017, accounts receivable from Astellas were $19.4 million and $4.0 million, respectively, and amounts due to Astellas were $0.4 million and $0.3 million, respectively. The accounts receivable from Astellas as of June 30, 2018 included $20.9 million related to a sale of roxadustat API to Astellas during the second quarter of 2018, which was received during the three months ended September 30, 2018. The sale was made pursuant to a material transfer agreement in anticipation of the execution of an amendment to the Japan Agreement allowing Astellas to manufacture roxadustat drug product, which is expected to be finalized in the fourth quarter of 2018. The sale enables Astellas to conduct the commercial scale manufacturing validation for roxadustat drug product in anticipation of commercial launch in Japan. The associated consideration was recorded as deferred revenue because Astellas' right to use the material was limited as of September 30, 2018.

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, 2017 filed with the SEC on February 27, 2018.

FORWARD-LOOKING STATEMENTS

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

BUSINESS OVERVIEW

We were incorporated in 1993 in Delaware and are a biopharmaceutical company discovering and developing first-in-class therapeutics. Roxadustat (FG-4592), our most advanced product candidate, is an oral small molecule inhibitor of hypoxia inducible factor ("HIF") prolyl hydroxylase ("HIF-PH") activity in Phase 3 clinical development for the treatment of anemia in chronic kidney disease ("CKD") and myelodysplastic syndromes ("MDS"). Pamrevlumab (FG-3019), a human monoclonal antibody that inhibits the activity of connective tissue growth factor ("CTGF") is in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer, and Duchenne muscular dystrophy ("DMD"). We are taking a global approach to the development and future commercialization of our product candidates, and this includes development and commercialization in the People's Republic of China ("China"). We are capitalizing on our extensive experience in fibrosis and HIF biology and clinical development to advance a pipeline of innovative medicines for the treatment of anemia, fibrotic disease cancer, corneal blindness and other serious unmet medical needs.

Financial Highlights

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017 *	2018	2017 *
	(in thousands, except for per share data)			
Result of Operations				
Revenue	$ 29,027	$ 40,550	$ 104,903	$ 100,260
Operating expenses	$ 71,799	$ 63,289	$ 211,516	$ 181,957
Net loss	$ (42,556)	$ (24,459)	$ (107,373)	$ (86,981)
Net loss per share - basic and diluted	$ (0.50)	$ (0.32)	$ (1.28)	$ (1.24)

	September 30, 2018	December 31, 2017
	(in thousands)	
Balance Sheet		
Cash and cash equivalents	$ 566,722	$ 673,658
Short-term and long-term investments	$ 126,611	$ 72,566
Accounts receivable	$ 23,187	$ 8,452

* Recast to reflect the adoption of the new revenue standards. See Note 1 to the condensed consolidated financial statements.

Our revenue for the three months ended September 30, 2018 decreased compared to the same period a year ago primarily due to the revenue related to a $15.0 million regulatory milestone recognized in prior year period. In October 2017, then the China Food and Drug Administration (now known as the National Medicine Products Administration ("NMPA")) accepted our New Drug Application ("NDA") for registration of roxadustat for anemia in DD CKD and NDD-CKD patients. This NDA submission triggered a $15.0 million milestone payment to FibroGen by AstraZeneca, which became probable of being achieved and therefore partially recognized as revenue under the new revenue standards during the third quarter of 2017.

Our revenue for the nine months ended September 30, 2018 increased compared to the same period a year ago primarily related to the recognition of $14.9 million of a $15.0 million regulatory milestone associated with NDA submission in Japan under the collaboration agreement with Astellas for roxadustat for the treatment of anemia in Japan ("Japan Agreement") that was included in the transaction price during the second quarter of 2018 when this milestone became probable of being achieved, as compared to the above mentioned partial recognition of a $15.0 million regulatory milestone in the prior year period.

Operating expenses for the three and nine months ended September 30, 2018 increased compared to the same periods a year ago primarily due to higher stock-based compensation due to the cumulative impact of stock option grant activities, higher drug development expenses associated with drug substance manufacturing activities related to pamrevlumab, and higher employee-related expenses resulting from higher average compensation level and higher headcount, partially offset by lower clinical trial activities related to roxadustat and pamrevlumab. Operating expenses for nine months ended September 30, 2018 were also impacted by higher facility related expenses relative to the prior period in which our property taxes were reduced as a result of a final settlement we obtained related to historical property tax payments.

During the three months ended September 30, 2018, we had a net loss of $42.6 million, or net loss per basic and diluted share of $0.50, as compared to a net loss of $24.5 million for the same period a year ago, due to an decrease in revenue and an increase in operating expenses. During the nine months ended September 30, 2018, we had a net loss of $107.4 million, or net loss per basic and diluted share of $1.28, as compared to a net loss of $87.0 million for the same period a year ago, due to an increase in operating expenses, partially offset by an increase in revenue.

Cash and cash equivalents, investments and accounts receivable totaled $716.5 million at September 30, 2018, a decrease of $38.2 million from December 31, 2017, primarily due to the cash used in operations.

Programs

Roxadustat for the Treatment of Anemia in Chronic Kidney Disease

Roxadustat, the most advanced HIF-PH inhibitor in clinical development, acts by stimulating the body's natural pathway of erythropoiesis, or red blood cell production. We, along with our collaboration partners, Astellas Pharma Inc. ("Astellas") and AstraZeneca AB ("AstraZeneca"), are nearing completion of a global Phase 3 program to support regulatory approvals of roxadustat in the United States ("U.S."), Europe, Japan, and China for anemia in both dialysis-dependent CKD ("DD-CKD") patients and non-dialysis-dependent CKD ("NDD-CKD") patients. These Phase 3 programs are studying multiple patient populations, including incident dialysis patients and stable dialysis patients in which roxadustat is compared to epoetin alfa, as well as non-dialysis patients in which roxadustat is compared to placebo.

For our U.S. and European CKD anemia programs, we have completed treatment of all Phase 3 patients (other than for a European reimbursement study), and expect to report topline individual study results in the fourth quarter of 2018, subject to adequate progress in our MACE adjudication procedures, and report pooled safety data prior to the submission of the NDA for roxadustat in the first half of 2019. In the third quarter of 2018, Astellas announced positive topline results for its ALPS study, a global Phase 3 trial of roxadustat in CKD anemia patients not on dialysis. Astellas has also completed its Phase 3 study in DD-CKD comparing roxadustat to darbepoetin or epoetin alfa.

In China, the NMPA continues to review our NDA submission for the registration of roxadustat to treat anemia for DD-CKD patients and NDD-CKD patients. While there is no fixed regulatory timeline for an NDA approval decision, we currently anticipate a market approval decision for our NDA in China by year-end for anemia in DD-CKD patients. We expect a decision regarding whether anemia in NDD-CKD will be added to the label in the first half of 2019 after the clinical site inspections have been completed for NDD-CKD.

In Japan, Astellas has reported positive results from four of its six Phase 3 anemia studies and has filed an NDA for roxadustat in anemia associated with DD-CKD. This NDA triggered a $15 million milestone payment from Astellas. Astellas has also completed one of its two Phase 3 NDD-CKD studies in Japan.

Astellas presented results from two of its four DD-CKD studies at ASN Kidney Week 2018. In the 303 patient double-blind Phase 3 hemodialysis study, treatment with oral roxadustat was as effective as darbepoetin alfa in maintaining hemoglobin levels within the target range of 10.0–12.0 g/dL in hemodialysis patients previously treated with erythropoiesis-stimulating agents ("ESAs"). The average hemoglobin levels at Weeks 18–24 was 11.00 (± 0.60) g/dL and 10.95 (± 0.63) g/dL in the roxadustat and darbepoetin alfa groups, respectively; the difference between the groups was 0.05 (95% CI: -0.10, ± 0.20) g/dL. The maintenance rate of target hemoglobin levels (10.0–12.0 g/dL) during Weeks 18–24 was 79.3% and 83.4% in the roxadustat and darbepoetin alfa groups, respectively; the difference between the 2 groups was -4.1% (95% CI: -13.6, ± 5.3). Among patients with at least one hemoglobin value during Weeks 18–24, the maintenance rate was 95.2% and 91.3% in the roxadustat and darbepoetin alfa groups, respectively; the difference between the 2 groups was 3.9% (95% CI: -2.9, ± 10.7). Roxadustat was well tolerated with a safety profile similar to that of darbepoetin alfa and consistent with previous reports. The proportions of patients who reported TEAEs were similar in the roxadustat and darbepoetin alfa groups. There was no increased risk of ophthalmological abnormalities, including retinal hemorrhages, observed in patients treated with roxadustat compared to darbepoetin alfa.

In Astellas's 56 patient open-label Phase 3 peritoneal dialysis ("PD") study in Japan, roxadustat was effective in achieving and maintaining hemoglobin levels within the target range of 10.0-12.0 g/dL at Weeks 18-24. This open-label trial treated two groups of patients with roxadustat: patients not previously treated with ESAs ("ESA-Naïve") and patients previously treated with ESAs ("ESA-Conversion"). The hemoglobin maintenance rate was 92.3% (95% CI: 64.0-99.8) for ESA-Naïve patients and 74.4% (95% CI: 58.8-86.5) for ESA-Conversion patients. Maintenance rates of patients with at least one hemoglobin value at Weeks 18-24 were 92.3% (95% CI: 64.0-99.8; ESA-Naïve) and 86.5% (95% CI: 71.2-95.5; ESA-Conversion). The mean of average hemoglobin levels at Weeks 18-24 was 11.05 g/dL (± 0.62) for ESA-Naïve patients and 10.93 g/dL (± 0.61) for ESA-Conversion patients. The mean change in average hemoglobin at Weeks 18-24 from baseline was 1.69 g/dL (± 1.05) for ESA-Naïve patients; and 0.14 g/dL (± 0.76) for ESA-Conversion patients. All iron parameters remained clinically stable despite robust erythropoiesis and without the need for IV iron supplementation, and hepcidin decreased in a manner consistent with previous Phase 2 and Phase 3 studies of roxadustat. Roxadustat was well tolerated with no safety concerns.

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

Pamrevlumab is our human monoclonal antibody that inhibits the activity of CTGF, a central mediator and critical common element in the progression of fibrotic and fibro-proliferative diseases. We are currently conducting Phase 2 trials in pancreatic cancer and DMD and we have completed our Phase 2 trial in IPF. In the U.S., pamrevlumab has received orphan drug designation for IPF and Fast Track designation for the treatment of both IPF patients and patients with locally advanced unresectable pancreatic cancer from the U.S. Food and Drug Administration ("FDA").

We plan to begin enrolling a double-blind placebo controlled Phase 3 trial of pamrevlumab as a neoadjuvant therapy for pancreatic cancer in the first quarter of 2019. We intend to enroll approximately 260 patients, randomized 1:1 to receive either pamrevlumab, in combination with gemcitabine and nab-paclitaxel, or chemotherapy with placebo.

We also plan to begin enrolling our double-blind, placebo-controlled Phase 3 trial of pamrevlumab in approximately 500 IPF patients in the first quarter of 2019. This study is powered to meet the FDA requirement of a highly statistically-significant result in the primary efficacy endpoint of change from baseline in forced vital capacity (FVC).

