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, 2021

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, 2021 was 92,128,227.

FIBROGEN, INC.

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SUMMARY RISK FACTORS

The success of the Company will depend on a number of factors, many of which are beyond our control and involve risks, including but not limited to the following:

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.
- 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 with our collaboration partners, our business would be harmed.
- Although regulatory approval has been obtained for roxadustat in China, Japan, and Chile, we may be unable to obtain regulatory approval for other countries, or such approval may be delayed or limited, due to a number of factors, many of which are beyond our control.
- The results of the FDA Cardiovascular and Renal Drugs Advisory Committee meeting may affect roxadustat's approvability and label in CKD anemia.
- Preclinical, Phase 1 and Phase 2 clinical trial results may not be indicative of the results that may be obtained in larger clinical trials.
- 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.
- 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.
- Clinical trials of our product candidates may not uncover all possible adverse effects that patients may experience.
- If our manufacturers or we cannot properly manufacture sufficient product, we may experience delays in development, regulatory approval, launch or successful commercialization.
- Regulatory authorities will do their own benefit risk analysis and may reach a different conclusion than we or our partners have, and these regulatory authorities may base their approval decision on different analyses, data, and statistical methods than ours.
- 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.
- We face substantial competition in the discovery, development and commercialization of product candidates.
- Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.
- 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.

Risks Related to Severe Acute Respiratory Syndrome Coronavirus 2 and the Resulting Coronavirus Disease ("COVID-19")

- Our business could continue to be adversely affected by the ongoing COVID-19 global pandemic.

Risks Related to Our Reliance on Third Parties

- If our collaborations were terminated or if Astellas or AstraZeneca were to prioritize other initiatives over their collaborations with us, our ability to successfully develop and commercialize our product candidates would suffer.
- If our preclinical and clinical trial contractors do not properly perform their agreed upon obligations, we may not be able to obtain or may be delayed in receiving regulatory approvals for our product candidates.
- 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 terminate these agreements or not perform satisfactorily.
- Certain components of our products are acquired from single-source suppliers or without long-term supply agreements. The loss of these suppliers, or their failure to supply, would materially and adversely affect our business.

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.
- Intellectual property disputes may be costly, time consuming, and may negatively affect our competitive position.
- 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.
- The cost of maintaining our patent protection is high and requires continuous review and diligence. We may not be able to effectively maintain our intellectual property position throughout the major markets of the world.
- 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.
- Intellectual property rights do not address all potential threats to any competitive advantage we may have.
- 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.

Risks Related to Government Regulation

- The regulatory approval process is highly uncertain and we may not obtain regulatory approval for our product candidates.
- Our product candidates could fail to receive regulatory approval from the FDA or other regulatory authorities.
- Our current and future relationships with customers, physicians, and third-party payors are subject to healthcare fraud and abuse laws, false claims laws, transparency laws, privacy and security laws, and other regulations. If we are unable to comply with such laws, we could face substantial penalties.
- We are subject to laws and regulations governing corruption, which will require us to maintain costly compliance programs.
- We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these, or if we otherwise fail to maintain an effective system of internal control, it may result in material misstatements in our financial statements.
- 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.
- 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 our partners and us.
- Our employees may engage in misconduct or improper activities, which could result in significant liability or harm our reputation.
- If we fail to comply with environmental, health or safety laws and regulations, we could incur fines, penalties or other costs.

Risks Related to Our International Operations

- We have established operations in China and are seeking approval to commercialize our product candidates outside of the U.S., and a number of risks associated with international operations could materially and adversely affect our business.
- The pharmaceutical industry in China is highly regulated and such regulations are subject to change.
- We have limited experience distributing drugs in China.
- We use our own manufacturing facilities in China to produce roxadustat API and drug product. There are risks inherent to operating commercial manufacturing facilities, and with these being our single source suppliers, we may not be able to continually meet market demand.
- As a company, we have limited experience in pharmacovigilance, medical affairs, and management of the third-party distribution logistics, and cannot assure you we will be able to meet regulatory requirements or operate in these capacities successfully.
- Our collaboration partner in China, AstraZeneca, and we may experience difficulties in successfully growing and sustaining sales of roxadustat in China.
- The retail prices of any product candidates that we develop may be subject to pricing control in China and elsewhere.
- 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.
- 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.
- 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.
- 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.
- We may be subject to tax inefficiencies associated with our offshore corporate structure.
- Our foreign operations, particularly those in China, are subject to significant risks involving the protection of intellectual property.
- Uncertainties with respect to the China legal system could have a material adverse effect on us.
- Changes in China’s economic, governmental, or social conditions could have a material adverse effect on our business.
- 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.

