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 March 31, 2020

OR

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

For the transition period from _____ to _____

Commission file number: 001-36740

FIBROGEN, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

The number of shares of common stock outstanding as of April 30, 2020 was 89,104,753.

FIBROGEN, INC.

TABLE OF CONTENTS

FIBROGEN, INC.

PART I—FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 121,560	$ 126,266
Short-term investments	413,869	407,491
Accounts receivable, net ($3,723 and $4,845 from a related party)	58,540	28,455
Inventories	8,408	6,887
Prepaid expenses and other current assets ($126,558 and $125,210 from a related party)	134,028	133,391
Total current assets	736,405	702,490
Restricted time deposits	2,072	2,072
Long-term investments	223	61,118
Property and equipment, net	40,058	42,743
Finance lease right-of-use assets	37,017	39,602
Other assets	8,602	9,372
Total assets	$ 824,377	$ 857,397
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 2,865	$ 6,088
Accrued and other current liabilities ($92 and $36,883 to a related party)	42,309	83,816
Deferred revenue	8,531	490
Finance lease liabilities, current	12,396	12,351
Total current liabilities	66,101	102,745
Long-term portion of lease obligations	1,040	1,141
Product development obligations	16,536	16,780
Deferred revenue, net of current	139,404	99,449
Finance lease liabilities, non-current	34,545	37,610
Other long-term liabilities	89,122	64,266
Total liabilities	346,748	321,991
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 125,000 shares authorized; no shares issued and outstanding at March 31, 2020 and December 31, 2019	—	—
Common stock, $0.01 par value; 225,000 shares authorized at March 31, 2020 and December 31, 2019; 88,896 and 87,657 shares issued and outstanding at March 31, 2020 and December 31, 2019	889	877
Additional paid-in capital	1,319,354	1,300,725
Accumulated other comprehensive income (loss)	1,183	(747)
Accumulated deficit	(863,068)	(784,720)
Total stockholders' equity	458,358	516,135
Non-controlling interests	19,271	19,271
Total equity	477,629	535,406
Total liabilities, stockholders' equity and non-controlling interests	$ 824,377	$ 857,397

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

FIBROGEN, INC.

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

	Three Months Ended March 31,	
	2020	**2019**
Revenue:		
License revenue	$ —	$ —
Development and other revenue (includes $4,737 and $4,859 from a related party)	19,446	23,863
Product revenue, net	4,955	—
Total revenue	24,401	23,863
Operating costs and expenses:		
Cost of goods sold	970	—
Research and development	54,902	50,496
Selling, general and administrative	49,603	22,210
Total operating costs and expenses	105,475	72,706
Loss from operations	(81,074)	(48,843)
Interest and other, net		
Interest expense	(633)	(770)
Interest income and other, net	3,165	4,177
Total interest and other, net	2,532	3,407
Loss before income taxes	(78,542)	(45,436)
Benefit from income taxes	(194)	(25)
Net loss	$ (78,348)	$ (45,411)
Net loss per share - basic and diluted	$ (0.89)	$ (0.53)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	88,219	85,704

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 March 31,	
	2020	**2019**
Net loss	$ (78,348)	$ (45,411)
Other comprehensive income (loss):		
Foreign currency translation adjustments	281	291
Available-for-sale investments:		
Unrealized gain on investments, net of tax effect	1,649	442
Other comprehensive income, net of taxes	1,930	733
Comprehensive loss	$ (76,418)	$ (44,678)

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

FIBROGEN, INC.

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

	For The Three Month Period						
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Non Controlling	
	Shares	Amount	Capital	Income (Loss)	Deficit	Interests	Total
Balance at December 31, 2019	87,657,489	$ 877	$ 1,300,725	$ (747)	$ (784,720)	$ 19,271	$ 535,406
Net loss	—	—	—	—	(78,348)	—	(78,348)
Change in unrealized gain or loss on investments	—	—	—	1,649	—	—	1,649
Foreign currency translation adjustments	—	—	—	281	—	—	281
Shares issued from stock plans, net of payroll taxes paid	1,238,141	12	1,713	—	—	—	1,725
Stock-based compensation	—	—	16,916	—	—	—	16,916
Balance at March 31, 2020	88,895,630	$ 889	$ 1,319,354	$ 1,183	$ (863,068)	$ 19,271	$ 477,629
Balance at December 31, 2018	85,432,102	$ 854	$ 1,226,453	$ (2,281)	$ (715,827)	$ 19,271	$ 528,470
Impact of adoption of ASC 842	—	—	—	—	8,688	—	8,688
Impact of change in accounting principle upon adoption of ASU 2018-02	—	—	—	611	(611)	—	—
Net loss	—	—	—	—	(45,411)	—	(45,411)
Change in unrealized gain or loss on investments	—	—	—	442	—	—	442
Foreign currency translation adjustments	—	—	—	291	—	—	291
Shares issued from stock plans, net of payroll taxes paid	697,462	7	(423)	—	—	—	(416)
Stock-based compensation	—	—	16,430	—	—	—	16,430
Balance at March 31, 2019	86,129,564	$ 861	$ 1,242,460	$ (937)	$ (753,161)	$ 19,271	$ 508,494

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)

	Three Months Ended March 31,	
	2020	2019
Operating activities		
Net loss	$ (78,348)	$ (45,411)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	2,868	2,744
Amortization of finance lease right-of-use assets	2,594	2,569
Net accretion of discount on investments	(143)	(1,350)
Unrealized loss (gain) on equity investments	21	(51)
Gain on disposal of property and equipment	—	(10)
Stock-based compensation	16,916	16,430
Tax benefit on unrealized gain on available-for-sale securities	(439)	(118)
Realized loss on sales of available-for-sale securities	258	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(30,085)	57,661
Inventories	(1,521)	—
Prepaid expenses and other current assets	(637)	(2,785)
Other assets	761	(51)
Accounts payable	(3,223)	(5,367)
Accrued and other liabilities	(41,224)	736
Deferred revenue	47,996	(2,580)
Accrued interest for finance lease liabilities	(216)	219
Other long-term liabilities	24,936	(156)
Net cash provided by (used in) operating activities	(59,486)	22,480
Investing activities		
Purchases of property and equipment	(459)	(483)
Purchases of available-for-sale securities and term deposit	(38)	(76,004)
Proceeds from sales of available-for-sale securities	10,606	—
Proceeds from maturities of investments	45,900	50,000
Net cash provided by (used in) investing activities	56,009	(26,487)
Financing activities		
Repayments of finance lease liabilities	(2,814)	(3,017)
Repayments of lease obligations	(101)	(101)
Cash paid for payroll taxes on restricted stock unit releases	(5,279)	(5,988)
Proceeds from issuance of common stock	7,004	5,572
Net cash used in financing activities	(1,190)	(3,534)
Effect of exchange rate change on cash and cash equivalents	(39)	(44)
Net decrease in cash and cash equivalents	(4,706)	(7,585)
Total cash and cash equivalents at beginning of period	126,266	89,258
Total cash and cash equivalents at end of period	$ 121,560	$ 81,673

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

FIBROGEN, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Significant Accounting Policies

Description of Operations

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

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

The Company's NDA filing in the United States ("U.S.") for roxadustat for the treatment of anemia in dialysis and non-dialysis CKD patients was accepted by the U.S. Food and Drug Administration ("FDA") in February 2020. In Europe, the Marketing Authorization Application ("MAA") filing with the European Medicines Agency ("EMA") is expected in the second quarter of 2020 for CKD in both dialysis and non-dialysis.

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

Pamrevlumab, an anti-CTGF human monoclonal antibody, is in Phase 3 clinical development for the treatment of both idiopathic pulmonary fibrosis ("IPF") and pancreatic cancer. Pamrevlumab is also currently in a Phase 2 trial for Duchenne muscular dystrophy ("DMD").

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 as one segment — the discovery, development and commercialization of novel therapeutics to treat serious unmet medical needs.

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

Use of Estimates

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

Net Loss per Share

Diluted weighted average shares did not include 8.7 million and 9.5 million securities for the three months March 31, 2020 and 2019, as they were anti-dilutive.

Risks and Uncertainties

The Company's business is subject to risks and uncertainties, including those related to the severe acute respiratory syndrome coronavirus 2 and the associated disease ("COVID-19") and the related shelter-in-place, stay-at-home and other similar governmental orders issued in response to the COVID-19 pandemic.

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

Recently Issued and Adopted Accounting Guidance

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

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

Recently Issued Accounting Guidance Not Yet Adopted

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

Significant Accounting Policies

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

Trade accounts receivable

The allowance for doubtful accounts is based on the Company's assessment of the collectability of customer accounts. The Company makes estimates of expected credit losses for the allowance for doubtful accounts by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, current economic and regulatory conditions that may affect a customer's ability to pay, and estimates of expected future losses. The Company's bad debt expense for the three months ended March 31, 2020 and the allowance for doubtful accounts as of March 31, 2020 were immaterial.

Credit losses – Available-for-sale debt securities

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

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

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

2. Collaboration Agreements

Astellas Agreements

Japan Agreement

In June 2005, the Company entered into a collaboration agreement with Astellas for the development and commercialization (but not manufacture) of roxadustat for the treatment of anemia in Japan ("Japan Agreement"). Under this agreement, Astellas paid license fees and other consideration totaling $40.1 million (such amounts were fully received as of February 2009). Under the Japan Agreement, the Company is also eligible to receive from Astellas an aggregate of approximately $132.5 million in potential milestone payments, comprised of (i) up to $22.5 million in milestone payments upon achievement of specified clinical and development milestone events (such amounts were fully received as of July 2016), (ii) up to $95.0 million in milestone payments upon achievement of specified regulatory milestone events, and (iii) up to approximately $15.0 million in milestone payments upon the achievement of specified commercial sales milestone. The Japan Agreement also provides for tiered payments based on net sales of product (as defined) in the low 20% range after commercial launch. The aggregate amount of consideration received through March 31, 2020 totals $90.1 million.

Europe Agreement

In April 2006, the Company entered into a separate collaboration agreement with Astellas for the development and commercialization of roxadustat for the treatment of anemia in Europe, the Middle East, the Commonwealth of Independent States and South Africa ("Europe Agreement"). Under the terms of the Europe Agreement, Astellas paid license fees and other upfront consideration totaling $320.0 million (such amounts were fully received as of February 2009). The Europe Agreement also provides for additional development and regulatory approval milestone payments up to $425.0 million, comprised of (i) up to $90.0 million in milestone payments upon achievement of specified clinical and development milestone events (such amounts were fully received as of 2012), (ii) up to $335.0 million in milestone payments upon achievement of specified regulatory milestone events. Under the Europe Agreement, Astellas committed to fund 50% of joint development costs for Europe and North America, and all territory-specific costs. The Europe Agreement also provides for tiered payments based on net sales of product (as defined) in the low 20% range. The aggregate amount of consideration received through March 31, 2020 totals $410.0 million.