In DMD, all 21 non-ambulatory patients from our fully enrolled Phase 2 trial will have completed one year of study in March 2019.

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 the Japan Agreement with Astellas for roxadustat for the treatment of anemia in Japan. In April 2006, we entered into the Europe Agreement with Astellas for roxadustat for the treatment of anemia in Europe, the Commonwealth of Independent States, the Middle East, and South Africa. Under these agreements, we provide Astellas the right to develop and commercialize roxadustat for anemia indications in these territories.

We share responsibility with Astellas for clinical development activities required for the United States ("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 September 30, 2018 totals $472.6 million. During the second quarter of 2018, Astellas reported positive results from the final Phase 3 CKD-dialysis trial of roxadustat in Japan, indicating that Astellas will be ready to make an NDA submission for the treatment of anemia with roxadustat in CKD-dialysis patients in 2018. We evaluated the regulatory milestone payment associated with NDA submission in Japan based on variable consideration requirements under the current revenue standards and concluded that this milestone became probable of being achieved in the second quarter of 2018. Accordingly, the consideration of $15.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the Japan Agreement in the second quarter of 2018. 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.

FibroGen and Astellas are currently negotiating an amendment to the Japan Agreement that will allow Astellas to manufacture roxadustat drug product for commercialization in Japan, and for which FibroGen would continue to manufacture and deliver to Astellas roxadustat API. The commercial terms of the Japan Agreement would remain substantially the same. In the second quarter of 2018, FibroGen delivered roxadustat API to Astellas under a material transfer agreement for Astellas to conduct commercial scale manufacturing validation for roxadustat drug product in Japan.

In addition, as of September 30, 2018, Astellas had separate investments of $80.5 million in the equity of FibroGen, Inc.

AstraZeneca

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

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

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

Under the AstraZeneca agreements, we will receive upfront and subsequent non-contingent payments totaling $402.2 million. Potential milestone payments under the agreements total $1.2 billion, of which $571.0 million are development and regulatory milestones and $652.5 million are commercial-based milestones. Total consideration under the agreements, excluding development cost reimbursement, transfer price payments, royalties and profit share, could reach $1.6 billion. The aggregate amount of such consideration received through September 30, 2018 totals $432.2 million.

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

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

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

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

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

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

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

Additional Information Related to Collaboration Agreements

Total cash consideration received through September 30, 2018 and potential cash consideration, other than development cost reimbursement, transfer price payments, royalties and profit share, pursuant to our existing collaboration agreements are as follows:

	Cash Received Through September 30, 2018	Additional Potential Cash Payments	Total Potential Cash Payments
		(in thousands)	
Astellas--related-party:			
Japan Agreement	$ 62,593	$ 110,000	$ 172,593
Europe Agreement	410,000	335,000	745,000
Total Astellas	472,593	445,000	917,593
AstraZeneca:			
U.S. / RoW Agreement	389,000	860,000	1,249,000
China Agreement	43,200	333,500	376,700
Total AstraZeneca	432,200	1,193,500	1,625,700
Total revenue	$ 904,793	$ 1,638,500	$ 2,543,293

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

RESULTS OF OPERATIONS

Revenue

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2018	2017 *	$	%	2018	2017 *	$	%
			(dollars in thousands)					
Revenue:								
License revenue	$ —	$ 9,933	$ (9,933)	(100) %	$ 14,323	$ 9,933	$ 4,390	44 %
Development and other revenue	29,027	30,617	(1,590)	(5) %	90,580	90,327	253	- %
Total revenue	$ 29,027	$ 40,550	$ (11,523)	(28) %	$ 104,903	$ 100,260	$ 4,643	5 %

* Recast to reflect the adoption of the new revenue standards. See Note 1 to the condensed consolidated financial statements.

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 standalone selling price method from other consideration received during the periods. This revenue is generally recognized as deliverables are met and services are performed.

Development revenue include co-development and other development related services. Co-development services are recognized as revenue in the period in which they are billed to our partners, excluding China. For China co-development services, revenue is deferred until the end of the development period once all performance obligations have been satisfied. Other development related services are recognized as revenue over the non-contingent development period, ranging from 36 to 89 months, based on a proportional performance method. Other revenues consist of sales of research and development material and have been included with Development and other revenue in the condensed consolidated statements of operations, as they have not been material for any of the years presented.

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

Total revenue decreased $11.5 million, or 28% for the three months ended September 30, 2018, and increased $4.6 million, or 5% for the nine months ended September 30, 2018, compared to the same periods a year ago for the reasons discussed in the sections below.

License Revenue

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2018	2017 *	$	%	2018	2017 *	$	%
	(dollars in thousands)							
License revenue:								
Astellas	$ —	$ —	$ —	— %	$ 14,323	$ —	$ 14,323	100 %
AstraZeneca	—	9,933	(9,933)	(100) %	—	9,933	(9,933)	(100) %
Total license and milestone revenue	$ —	$ 9,933	$ (9,933)	(100) %	$ 14,323	$ 9,933	$ 4,390	44 %

* Recast to reflect the adoption of the new revenue standards. See Note 1 to the condensed consolidated financial statements.

License revenue for the nine months ended September 2018 was related to a $15.0 million regulatory milestone associated with Astellas' expected NDA submission in Japan that was included in the transaction price during the second quarter of 2018 when this milestone became probable of being achieved. Of this amount, $14.3 million was allocated to license revenue and recognized during the second quarter of 2018.

License revenue for the three and nine months ended September 30, 2017 was related to a $15.0 million regulatory milestone payment to FibroGen by AstraZeneca. In October 2017, the NMPA accepted our NDA for registration of roxadustat for anemia in DD CKD and NDD-CKD patients. This NDA submission triggered a $15.0 million milestone payment, which became probable of being achieved and therefore partially recognized as revenue under the new revenue standards during the third quarter of 2017.

Development and other Revenue

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2018	2017 *	$	%	2018	2017 *	$	%
	(dollars in thousands)							
Development revenue:								
Astellas	$ 5,132	$ 5,322	$ (190)	(4) %	$ 16,449	$ 15,106	$ 1,343	9 %
AstraZeneca	23,895	25,295	(1,400)	(6) %	74,096	75,218	(1,122)	(1) %
Total development revenue	29,027	30,617	(1,590)	(5) %	90,545	90,324	221	— %
Other revenue	—	—	—	— %	35	3	32	1,067 %
Total development and other revenue	$ 29,027	$ 30,617	$ (1,590)	(5) %	$ 90,580	$ 90,327	$ 253	— %

* Recast to reflect the adoption of the new revenue standards. See Note 1 to the condensed consolidated financial statements.

Development revenue recognized under our collaboration agreements with AstraZeneca decreased $1.4 million, or 6% for the three month period, and decreased $1.1 million, or 1% for the nine month period, primarily due to a decrease in co-development billings related to the development of roxadustat.

Development revenue recognized under our collaboration agreements with Astellas increased $1.3 million, or 9% for the nine month period primarily due to the allocated revenue related to the above mentioned $15.0 million associated with the regulatory milestone of NDA submission in Japan in the second quarter of 2018.

Operating Expenses

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2018	2017	$	%	2018	2017	$	%
	(dollars in thousands)							
Operating expenses								
Research and development	$ 56,443	$ 50,336	$ 6,107	12 %	$ 165,555	$ 144,049	$ 21,506	15 %
General and administrative	15,356	12,953	2,403	19 %	45,961	37,908	8,053	21 %
Total operating expenses	$ 71,799	$ 63,289	$ 8,510	13 %	$ 211,516	$ 181,957	$ 29,559	16 %

Total operating expenses increased $8.5 million, or 13%, for the three months ended September 30, 2018, and increased $29.6 million, or 16%, compared to the same periods a year ago, for the reasons discussed in the sections below.

Research and Development Expenses

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

The following table summarizes our research and development expenses incurred during the three and nine months ended September 30, 2018 and 2017:

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2018	2017	2018	2017
Product Candidate	Phase of Development	(in thousands)			
Roxadustat	Phase 3	$ 34,308	$ 32,493	$ 104,700	$ 92,595
Pamrevlumab	Phase 2	16,125	12,230	42,754	37,366
FG-5200	Preclinical	1,046	1,319	3,653	3,457
Other research and development expenses		4,964	4,294	14,448	10,631
Total research and development expenses		$ 56,443	$ 50,336	$ 165,555	$ 144,049

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

Research and development expenses increased $6.1 million, or 12%, for the three months ended September 30, 2018, compared to the same period a year ago. The increase was primarily due to increases in drug development expenses of $2.9 million, stock-based compensation expense of $2.9 million, and employee-related costs of $2.1 million, partially offset by a decrease in clinical trials costs of $2.8 million. Drug development expenses increased primarily due to higher drug substance manufacturing activities related to pamrevlumab. Stock-based compensation expense increased due to the cumulative impact of stock option grant activities. Employee-related costs increased due to higher headcount and higher average compensation level. Clinical trial costs decreased as a result of the completion of Phase 3 trials for roxadustat and the Phase 2 trials for pamrevlumab. We expect development expenses to increase as we begin Phase 3 trials for pamrevlumab.

Research and development expenses increased $21.5 million, or 15%, for the nine months ended September 30, 2018, compared to the same period a year ago. The increase was primarily due to increases in employee-related costs of $8.9 million, drug development expenses of $6.9 million, stock-based compensation expense of $6.7 million, allocated facility related expense of $5.2 million, and outside services of $1.6 million, partially offset by a decrease in clinical trials costs of $8.4 million. Employee-related costs increased due to higher headcount, higher average compensation level, and increased seminar and conference costs. Drug development expenses increased primarily due to higher drug substance manufacturing activities related to pamrevlumab. Stock-based compensation expense increased due to the cumulative impact of stock option grant activities. Facility related expenses, as part of the allocated overhead costs, was higher relative to the prior period in which our property taxes were reduced as a result of a final settlement we obtained related to historical property tax payments. Outside services costs increased due to higher scientific contract work related to roxadustat and other HIF-PH inhibitors. Clinical trial costs decreased as a result of nearing completion of Phase 3 trials for roxadustat and Phase 2 trials for pamrevlumab. We expect development expenses to increase as we begin Phase 3 trials for pamrevlumab.

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 $2.4 million, or 19%, for the three months ended September 30, 2018, compared to the same period a year ago, primarily due to increases in stock-based compensation expense of $1.8 million and employee-related costs of $0.5 million. Stock-based compensation expense increased due to cumulative impact of stock option grant activities. Employee-related costs increased due to higher average compensation level and higher headcount.

General and administrative expenses increased $8.1 million, or 21%, for the nine months ended September 30, 2018, compared to the same period a year ago, primarily due to increases in stock-based compensation expense of $4.2 million, employee-related costs of $2.5 million, and facility related expense of $1.3 million. Stock-based compensation expense increased due to cumulative impact of stock option grant activities. Employee-related costs increased due to higher average compensation level and higher headcount. Facility related expenses, as part of the allocated overhead costs, was higher relative to the prior period in which our property taxes were reduced as a result of a final settlement we obtained related to historical property tax payments.