During the second quarter of 2019, the Company received positive topline results from analyses of pooled major adverse cardiac event ("MACE") and MACE+ data from its Phase 3 trials evaluating roxadustat as a treatment for dialysis and non-dialysis CKD patients, enabling Astellas to prepare for an MAA submission to the EMA, following the Company's NDA submission to the FDA. These milestones became probable of being achieved in the second quarter of 2019, and the total consideration of $130.0 million associated with these milestones was included in the transaction price and allocated to performance obligations under the Europe Agreement in the second quarter of 2019, of which $128.8 million was recognized as revenue during 2019, and $0.3 million was recognized as revenue during the three months ended March 31, 2020, from performance obligations satisfied or partially satisfied. According to the Europe Agreement, these milestone payments are not billable to Astellas until the submission of an MAA, which is expected in the second quarter of 2020. Therefore this $130.0 million remained as an unbilled contract asset as of March 31, 2020.

AstraZeneca Agreements

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

Effective July 30, 2013, the Company entered into a collaboration agreement with AstraZeneca AB ("AstraZeneca") for the development and commercialization of roxadustat for the treatment of anemia in the U.S. and all other countries in the world, other than China, not previously licensed under the Astellas Europe and Astellas Japan Agreements ("U.S./RoW Agreement"). It also excludes China, which is covered by a separate agreement with AstraZeneca described below. Under the terms of the U.S./RoW Agreement, AstraZeneca paid upfront, non-contingent, non-refundable and time-based payments totaling $374.0 million (such amounts were fully received as of June 2016). Under the U.S./RoW Agreement, the Company is also eligible to receive from AstraZeneca an aggregate of approximately $875.0 million in potential milestone payments, comprised of (i) up to $65.0 million in milestone payments upon achievement of specified clinical and development milestone events, $15.0 million of which was received in 2015 as a result of the finalization of its two audited pre-clinical carcinogenicity study reports, and the remaining $50.0 million was received in April 2020 as a result of the NDA submission milestone, (ii) up to $325.0 million in milestone payments upon achievement of specified regulatory milestone events, (iii) up to $160.0 million in milestone payments related to activity by potential competitors and (iv) up to approximately $325.0 million in milestone payments upon the achievement of specified commercial sales events. The aggregate amount of consideration received through March 31, 2020 totals $389.0 million.

As mentioned above, during the second quarter of 2019, the Company received positive topline results from analyses of pooled MACE and MACE+ data from its Phase 3 trials for roxadustat, enabling the Company's NDA submission to the FDA. The regulatory milestone payment associated with this NDA submission became probable of being achieved in the second quarter of 2019. Accordingly, the consideration of $50.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the U.S./ RoW Agreement in the second quarter of 2019, of which $42.4 million was recognized as revenue during 2019, and $0.2 million was recognized as revenue during the three months ended March 31, 2020, from performance obligations satisfied or partially satisfied. The Company submitted such NDA in December 2019, which was accepted by the FDA for review in February 2020. According to the U.S/RoW Agreement, this milestone payment is billable to AstraZeneca when the NDA is accepted by the FDA. Therefore this $50.0 million was billed during the first quarter of 2020, the payment of which was fully received in April 2020.

China Agreement

Effective July 30, 2013, the Company (through its subsidiaries affiliated with China) entered into a collaboration agreement with AstraZeneca for the development and commercialization (but not manufacture) of roxadustat for the treatment of anemia in China ("China Agreement"). Under the terms of the China Agreement, AstraZeneca agreed to pay upfront consideration totaling $28.2 million (such amounts were fully received in 2014). Under the China Agreement, the Company is also eligible to receive from AstraZeneca an aggregate of approximately $348.5 million in potential milestone payments, comprised of (i) up to $15.0 million in milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $146.0 million in milestone payments upon achievement of specified regulatory milestone events, and (iii) up to approximately $187.5 million in milestone payments upon the achievement of specified commercial sales and other events. The China Agreement is structured as a 50/50 profit or loss share (as defined) and provides for joint development costs (including capital and equipment costs for construction of the manufacturing plant in China), to be shared equally during the development. The aggregate amount of such consideration received through March 31, 2020 totals $77.2 million.

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

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

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 March 31,	
Agreement	**Performance Obligation**	**2020**	**2019**
Japan	License revenue	$ —	$ —
	Development revenue	$ 163	$ 246

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 March 31, 2020**	**Deferred Revenue at March 31, 2020**	**Total Consideration Through March 31, 2020**
License	$ 86,024	$ —	$ 86,024
Development revenue	15,293	269	15,562
Total license and development revenue	$ 101,317	$ 269	$ 101,586

The revenue recognized under the Japan Agreement for the three months ended March 31, 2020 included an increase in revenue of $0.1 million resulting from changes to estimated variable consideration in the current period relating to performance obligations satisfied or partially satisfied in previous periods. The remainder of the transaction price related to the Japan Agreement includes no further variable consideration from estimated future co-development billing.

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

Agreement	Performance Obligation	Three Months Ended March 31, 2020	2019
Europe	License revenue	$ —	$ —
	Development revenue	$ 4,574	$ 4,613

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 March 31, 2020	Deferred Revenue at March 31, 2020		Total Consideration Through March 31, 2020
License	$ 487,951	$ —		$ 487,951
Development revenue	235,582	3,442		239,024
Total license and development revenue	$ 723,533	$ 3,442	*	$ 726,975

* Contract assets and liabilities related to rights and obligations in the same contract are recorded net on the condensed consolidated balance sheets. As of March 31, 2020, prepaid expenses and other current assets included a net unbilled contract asset of $126.6 million related to the Europe Agreement, which represents the net of the above-mentioned unbilled contract asset of $130.0 million, and $3.4 million of deferred revenue presented above.

The revenue recognized under the Europe Agreement for the three months ended March 31, 2020 included an increase in revenue of $0.9 million resulting from changes to estimated variable consideration in the current period relating to performance obligations satisfied or partially satisfied in previous periods. The remainder of the transaction price related to the Europe Agreement includes $38.2 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):

Agreement	Performance Obligation	Three Months Ended March 31, 2020	2019
U.S. / RoW and China	License revenue	$ —	$ —
	Development revenue	14,556	19,004
	China performance obligation	$ 153	$ —

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 March 31, 2020	Deferred Revenue at March 31, 2020	Total Consideration Through March 31, 2020
License	$ 341,844	$ —	$ 341,844
Co-development, information sharing & committee services	507,822	6,323	514,145
China performance obligation	243	141,079	141,322
Total license and development revenue	$ 849,909	$ 147,402	$ 997,311

The revenue recognized under the U.S./RoW Agreement for the three months ended March 31, 2020 included an insignificant decrease in revenue resulting from changes to estimated variable consideration in the current period relating to performance obligations satisfied or partially satisfied in previous periods. The remainder of the transaction price related to the U.S./RoW Agreement and China Agreement includes $115.3 million of variable consideration from estimated future co-development billing and is expected to be recognized over the remaining development service period, except for amounts allocated to the China performance obligation, which are expected to be recognized in a pattern consistent with estimated deliveries of the commercial drug product.

Product Revenue, Net

The Company started commercial sales of roxadustat drug product in China in the third quarter of 2019. Drug product revenue is recognized in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those products, net of price adjustment, contractual sales rebate and other discounts. Product revenue, net was as follows (in thousands):

	Three Months Ended March 31, 2020
Gross revenue	$ 5,372
Contractual sales rebate	(376)
Key account hospital sales rebate	(27)
Transfer fee discount	(14)
Product revenue, net	$ 4,955

For the three months ended March 31, 2020, the contractual sales rebate was $0.4 million, which was calculated based on the stated percentage of gross sales by each distributor in the distribution agreement entered between FibroGen and each distributor. All other rebates including sales return allowance were immaterial for the period.

The following table is a roll-forward of accounts receivable allowances related to product revenue:

	Balance at December 31, 2019	Current Period Additions	Credits / Payments	Balance at March 31, 2020
Price adjustment	$ 936	$ —	$ —	$ 936
Contractual sales rebate	148	376	—	524
Key account hospital sales rebate	12	27	—	39
Transfer fee discount	6	14	—	20
Total	$ 1,102	$ 417	$ —	$ 1,519

The above contractual allowances are recorded as reductions of the gross accounts receivable from the distributor in the same period that the related revenue is recorded, and applied to future sales orders made by the distributor under the Company's discretion.

Other Revenues

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

Deferred Revenue

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

Deferred revenue includes amounts allocated to the China unit of accounting under the AstraZeneca arrangement as revenue recognition associated with this unit of accounting is tied to the commercial launch of the products within China. As of March 31, 2020, approximately $1.7 million of the related deferred revenue was included in short-term deferred revenue, which represents the amount of deferred revenue associated with the China unit of accounting that is expected to be recognized within the next 12 months, as a result of the transfer of control of commercial drug product in China.

3. Fair Value Measurements

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

	March 31, 2020			
	Level 1	Level 2	Level 3	Total
U.S. treasury notes and bills	$ 303,265	$ 80,489	$ —	$ 383,754
Equity investments	223	—	—	223
Money market funds	72,148	—	—	72,148
Certificate of deposit	—	30,115	—	30,115
Total	$ 375,636	$ 110,604	$ —	$ 486,240

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

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

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

	March 31, 2020			
	Level 1	Level 2	Level 3	Total
Lease obligations	$ —	$ —	$ 1,443	$ 1,443

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

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

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

4. Leases

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

	Balance Sheet Line Item	March 31, 2020	December 31, 2019
Assets			
Finance:			
Right-of-use assets - cost		$ 49,918	$ 49,909
Accumulated amortization		(12,901)	(10,307)
Finance lease right-of-use assets, net	Finance lease right-of-use assets	37,017	39,602
Operating:			
Right-of-use assets - cost		2,736	2,736
Accumulated amortization		(1,078)	(805)
Operating lease right-of-use assets, net	Other assets	1,658	1,931
Total lease assets		$ 38,675	$ 41,533
Liabilities			
Current:			
Finance lease liabilities	Finance lease liabilities, current	$ 12,396	$ 12,351
Operating lease liabilities	Accrued and other current liabilities	900	983
Non-current:			
Finance lease liabilities	Finance lease liabilities, non-current	34,545	37,610
Operating lease liabilities	Other long-term liabilities	678	942
Total lease liabilities		$ 48,519	$ 51,886

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

	Statement of Operations Line Item	Three Months Ended March 31, 2020	2019
Finance lease cost:			
Amortization of right-of-use assets	Cost of goods sold; Research and development; Selling, general and administrative expenses	$ 2,594	$ 2,569
Interest on lease liabilities	Interest expense	515	640
Operating lease cost	Cost of goods sold; Research and development; Selling, general and administrative expenses	309	126
Sublease income	Selling, general and administrative expenses	(292)	(588)
Total lease cost		$ 3,126	$ 2,747

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

	Three Months Ended March 31,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 149	$ 99
Operating cash flows from finance leases	517	435
Financing cash flows from finance leases	2,814	3,017
Right-of-use assets obtained in exchange for new lease liabilities:		
Finance leases	9	49,598
Operating leases	$ —	$ 730

Lease term and discount rate were as follows:

	March 31, 2020	December 31, 2019
Weighted-average remaining lease term (years):		
Finance leases	3.4	3.6
Operating leases	1.9	2.1
Weighted-average discount rate:		
Finance leases	4.42%	4.42%
Operating leases	4.75%	4.75%

Maturities of lease liabilities as of March 31, 2020 are as follows (in thousands):

Year Ending	Finance Leases	Operating Leases
2020 (Remaining nine month period)	$ 10,535	$ 689
2021	13,680	657
2022	13,883	302
2023	12,523	—
Total future lease payments	50,621	1,648
Less: Interest	(3,680)	(70)
Present value of lease liabilities	$ 46,941	$ 1,578

5. Balance Sheet Components

Cash and Cash Equivalents

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

	March 31, 2020	December 31, 2019
Cash	$ 49,412	$ 40,715
Money market funds	72,148	85,551
Total cash and cash equivalents	$ 121,560	$ 126,266

At March 31, 2020 and December 31, 2019, a total of $29.8 million and $11.9 million, respectively, of the Company’s cash and cash equivalents were held outside of the U.S. in its foreign subsidiaries to be used primarily for its China operations.

Investments

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

	March 31, 2020			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
U.S. treasury notes and bills	$ 381,238	$ 2,516	$ —	$ 383,754
Certificates of deposit	30,000	115	—	30,115
Equity investments	125	98	—	223
Total investments	$ 411,363	$ 2,729	$ —	$ 414,092

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

At March 31, 2020, all of the available-for-sale investments had contractual maturities within one year. During the three months ended March 31, 2020, the Company did not recognize any other-than-temporary impairment loss.

Inventories

Inventories consisted of the following (in thousands):

	March 31, 2020	December 31, 2019
Raw materials	$ 459	$ 325
Work-in-progress	2,948	2,264
Finished goods	5,001	4,298
Total inventories	$ 8,408	$ 6,887

The provision to write-down excess and obsolete inventory was nominal for the three months ended March 31, 2020.

Prepaid expenses and other current assets

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

	March 31, 2020	December 31, 2019
Unbilled contract assets	$ 130,000	$ 180,000
Deferred revenues from associated contracts	(3,442)	(54,790)
Net unbilled contract assets	126,558	125,210
Prepaid assets	5,267	6,464
Other current assets	2,203	1,717
Total prepaid expenses and other current assets	$ 134,028	$ 133,391

The unbilled contract assets as of March 31, 2020 were related to two regulatory milestones totaling $130.0 million under the Europe Agreement with Astellas associated with the planned MAA submission in Europe. The unbilled contract assets as of December 31, 2019 also included a $50.0 million regulatory milestone under the U.S./RoW Agreement with AstraZeneca associated with the NDA submission in the U.S, which was submitted in December 2019 and accepted for review in February 2020. Therefore, the $50.0 million milestone was billed during the first quarter of 2020, and recorded as accounts receivable as of March 31, 2020. See Note 2 for details.

Property and Equipment

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

	March 31, 2020	December 31, 2019
Leasehold improvements	$ 101,721	$ 101,548
Laboratory equipment	17,359	17,329
Machinery	8,229	8,217
Computer equipment	8,879	8,399
Furniture and fixtures	5,883	5,822
Construction in progress	1,212	1,792
Total property and equipment	$ 143,283	$ 143,107
Less: accumulated depreciation	(103,225)	(100,364)
Property and equipment, net	$ 40,058	$ 42,743

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2020	December 31, 2019
Preclinical and clinical trial accruals	$ 16,704	$ 16,279
API product price adjustment	—	36,324
Payroll and related accruals	11,899	19,784
Property taxes and other	4,033	2,044
Professional services	4,608	4,842
Other	5,065	4,543
Total accrued liabilities	$ 42,309	$ 83,816

The amount of $36.3 million accrued as of December 31, 2019 was related to the change in estimated variable consideration of active pharmaceutical ingredient (“API”) product at the time the roxadustat listed price was issued by the Japanese Ministry of Health, Labour and Welfare. The amount was fully paid during the first quarter of 2020.

Other Long-term Liabilities

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

	March 31, 2020	December 31, 2019
Accrued long-term co-promotional expenses	$ 78,301	$ 53,071
Other long-term tax liabilities	8,786	8,913
Operating lease liabilities, non-current	678	942
Other	1,357	1,340
Total other long-term liabilities	$ 89,122	$ 64,266

The accrued long-term co-promotional expenses of $78.3 million and $53.1 million as of March 31, 2020 and December 31, 2019, respectively, were related to the estimated amount payable to AstraZeneca for its sales and marketing efforts related to the commercial launch for roxadustat in China. The payment for such amount is not expected to occur within the next year.

6. Stock-Based Compensation

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

	Three Months Ended March 31,	
	2020	2019
Research and development	$ 10,637	$ 9,578
Selling, general and administrative	6,279	6,852
Total stock-based compensation expense	$ 16,916	$ 16,430

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 March 31,	
	2020	2019
Stock Options		
Expected term (in years)	5.7	5.3
Expected volatility	68.3 %	67.9 %
Risk-free interest rate	0.9 %	2.6 %
Expected dividend yield	—	—
Weighted average estimated fair value	$ 17.24	$ 34.14
ESPPs		
Expected term (in years)	0.5 - 2.0	0.5 - 2.0
Expected volatility	49.5 - 57.7 %	48.1 - 62.1 %
Risk-free interest rate	1.5 - 2.9 %	1.3 - 2.9 %
Expected dividend yield	—	—
Weighted average estimated fair value	$ 18.57	$ 20.57

7. Income Taxes

The benefits from income taxes for the three months ended March 31, 2020 and 2019 were primarily due to the tax effect arising from other comprehensive income related to available-for-sale securities, partially offset by foreign taxes.

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

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

8. Related Party Transactions

Astellas is an equity investor in the Company and considered a related party. The Company recorded revenue related to collaboration agreements with Astellas of $4.7 million and $4.9 million for the three months ended March 31, 2020 and 2019, respectively.

The Company recorded expense related to collaboration agreements with Astellas of $0.1 million and $0.5 million during the three months ended March 31, 2020 and 2019, respectively.

As of March 31, 2020 and December 31, 2019, accounts receivable from Astellas were $3.7 million and $4.8 million, respectively, and amounts due to Astellas were $0.1 million and $36.9 million, respectively. The amounts due to Astellas as of December 31, 2019 included $36.3 million of a change in estimated variable consideration related to the API product revenue recognized in 2018, at the time the roxadustat listed price was issued by the Japanese Ministry of Health, Labour and Welfare. Such amount was fully paid during the first quarter of 2020.

Prepaid expenses and other current assets as of March 31, 2020 and December 31, 2019 included $126.6 and $125.2 million of net unbilled contract assets, respectively, representing a $130.0 million unbilled contract asset related to two regulatory milestones under the Europe Agreement with Astellas associated with the planned MAA submission to the EMA, net of $3.4 million and $4.8 million of associated deferred revenue. See Note 2 for details. According to the Europe Agreement, this $130.0 million is not billable to Astellas until the submission of an MAA, therefore the net contract asset was included in the prepaid expenses and other current assets line on the Company's consolidated balance sheet.

9. Commitments and Contingencies

Contract Obligations

As of March 31, 2020, the Company had outstanding total non-cancelable contract obligations of $23.5 million, including $11.9 million for manufacture and supply of roxadustat, $11.0 million for future milestone payments for research and pre-clinical stage development programs, and $0.6 million for other purchases. The Company expects to fulfill our commitments under these agreements in the normal course of business, and as such, no liability has been recorded.

Legal Proceedings

The Company is a party to various legal actions that arose in the ordinary course of its business. The Company did not have any material accruals for any currently active legal action in its consolidated balance sheets as of March 31, 2020, as it could not predict the ultimate outcome of these matters, or reasonably estimate the potential exposure.

Indemnification Agreements

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

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

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

FORWARD-LOOKING STATEMENTS

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

BUSINESS OVERVIEW

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

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

Our U.S. NDA filing for roxadustat for the treatment of anemia in dialysis and non-dialysis CKD patients was accepted by the U.S. Food and Drug Administration ("FDA") in February 2020. In Europe, the Marketing Authorization Application ("MAA") filing with the European Medicines Agency ("EMA") is expected in the second quarter of 2020 for CKD in both dialysis and non-dialysis.

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

Pamrevlumab, an anti-CTGF human monoclonal antibody, is in Phase 3 clinical development for the treatment of both idiopathic pulmonary fibrosis ("IPF") and pancreatic cancer. Pamrevlumab is also currently in a Phase 2 trial for Duchenne muscular dystrophy ("DMD").

Impact of COVID-19

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

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

The financial results for the three months ended March 31, 2020 were not significantly impacted by COVID-19 relative to prior quarters. However, we will continue to monitor, and to the extent possible, mitigate the impact of the COVID-19 pandemic on our business.

Financial Highlights

	Three Months Ended March 31,	
	2020	2019
	(in thousands, except for per share data)	
Result of Operations		
Revenue	$ 24,401	$ 23,863
Operating costs and expenses	$ 105,475	$ 72,706
Net loss	$ (78,348)	$ (45,411)
Net loss per share - basic and diluted	$ (0.89)	$ (0.53)

	March 31, 2020	December 31, 2019
	(in thousands)	
Balance Sheet		
Cash and cash equivalents	$ 121,560	$ 126,266
Short-term and long-term investments	$ 414,092	$ 468,609
Accounts receivable	$ 58,540	$ 28,455

Our revenue for the three months ended March 31, 2020 included the revenue recognized related to the following:

- $19.4 million of development revenue recognized under our collaboration agreements with our partners Astellas and AstraZeneca AB (“AstraZeneca”); and
- $5.0 million net product revenue from commercial sales of roxadustat drug product in China.

As comparison, our revenue for the three months ended March 31, 2019 was solely from development revenue recognized under our collaboration agreements with Astellas and AstraZeneca.

Operating costs and expenses for the three months ended March 31, 2020 increased compared to the same period a year ago primarily due to the following:

- Higher outside service expenses associated with co-promotional activities expenses with AstraZeneca sales and marketing efforts in China related to the commercial launch of roxadustat;
- Higher drug development expenses associated with higher drug substance manufacturing activities related to pamrevlumab, and higher drug substance manufacturing activities related to roxadustat in its global program; and
- Higher clinical trial expenses associated with commencement of Phase 3 trials for pamrevlumab, offset by lower activities due to substantial completion of Phase 3 trials for roxadustat.