Interest and Other Income (Expense), Net

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2018	2017	$	%	2018	2017	$	%
	(dollars in thousands)							
Interest and other, net:								
Interest expense	$ (2,739)	$ (2,769)	$ 30	(1) %	$ (8,257)	$ (7,901)	$ (356)	5 %
Interest income and other, net	3,079	1,106	1,973	178 %	7,796	2,783	5,013	180 %
Total interest and other, net	$ 340	$ (1,663)	$ 2,003	(120) %	$ (461)	$ (5,118)	$ 4,657	(91) %

Interest Expense

Interest expense includes payments made for imputed interest related to the facility lease financing obligations for our leased facilities in San Francisco and China, as well as interest related to the Technology Development Center of the Republic of Finland product development obligations. Interest expense remained flat for the three months ended September 30, 2018. Interest expense increased $0.4 million, or 5%, for the nine months ended September 30, 2018, compared to the same period a year ago, primarily due to a reduction in the imputed interest resulting from the government rent subsidy received by FibroGen China in 2017.

Interest Income and Other, Net

Interest income and other, net primarily include interest income earned on our cash, cash equivalents and investments, foreign currency transaction gains (losses), remeasurement of certain monetary assets and liabilities in non-functional currency of our subsidiaries into the functional currency, realized gains (losses) on sales of investments. Interest income and other, net increased $2.0 million, or 178%, for the three months ended September 30, 2018, and increased $5.0 million, or 180%, for the nine months ended September 30, 2018 compared to the same periods a year ago primarily due to higher interest earned on our cash, cash equivalents and investments associated with the higher average balances, and realized foreign currency gain during the current year periods. The increases for the nine month period was partially offset by the unrealized loss on our marketable equity investments during the current year period.

Provision for Income Taxes

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017 *	2018	2017 *
	(dollars in thousands)			
Loss before income taxes	$ (42,432)	$ (24,402)	$ (107,074)	$ (86,815)
Provision for income taxes	124	57	299	166
Effective tax rate	(0.3)%	(0.2)%	(0.3)%	(0.2)%

* Recast to reflect the adoption of the new revenue standards. See Note 1 to the condensed consolidated financial statements.

The provisions for income taxes for the three and nine months ended September 30, 2018 and 2017 were due to foreign taxes.

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

LIQUIDITY AND CAPITAL RESOURCES

Financial Conditions

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

As of September 30, 2018, we had cash and cash equivalents of $566.7 million. Cash is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting principally of corporate and government debt securities and stated at fair value, are also available as a source of liquidity. As of September 30, 2018, we had short-term and long-term investments of $86.0 million and $40.6 million, respectively. As of September 30, 2018, a total of $25.5 million of our cash and cash equivalents was held outside of the U.S. in our foreign subsidiaries to be used primarily for our China operations.

Operating Capital Requirements

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one or more of our current or future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. To date, we have funded certain portions of our research and development and manufacturing efforts in China and Europe through outside parties. There is no guarantee that sufficient funds will be available to continue to fund these development efforts through commercialization or otherwise. Although our share of expenses for roxadustat will decrease as a result of AstraZeneca funding all non-China collaboration expenses not reimbursed by Astellas, we expect our research and development expenses to continue to increase as we invest in our other programs. We are subject to all the risks related to the development and commercialization of novel therapeutics, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

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

Cash Sources and Uses

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

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (58,679)	$ (65,327)
Investing activities	(59,267)	49,869
Financing activities	11,057	493,059
Effect of exchange rate changes on cash and cash equivalents	(47)	(10)
Net decrease in cash and cash equivalents	$ (106,936)	$ 477,591

Operating Activities

Net cash used in operating activities was $58.7 million for the nine months ended September 30, 2018 and consisted primarily of net loss of $107.4 million adjusted for non-cash items of $43.7 million and a net increase in operating assets and liabilities of $5.0 million. The significant non-cash items included stock-based compensation expense of $38.4 million, depreciation expense of $4.7 million, unrealized loss on our marketable equity investments of $1.1 million, and realized foreign currency gain of $1.1 million. The significant items in the changes in operating assets and liabilities included increases resulting from deferred revenue of $19.7 million, accounts payable of $4.6 million, prepaid expenses and other current assets of $1.9 million, and other assets of $1.4 million, partially offset by decreases resulting from accounts receivable of $14.7 million and accrued liabilities of $9.9 million. The changes in deferred revenue were primarily related to a sale of roxadustat API to Astellas during the second quarter of 2018. The sale was made pursuant to a material transfer agreement in anticipation of the execution of an amendment to the Japan Agreement. The associated consideration was recorded as deferred revenue as of September 30, 2018 as control of the product had not fully transferred to Astellas as of September 30, 2018. The changes in accrued liabilities and accounts payable were primarily driven by clinical trial activities and the timing of payments. The change in prepaid expenses and other current assets was primarily driven by the timing of invoicing and payments. The change in other assets was primarily related to a cash refund for value added tax received by FibroGen China during the third quarter of 2018. The change in accounts receivable was related to the timing of the receipt of upfront payments and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca.

Net cash used in operating activities was $65.3 million for the nine months ended September 30, 2017 and consisted primarily of net loss of $87.0 million adjusted for non-cash items of $33.6 million and a net decrease in operating assets and liabilities of $11.9 million. The significant non-cash items included stock-based compensation expense of $27.6 million, depreciation expense of $4.6 million and amortization of premium on investments of $1.5 million. The significant items in the changes in operating assets and liabilities included decreases resulting from accounts receivable of $13.2 million and other assets of $1.7 million, partially offset by an increase resulted from deferred revenue of $2.0 million. The changes in deferred revenue and accounts receivable were related to the timing of the receipt of upfront payments and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca. The change in other assets was primarily driven by the payment during the 2017 period for the land use right fee for the commercial active pharmaceutical ingredients manufacturing facility that we are establishing in China.

Investing Activities

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

Net cash used in investing activities was $59.3 million for the nine months ended September 30, 2018 and consisted of cash used in purchases of available-for-sale securities of $110.2 million and purchases of property and equipment of $4.9 million, partially offset by proceeds from maturities of available-for-sale securities of $47.4 million and sales of available-for-sale securities of $8.2 million.

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

Financing Activities

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

Net cash provided by financing activities was $11.1 million for the nine months ended September 30, 2018 and consisted primarily of $24.6 million of proceeds from the issuance of common stock upon exercise of stock options and purchases under ESPP, partially offset by $13.3 million of cash paid for payroll taxes on restricted stock unit releases.

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

Off-Balance Sheet Arrangements

During the three and nine months ended September 30, 2018, 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, 2017.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

There have been no material changes in our critical accounting policies, estimates and judgments during the three and nine months ended September 30, 2018 compared with the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2017, except for the following:

Revenue Recognition

Substantially all of our revenues to date have been generated from our collaboration agreements.

Our collaboration agreements include multiple performance obligations comprised of promised services, or bundles of services, that are distinct. Services that are not distinct are combined with other services in the agreement until they form a distinct bundle of services. Our process for identifying performance obligations and an enumeration of each obligation for each agreement is outlined in Note 2 "Collaboration Agreements" to our condensed consolidated financial statements. Determining the performance obligations within a collaboration agreement often involves significant judgment and is specific to the facts and circumstances contained in each agreement.

We have identified the following material promises under our collaboration agreements: (1) license of FibroGen technology, (2) the performance of co-development services, including manufacturing of clinical supplies and other services during the development period, and (3) manufacture of commercial supply. The evaluation as to whether these promises are distinct, and therefore represent separate performance obligations, is described in more details in Note 2 "Collaboration Agreements" to our condensed consolidated financial statements.

For revenue recognition purposes, we determine that the term of our collaboration agreements begin on the effective date and ends upon the completion of all performance obligations contained in the agreements. In each agreement, the contract term is defined as the period in which parties to the contract have present and enforceable rights and obligations. We believe that the existence of what it considers to be substantive termination penalties on the part of the counterparty create sufficient incentive for the counterparty to avoid exercising its right to terminate the agreement unless in exceptionally rare situations.

The transaction price for each collaboration agreement is determined based on the amount of consideration we expect to be entitled for satisfying all performance obligations within the agreement. Our collaboration agreements include payments to us of one or more of the following: non-refundable upfront license fees; co-development billings; development, regulatory, and commercial milestone payments; and royalties on net sales of licensed products.

Upfront license fees are non-contingent and non-refundable in nature and are included in the transaction price at the point when the license fees become due to us. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Co-development billings resulting from our research and development efforts, which are reimbursable under our collaboration agreements, are considered variable consideration. Determining the amount of variable consideration from co-development billings requires us to make estimates of future research and development efforts, which involves significant judgment. Co-development billings are allocated entirely to the co-development services performance obligation when amounts are related specifically to research and development efforts necessary to satisfy the performance obligation, and such an allocation is consistent with the allocation objective.

Milestone payments are also considered variable consideration, which requires us to make estimates of when achievement of a particular milestone becomes probable. Similar to other forms of variable consideration, milestone payments are included in the transaction price when it becomes probable that such inclusion would not result in a significant revenue reversal. Milestone payments are therefore included in the transaction price when achievement of the milestone becomes probable.

For arrangements that include sales-based royalties and for which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from our collaboration arrangements.

The transaction price is allocated to performance obligations based on their relative standalone selling price ("SSP"), with the exception of co-development billings allocated entirely to co-development services performance obligations. The SSP is determined based on observable prices at which we separately sell the products and services. If an SSP is not directly observable, then we will estimate the SSP considering marketing conditions, entity-specific factors, and information about the customer or class of customer that is reasonably available. The process for determining SSP involves significant judgment and includes consideration of multiple factors, including assumptions related to the market opportunity and the time needed to commercialize a product candidate pursuant to the relevant license, estimated direct expenses and other costs, which include the rates normally charged by contract research and contract manufacturing organizations for development and manufacturing obligations, and rates that would be charged by qualified outsiders for committee services.

Significant judgment may be required in determining whether a performance obligation is distinct, determining the amount of variable consideration to be included in the transaction price, and estimating the SSP of each performance obligation. An enumeration of our significant judgments is outlined in Note 2 "Collaboration Agreements" to our consolidated condensed financial statements.

For each performance obligation identified within an arrangement, we determine the period over which the promised services are transferred and the performance obligation is satisfied. Service revenue is recognized over time based on progress toward complete satisfaction of the performance obligation. We use an input method to measure progress toward the satisfaction of co-development services and certain other related performance obligations, which is based on costs of labor hours or full time equivalents and out-of-pocket expenses incurred relative to total expected costs to be incurred. We believe this measure of progress provides a faithful depiction of the transfer of services because other measures do not measure as accurately how we transfer our performance obligations to our collaboration partners.