During the three months ended March 31, 2020, we had a net loss of $78.3 million, or net loss per basic and diluted share of $0.89, as compared to a net loss of $45.4 million for the same period a year ago, primarily due to an increase in operating costs and expenses.

Cash and cash equivalents, investments and accounts receivable totaled $594.2 million at March 31, 2020, a decrease of $29.1 million from December 31, 2019, primarily due to the cash used in operations.

Commercial and Development Programs

Roxadustat for the Treatment of Anemia in Chronic Kidney Disease

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

We continue our commercial launch efforts for roxadustat (tradename: 爱瑞卓®) in China after receiving marketing authorization for the treatment of anemia caused by CKD in non-dialysis and dialysis patients. The Chinese government is rapidly implementing the 2019 National Reimbursement Drug List ("NRDL"), to which roxadustat was added effective January 1, 2020. While there was some impact to sales in China during the first quarter due to COVID-19, particularly in February and March, we do not know if, or to what extent, these effects will continue going forward. Now that China has largely re-opened, we and our partner AstraZeneca continue our strong focus on hospital listing efforts for roxadustat.

In Japan, our partner Astellas continues the commercial launch of Evrenzo® (roxadustat), which was approved for the treatment of anemia associated with CKD in dialysis patients. In January 2020, Astellas submitted a supplemental NDA in Japan for the treatment of anemia in CKD patients not on dialysis.

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

Our NDA filing for roxadustat for the treatment of anemia in dialysis and non-dialysis CKD patients was accepted by the FDA in February 2020. The FDA set a Prescription Drug User Fee Act goal date of December 20, 2020.

The planned MAA filing with the EMA for roxadustat in CKD anemia is expected in the second quarter of 2020 for dialysis and non-dialysis patients. In addition, in collaboration with AstraZeneca, applications for marketing authorization of roxadustat in CKD anemia have been submitted for Canada, Australia, Mexico, Brazil, Chile, Taiwan, South Korea, Philippines, Singapore and India.

During the first quarter of 2020, we presented two roxadustat posters at the annual National Kidney Foundation Spring Clinical meeting. These posters showed that, in our Phase 3 non-dialysis trials in CKD anemia, roxadustat corrected and maintained hemoglobin using similar doses regardless of iron status at baseline. Roxadustat also reduced the risk of red blood cell transfusions and IV iron rescue compared to placebo regardless of iron status at baseline. In addition, we presented data from our Phase 3 dialysis trials in CKD anemia, showing roxadustat reduced the risk of red blood cell transfusion as compared with epoetin alfa.

Roxadustat for the Treatment of Chemotherapy-Induced Anemia

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

Roxadustat for the Treatment of Anemia in Myelodysplastic Syndromes

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

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

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

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

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

Idiopathic Pulmonary Fibrosis

We are conducting ZEPHYRUS, our Phase 3 trial of pamrevlumab in IPF patients, and are preparing to initiate ZEPHYRUS-2, a second IPF Phase 3 study. Both studies are double-blind, placebo-controlled Phase 3 trials targeting approximately 340 patients with a primary U.S. efficacy endpoint of change from baseline in forced vital capacity. In order to minimize the risk of exposure to COVID-19 in this vulnerable IPF patient population with compromised lung function, we decided to pause near-term enrollment in the ongoing ZEPHYRUS Phase 3 clinical study. We look forward to re-initiating enrollment in this study and initiating the ZEPHYRUS-2 trial as conditions improve.

Locally Advanced Unresectable Pancreatic Cancer

In 2019, we initiated LAPIS, our double-blind placebo controlled Phase 3 clinical program for pamrevlumab as a neoadjuvant therapy for locally advanced unresectable pancreatic cancer. We intend to enroll approximately 260 patients, randomized at a 1:1 ratio to receive either pamrevlumab or placebo, in each case in combination with gemcitabine and nab-paclitaxel. We are working with clinical trial sites and investigators in order to mitigate risks and other challenges associated with COVID-19 and the restrictions instituted to combat COVID-19.

Duchenne Muscular Dystrophy

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

Collaboration Partnerships for Roxadustat

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

Astellas

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

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

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

Consideration under these agreements includes a total of $360.1 million in upfront and non-contingent payments, and milestone payments totaling $557.5 million, of which $542.5 million are development and regulatory milestones and $15.0 million are commercial-based milestones. Total consideration, excluding development cost reimbursement and product sales-related payments, could reach $917.6 million. The aggregate amount of such consideration received through March 31, 2020 totals $500.1 million. Additionally, under these agreements, Astellas pays 100% of the commercialization costs in its territories. Astellas will pay us a transfer price, based on net sales, in the low 20% range for our manufacture and delivery of roxadustat.

During the second quarter of 2019, we received positive topline results from analyses of pooled major adverse cardiac event (“MACE”) and MACE+ data from its Phase 3 trials evaluating roxadustat as a treatment for dialysis and non-dialysis CKD patients, enabling Astellas to prepare for an MAA submission to the EMA, following our NDA submission to the FDA in 2019. These milestones became probable of being achieved in the second quarter of 2019, and substantially all of the total consideration of $130.0 million associated with these milestones was included in the transaction price and allocated to performance obligations under the Europe Agreement in the second quarter of 2019, of which $128.8 million was recognized as revenue during 2019, and $0.3 million was recognized as revenue during the three months ended March 31, 2020, from performance obligations satisfied or partially satisfied. According to the Europe Agreement, these milestone payments are not billable to Astellas until the submission of an MAA, which is expected in the second quarter of 2020. Therefore this $130.0 million remained as an unbilled contract asset as of March 31, 2020.

In addition, as of March 31, 2020, Astellas had separate investments of $80.5 million in the equity of FibroGen, Inc.

AstraZeneca

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

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

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

Under the AstraZeneca agreements, we will receive upfront and subsequent non-contingent payments totaling $402.2 million. Potential milestone payments under the agreements total $1.2 billion, of which $571.0 million are development and regulatory milestones and $652.5 million are commercial-based milestones. Total consideration under the agreements, excluding development cost reimbursement, transfer price payments, royalties and profit share, could reach $1.6 billion. The aggregate amount of such consideration received through March 31, 2020 totals $466.2 million.

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

Under the China Agreement, which is conducted through FibroGen China Anemia Holdings, Ltd. ("FibroGen China"), the commercial collaboration is structured as a 50/50 profit share. AstraZeneca will conduct commercialization activities in China and fund roxadustat launch costs in China 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. As of March 31, 2020, we accrued $78.3 million of cumulative co-promotional expenses related to the estimated amount payable to AstraZeneca for such sales and marketing efforts. The payment for such amount is not expected to occur within the next year.

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

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

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

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

As mentioned above, during the second quarter of 2019, we received positive topline results from analyses of pooled MACE and MACE+ data from its Phase 3 trials for roxadustat, enabling our NDA submission to the FDA. The regulatory milestone payment associated with this NDA submission became probable of being achieved in the second quarter of 2019. Accordingly, the consideration of $50.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the U.S./ RoW Agreement in the second quarter of 2019, of which $42.4 million was recognized as revenue during 2019, and $0.2 million was recognized as revenue during the three months ended March 31, 2020, from performance obligations satisfied or partially satisfied. The Company submitted such NDA in December 2019, which was accepted by the FDA for review in February 2020. According to the U.S/RoW Agreement, this milestone payment is billable to AstraZeneca when the NDA is accepted by the FDA. Therefore, this $50.0 million milestone was billed during the first quarter of 2020, the payment of which was fully received in April 2020.

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

Additional Information Related to Collaboration Agreements

Total cash consideration received through March 31, 2020 and potential cash consideration, other than development cost reimbursement, transfer price payments, royalties and profit share, pursuant to our existing collaboration agreements are as follows:

	Cash Received Through March 31, 2020	Additional Potential Cash Payments	Total Potential Cash Payments
		(in thousands)	
Astellas--related-party:			
Japan Agreement	$ 90,093	$ 82,500	$ 172,593
Europe Agreement	410,000	335,000	745,000
Total Astellas	500,093	417,500	917,593
AstraZeneca:			
U.S. / RoW Agreement	389,000	860,000	1,249,000
China Agreement	77,200	299,500	376,700
Total AstraZeneca	466,200	1,159,500	1,625,700
Total revenue	$ 966,293	$ 1,577,000	$ 2,543,293

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

RESULTS OF OPERATIONS

Revenue

	Three Months Ended March 31,		Change	
	2020	2019	$	%
	(dollars in thousands)			
Revenue:				
License revenue	$ —	$ —	$ —	— %
Development and other revenue	19,446	23,863	(4,417)	(19) %
Product revenue, net	4,955	—	4,955	100 %
Total revenue	$ 24,401	$ 23,863	$ 538	2 %

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

Under our revenue recognition policy, license revenue includes amounts from upfront, non-refundable license payments and amounts allocated pursuant to the standalone selling price method from other consideration received during the periods. This revenue is generally recognized as deliverables are met and services are performed. We did not have any license revenue for the three months ended March 31, 2020 and 2019.

Development and other revenue includes co-development and other development related services. Co-development services are recognized as revenue in the period in which they are billed to our partners, excluding China. For China co-development services, revenue is deferred until the end of the development period once all performance obligations have been satisfied. Other development related services are recognized as revenue over the non-contingent development period based on a proportional performance method. As of December 31, 2019, the future non-contingent development periods range from 12 to 60 months. Other revenues consist of sales of research and development material and have been included with development and other revenue in the consolidated statements of operations, as they have not been material for any of the periods presented.

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

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

In addition, for the first quarter of 2020, our $5.0 million of net product revenue from roxadustat sales in China was affected by the COVID-19 pandemic and the fact that patient and physician interaction was limited during a significant portion of the quarter, particularly in February and March. However, it is difficult to estimate how much sales were affected by COVID-19 due to the limited history of roxadustat product revenue to compare to.

Total revenue increased $0.5 million, or 2% for the three months ended March 31, 2020 compared to the same period a year ago for the reasons discussed in the sections below.

Development and Other Revenue

	Three Months Ended March 31,		Change	
	2020	2019	$	%
	(dollars in thousands)			
Development revenue:				
Astellas	$ 4,737	$ 4,859	$ (122)	(3)%
AstraZeneca	14,709	19,004	(4,295)	(23)%
Total development revenue	19,446	23,863	(4,417)	(19)%

Development and other revenue decreased $4.4 million, or 19% for the three months ended March 31, 2020 compared to the same period a year ago. Development revenue recognized under our collaboration agreements with AstraZeneca and Astellas decreased $4.3 million, or 23%, and $0.1 million, or 3%, respectively primarily due to decreases in co-development billings related to the development of roxadustat as a result of the substantial completion of Phase 3 trials for roxadustat.