Recently Issued and Adopted Accounting Guidance

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which supersedes the revenue recognition requirements in Accounting Standards Codification ("ASC") 605, *Revenue Recognition*. ASU 2014-09 is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. Subsequently, the FASB has issued the following standards related to ASU 2014-09: ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations*; ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*; ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*; and ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers* (collectively, the "new revenue standards"). Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. We adopted the new revenue standards as of January 1, 2018 using the full retrospective method, which required us to recast the prior reporting period presented in the condensed consolidated financial statements. The primary impact upon adoption of the new revenue standards relates to the manner in which revenue is recognized for co-development billings and milestone payments under our collaboration arrangements. Under the new revenue standards, both of these elements of consideration are considered variable consideration which requires us to make estimates of when co-development billings become due or when achievement of a particular milestone becomes probable. Payments are included in the transaction price when it becomes probable that inclusion would not lead to a significant revenue reversal. We have recast our condensed consolidated statement of operations and condensed balance sheet from amounts previously reported due to the adoption of the new revenue standards, which resulted in increases in revenue of $13.3 million and $17.1 million for the three and nine months ended September 30, 2017, respectively. The adoption of the new revenue standards resulted in an increase in revenue of $5.3 million and $3.6 million for the years ended December 31, 2017 and 2016, respectively, and an increase in the opening accumulated deficit of $43.7 million as of January 1, 2016. The adoption of the new revenue standards had no impact to our previously reported condensed consolidated statement of cash flows. Refer to Note 1 to the condensed consolidated financial statements for details.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments-Overall (Subtopic 825-10)*. This guidance requires equity investments that are not accounted for under the equity method of accounting to be measured at fair value with changes recognized in net income, simplifies the impairment assessment of certain equity investments, and updates certain presentation and disclosure requirements. This guidance was effective for the annual reporting period beginning after December 15, 2017 and interim periods within those annual periods. We adopted this guidance as of January 1, 2018 using the modified retrospective approach, which resulted in a cumulative-effect adjustment of $1.3 million as a decrease in accumulated deficit on January 1, 2018, and an increase in accumulated other comprehensive loss. The adoption of this guidance had no impact to our condensed consolidated statement of operations or condensed consolidated statement of cash flows for the nine months ended September 30, 2018. Refer to Note 1 to the condensed consolidated financial statements for details.

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting*. This guidance provides guidance about which changes to the terms or conditions of a stock-based payment award require an entity to apply modification accounting in Topic 718. This guidance was effective for annual reporting period beginning after December 15, 2017, including interim periods. We adopted this guidance as of January 1, 2018, and the adoption of this guidance had no impact to our condensed consolidated financial statements.

In October 2016, the FASB issued ASU 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory*. This guidance requires companies to recognize the income tax effects of intercompany sales or transfer of assets, other than inventory, in the income statement as income tax expense (or benefit) in the period the sale or transfer occurs. The exception to recognizing the income tax effects of intercompany sales or transfer sales or transfer of assets remains in place for intercompany inventory sales and transfers. This guidance was effective for annual reporting period beginning after December 15, 2017, including interim periods. We adopted this guidance as of January 1, 2018 using the modified retrospective method. The adoption of this guidance did not result in any recognition of previously unrecognized deferred charges using a modified retrospective method, thus had no impact to our condensed consolidated financial statements.

Recently Issued Accounting Guidance Not Yet Adopted

In August 2018, the FASB issued ASU 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.* This guidance requires capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). This guidance should be applied either retrospectively or prospectively, and is effective for annual reporting period beginning after December 15, 2019 including interim periods, with early adoption permitted. We are currently evaluating the impact on its consolidated financial statements upon the adoption of this guidance.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement.* This guidance amends existing fair value measurement disclosure requirements by adding, changing, or removing certain disclosures. This guidance is effective for annual reporting period beginning after December 15, 2019 including interim periods, with early adoption permitted. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. We do not anticipate a material impact to its consolidated financial statements upon adoption of this guidance.

In June 2018, the FASB issued ASU 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.* This guidance expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance also specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. This guidance is effective for annual reporting period beginning after December 15, 2018, including interim periods. We will adopt this guidance on January 1, 2019 and do not anticipate a material impact to our consolidated financial statements upon adoption.

In February 2018, the FASB issued ASU 2018-02, *Income Statement - Reporting Comprehensive Income: Reclassification of Certain Tax effects from Accumulated Other Comprehensive Income*. This guidance allows for the reclassification from accumulated other comprehensive income to retained earnings for the stranded tax effects arising from the change in the reduction of the U.S. federal statutory income tax rate from 35% to 21%. This guidance is effective for annual reporting period beginning after December 15, 2018, including interim periods, with early adoption permitted. We will adopt this guidance on January 1, 2019 and do not anticipate a material reclassification between our accumulated other comprehensive loss and accumulated deficit upon adoption.

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

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). 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. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements* ("ASU 2018-11"), which provides entities the option to initially apply ASU 2016-02 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. ASU 2016-02 and ASU 2018-11 are effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period. We will adopt this guidance as of January 1, 2019 and are currently in the stages of gathering data and assessing the impact of the new lease accounting standard. We anticipate that the adoption of this guidance will result in additional assets and liabilities being recorded on our consolidated balance sheet.

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, 2017.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

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

Based on management's evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of September 30, 2018 at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

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

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

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

We have marked with an asterisk (*) those risks described below that reflect substantive changes from the risks described under Part I, Item 1A *"Risk Factors"* included in our Annual Report on Form 10-K for the year ended December 31, 2017.

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 myelodysplastic syndromes ("MDS"), and pamrevlumab (FG-3019) in idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer and Duchenne muscular dystrophy ("DMD"). 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 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, 2017, 2016, and 2015, recast from amounts previously reported due to the adoption of the new revenue standards, were approximately $120.9 million, $58.1 million, and $94.2 million, respectively. As of September 30, 2018, we had an accumulated deficit of $736.8 million. As of September 30, 2018, we had capital resources consisting of cash, cash equivalents and short-term investments of $652.7 million plus $40.6 million of long-term investments classified as available for sale securities. Despite contractual development and cost coverage commitments from our collaboration partners, AstraZeneca AB ("AstraZeneca") and Astellas, and the potential to receive milestone and other payments from these partners, we anticipate we will continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, and seek regulatory approval for our product candidates. If we do not successfully develop and obtain regulatory approval for our existing or any future product candidates and effectively manufacture, market and sell any product candidates that are approved, we may never generate product sales, and even if we do generate product sales, we may never achieve or sustain profitability on a quarterly or annual basis. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

We believe that we will continue to expend substantial resources for the foreseeable future as we continue late-stage clinical development of roxadustat, grow our operations in the People's Republic of China ("China"), expand our clinical development efforts on pamrevlumab, seek regulatory approval, prepare for the commercialization of our product candidates, and pursue additional indications. These expenditures will include costs associated with research and development, conducting preclinical trials and clinical trials, obtaining regulatory approvals in various jurisdictions, and manufacturing and supplying products and product candidates for ourselves and our partners. In particular, in our planned Phase 3 clinical trial program for roxadustat, which we believe will be the largest Phase 3 program ever conducted for an anemia product candidate, we are expecting to enroll more than 8,000 patients for our U.S. and European programs alone. We are conducting this Phase 3 program in conjunction with Astellas and AstraZeneca, and we are substantially dependent on Astellas and AstraZeneca for the funding of this large program. The outcome of any clinical trial and/or regulatory approval process is highly uncertain and we are unable to fully estimate the actual costs necessary to successfully complete the development and regulatory approval process for our compounds in development and any future product candidates. We believe that the net proceeds from our 2017 public offerings, our existing cash and cash equivalents, short-term and long-term investments and accounts receivable, and expected third party collaboration revenues will allow us to fund our operating plans through at least the next 12 months. Our operating plans or third party collaborations may change as a result of many factors, which are discussed in more detail below, and other factors that may not currently be known to us, and we therefore may need to seek additional funds sooner than planned, through offerings of public or private securities, debt financings or other sources, such as royalty monetization or other structured financings. Such financings may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may adversely affect our business. We may also seek additional capital due to favorable market conditions or strategic considerations even if we currently believe that we have sufficient funds for our current or future operating plans.

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

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

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

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

Substantially all of our revenues recognized in recent years have been from our collaboration partners.

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

If either or both of these collaborations were to be terminated, we could require significant additional capital in order to proceed with development and commercialization of our product candidates, or we may require additional partnering in order to help fund such development and commercialization. If adequate funds or partners are not available to us on a timely basis or on favorable terms, we may be required to delay, limit, reduce or terminate our research and development efforts or other operations.

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

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

Risks Related to the Development and Commercialization of Our Product Candidates

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

To date, we have invested a substantial portion of our efforts and financial resources in the research and development of roxadustat, which is currently our lead product candidate. Roxadustat is our only product candidate that has advanced into a potentially pivotal trial, and it may be years before the studies required for its approval are completed, if ever. Our other product candidates are less advanced in development and may never enter into pivotal studies. We have completed 26 Phase 1 and 2 clinical studies with roxadustat in North America, Europe and Asia, in which more than 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 New Drug Application ("NDA") submissions in the U.S. and China. We have discussed our Phase 3 clinical development program with three national health authorities in the EU and obtained scientific advice from the European Medicines Agency. Our near-term prospects, including maintaining our existing collaborations with Astellas and AstraZeneca, will depend heavily on successful Phase 3 development and commercialization of roxadustat.

Our other lead product candidate, pamrevlumab, is currently in clinical development for IPF, pancreatic cancer and DMD. Pamrevlumab requires substantial further development and investment. We do not have a collaboration partner for support of this compound, and, while we have promising open-label safety data and potential signals of efficacy, we would need to complete larger and more extensive controlled clinical trials to validate the results to date in order to continue further development of this product candidate. In addition, although there are many potentially promising indications beyond IPF, pancreatic cancer and DMD, we are still exploring indications for which further development of, and investment for, pamrevlumab may be appropriate. Accordingly, the costs and time to complete development and related risks are currently unknown. Moreover, pamrevlumab is a monoclonal antibody, which may require experience and expertise that we may not currently possess as well as financial resources that are potentially greater than those required for our small molecule lead compound, roxadustat.

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

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

- the timely initiation, continuation and completion of our Phase 3 clinical trials for roxadustat, which will depend substantially upon requirements for such trials imposed by the U.S. Food and Drug Administration ("FDA") and other regulatory agencies and bodies and the continued commitment and coordinated and timely performance by our third party collaboration partners, AstraZeneca and Astellas;
- the timely initiation and completion of our Phase 2 clinical trials for pamrevlumab, including in IPF, pancreatic cancer and DMD;
- our ability to demonstrate the safety and efficacy of our product candidates to the satisfaction of the relevant regulatory authorities;
- whether we are required by the FDA or other regulatory authorities to conduct additional clinical trials, and the scope and nature of such clinical trials, prior to approval to market our products;

- the timely receipt of necessary marketing approvals from the FDA and foreign regulatory authorities, including pricing and reimbursement determinations;
- the ability to successfully commercialize our product candidates, if approved, for marketing and sale by the FDA or foreign regulatory authorities, whether alone or in collaboration with others;
- our ability and the ability of our third party manufacturing partners to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability;
- our success in educating health care providers and patients about the benefits, risks, administration and use of our product candidates, if approved;
- acceptance of our product candidates, if approved, as safe and effective by patients and the healthcare community;
- the success of efforts to enter into relationships with large dialysis organizations involving the administration of roxadustat to dialysis patients;
- the achievement and maintenance of compliance with all regulatory requirements applicable to our product candidates;
- the maintenance of an acceptable safety profile of our products following any approval;
- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competitive treatments;
- our ability to obtain and sustain an adequate level of pricing or reimbursement for our products by third party payors;
- our ability to enforce successfully our intellectual property rights for our product candidates and against the products of potential competitors; and
- our ability to avoid or succeed in third party patent interference or patent infringement claims.