Product Revenue, Net

	Three Months Ended March 31, 2020
	(dollars in thousands)
Gross revenue	$ 5,372
Contractual sales rebate	(376)
Key account hospital sales rebate	(27)
Transfer fee discount	(14)
Product revenue, net	$ 4,955

We started commercial sales of roxadustat drug product in China in the third quarter of 2019. Product revenue is recognized in an amount that reflects the consideration to which we expect to be entitled in exchange for those products, net of contractual sales rebate and other discounts. The gross product revenue for the three months ended March 31, 2020 was $5.4 million. The contractual sales rebate was $0.4 million, which was calculated based on the stated percentage of gross sales by each distributor in the distribution agreement entered between us and each distributor. Key account hospital sales rebate, transfer fee discount and sales return allowance were immaterial for the period.

Operating Costs and Expenses

	Three Months Ended March 31,		Change	
	2020	2019	$	%
	(dollars in thousands)			
Operating costs and expenses				
Cost of goods sold	$ 970	$ —	$ 970	100 %
Research and development	54,902	50,496	4,406	9 %
Selling, general and administrative	49,603	22,210	27,393	123 %
Total operating costs and expenses	$ 105,475	$ 72,706	$ 32,769	45 %

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

Total operating costs and expenses increased $32.8 million, or 45% for the three months ended March 31, 2020, compared to the same periods a year ago, for the reason discussed in the sections below.

Cost of Goods Sold

Cost of goods sold, associated with the commercial sales of roxadustat drug product in China, consists of direct costs to manufacture commercial drug product, as well as indirect costs including factory overhead, storage, shipping, quality assurance, idle capacity charges, and inventory valuation reserve. Cost of goods sold was $1.0 million for the three months ended March 31, 2020, primarily consisted of costs associated with the manufacturing of roxadustat drug product.

Research and Development Expenses

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

The following table summarizes our research and development expenses incurred during the three months ended March 31, 2020 and 2019:

Product Candidate	Phase of Development	Three Months Ended March 31, 2020	2019
		(in thousands)	
Roxadustat	Phase 3	$ 26,038	$ 33,143
Pamrevlumab	Phase 2/3	22,100	12,426
FG-5200	Preclinical	1,035	1,336
Other research and development expenses		5,729	3,591
Total research and development expenses		$ 54,902	$ 50,496

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

Research and development expenses increased $4.4 million, or 9% for the three months ended March 31, 2020, compared to the same period a year ago, as a result of the following:

- Increase of $3.2 million in drug development expenses, primarily due to higher drug substance manufacturing activities related to pamrevlumab, and higher drug substance manufacturing activities related to roxadustat in its global program;
- Increase of $2.4 million in clinical trials costs, primarily due to commencement of Phase 3 trials for pamrevlumab, partially offset by the substantial completion of Phase 3 trials for roxadustat and lower activities related to NDA preparation as it was submitted in December 2019;
- Increase of $2.2 million in facility related expense, primarily due to higher allocated overhead costs and higher depreciation expenses related to China facilities;
- Increase of $1.1 million in stock-based compensation expense, primarily due to the cumulative impact of stock option grant activities;
- Decrease of $2.8 million due to capitalization of inventory manufacturing costs associated with roxadustat production; and
- Decrease of $1.5 million in outside services due to lower consulting expenses and scientific contract work related to roxadustat Phase 3 and submission activities.

Selling, General and Administrative Expenses

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

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

SG&A expenses increased $27.4 million, or 123% for the three months ended March 31, 2020, compared to the same period a year ago, as a result of the following:

- Increase of $26.8 million in outside service expenses, due to the recognition of our share of co-promotional expenses incurred during the current period with AstraZeneca sales and marketing efforts related to the commercial launch of roxadustat in China; and
- Increase of $1.0 million in employee-related costs primarily due to higher headcount in the sales and marketing functions in China and higher compensation levels.

Interest and Other, Net

	Three Months Ended March 31,		Change	
	2020	2019	$	%
	(dollars in thousands)			
Interest and other, net:				
Interest expense	$ (633)	$ (770)	$ 137	(18) %
Interest income and other, net	3,165	4,177	(1,012)	(24) %
Total interest and other, net	$ 2,532	$ 3,407	$ (875)	(26) %

Interest Expense

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

Interest Income and Other, Net

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

Interest income and other, net decreased $1.0 million, or 24% for the three months ended March 31, 2020, compared to the same period a year ago, primarily due to $1.5 million lower interest earned on our cash, cash equivalents and investments associated with the lower average balances, partially offset by $0.9 million higher unrealized foreign currency gain during the current year period.

Benefit from Income Taxes

	Three Months Ended March 31,	
	2020	2019
	(dollars in thousands)	
Loss before income taxes	$ (78,542)	$ (45,436)
Benefit from income taxes	(194)	(25)
Effective tax rate	0.2%	0.1%

The benefits from income taxes for the three months ended March 31, 2020 and 2019 were primarily due to the tax effect arising from other comprehensive income related to available-for-sale securities, partially offset by foreign taxes.

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

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

LIQUIDITY AND CAPITAL RESOURCES

Financial Conditions

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

As of March 31, 2020, we had cash and cash equivalents of $121.6 million. Cash is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting of available-for-sale debt investments, marketable equity investments, and certificate of deposit, and stated at fair value, are also available as a source of liquidity. As of March 31, 2020, we had short-term and long-term investments of $413.9 million and $0.2 million, respectively. As of March 31, 2020, a total of $29.8 million of our cash and cash equivalents was held outside of the U.S. in our foreign subsidiaries to be used primarily for our China operations.

Operating Capital Requirements

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

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

Cash Sources and Uses

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

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (59,486)	$ 22,480
Investing activities	56,009	(26,487)
Financing activities	(1,190)	(3,534)
Effect of exchange rate changes on cash and cash equivalents	(39)	(44)
Net increase (decrease) in cash and cash equivalents	$ (4,706)	$ (7,585)

Operating Activities

Net cash used in operating activities was $59.5 million for the three months ended March 31, 2020 and consisted primarily of net loss of $78.3 million adjusted for non-cash items of $22.1 million, offset by a net decrease in operating assets and liabilities of $3.2 million. The significant non-cash items included stock-based compensation expense of $16.9 million, depreciation expense of $2.9 million and amortization of finance lease ROU of $2.6 million. The significant items in the changes in operating assets and liabilities included the decreases resulting from the following:

- Accrued and other liabilities of $41.2 million, primarily driven by the payment of $36.3 million that was accrued at December 31, 2019, related to the change in estimated variable consideration associated with the roxadustat active pharmaceutical ingredient ("API") delivery; as well as driven by the timing of invoicing and payment;
- Accounts receivable of $30.1 million, primarily related to the billing of a $50.0 million regulatory milestone under the U.S./RoW Agreement with AstraZeneca associated with the FDA acceptance of our NDA submission for review in the U.S., as well as driven by the timing of the receipt of upfront payments and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca;

- Accounts payable of $3.2 million, primarily driven by the timing of invoicing and payment; and
- Inventories of $1.5 million, driven by the increased inventory level related to FibroGen Beijing's productions of roxadustat for commercial sales purposes.

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

- Deferred revenue of $48.0 million, primarily related to the above-mentioned billing of the $50.0 million regulatory milestone. Such milestone was not billable to AstraZeneca as of December 31, 2019 under the U.S./RoW Agreement. As a result, the associated deferred revenues was net by $50.0 million at December 31, 2019. The change in deferred revenue was also driven by the recognition of revenues under our collaboration agreements with Astellas and AstraZeneca; and
- Other long-term liabilities of $24.9 million, primarily due to the additional accrual of co-promotional expenses with AstraZeneca for sales and marketing efforts related to the commercial launch of roxadustat in China that are not expected to be paid in the next year.

Net cash provided by operating activities was $22.5 million for the three months ended March 31, 2019 and consisted primarily of net loss of $45.4 million adjusted for non-cash items of $20.2 million and a net increase in operating assets and liabilities of $47.7 million. The significant non-cash items included stock-based compensation expense of $16.4 million, depreciation expense of $2.7 million, amortization of finance lease ROU of $2.6 million, and net amortization of premium and discount on investments of $1.4 million. The significant items in the changes in operating assets and liabilities included an increase resulting from the following:

- Accounts receivable of $57.7 million, primarily related to the collection of $43.9 million from Astellas for the roxadustat API delivery in December 2018 under the Japan Amendment, as well as the timing of the receipt of upfront payments and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca.

The increase was partially offset by decreases resulting from the following:

- Accounts payable of $5.4 million, primarily driven by the timing of invoicing and payments;
- Prepaid expenses and other current assets of $2.8 million, primarily driven by the timing of invoicing and payments; and
- Deferred revenue of $2.6 million, related to the recognition of revenues under our collaboration agreements with Astellas and AstraZeneca.

Investing Activities

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

Net cash provided by investing activities was $56.0 million for the three months ended March 31, 2020 and consisted primarily of $45.9 million of proceeds from maturities of investments, and $10.6 million of proceeds from sales of available-for-sale securities.

Net cash used in investing activities was $26.5 million for the three months ended March 31, 2019 and consisted primarily of $76.0 million of cash used in purchases of available-for-sale securities, partially offset by $50.0 million of proceeds from maturities of investments.

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 used in financing activities was $1.2 million for the three months ended March 31, 2020 and consisted primarily of $5.3 million of cash paid for payroll taxes on restricted stock unit releases and $2.8 million of repayments of finance lease liabilities, partially offset by $7.0 million of proceeds from the issuance of common stock upon exercise of stock options.

Net cash provided by financing activities was $3.5 million for the three months ended March 31, 2019 and consisted primarily of $6.0 million of cash paid for payroll taxes on restricted stock unit releases and $3.0 million of repayments of finance lease liabilities partially offset by $5.6 million of proceeds from the issuance of common stock upon exercise of stock options.

Off-Balance Sheet Arrangements

During the three months ended March 31, 2020, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements.

Contractual Obligations and Commitments

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

As of March 31, 2020, the Company had outstanding total non-cancelable contract obligations of $23.5 million, including $11.9 million for manufacture and supply of roxadustat (including $10.7 million for the above-mentioned agreement), $11.0 million for future milestone payments for research and pre-clinical stage development programs, and $0.6 million for other purchases. We expect to fulfill our commitments under these agreements in the normal course of business, and as such, no liability has been recorded.

Recently Issued and Adopted Accounting Guidance

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

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

Recently Issued Accounting Guidance Not Yet Adopted

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

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

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

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

Based on management's evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of March 31, 2020 at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended March 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

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

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

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

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

Risks Related to Our Financial Condition and History of Operating Losses

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

We are a biopharmaceutical company with two lead product candidates in clinical development, roxadustat in anemia in chronic kidney disease ("CKD"), myelodysplastic syndromes ("MDS"), and chemotherapy-induced anemia, and pamrevlumab in idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer, and Duchenne muscular dystrophy ("DMD"). Most of our revenue generated to date has been based on our collaboration agreements and we have limited commercial drug product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. Our net loss for the year ended December 31, 2019, 2018 and 2017 were $77.0 million, $86.4 million and $120.9 million, respectively. As of March 31, 2020, we had an accumulated deficit of $863.1 million. As of March 31, 2020, we had capital resources consisting of cash, cash equivalents and short-term investments of $535.4 million plus $0.2 million of long-term investments classified as available for sale securities. Despite contractual development and cost coverage commitments from our collaboration partners, AstraZeneca AB ("AstraZeneca") and Astellas Pharma Inc. ("Astellas"), and the potential to receive milestone and other payments from these partners, and despite commercialization efforts in the People's Republic of China ("China") and Japan for roxadustat for the treatment of anemia caused by CKD, we anticipate we will continue to incur losses on an annual basis for the foreseeable future. If we do not successfully develop and continue to obtain regulatory approval for our existing or any future product candidates and effectively manufacture, market and sell the product candidates that are approved, we may never achieve or sustain profitability on a quarterly or annual basis. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

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

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

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

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

Risks Related to the Development and Commercialization of Our Product Candidates

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

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

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

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

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

- the timely initiation and completion of our clinical trials, including for the duration of the COVID-19 pandemic, which could cause delays in our clinical trial initiation and patient enrollment and completion;
- our ability to demonstrate the safety and efficacy of our product candidates to the satisfaction of the relevant regulatory authorities;
- the ultimate approval criteria (which may include non-inferiority margins and statistical analyses methods), indications, patient populations, and ultimate benefit-risk analysis used by regulatory authorities in their approval processes;
- whether we are required by the United States ("U.S.") Food and Drug Administration ("FDA") or other regulatory authorities to conduct additional clinical trials, and the scope and nature of such clinical trials, prior to approval to market our products;
- the clinical indications for which the product is approved and the labeling required by regulatory authorities for use with the product, including any warnings that may be required in the labeling;
- the receipt or timely receipt of marketing approvals from the FDA and foreign regulatory authorities, including pricing and reimbursement determinations;
- the ability to successfully commercialize, market, sell and distribute our product candidates, if approved, for marketing and sale by the FDA or foreign regulatory authorities, whether alone or in collaboration with others;
- whether we or our partners are able to recruit and retain adequate numbers of effective sales and marketing personnel for the sale of our products;
- whether we will maintain sufficient funding to cover the costs and expenses associated with creating and sustaining a capable sales and marketing organization and related commercial infrastructure;

- whether we can compete successfully as a new entrant in the treatment of anemia caused by CKD;
- our ability and the ability of our third-party manufacturing partners to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability;
- our success in educating health care providers, patients and the healthcare community about the benefits, risks, administration and use of our product candidates, if approved;
- acceptance of our product candidates, if approved, as safe and effective by patients and the healthcare community;
- the success of efforts to enter into relationships with large dialysis organizations involving the administration of roxadustat to dialysis patients;
- the achievement and maintenance of compliance with all regulatory requirements applicable to us and our product candidates;
- the maintenance of an acceptable benefit/risk profile of our products following any approval;
- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competitive treatments;
- the restrictions on the use of our products together with other medications, if any;
- our ability to negotiate, obtain and sustain an adequate level of pricing or reimbursement for our products by third-party payors;
- the availability of adequate coverage and reimbursement or pricing by third-party payors and government authorities;
- our ability to enforce successfully our intellectual property rights for our product candidates and against the products of potential competitors;
- our ability to avoid or succeed in third-party patent interference or patent infringement claims; and
- sufficient stability data for launch and market supply.

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

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

We do not have a sales or marketing infrastructure and have 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.

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

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

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

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

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

- our failure to adequately demonstrate to the satisfaction of regulatory authorities that roxadustat is safe and effective in treating anemia in CKD or that pamrevlumab is safe and effective in treating IPF, pancreatic cancer or DMD;
- our failure to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- our failure of clinical trials to meet the level of statistical significance required for approval;
- the determination by regulatory authorities that additional clinical trials are necessary to demonstrate the safety and efficacy of roxadustat or pamrevlumab, or that ongoing clinical trials need to be modified in design, size, conduct or implementation;
- our product candidates may exhibit an unacceptable safety signal as they advance through clinical trials, in particular controlled Phase 3 trials;

- the clinical research organizations ("CROs") that conduct clinical trials on our behalf may take actions outside of our control that materially adversely impact our clinical trials;
- we or third-party contractors manufacturing our product candidates may not maintain current good manufacturing practices ("cGMP"), successfully pass inspection or meet other applicable manufacturing regulatory requirements;
- regulatory authorities may not agree with our interpretation of the data from our preclinical trials and clinical trials; or
- collaboration partners may not perform or complete their clinical programs in a timely manner, or at all.

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

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

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

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

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

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

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

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

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

- severity of the disease under investigation;
- availability of alternative treatments;
- size and nature of the patient population;
- eligibility criteria for and design of the study in question;
- perceived risks and benefits of the product candidate under study;

- ability to enroll patients in clinical trials during the COVID-19 pandemic;
- ongoing clinical trials of competitive agents;
- physicians' and patients' perceptions of the potential advantages of our product candidates being studied in relation to available therapies or other products under development;
- our CRO's and our trial sites' efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients and collect patient data adequately during and after treatment.

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

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

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

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

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

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

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

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

If we or third-party manufacturers and other service providers on which we rely cannot manufacture sufficient quantities of our products and product candidates, or at sufficient quality, or perform other services we require, we may experience delays in development, regulatory approval, launch or successful commercialization.*

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

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

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

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

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

- costs and challenges associated with scale-up and attaining sufficient manufacturing yields, in particular for biologic products such as pamrevlumab, which is a monoclonal antibody;
- contracting with additional suppliers and validation/qualification of additional facilities to meet growing demand;
- supply chain issues, including coordination of multiple contractors in our supply chain and securing necessary licenses (such as export licenses);
- the timely availability and shelf life requirements of raw materials and supplies;
- equipment maintenance issues or failure;
- quality control and quality assurance issues;

- shortages of qualified personnel and capital required to manufacture large quantities of product;
- compliance with regulatory requirements that vary in each country where a product might be sold;
- capacity or forecasting limitations and scheduling availability in contracted facilities; and
- natural disasters, such as pandemics, including the COVID-19 pandemic, floods, storms, earthquakes, tsunamis, and droughts, or accidents such as fire, that affect facilities, possibly limit or postpone production, and increase costs.

The FDA and European Medicines Agency ("EMA") will do their own benefit risk analysis and may reach a different conclusion than we or our partners have internally, and these regulatory authorities may base their approval decision on different analyses, data, and statistical methods than ours.

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

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

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

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

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

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

We may also face competition from potential new anemia therapies currently in clinical development, including in those patient segments not currently addressed by ESAs. Companies that are currently developing hypoxia-inducible factor ("HIF") prolyl hydroxylase ("HIF-PH") inhibitors for anemia in CKD indications include GlaxoSmithKline plc ("GSK"), Bayer Corporation ("Bayer"), Akebia Therapeutics, Inc. ("Akebia"), Japan Tobacco, and Zydus Cadila. Akebia is currently conducting Phase 3 studies in CKD patients on dialysis and not on dialysis, as well as a Phase 2 study evaluating pharmacokinetics and pharmacodynamics in dialysis patients with three-times weekly versus once-a-day dosing. Akebia expects to complete these studies by August 2020. In Japan, Mitsubishi Tanabe Pharmaceutical Corporation, Akebia's collaboration partner, submitted an NDA for treatment of anemia in dialysis and non-dialysis CKD patients in July 2019, and is awaiting an approval decision later in 2020. GSK is also conducting global Phase 3 studies in CKD patients on dialysis and not on dialysis, and expects to complete those studies by March 2022. GSK and Kyowa Hakko Kirin announced in November 2018 that the two companies signed a strategic commercialization deal in Japan for daprodustat. GSK submitted a Japan NDA for treatment of anemia in dialysis and non-dialysis in August 2019 and is awaiting approval later in 2020. Bayer has completed global Phase 2 studies and its HIF-PH inhibitor is now in Phase 3 development in CKD populations on dialysis and not on dialysis in Japan. Japan Tobacco submitted an NDA for treatment of anemia associated with CKD in Japan in November 2019, supported by the six Phase 3 studies conducted in CKD patients on dialysis and not on dialysis in Japan, and its partner JW Pharmaceuticals started a Phase 3 study in dialysis patients in Korea in 2019. Zydus Cadila (India) started Phase 3 studies in dialysis and non-dialysis CKD patients in India in 2019.

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

In China, locally manufactured epoetin alfa are offered by Chinese pharmaceutical companies such as EPIAO marketed by 3SBio Inc. as well as more than 15 other local manufacturers. We may also face competition by HIF-PH inhibitors from other companies such as Akebia, Bayer, and GSK, which was authorized by the National Medical Products Administration ("NMPA") to conduct trials in China to support its ex-China regulatory filings. Two domestic companies, Jiangsu Hengrui Medicine Co., Ltd. and Guandong Sunshine Health Investment Co., Ltd, have been permitted by the NMPA to conduct clinical trials for CKD anemia patients both on dialysis and not on dialysis, and 3SBio Inc. has submitted a clinical trial application to the NMPA to initiate trials for their HIF-PH inhibitor. Another domestic company, China Medical System, in-licensed desidustat, a compound that is currently in Phase 3 trials in India, from Zydus Cadila for greater China in January 2020. Akebia announced in December 2015 that it had entered into a development and commercialization partnership with Mitsubishi Tanabe Pharmaceutical Corporation for its HIF-PH inhibitor vadadustat in Japan, Taiwan, South Korea, India and certain other countries in Asia, and announced in April 2017 an expansion of their U.S. collaboration with Otsuka to add markets, including China. 3SBio Inc. announced in 2016 its plan to begin a Phase 1 clinical trial of a HIF-PH inhibitor for the China market.

The first biosimilar ESA, Pfizer's Retacrit® (epoetin zeta), entered the U.S. market in November 2018. Market penetration of Retacrit and the potential addition of other biosimilar ESAs currently under development may alter the competitive and pricing landscape of anemia therapy in CKD patients on dialysis under the ESRD bundle. The patents for Amgen's EPOGEN® (epoetin alfa) expired in 2004 in Europe, and the final material patents in the U.S. expired in May 2015. Several biosimilar versions of currently marketed ESAs are available for sale in Europe, China and other territories. In the U.S., a few ESA biosimilars are currently under development. Sandoz, a division of Novartis, markets Binocrit® (epoetin alfa) in Europe and may file a biosimilar 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 more than 80% of U.S. dialysis patients, and therefore have historically won long-term contracts including rebate terms with Amgen. DaVita has a six-year sourcing and supply agreement with Amgen effective through 2022. Fresenius' contract with Amgen expired in 2015, following which Fresenius is providing Roche's ESA Mircera® to a significant portion of its U.S. dialysis patients. Successful penetration in this market may require a significant agreement with Fresenius or DaVita, on favorable terms and on a timely basis.