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

We may be unable to obtain regulatory approval for our product candidates, or such approval may be delayed or limited, due to a number of factors, many of which are beyond our control.

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

We have not obtained regulatory approval for any of our product candidates and it is possible that roxadustat and pamrevlumab will never receive regulatory approval in any country. Regulatory authorities may take actions or impose requirements that delay, limit or deny approval of roxadustat or pamrevlumab for many reasons, including, among others:

- our failure to adequately demonstrate to the satisfaction of regulatory authorities that roxadustat is safe and effective in treating anemia in CKD or that pamrevlumab is safe and effective in treating IPF, pancreatic cancer or DMD;
- our failure to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- the determination by regulatory authorities that additional clinical trials are necessary to demonstrate the safety and efficacy of roxadustat or pamrevlumab, or that ongoing clinical trials need to be modified in design, size, conduct or implementation;

- our product candidates may exhibit an unacceptable safety signal as they advance through clinical trials, in particular controlled Phase 3 trials;
- the clinical research organizations ("CROs") that conduct clinical trials on our behalf may take actions outside of our control that materially adversely impact our clinical trials;
- we or third party contractors manufacturing our product candidates may not maintain current good manufacturing practices ("cGMP"), successfully pass inspection or meet other applicable manufacturing regulatory requirements;
- regulatory authorities may not agree with our interpretation of the data from our preclinical trials and clinical trials;
- collaboration partners may not perform or complete their clinical programs in a timely manner, or at all; or
- principal investigators may determine that one or more serious adverse events ("SAEs"), is related or possibly related to roxadustat, and any such determination may adversely affect our ability to obtain regulatory approval, whether or not the determination is correct.

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

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

Preclinical, Phase 1 and Phase 2 clinical trial results may not be indicative of the results that may be obtained in larger, controlled Phase 3 clinical trials required for approval.*

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

We have conducted a limited number of Phase 2 clinical trials with pamrevlumab. We have conducted a randomized placebo-controlled study in 103 IPF patients with sub-studies in an additional 57 IPF patients comparing pamrevlumab to one of two standards of care, an open-label Phase 2 dose escalation study of pamrevlumab for IPF in 89 patients and a randomized double-blind placebo controlled study for liver fibrosis in subjects with hepatitis B, and we are currently conducting an open-label randomized, active-control, neoadjuvant Phase 2 trial in pancreatic cancer combining pamrevlumab with nab-paclitaxel plus gemcitabine in 37 patients. We cannot be sure that the results we have received to date from these trials will be substantiated in larger, well-controlled Phase 3 clinical trials, that larger trials will demonstrate the safety and efficacy of pamrevlumab for these or other indications, that further studies will provide benefits over existing approved products or that new safety issues will not be uncovered in further trials. In addition, while we believe that the limited animal and human studies conducted to date suggest that pamrevlumab has the potential to arrest or reverse fibrosis and reduce tumor mass in some patients or diseases, we cannot be sure that these results will be indicative of the effects of pamrevlumab in larger human trials. In addition, the IPF and pancreatic cancer patient populations are extremely ill and routinely experience SAEs, including death, which may be attributed to pamrevlumab in a manner that negatively impacts the safety profile of our product candidate. If the additional clinical trials that we are planning or are currently conducting for pamrevlumab do not show favorable efficacy results or result in safety concerns, or if we do not meet our clinical endpoints with statistical significance, or demonstrate an acceptable risk-benefit profile, we may be prevented from or delayed in obtaining regulatory approval for pamrevlumab in one or both of these indications.

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 information 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 are 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. 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. And while the data monitoring committee for our global Phase 3 anemia trials has consistently determined that our trials should continue without modification to the protocol, safety issues may still be discovered upon review of unblinded data when studies are completed. 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.

Our Phase 3 trials include a major adverse cardiac event ("MACE") safety 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 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 ("NDD")-CKD patients and our Phase 3 trials in dialysis dependent ("DD")-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 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 larger U.S. and European 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 and China Phase 3 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 clinical trials to date, 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 hemoglobin 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 hemoglobin 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.

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

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

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

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

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

Undesirable side effects caused by our product candidates or that may be identified as related to our product candidates by physician investigators conducting our clinical trials or even competing products in development that utilize a similar mechanism of action or act through a similar biological disease pathway could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. Adverse events and SAEs that emerge during treatment with our product candidates or other compounds acting through similar biological pathways may be deemed to be related to our product candidate and may result in:

- our Phase 3 clinical trial development plan becoming longer and more extensive;
- regulatory authorities increasing the data and information required to approve our product candidates and imposing other requirements; and
- our collaboration partners terminating our existing agreements.

The occurrence of any or all of these events may cause the development of our product candidates to be delayed or terminated, which could materially and adversely affect our business and prospects. Refer to "*Business — Our Development Program for Roxadustat*" and "*Business — Pamrevlumab for the Treatment of Fibrosis and Cancer*" for a discussion of the adverse events and SAEs that have emerged in clinical trials of roxadustat and pamrevlumab.

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

Clinical trials are conducted in representative samples of the potential patient population, which may have significant variability. Clinical trials are by design based on a limited number of subjects and of limited duration for exposure to the product used to determine whether, on a potentially statistically significant basis, the planned safety and efficacy of any product candidate can be achieved. As with the results of any statistical sampling, we cannot be sure that all side effects of our product candidates may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to the product candidate for a longer duration, may a more complete safety profile be identified. Further, even larger clinical trials may not identify rare serious adverse effects or the duration of such studies may not be sufficient to identify when those events may occur. There have been other products, including ESAs, for which safety concerns have been uncovered following approval by regulatory authorities. Such safety concerns have led to labeling changes or withdrawal of ESAs products from the market. While our most advanced product candidate is chemically unique from ESAs, it or any of our product candidates may be subject to 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.

To date we have not seen evidence of significant safety concerns with our product candidates currently in clinical trials, patients treated with our products, if approved, may experience adverse reactions and it is possible that the FDA or other regulatory authorities may ask for additional safety data as a condition of, or in connection with, our efforts to obtain approval of our product candidates. If safety problems occur or are identified after our product candidates reach the market, we may, or regulatory authorities may require us to amend the labeling of our products, recall our products or even withdraw approval for our products.

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

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

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

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

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

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

We have a limited amount of roxadustat and pamrevlumab in storage, limited capacity reserved at our third-party manufacturers, and there are long lead times required to manufacture and scale-up the manufacture of additional supply, as required for both late-stage clinical trials and commercial supply. If we are unable to forecast, order or manufacture sufficient quantities of roxadustat or pamrevlumab on a timely basis, it may delay our development, launch or commercialization in some or all indications we are currently pursuing. For example, prior to agreement with regulatory authorities on the scope of our Phase 3 IPF trial design, there is uncertainty as to whether our supply plans will meet our clinical requirements in a timely manner. Any delay or interruption in the supply of our product candidates or products could have a material adverse effect on our business and operations.

Our clinical trials must be conducted with product produced under applicable cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We and even an experienced third party manufacturer may encounter difficulties in production, which difficulties may include:

- costs and challenges associated with scale-up and attaining sufficient manufacturing yields, in particular for biologic products such as pamrevlumab, which is a monoclonal antibody;
- supply chain issues, including coordination of multiple contractors in our supply chain;
- the timely availability and shelf life requirements of raw materials and supplies;
- quality control and assurance;
- shortages of qualified personnel and capital required to manufacture large quantities of product;
- compliance with regulatory requirements that vary in each country where a product might be sold;
- capacity or forecasting limitations and scheduling availability in contracted facilities; and
- natural disasters, such as floods, storms, earthquakes, tsunamis, and droughts, or accidents such as fire, that affect facilities, possibly limit or postpone production, and increase costs.

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

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

As an organization, we have not successfully commercialized any drug product and have only completed a Phase 3 clinical trial in China. Therefore, we may not be able to efficiently execute our development and commercialization plans.*

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

In addition, in order for any Phase 3 clinical trial to support an NDA submission for approval, the FDA and foreign regulatory authorities require compliance with regulations and standards, including good clinical practices ("GCP") requirements for designing, conducting, monitoring, recording, analyzing and reporting the results of clinical trials to ensure that the data and results from trials are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Although we rely on third parties to conduct our clinical trials, we as the sponsor remain responsible for ensuring that each of these clinical trials is conducted in accordance with its general investigational plan and protocol under legal and regulatory requirements, including GCP. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs, trial sites, principal investigators or other third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require us to exclude the use of patient data from our clinical trials not conducted in compliance with GCP or perform additional clinical trials before approving our marketing applications. They may even reject our application for approval or refuse to accept our future applications for an extended time period. For example in China in March 2016, the State Drug Administration, now known as the National Medicine Products Administration ("NMPA") issued guidance related to its clinical trial data integrity regulations. While trial sites and CROs bear liability for the accuracy and authenticity of data they are directly responsible for, the sponsor ultimately bears full responsibility for submitted clinical data and the drug application dossier. Fraudulent clinical data could result in a ban in China of a sponsor's product-related NDA applications for three years and other NDA applications for one year. We have taken extensive steps to ensure the integrity of our China clinical data. However, we cannot assure you that upon inspection by a regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements or that our results will be deemed authentic or may be used in support of our regulatory submissions.

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

We do not have a sales or marketing infrastructure and have no experience in the sales, marketing or distribution of pharmaceutical products in any country. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish sales and marketing capabilities or make and maintain our existing arrangements with third parties to perform these services at a level sufficient to support our commercialization efforts.

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

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

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

We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.*

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

If roxadustat is approved and launched commercially, competing drugs are expected to include ESAs, particularly in those patient segments where ESAs are used. Currently available ESAs include epoetin alfa (EPOGEN ®, marketed by Amgen Inc. in the U.S., Procrit ® and Erypo ®/Eprex ®, marketed by Johnson & Johnson Inc., and Espo ® marketed by Kyowa Hakko Kirin in Japan and China), darbepoetin (Amgen/Kyowa Hakko Kirin's Aranesp ® and NESP ®) and Mircera ® marketed by Hoffmann-La Roche ("Roche") outside of the U.S. and by Vifor Pharma ("Vifor"), a Roche licensee, in the U.S. and Puerto Rico, as well as biosimilar versions of these currently marketed ESA products. ESAs have been used in the treatment of anemia in CKD for more than 20 years, serving a significant majority of DD-CKD patients. While NDD-CKD patients who are not under the care of nephrologists, including those with diabetes and hypertension, do not typically receive ESAs and are often left untreated, some patients under nephrology care may be receiving ESA therapy. It may be difficult to encourage healthcare providers and patients to switch to roxadustat from products with which they have become familiar.