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

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

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

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

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

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

Pamrevlumab may also face competition from other drugs currently in clinical development in patient recruiting and enrollment in clinical trials, and, if approved, in commercialization. Examples of those compounds currently under clinical development are the drug candidates from Pfizer, Catabasis Pharmaceuticals ("Catabasis"), Santhera Pharmaceuticals ("Santhera") and Sarepta. Pfizer initiated a Phase 3 study with PF-06939926, its AAV9 mini-dystrophin gene therapy for DMD in February 2020. Catabasis' edasalonexent was reported to have preserved muscle function and slowed the progression of DMD compared to rates of change in the control period prior to treatment with edasalonexent in a Phase 2 study, and is currently undergoing Phase 3 development. Santhera's Puldysa® (idebenone) MAA for treatment of DMD was filed with the EMA, and the opinion from the Committee for Medicinal Products for Human Use is expected in the second quarter of 2020. The FDA requested additional clinical data from the idebenone Phase 3 trial currently ongoing in the U.S. and Europe. Santhera offers compassionate use of idebenone in patients with DMD in U.S. and UK. Sarepta's SRP-9001 is an investigational gene therapy for DMD. Sarepta announced in December 2019 the licensing agreement with Roche that grants Roche the commercial rights to SRP-9001 outside the U.S.

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

Moreover, many of our competitors have significantly greater resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients, manufacturing pharmaceutical products, and commercialization. In the potential anemia market for roxadustat, for example, large and established companies such as Amgen and Roche, among others, compete aggressively to maintain their market shares. In particular, the currently marketed ESA products are supported by large pharmaceutical companies that have greater experience and expertise in commercialization in the anemia market, including in securing reimbursement, government contracts and relationships with key opinion leaders; conducting testing and clinical trials; obtaining and maintaining regulatory approvals and distribution relationships to market products; and marketing approved products. These companies also have significantly greater scale, research and marketing capabilities than we do and may also have products that have been approved or are in later stages of development and have collaboration agreements in our target markets with leading dialysis companies and research institutions. These competitors have in the past successfully prevented new and competing products from entering 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.

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

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

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

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

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

Risks Related to COVID-19

Our business could be adversely affected by the ongoing COVID-19 global pandemic as a result of the current and potential future impacts on our commercialization efforts, supply chain, regulatory and clinical development activities, and other business operations, in addition to the impact of a global economic slowdown.*

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

The effects of the COVID-19 pandemic, the associated government-mandated restrictions and the other effects on healthcare systems, the economy, and society as a whole, may negatively impact productivity, disrupt our business, and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the progression of the disease, the length and severity of the restrictions, and other impacts and limitations on our ability to conduct our business in the ordinary course. These disruptions in our operations could negatively impact our business, operating results, and financial condition.

We have taken measures to minimize the health risks of COVID-19 to our staff, patients, healthcare providers, and their communities, as their safety and well-being are our top priority. Despite these efforts, there is a risk that one or more of our employees, including members of senior management, could contract COVID-19. Our U.S. employees are working remotely when possible, and we may experience reduced productivity due to the remote work environment. In addition, there are increased risks from remote work including but not limited to risks related to reduced oversight of third parties we work with, such as manufacturing and clinical sites. In China, our staff have returned to work in our offices, manufacturing plants, and are performing medical affairs out in the field. We have implemented protocols globally to minimize the risk of illness for our employees who need to work on-site at any of our facilities.

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

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

We believe we have sufficient roxadustat and pamrevlumab supplies for our expected commercial and clinical requirements over the next year and we and our manufacturing partners are currently continuing manufacturing operations. However, we only have a limited stockpile of these drug supply products, and therefore, if there is a greater impact from the COVID-19 pandemic than we currently expect, or if manufacturing operations are halted again, we could face shortages in our global supply chains.

Any such supply disruptions could adversely impact our clinical development and ability to generate revenues from our approved products and our business, financial condition, results of operations and growth prospects could be materially adversely affected.

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

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

Risks Related to Our Reliance on Third Parties

If our collaborations with Astellas or AstraZeneca were terminated, if Astellas or AstraZeneca were to prioritize other initiatives over their collaborations with us, whether as a result of a change of control or otherwise, if conflicts arise between us and Astellas or AstraZeneca, or if Astellas or AstraZeneca becomes our competitor in the future, our ability to successfully develop and commercialize our product candidates would suffer.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how, information, or technology that is not covered by our patents. Although our agreements require all of our employees to 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 may consider administrative proceedings and other means for challenging third-party patents and patent applications. An unfavorable outcome in any such challenge could require us to cease using the related technology and to attempt to license rights to it from the prevailing third party, which may not be available on commercially reasonable terms, if at all, in which case our business could be harmed.

We intend, if necessary, to vigorously enforce our intellectual property in order to protect the proprietary position of our product candidates, including roxadustat and pamrevlumab. In addition, our collaboration partners who have been granted licenses to our patents may also have rights related to enforcement of those patents. Active efforts to enforce our patents by us or by our partners may include litigation, administrative proceedings, or both, depending on the potential benefits that might be available from those actions and the costs associated with undertaking those efforts against third parties. We carefully review and monitor publicly available information regarding products that may be competitive with our product candidates and assert our intellectual property rights where appropriate. For example, 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. In addition, our partner Astellas initiated *quia timet* infringement actions against Akebia and GSK based on our specific patents in the United Kingdom in response to actions taken by Akebia and GSK against those patents, as further detailed below.

Third parties may also challenge our patents and patent applications, through interference, reexamination, *inter partes* review, and post-grant review proceedings before the U.S. Patent and Trademark Office ("USPTO") or through comparable proceedings in other territories. For example, Akebia and others have filed oppositions against certain European patents within our HIF anemia-related technologies patent portfolio. In three of these proceedings, for FibroGen European Patent Nos. 1463823, 1633333, and 2322155, the European Patent Office has handed down decisions unfavorable to FibroGen. In a fourth of these proceedings, the European Patent Office issued a decision favorable to FibroGen, maintaining FibroGen European Patent No. 2322153 in amended form. All of these decisions are currently under appeal, and these four patents are valid and enforceable pending resolution of the appeals. In addition, Akebia has filed oppositions against FibroGen European Patent Nos. 2289531 and 2298301. As mentioned above, Akebia and GSK initiated invalidation actions in the United Kingdom against the United Kingdom counterparts of each of these European patents, and GSK filed for a declaration of non-infringement of certain United Kingdom patents (corresponding to FibroGen European Patent Nos. 2322153 and 2322155) with respect to its daprodustat product. We reached a settlement agreement with GSK to resolve the actions to which GSK was a party, resulting in dismissal of the UK court actions as well as the proceedings filed by GSK against the patents in the EPO. Astellas' proceedings brought against GSK on a *quia timet* basis have also been dismissed as a result of the settlement agreement. On April 20, 2020, the UK court handed down a decision invalidating UK designations of European Patent Nos. 1463823, 1633333, 2298301, 2322153, and 2322155. The UK designation to European Patent No. 2289531 was held to be valid in amended form, but not infringed by Akebia. Akebia is also pursuing invalidation actions against corresponding patents in Canada and in Japan. We note that, in each case described above, narrowing or even revocation of any of these patents does not affect our exclusivity for roxadustat or our freedom-to-operate with respect to use of roxadustat for the treatment of anemia.

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

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

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

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

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

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

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain countries. The legal systems of certain countries, 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, and are often lower cost, lower quality, different potency, or have different ingredients or formulations, and have the potential to damage the reputation for quality and effectiveness of the genuine product. Such products may be used for indications or purposes that are not recommended or approved or for which there is no data or inadequate data with regard to safety or efficacy. Such products divert sales from genuine products. If counterfeit pharmaceuticals illegally sold or used for research result in adverse events or side effects to consumers, we may be associated with any negative publicity resulting from such incidents. Consumers may buy counterfeit pharmaceuticals that are in direct competition with our pharmaceuticals, which could have an adverse impact on our revenues, business and results of operations. In addition, the use of counterfeit products could be used in non-clinical or clinical studies, or could otherwise produce undesirable side effects or adverse events that may be attributed to our products as well, which could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. With respect to China, although the government has recently been increasingly active in policing counterfeit pharmaceuticals, there is not yet an effective counterfeit pharmaceutical regulation control and enforcement system in China. As a result, we may not be able to prevent third parties from selling or purporting to sell our products in China. The proliferation of counterfeit pharmaceuticals has grown in recent years and may continue to grow in the future. The existence of and any increase in the sales and production of counterfeit pharmaceuticals, or the technological capabilities of counterfeiters, could negatively impact our revenues, brand reputation, business and results of operations.

Risks Related to Government Regulation

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

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

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

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

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

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

Our relationships with customers, physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Further, in the U.S. there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. At the federal level, the Trump administration's budget proposals for fiscal year 2020 contains further drug price control measures that could be enacted during the budget process or in other future legislation. In addition, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services has solicited feedback on some of these measures and has implemented others under its existing authority. While some of these measures may require additional authorization to become effective, the U.S. Congress and the Trump administration have indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional U.S. healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for any future products or additional pricing pressures.

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

Roxadustat is considered a Class 2 substance on the World Anti-Doping Agency ("WADA") Prohibited List. There are enhanced security and distribution procedures we and our collaboration partners and third-party contractors will have to take to limit the risk of loss of product in the supply chain. As a result, our distribution, manufacturing and sales costs for roxadustat, as well as for our partners, will be increased which will reduce profitability. In addition, there is a risk of reduced sales due to patient access to this drug. This is particularly the case in China where we will not be able to sell roxadustat in private pharmacies due to the WADA classification. While private pharmacies only represent approximately 10% of the market in China, this will negatively affect sales and therefore the profitability of roxadustat and the Company as a whole.

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

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

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

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

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

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

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

Risks Related to Our International Operations

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

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

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

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

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

The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. Refer to "*Business — Government Regulation — Regulation in China*" for a discussion of the regulatory requirements that are applicable to our current and planned business activities in China. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. For example, the Chinese government has implemented regulations that impact distribution of pharmaceutical products in China. These regulations generally require that at most two invoices may be issued throughout the distribution chain. Failure to comply with the "Two-Invoices" regulations would prevent us from accessing the market in China. As a result of the "Two-Invoices" regulation, we, rather than AstraZeneca, have been directly engaging distributors and a third-party logistics provider, and we are planning on modifying the distribution responsibilities under the China Agreement such that both companies will work together to manage the distribution network. FibroGen China Anemia Holdings, Ltd ("FibroGen China") has never managed distribution of pharmaceutical products, and this new distribution structure may impose higher costs or limit or delay our ability to sell products to our principal customers, and may limit the near term sales of our products. Any other such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our product candidates in China. Any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China.