We may also face competition from potential new anemia therapies currently in clinical development, including in those patient segments not currently addressed by ESAs. Companies such as GlaxoSmithKline plc ("GSK"), Bayer Corporation ("Bayer"), Akebia Therapeutics, Inc. ("Akebia"), and Japan Tobacco, are currently developing HIF prolyl hydroxylase ("HIF-PH") inhibitors for anemia in CKD indications. We may face competition for patient recruitment and enrollment for clinical trials and potentially in commercial sales. Akebia is currently conducting two Phase 3 studies in NDD–CKD, one started in December 2015 and the other in February 2016, and initiated two Phase 3 studies in DD-CKD, one started in July 2016 and the other in August 2016. Akebia also started a Phase 2 study in May 2017 with 20-week dosing in ESA-hyporesponsive DD-CKD patients, and a Phase 3 study with three-times a week dosing in August 2017. Akebia terminated the hyporesponsive DD-CKD study and withdrew the three-times a week study, and announced its plan to replace these studies with new modified designs of studies in April 2018, neither of which has been initiated as of November 2, 2018 according to clinicaltrials.gov. In Japan, Mitsubishi Tanabe Pharmaceutical Corporation, Akebia's collaboration partner, started a Phase 3 program in November 2017. GSK started Phase 3 studies in NDD-CKD and DD-CKD in the U.S. in September 2016, and in Japan in June 2016. Two of the GSK Japan Phase 3 studies were completed in July 2018. Bayer has completed global Phase 2 studies and announced in May 2017 its HIF-PH inhibitor is now in continued development in Japan only, and started Japan Phase 3 studies in NDD-CKD and DD-CKD in December 2017. Beginning in September 2017, Japan Tobacco is currently conducting four Phase 3 open label studies in NDD-CKD and DD-CKD as well as one Phase 3 ESA-controlled study each in NDD-CKD and DD-CKD in Japan. Some of these product candidates may enter the market prior to roxadustat.

In addition, there are other companies developing biologic therapies for the treatment of other anemia indications that we may also seek to pursue in the future, including anemia of MDS. For example, Acceleron Pharma Inc., in partnership with Celgene Corporation ("Celgene"), is in Phase 3 development of protein therapeutic candidates to treat anemia and associated complications in patients with ß-thalassemia and MDS, and has received orphan drug status from the EMA and FDA for these indications. Celgene announced in July 2018 that it plans to submit a marketing approval application for luspatercept in the U.S. and European Union ("EU") in the first half of 2019. There may also be new therapies for renal-related diseases that could limit the market or level of reimbursement available for roxadustat if and when it is commercialized.

In China, biosimilars of epoetin alfa are offered by Chinese pharmaceutical companies such as EPIAO marketed by 3SBio Inc. as well as more than 15 other local manufacturers. We may also face competition by HIF-PH inhibitors from other companies such as Akebia, Bayer, and GSK, which was authorized by the NMPA to conduct trials in China to support its ex-China regulatory filings. Furthermore, while it is too early to understand how the NMPA will implement its recently approved guidelines to allow multinational companies to use their ex-China clinical data in their NDAs in China, these guidelines could in theory allow competitors to accelerate their NDA applications in China. Akebia announced in December 2015 that it has entered into a development and commercialization partnership with Mitsubishi Tanabe Pharmaceutical Corporation for its HIF-PH inhibitor vadadustat in Japan, Taiwan, South Korea, India, and certain other countries in Asia, and announced in April 2017 an expansion of their U.S. collaboration with Otsuka to add markets, including China. 3SBio Inc. also announced in 2016 its plan on beginning a Phase 1 clinical trial of a HIF-PH inhibitor for the China market.

The introduction of biosimilar ESAs into the market in the U.S. may occur by the time roxadustat enters the market and may alter the competitive and pricing landscape of anemia therapy in DD-CKD patients under the end stage renal disease bundle. The patents for Amgen's epoetin alfa, EPOGEN, expired in 2004 in the EU, and the final material patents in the U.S. expired in May 2015. Several biosimilar versions of currently marketed ESAs are available for sale in the EU, China and other territories. In the U.S., a few ESA biosimilars are currently under development or regulatory review. For example, the FDA approved Pfizer's Biologics License Application ("BLA") for Retacrit® (epoetin zeta) in May 2018 that has been marketed by Pfizer in Europe. Sandoz, a division of Novartis, markets Binocrit ® (epoetin alfa) in Europe and plans to file a biosimilar BLA 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 U.S. dialysis patients, and therefore have historically won long-term contracts including rebate terms with Amgen. In January 2017, DaVita entered into a new 6-year sourcing and supply agreement with Amgen that is effective through 2022. Fresenius' contract with Amgen expired in 2015, and Fresenius is now administering Mircera® in a significant portion of its U.S. dialysis patients since Mircera was made available by Vifor. Successful penetration of this market may require a significant agreement with Fresenius or DaVita on favorable terms and on a timely basis.

If pamrevlumab is approved and launched commercially to treat IPF, competing drugs are expected to include Roche's pirfenidone, which is approved for marketing in Europe, Canada, Japan and the U.S., and Boehringer Ingelheim Pharma GmbH & Co. KG'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 development for IPF include Promedior Inc.'s PRM-151, Biogen-Idec's STX-100, Prometic Life Sciences Inc.'s PBI-4050, Kadmon Holdings, Inc.'s KD025, and two compounds from Galapagos NV. Galapagos recently initiated a Phase 2 study in Europe for GLPG 1205 and is expected to start a Phase 3 study for GLPG 1690 by the end of 2018.

If pamrevlumab is approved and launched commercially to treat locally advanced pancreatic cancer patients who are not candidates for surgical resection, pamrevlumab may face competition from agents seeking approval in combination with gemcitibine and nab-paclitaxel from companies such as NewLink Genetics Corporation 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.

If pamrevlumab is approved and launched commercially to treat DMD, pamrevlumab may face competition for some patients from Sarepta Therapeutics, Inc. ("Sarepta"), as well as PTC Therapeutics, Santhera Pharmaceuticals, Catabasis Pharmaceuticals, Solid Biosciences Inc., and Pfizer.

Sarepta is researching and developing clinical candidates for many of the specific mutations in the dystrophin gene and received accelerated approval in the U.S. for its first, drug Exondys 51 (eteplirsen) for patients who have a confirmed mutation in the DMD gene that is amenable to exon 51 skipping. This mutation represents a subset of approximately 13% of patients with DMD. Sarepta recently received a negative opinion from the European Medicines Agency regarding eteplirsen approval in Europe. In addition to eteplirsen, Sarepta has two additional exon skipping programs in Phase 3 development, each of which targets approximately 8% of patients with DMD. Sarepta is also developing gene therapies for the treatment of DMD and reported positive preliminary results from a Phase 1/2a program in June, 2018. In addition to Sarepta, Pfizer and Solid Biosciences, Inc. are also pursuing gene therapies in early clinical trials for DMD.

Marathon Pharmaceuticals received approval for its drug Emflaza (deflazacort) on February 9, 2017 and on March 16, 2017 announced that it had sold the commercialization rights to Emflaza to PTC Therapeutics.

PTC Therapeutics' product ataluren (Translarna ™) received conditional approval in Europe in 2014 and a complete response letter from the FDA in October of 2017 stating that the FDA is unable to approve the application in its current form. Translarna targets a different set of DMD patients from those being targeted by Sarepta's existing exon-skipping therapeutic candidate; however, it is also limited to a subset of patients who carry a specific mutation.

While pamrevlumab and some other potential competitors are intended to treat DMD patients regardless of the specific mutation, there can be no assurance that clinical trials will support broadly treating DMD patients. For example, Santhera Pharmaceuticals reported positive Phase 3 data with its drug idebenone (Raxone ®/Catena ®) in a trial measuring changes in lung function for DMD patients, however the FDA has asked for additional data from an ongoing trial prior to considering Raxone for approval. Santhera recently announced its intentions to submit marketing authorization applications for idebenone in the US and Europe in 2019.

Catabasis Pharmaceuticals recently reported positive Phase 2 data from its clinical trial candidate edasalonexent. Edasalonexent was reported to have preserved muscle function and slowed the progression of DMD compared to rates of change in the control period prior to treatment with edasalonexent. The company started a single placebo controlled Phase 3 trial in September 2018. Catabasis expects topline data from this trial in the second quarter of 2020.

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

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.

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

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

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

- the clinical indications for which the product is approved and the labeling required by regulatory authorities for use with the product, including any warnings that may be required in the labeling;
- acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new therapies and of physicians to prescribe new therapies;
- the cost, safety, efficacy and convenience of treatment in relation to alternative treatments;
- the restrictions on the use of our products together with other medications, if any;
- the availability of adequate coverage and reimbursement or pricing by third party payors and government authorities;

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

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

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

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

The review and publication cycle for the Chinese government to update their reimbursement lists (national or provincial) is unpredictable and is outside our control.

Obtaining coverage and reimbursement approval for a product from a government or other third party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor, which we may not be able to provide. Furthermore, the reimbursement policies of third party payors may significantly change in a manner that renders our clinical data insufficient for adequate reimbursement or otherwise limits the successful marketing of our products. Even if we obtain coverage for our product candidates, third party payors may not establish adequate reimbursement amounts, which may reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our products.

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

Risks Related to Our Reliance on Third Parties

If our collaborations with Astellas or AstraZeneca were terminated, or if Astellas or AstraZeneca were to prioritize other initiatives over their collaborations with us, whether as a result of a change of control or otherwise, our ability to successfully develop and commercialize our lead product candidate, roxadustat, would suffer.

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

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

If we fail to establish and maintain strategic collaborations related to our product candidates, we will bear all of the risk and costs related to the development and commercialization of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise at significant cost. This in turn may negatively affect the development of our other product candidates as we direct resources to our most advanced product candidates.

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

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

With respect to our collaboration agreements for roxadustat, there are additional complexities in that we and our collaboration partners, Astellas and AstraZeneca, must reach consensus on our Phase 3 development program. Multi-party decision-making is complex and involves significant time and effort, and there can be no assurance that the parties will cooperate or reach consensus, or that one or both of our partners will not ask to proceed independently in some or all of their respective territories or functional areas of responsibility in which the applicable collaboration partner would otherwise be obligated to cooperate with us. Any disputes or lack of cooperation with us by either Astellas or AstraZeneca may negatively impact the timing or success of our planned Phase 3 clinical studies.

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

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

We rely on third parties for the conduct of most of our preclinical and clinical trials for our product candidates, and if our third party contractors do not properly and successfully perform their obligations under our agreements with them, we may not be able to obtain or may be delayed in receiving regulatory approvals for our product candidates.

We rely heavily on university, hospital, dialysis centers and other institutions and third parties, including the principal investigators and their staff, to carry out our clinical trials in accordance with our clinical protocols and designs. We also rely on a number of third party CROs to assist in undertaking, managing, monitoring and executing our ongoing clinical trials, including those for roxadustat. We expect to continue to rely on CROs, clinical data management organizations, medical institutions and clinical investigators to conduct our development efforts in the future, including our Phase 3 development program for roxadustat. We compete with many other companies for the resources of these third parties, and large pharmaceutical companies often have significantly more extensive agreements and relationships with such third party providers, and such third party providers may prioritize the requirements of such large pharmaceutical companies over ours. The third parties on whom we rely may terminate their engagements with us at any time, which may cause delay in the development and commercialization of our product candidates. If any such third party terminates its engagement with us or fails to perform as agreed, we may be required to enter into alternative arrangements, which would result in significant cost and delay to our product development program. Moreover, our agreements with such third parties generally do not provide assurances regarding employee turnover and availability, which may cause interruptions in the research on our product candidates by such third parties.