We plan to use our own manufacturing facilities in China to produce roxadustat API and roxadustat drug product. As an organization, we have limited experience in the construction, licensure, and operation of a manufacturing plant, and accordingly we cannot assure you we will be able to continually meet regulatory requirements to operate our plant and to sell our products.*

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

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

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

In addition to manufacturing, we are responsible for pharmacovigilance, medical affairs, and management of the third-party distribution logistics for roxadustat in China. We have no experience in these areas as a company, and accordingly we cannot assure you we will be able to meet regulatory requirements or operate in these capacities successfully.

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

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

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

The retail prices of any product candidates that we develop may be subject to control, including periodic downward adjustment, by Chinese government authorities.

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

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

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

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

We plan to conduct all of our business in China through FibroGen China and FibroGen Beijing. We may rely on dividends and royalties paid by FibroGen Beijing for a portion of our cash needs, including the funds necessary to service any debt we may incur and to pay our operating costs and expenses. The payment of dividends by FibroGen Beijing is subject to limitations. Regulations in China currently permit payment of dividends only out of accumulated profits as determined in accordance with accounting standards and regulations in China. FibroGen Beijing is not permitted to distribute any profits until losses from prior fiscal years have been recouped and in any event must maintain certain minimum capital requirements. FibroGen Beijing is also required to set aside at least 10.0% of its after-tax profit based on Chinese accounting standards each year to its statutory reserve fund until the cumulative amount of such reserves reaches 50.0% of its registered capital. Statutory reserves are not distributable as cash dividends. In addition, if FibroGen Beijing incurs debt on its own behalf in the future, the agreements governing such debt may restrict its ability to pay dividends or make other distributions to us. As of March 31, 2020, approximately $9.2 million of our cash and cash equivalents is held in China.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to the Operation of Our Business

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

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

Loss of senior management and key personnel could adversely affect our ability to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

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

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

- results of clinical trials of our product candidates, including roxadustat and pamrevlumab;
- the timing of the release of results of and regulatory updates regarding our clinical trials;
- the level of expenses related to any of our product candidates or clinical development programs;

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

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

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

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

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

As of April 30, 2020, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 40.02% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after such date and shares issuable upon settlement of restricted stock units that will vest within 60 days after such date. This percentage is based upon information supplied by officers, directors and principal stockholders and Schedules 13D and 13G, if any, filed with the SEC, which information may not be accurate as of January 31, 2020. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. The interests of this group may differ from those of other stockholders and they may vote their shares in a way that is contrary to the way other stockholders vote their shares. This concentration of ownership could have the effect of entrenching our management and/or the board of directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

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

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 us. In connection with these acquisitions or investments, we may:

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

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

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

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

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

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

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

- require a supermajority vote of the holders of our common stock or the majority vote of our board of directors to amend our bylaws; and
- require a supermajority vote of the holders of our common stock to amend the classification of our board of directors into three classes and to amend certain other provisions of our certificate of incorporation.

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

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

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

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

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

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

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

Tariffs imposed by the U.S. and those imposed in response by other countries, as well as rapidly changing trade relations, could have a material adverse effect on our business and results of operations.

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

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

Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the state and federal courts located in the State of Delaware will be the sole and exclusive forum for (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
4.5	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
10.1*+	FibroGen, Inc. Non-Employee Director Compensation Policy, as amended.	—	—	—	—
10.2	Commercial Supply Agreement by and between FibroGen, Inc. and Catalent Pharma Solutions, LLC, effective as of January 1, 2020.	10-K	001-36740	10.28	3/2/2020
10.3+	Offer Letter, by and between FibroGen, Inc. and Enrique Conterno, dated as of December 17, 2019.	10-K	001-36740	10.34	3/2/2020
10.4	Master Supply Agreement by and among FibroGen, Inc., Shanghai SynTheAll Pharmaceutical Co., Ltd. and STA Pharmaceutical Hong Kong Limited, effective as of March 2, 2020.	8-K	001-36740	99.1	3/24/2020
31.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a).	—	—	—	—
31.2*	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a).	—	—	—	—
32.1*	Certification of Principal Executive Officer and Principal Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)(1)).	—	—	—	—
101.INS	Inline XBRL Instance Document: the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document	—	—	—	—
101.SCH	Inline XBRL Taxonomy Extension Schema Document	—	—	—	—
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	—	—	—	—
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	—	—	—	—
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	—	—	—	—
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	—	—	—	—
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)	—	—	—	—

* Filed herewith
\+ Indicates a management contract or compensatory plan
† Confidential information omitted

SIGNATURES

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

FibroGen, Inc.

Dated: May 7, 2020

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

Dated: May 7, 2020

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

FibroGen, Inc.

Non-Employee Director Compensation Policy

This Non-Employee Director Compensation Policy (the "***Policy***") documents the terms and conditions of the cash and equity compensation that non-employee members of the Board of Directors (the "***Board***") of FibroGen, Inc. ("***FibroGen***") may earn for their service on the Board from and after the initial public offering of the common stock of FibroGen.

Eligible Directors

Only members of the Board who are not concurrently employees of FibroGen are eligible for compensation under this Policy (each such member, a "***Director***"). Any director may also decline compensation per policy of their affiliated entity or for any other reason prior to the start of the period of service to which the compensation relates.

Annual Cash Compensation

The annual cash compensation set forth below is payable in equal quarterly installments, in arrears, on the last day of each quarter in which the service occurred, pro-rated for any partial quarters of service. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
   a. All Directors: $50,000

2. Annual Committee Chair Service Fee:
   a. Chairman of the Audit Committee: $20,000
   b. Chairman of the Compensation Committee: $17,500
   c. Chairman of the Nominating and Governance Committee: $10,000

3. Annual Committee Member (non-Chair) Service Fee:
   a. Audit Committee: $10,000
   b. Compensation Committee: $7,500
   c. Nominating and Governance Committee: $5,000

4. Annual Non-Executive Chairperson/Lead Independent Director Service Retainer:
   a. Lead Independent Director: $22,500
   b. Non-Executive Chairperson: $100,000

Equity Compensation

Equity awards will be granted under the FibroGen, Inc. 2014 Equity Incentive Plan (or any successor thereto, the "***Plan***"). All stock options granted under this policy will be non-statutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying Company common stock on the date of grant, and a term of ten (10) years from the date of grant (subject to earlier termination in connection with a termination of service or a corporate transaction as provided in the Plan). All equity awards granted under this Policy will be documented on the applicable form of equity award agreement most recently approved for use by the Board (or a duly authorized committee thereof) for Directors. The terms of the equity awards described in this Policy will be automatically adjusted upon any Capitalization Adjustment (as defined and provided for under the Plan).

1. Initial Grant: On the date of the Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Director will be automatically, and without further action by the Board, granted stock options covering 10,400 shares of FibroGen's common stock. Such options will vest in equal quarterly installments over three years from the grant date, subject to the Director's Continuous Service. A Director who, in the one year prior to his or her initial election to serve on the Board as a Director, served as an employee of FibroGen or one of its subsidiaries, will not be eligible for an initial grant.

2. Annual Grant: On the date of each Company annual stockholder meeting, each person who is elected or appointed as a Director, and each other Director who continues to serve as a Director immediately after such annual stockholder meeting, will be automatically, and without further action by the Board, granted (a) stock options covering 7,800 shares of FibroGen's common stock, and (b) RSUs covering 4,700 shares of FibroGen common stock. Such options and RSUs will vest upon the earlier of (x) June 6 of the following year and (y) the following year's annual stockholder meeting, subject to the Director's Continuous Service.

3. Prorated Annual Grants. If a Director is elected or appointed to the Board at a time other than at the annual stockholder meeting, then on the date of such election or appointment (or, if such date is not a market trading day, the first market trading day thereafter), the Director will be automatically, and without further action by the Board, granted stock options covering the number of shares of FibroGen's common stock equal to the product of each of (x) 7,800 shares and (y) 4,700 RSUs, by (z) the Applicable Fraction (a "***Prorated Annual Grant***"). The Applicable Fraction means a fraction with (a) a numerator equal to the number of days between the date of the Director's initial election or appointment to the Board and the date which is the first anniversary of the date of the most recent annual stockholder meeting occurring before the Director is elected or appointed to the Board, and (b) a denominator equal to 365.

4. Vesting. Vesting of awards granted under this Policy will cease if the Director resigns from the Board or otherwise ceases to serve as a Director, unless the Board determines that the circumstances warrant continuation of vesting. All equity awards granted under this Policy will vest in full immediately prior to a Change in Control (as defined in the Plan), subject to the Director's Continuous Service (as defined in the Plan) as of the day prior to the closing of the Change in Control.

Reimbursement of Expenses

The Company will reimburse Directors for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in Board meetings, and other activities performed in the course of their service on the Board.

Philosophy

This Policy is designed to attract and retain experienced, talented individuals to serve on the Board. The Board anticipates that the Board, or a duly authorized committee thereof, will generally review Director compensation on an annual basis following the initial public offering. The Policy, as amended from time to time, may take into account the time commitment expected of Directors, best practices and market rates in Director compensation, the economic position of FibroGen, broader economic conditions, historical compensation structure, the advice of the compensation consultant that the Compensation Committee or the Board may retain from time to time, and the potential dilutive effect of equity awards on our stockholders.

Under this Policy, Directors receive cash compensation in the form of retainers to recognize their day to day contributions, the level of responsibility as well as the necessary time commitment involved in serving in a leadership role and/or on committees. Directors also receive equity compensation because we believe that stock ownership provides an incentive to act in ways that maximize long-term stockholder value. Further, we believe that stock-based awards are essential to attracting and retaining talented Board members. When options are granted, these options have an exercise price equal to not less than the fair market value of FibroGen's Common Stock on the date of grant, so that options provide a return only if the fair market value appreciates over the period in which the option vests and remains exercisable. We believe that the vesting acceleration provided in the case of a change in control is consistent with market practices and is critical to attracting and retaining high quality Directors.

Adopted: September 17, 2014
Amended: March 4, 2015
Amended: February 23, 2016, Effective as of the 2016 Annual Meeting of Stockholders
Amended: June 5, 2018
Amended: June 5, 2019
Amended: February 10, 2020

Exhibit 31.1

CERTIFICATION

I, Enrique Conterno, certify that;

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

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

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

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

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

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

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

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

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

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

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

Date: May 7, 2020

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

Exhibit 31.2

CERTIFICATION

I, Pat Cotroneo, certify that;

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

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

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

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

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

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

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

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

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

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

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

Date: May 7, 2020

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

Exhibit 32.1

CERTIFICATION

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

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2020, to which this Certification is attached as Exhibit 32.1 ("Periodic Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 7, 2020

In Witness Whereof, the undersigned have set their hands hereto as of the 7th day of May, 2020.

/s/ Enrique Conterno
Enrique Conterno
Chief Executive Officer

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

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