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

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

We currently rely, and expect to continue to rely, on third parties to conduct many aspects of our clinical studies and product manufacturing, and these third parties may not perform satisfactorily.

We do not have any operating manufacturing facilities at this time other than our roxadustat and FG-5200 manufacturing facility in China, and our current commercial manufacturing facility plans in China are not expected to satisfy the requirements necessary to support development and commercialization outside of China. Other than in and for China specifically, we do not expect to independently manufacture our products. We currently rely, and expect to continue to rely, on third parties to scale-up, manufacture and supply roxadustat and our other product candidates outside of China. Risks arising from our reliance on third party manufacturers include:

- reduced control and additional burdens of oversight as a result of using third party manufacturers for all aspects of manufacturing activities, including regulatory compliance and quality control and assurance;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that may negatively impact our planned development and commercialization activities;
- the possible misappropriation of our proprietary technology, including our trade secrets and know-how; and
- disruptions to the operations of our third party manufacturers or suppliers unrelated to our product, including the bankruptcy of the manufacturer or supplier or a catastrophic event affecting our manufacturers or suppliers.

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

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

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

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

If any third party manufacturer terminates its engagement with us or fails to perform as agreed, we may be required to find replacement manufacturers, which would result in significant cost and delay to our development programs. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur significant delays and added costs in identifying, qualifying and contracting with any such third party or potential second source manufacturer. In any event, with any third party manufacturer we expect to enter into technical transfer agreements and share our know-how with the third party manufacturer, which can be time-consuming and may result in delays. These delays could result in a suspension or delay of our Phase 3 clinical trials or, if roxadustat is approved and marketed, a failure to satisfy patient demand.

Certain of the components of our product candidates are acquired from single-source suppliers and have been purchased without long-term supply agreements. The loss of any of these suppliers, or their failure to supply us with supplies of sufficient quantity and quality to complete our drug substance or finished drug product of acceptable quality and an acceptable price, would materially and adversely affect our business.

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

Intellectual property disputes with third parties and competitors may be costly and time consuming, and may negatively affect our competitive position.

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

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

We intend, if necessary, to vigorously enforce our intellectual property in order to protect the proprietary position of our product candidates, including roxadustat and pamrevlumab. Active efforts to enforce our patents may include litigation, administrative proceedings, or both, depending on the potential benefits that might be available from those actions and the costs associated with undertaking those efforts against third parties. We carefully review and monitor publicly available information regarding products that may be competitive with our product candidates and assert our intellectual property rights where appropriate. We previously prevailed in an administrative challenge initiated by a major biopharmaceutical company regarding our intellectual property rights, maintaining our intellectual property in all relevant scope, and will continue to protect and enforce our intellectual property rights. Moreover, third parties may continue to initiate new proceedings in the U.S. and foreign jurisdictions to challenge our patents from time to time.

We may consider administrative proceedings and other means for challenging third party patents and patent applications. 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.

Third parties may also challenge our patents and patent applications, through interference, reexamination, IPR, and post-grant review proceedings before the U.S. Patent and Trademark Office ("USPTO") or through comparable proceedings in other territories. For example, oppositions have been filed against four FibroGen European patents (European Patent Nos. 1463823, 1633333, 2322155, and 2322153) within our HIF Anemia-related Technologies Patent Portfolio. In three of these proceedings (1463823, 1633333, and 2322155), the European Patent Office has handed down decisions unfavorable to FibroGen. Each of these decisions is currently under appeal, and remain valid and enforceable pending resolution of the appeals. However, the ultimate outcomes of such proceedings remain uncertain and resolution of such may take an additional two to three years. A final decision adverse to FibroGen in any of these cases could result in invalidation of the subject patent, in whole or in part. Akebia is also pursuing challenges against corresponding patents in Canada and in Japan.

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

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

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

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

We have an extensive worldwide patent portfolio. The cost of maintaining our patent protection is high and maintaining our patent protection requires continuous review and compliance in order to maintain worldwide patent protection. We may not be able to effectively maintain our intellectual property position throughout the major markets of the world.

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

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

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

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

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

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

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

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

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

Risks Related to Government Regulation

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

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

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

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

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

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

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

If we obtain approval for any of our product candidates, the regulatory requirements applicable to our operations, in particular our sales and marketing efforts, will increase significantly with respect to our operations and the potential for civil and criminal enforcement by the federal government and the states and foreign governments will increase with respect to the conduct of our business. The laws that may affect our operations in the U.S. include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent;
- the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

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

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

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

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

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

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

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

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

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

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

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

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

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

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could result in significant liability for us and harm our reputation.

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

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

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

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

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

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

Risks Related to Our International Operations

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

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

- different regulatory requirements for drug approvals in 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;
- changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems and different competitive drugs indicated to treat the indications for which our product candidates are being developed;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- compliance with the FCPA, and other anti-corruption and anti-bribery laws;
- U.S. and foreign taxes, including 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. For example, the NMPA recently adopted the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use guidelines, and accordingly imposed regulatory oversight earlier in our production process for roxadustat manufactured and sold in China. The change in regulatory starting material triggers an extension of the inspection to our contract manufacturer STA, which could cause delay or additional cost in our NDA application or commercialization. In addition, Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry, in some cases launching industry-wide investigations, oftentimes appearing to focus on foreign companies. The costs and time necessary to respond to an investigation can be material. Any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China.

Patients' use of traditional Chinese medicine in violation of study protocols in our China studies may lead the NMPA 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 NMPA and regulators in other jurisdictions in which we are seeking approval to, among other things, suspend our studies, reject our study data and withhold approval for roxadustat.

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

We have two manufacturing facilities in China, with one located in Beijing and the other in Cangzhou, Hebei. We will not receive a license for commercial manufacture of roxadustat in either facility until after NDA approval. We are currently planning on manufacturing commercial API at our Cangzhou facility, and expect to receive a license to produce roxadustat API at that site in the second half of 2019. However, as an organization, we have limited experience building and licensing manufacturing facilities that must be constructed, licensed and operated in conformity with applicable cGMP, building and other requirements. There can be no assurance that we will be successful or timely in receiving licensure in Cangzhou or Beijing, either of which would be expected to delay or preclude our ability to develop and commercialize roxadustat in China and may materially adversely affect our business and operations and prospects in China.

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

We would require separate approval for the manufacture of FG-5200. In addition, we may convert the 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 FG-5200, either of which would be expected to delay or preclude our ability to develop FG-5200 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 NMPA and other regulatory authorities. We expect to depend on these facilities for our product candidates and business operations in China. Natural disasters or other unanticipated catastrophic events, including power interruptions, water shortages, storms, fires, earthquakes, terrorist attacks, government appropriation of our facilities, and wars, could significantly impair our ability to operate our manufacturing facilities. Certain equipment, records and other materials located in these facilities would be difficult to replace or would require substantial replacement lead time that would impact our ability to successfully commercialize our product candidates in China. The occurrence of any such event could materially and adversely affect our business, financial condition, results of operations, cash flows and prospects.

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

Our subsidiary FibroGen (China) Medical Technology Development Co., Ltd. ("FibroGen Beijing"), is currently seeking approval for roxadustat in China as a Domestic Class 1 Drug, which we believe, if approved, would be the first NMPA 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 NMPA approval process may take longer than we currently expect, or the NMPA 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 affect the NMPA 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 NMPA, some of which are not reflected in formal written communications, regulations, findings or determinations. Accordingly, while we believe we have understandings with the NMPA regarding the domestic drug approval process and the clinical and manufacturing (including bio-equivalency) data currently required for approval and the timing and process of a potential approval, the regulatory authorities may later determine that changes are required in the drug approval process, or that additional or different clinical or manufacturing data must be generated, any of which could significantly delay approval of roxadustat or any of our other product candidates, and materially and adversely affect our plans and operations in China. It is possible that other unforeseen delays in the China regulatory process could have a material adverse effect on our development and commercialization of roxadustat in China.

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

In addition, there are new and evolving environmental and manufacturing regulations in China. The application thereof may impact our API manufacturing location or strategy. In order to prevent or mitigate any delay in commercialization, we are establishing a 5,500 square meter commercial API manufacturing facility in Cangzhou, Hebei, with the intention of being operational in the second half of 2019. We have limited experience building and licensing manufacturing facilities that must be constructed, licensed and operated in conformity with applicable cGMP, and building and other requirements. Any delays related to these regulations or our new manufacturing facility could adversely affect the cost timing of our commercialization in China.

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

Even if roxadustat is approved in China, we and our collaboration partner in China, AstraZeneca, may experience difficulties in successfully generating sales of roxadustat in China.

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

The market for treatment 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 treatment of anemia in CKD. Roxadustat would compete with ESAs, which are offered by established multinational pharmaceutical companies such as Kyowa Hakko Kirin China Pharmaceutical Co., Ltd., 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. 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.

The Chinese government is implementing a new "Two Invoices" regulation which could affect the way we structure our distributorship relationships in China for roxadustat.*

The Chinese government is implementing new regulations that may impact our current distribution plans. These regulations generally require that at most two invoices may be issued throughout the distribution chain, which may affect the structure of the FibroGen-AstraZeneca commercial distribution plan by imposing higher costs or slowing our ability under the agreement to sell products to our principal customers. Any change in distribution would be expected to have an adverse impact on the cost of delivery of product to the end user customer, potentially raising cost of operations through the chain of distribution and potentially delaying launch or initial sales. Although we have time to prepare for these changes in advance of our commercial launch, we may not have sufficient visibility or understanding of the implementation across some or all of the various provinces, the result of which may be a delay in the planned distribution efforts and near-term potential for sales growth in China for roxadustat as we and our distribution partners understand and adjust our distribution plans in response to the new regulation. Failure to comply with the Two-Invoice regulations would prevent us from accessing the market in China.

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 in China. The Ministry of Labor and Social Security in China ("MLSS") together with other government authorities, select medicines to be included in the Medical Insurance Catalogs based on a variety of factors, including treatment requirements, frequency of use, effectiveness and price. The MLSS also occasionally removes medicines from such catalogs. There can be no assurance that roxadustat will be included, and once included, remain in the Medical Insurance Catalogs. The exclusion or removal of roxadustat from the Medical Insurance Catalogs may materially and adversely affect sales of roxadustat.

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

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

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

We have not yet received a license to manufacture FG-5200 in our Beijing manufacturing facility or at scale, and we will have to show that FG-5200 produced in 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 that may be sold, either of which may have a material and adverse effect on potential revenues from sales of roxadustat in China. Moreover, the process and timing for the implementation of price restrictions is unpredictable, which may cause potential revenues from the sales of roxadustat to fluctuate from period to period.

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

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

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

We plan to conduct all of our business in China through FibroGen China Anemia Holdings, Ltd. and FibroGen Beijing. We may rely on dividends and royalties paid by FibroGen Beijing for a portion of our cash needs, including the funds necessary to service any debt we may incur and to pay our operating expenses. The payment of dividends by FibroGen Beijing is subject to limitations. Regulations in China currently permit payment of dividends only out of accumulated profits as determined in accordance with accounting standards and regulations in China. FibroGen Beijing is not permitted to distribute any profits until losses from prior fiscal years have been recouped and in any event must maintain certain minimum capital requirements. FibroGen Beijing is also required to set aside at least 10.0% of its after-tax profit based on Chinese accounting standards each year to its statutory reserve fund until the cumulative amount of such reserves reaches 50.0% of its registered capital. Statutory reserves are not distributable as cash dividends. In addition, if FibroGen Beijing incurs debt on its own behalf in the future, the agreements governing such debt may restrict its ability to pay dividends or make other distributions to us. As of September 30, 2018, approximately $8.4 million of our cash and cash equivalents is held in China.

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

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

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

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

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

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

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

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

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

In 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.

On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act ("Tax Act") that instituted fundamental changes to the taxation of multinational corporations. The Tax Act includes changes to the taxation of foreign earnings by implementing a dividend exemption system, expansion of the current anti-deferral rules, a minimum tax on low-taxed foreign earnings and new measures to deter base erosion. The Tax Act also includes a permanent reduction in the corporate tax rate to 21%, repeal of the corporate alternative minimum tax, expensing of capital investment, and limitation of the deduction for interest expense. Furthermore, as part of the transition to the new tax system, a one-time transition tax is imposed on a U.S. shareholder's historical undistributed earnings of foreign affiliates. Although the Tax Act is generally effective January 1, 2018, GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date, which was December 22, 2017.

As a result of the impacts of the Tax Act, the SEC provided guidance that allows us to record provisional amounts for those impacts, with the requirement that the accounting be completed in a period not to exceed one year from the date of enactment. As of September 30, 2018, we have not completed the accounting for the tax effects of the Tax Act. Therefore, we have recorded provisional amounts for the effects of the Tax Act. For the three and nine months ended September 30, 2018, no changes have been made to the provisional amounts previously recorded. The primary impact of the Tax Act relates to the re-measurement of deferred tax assets and liabilities resulting from the change in the corporate tax rate ("Corporate Tax Rate Change"), which was recorded as of December, 2017. We are evaluating other accounting policies with respect to other provisions of the Tax Act.

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

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

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

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

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

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

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

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

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

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

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

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

Changes in China's economic, political or social conditions or government policies could have a material adverse effect on our business and operations.*

Chinese society and the Chinese economy 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.

As part of a sweeping and ongoing government restructuring effort, China's highest legislative body, the National People's Congress, approved a plan to establish a State Administration for Market Regulation ("SAMR"), which will merge and undertake the responsibilities previously held by the State Administration for Industry and Commerce, the General Administration of Quality Supervision, Inspection and Quarantine, the Certification and Accreditation Administration, the Standardization Administration of China, and the China Food and Drug Administration ("CFDA"), as well as anti-monopoly responsibilities previously held by the National Development and Reform Commission, Ministry of Commerce, and the Anti-Monopoly Office under the State Council. The restructuring also established the NMPA which has taken over much of the functions of the CFDA and will be supervised by the SAMR, while maintaining branches at the provincial level. A major government restructuring such as this one could cause significant delays and cost increases to our development, manufacturing, approval, and commercialization timelines in China. There has been significant turnover in government leadership and officials may be further assigned new roles and responsibilities, which is likely to create delays and possibly new policies and priorities, and existing rules may be interpreted differently. It will take time for the restructuring to be fully implemented and the new structure to operate efficiently. As a result, our existing plans could be delayed or modified due to changes in regulations, policies or personnel decisions, all of which could have a material adverse impact on our operating results and business prospects.

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

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

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

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

Risks Related to the Operation of Our Business

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

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

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

We are highly dependent on our chief executive officer, Thomas B. Neff, and other members of our senior management team. The loss of the services of Mr. Neff or any of these other individuals would be expected to significantly negatively impact the development and commercialization of our product candidates, our existing collaborative relationships and our ability to successfully implement our business strategy.

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

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

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

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

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

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

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

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

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

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

Our headquarters and data storage facilities are located near known earthquake fault zones. The occurrence of an earthquake, fire or any other catastrophic event could disrupt our operations or the operations of third parties who provide vital support functions to us, which could have a material adverse effect on our business, results of operations and financial condition.

We and some of the third party service providers on which we depend for various support functions, such as data storage, are vulnerable to damage from catastrophic events, such as power loss, natural disasters, terrorism and similar unforeseen events beyond our control. Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes and fires.

We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

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

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

Risks Related to Our Common Stock

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

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

- results of clinical trials of our product candidates, including roxadustat and pamrevlumab;
- the timing of the release of results of and regulatory updates regarding our clinical trials;
- the level of expenses related to any of our product candidates or clinical development programs;
- results of clinical trials of our competitors' products;
- safety issues with respect to our product candidates or our competitors' products;
- regulatory actions with respect to our product candidates and any approved products or our competitors' products;

- fluctuations in our financial condition and operating results, which will be significantly affected by the manner in which we recognize revenue from the achievement of milestones under our collaboration agreements;
- adverse developments concerning our collaborations and our manufacturers;
- the termination of a collaboration or the inability to establish additional collaborations;
- the publication of research reports by securities analysts about us or our competitors or our industry or negative recommendations or withdrawal of research coverage by securities analysts;
- the inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- the ineffectiveness of our internal controls;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- announced strategic decisions by us or our competitors;
- changes in legislation or other regulatory developments affecting our product candidates or our industry;
- fluctuations in the valuation of the biotechnology industry and particular companies perceived by investors to be comparable to us;
- sales of our common stock by us, our insiders or our other stockholders;
- speculation in the press or investment community;
- announcement or expectation of additional financing efforts;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- changes in accounting principles;
- activities of the government of China, including those related to the pharmaceutical industry as well as industrial policy generally;
- performance of other U.S. publicly traded companies with significant operations in China;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters such as earthquakes and other calamities;
- changes in market conditions for biopharmaceutical stocks;
- changes in general market and economic conditions; and
- the other factors described in this "Risk Factors" section.

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

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

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

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

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

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

As of October 31, 2018, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 34.39% 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 October 31, 2018. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. The interests of this group may differ from those of other stockholders and they may vote their shares in a way that is contrary to the way other stockholders vote their shares. This concentration of ownership could have the effect of entrenching our management and/or the board of directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

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

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

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

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

We may engage in future acquisitions that could disrupt our business, cause dilution to our stockholders and harm our business, results of operations, financial condition and cash flows and future prospects.

While we currently have no specific plans to acquire any other businesses, we may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our present or future product candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

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

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

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

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

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

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

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;

- specify that special meetings of our stockholders can be called only by our board of directors pursuant to a resolution adopted by a majority of the total number of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that our directors may be removed prior to the end of their term only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- require a supermajority vote of the holders of our common stock or the majority vote of our board of directors to amend our bylaws; and
- require a supermajority vote of the holders of our common stock to amend the classification of our board of directors into three classes and to amend certain other provisions of our certificate of incorporation.

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

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

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

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, gross receipts, and goods and services taxes in the U.S., state and local, or various foreign jurisdictions. We are subject to audit and assessments by tax authorities with respect to these non-income taxes and may have exposure to additional non-income tax liabilities which could have an adverse effect on our results of operations and financial condition.

On December 22, 2017, the U.S. enacted the Tax Act that instituted fundamental changes to the taxation of multinational corporations. The Tax Act includes changes to the taxation of foreign earnings by implementing a dividend exemption system, expansion of the current anti-deferral rules, a minimum tax on low-taxed foreign earnings and new measures to deter base erosion. The Tax Act also includes a permanent reduction in the corporate tax rate to 21%, repeal of the corporate alternative minimum tax, expensing of capital investment, and limitation of the deduction for interest expense. Furthermore, as part of the transition to the new tax system, a one-time transition tax is imposed on a U.S. shareholder's historical undistributed earnings of foreign affiliates. Although the Tax Act is generally effective January 1, 2018, GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date, which was December 22, 2017.

As a result of the impacts of the Tax Act, the SEC provided guidance that allows us to record provisional amounts for those impacts, with the requirement that the accounting be completed in a period not to exceed one year from the date of enactment. As of September 30, 2018, we have not completed the accounting for the tax effects of the Tax Act. Therefore, we have recorded provisional amounts for the effects of the Tax Act. For the three and nine months ended September 30, 2018, no changes have been made to the provisional amounts previously recorded. The primary impact of the Tax Act relates to the re-measurement of deferred tax assets and liabilities resulting from the Corporate Tax Rate Change, which was recorded as of December 31, 2017. We are evaluating other accounting policies with respect to other provisions of the Tax Act.

Our amended and restated certificate of incorporation designates the state or federal courts located in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the state and federal courts located in the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated by-laws, or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

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

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

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

Use of Proceeds from Initial Public Offering of Common Stock

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

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of FibroGen, Inc.	8-K	001-36740	3.1	11/21/2014
3.2	Amended and Restated Bylaws of FibroGen, Inc.	S-1/A	333-199069	3.4	10/23/2014
4.1	Form of Common Stock Certificate.	8-K	001-36740	4.1	11/21/2014
4.2	Investor Rights Agreement by and among FibroGen, Inc. and certain of its stockholders, dated as of December 1995.	S-1	333-199069	4.2	10/01/2014
4.3	Investor Rights Agreement by and among FibroGen, Inc. and certain of its warrant holders, dated as of February 8, 2000.	S-1	333-199069	4.7	10/01/2014
4.4	Warrant to Purchase 11,076 Shares of Common Stock issued to Bristow Investments, L.P, dated as of February 8, 2000.	S-1	333-199069	4.12	10/01/2014
4.5	Common Stock Purchase Agreement by and between FibroGen, Inc. and AstraZeneca AB, dated as of October 20, 2014.	S-1/A	333-199069	4.17	10/24/2014
4.6	Shareholders' Agreement by and among FibroGen International (Cayman) Limited and certain of its shareholders, dated as of September 8, 2017.	10-Q	001-36740	4.6	11/8/2017
31.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a).	—	—	—	—
31.2*	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a).	—	—	—	—
32.1*	Certification of Principal Executive Officer and Principal Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)(1)).	—	—	—	—
101*	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended September 30, 2018, formatted in XBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations (iii) the Condensed Consolidated Statement of Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash Flows and (v) the Notes to the Condensed Consolidated Financial Statements.	—	—	—	—

* Filed herewith

SIGNATURES

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

FibroGen, Inc.

Dated: November 8, 2018

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

Dated: November 8, 2018

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

Exhibit 31.1

CERTIFICATION

I, Thomas B. Neff, certify that;

1. I have reviewed this Form 10-Q of FibroGen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2018

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

Exhibit 31.2

CERTIFICATION

I, Pat Cotroneo, certify that;

1. I have reviewed this Form 10-Q of FibroGen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2018

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

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended ("Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Thomas B. Neff, Chief Executive Officer of FibroGen, Inc. ("the Company"), and Pat Cotroneo, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2018, to which this Certification is attached as Exhibit 32.1 ("Periodic Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 8, 2018

In Witness Whereof, the undersigned have set their hands hereto as of the 8th day of November, 2018.

/s/ Thomas B. Neff
Thomas B. Neff
Chairman of the Board and Chief Executive Officer

/s/ Pat Cotroneo
Pat Cotroneo
Senior Vice President, Finance and
Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of FibroGen, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.