Risks Related to the Operation of Our Business

- Please see *Part II – Other Information, Item 1A. Risk Factors* for additional risk factors related to the operation of our Business.

There are also a variety of Risks Related to Our Common Stock

- Please see *Part II – Other Information, Item 1A. Risk Factors* for additional risk factors to our Common Stock.

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, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 433,508	$ 678,393
Short-term investments	110,724	8,144
Accounts receivable, net ($32,847 and $4,127 from related parties)	40,543	41,883
Inventories	20,764	16,530
Prepaid expenses and other current assets ($5,015 and $889 from related parties)	16,155	10,160
Total current assets	621,694	755,110
Restricted time deposits	2,072	2,072
Long-term investments	93,679	244
Property and equipment, net	30,933	33,647
Finance lease right-of-use assets	27,311	29,606
Equity method investment in unconsolidated variable interest entity	2,483	2,728
Other assets	9,129	3,433
Total assets	$ 787,301	$ 826,840
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable ($0 and $1,118 to a related party)	$ 24,061	$ 24,789
Accrued and other current liabilities ($121 and $24 to a related party)	119,781	119,521
Deferred revenue ($4,005 and $2,907 to a related party)	10,725	6,547
Finance lease liabilities, current	12,480	12,330
Total current liabilities	167,047	163,187
Product development obligations	17,962	18,697
Deferred revenue, net of current ($14,638 and $4,636 to a related party)	151,491	138,474
Finance lease liabilities, non-current	22,193	25,391
Other long-term liabilities	38,335	39,642
Total liabilities	397,028	385,391
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 125,000 shares authorized; no shares issued and outstanding at March 31, 2021, and December 31, 2020	—	—
Common stock, $0.01 par value; 225,000 shares authorized at March 31, 2021, and December 31, 2020; 92,080 and 91,441 shares issued and outstanding at March 31, 2021, and December 31, 2020	921	914
Additional paid-in capital	1,420,471	1,399,774
Accumulated other comprehensive loss	(4,624)	(4,499)
Accumulated deficit	(1,045,766)	(974,011)
Total stockholders' equity	371,002	422,178
Non-controlling interests	19,271	19,271
Total equity	390,273	441,449
Total liabilities, stockholders' equity and non-controlling interests	$ 787,301	$ 826,840

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,	
	2021	2020
Revenue:		
License revenue	$ —	$ —
Development and other revenue (includes $3,611 and $4,737 from a related party)	14,587	19,446
Product revenue, net (includes $10,406 and $0 from a related party)	15,362	4,955
Drug product revenue (includes $4,030 and $0 from a related party)	8,480	—
Total revenue	38,429	24,401
Operating costs and expenses:		
Cost of goods sold	3,401	970
Research and development	74,676	54,902
Selling, general and administrative	30,779	49,603
Total operating costs and expenses	108,856	105,475
Loss from operations	(70,427)	(81,074)
Interest and other, net		
Interest expense	(501)	(633)
Interest income and other income (expenses), net	(453)	3,165
Total interest and other, net	(954)	2,532
Loss before income taxes	(71,381)	(78,542)
Provision for (benefit from) income taxes	134	(194)
Investment loss in unconsolidated variable interest entity	(240)	—
Net loss	$ (71,755)	$ (78,348)
Net loss per share - basic and diluted	$ (0.78)	$ (0.89)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	91,688	88,219

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,	
	2021	**2020**
Net loss	$ (71,755)	$ (78,348)
Other comprehensive income (loss):		
Foreign currency translation adjustments	(70)	281
Available-for-sale investments:		
Unrealized gain (loss) on investments, net of tax effect	(55)	1,649
Other comprehensive income, net of taxes	(125)	1,930
Comprehensive loss	$ (71,880)	$ (76,418)

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, 2020	91,440,633	$ 914	$ 1,399,774	$ (4,499)	$ (974,011)	$ 19,271	$ 441,449
Net loss	—	—	—	—	(71,755)	—	(71,755)
Change in unrealized gain or loss on investments	—	—	—	(55)	—	—	(55)
Foreign currency translation adjustments	—	—	—	(70)	—	—	(70)
Shares issued from stock plans, net of payroll taxes paid	639,766	7	1,313	—	—	—	1,320
Stock-based compensation	—	—	19,384	—	—	—	19,384
Balance at March 31, 2021	92,080,399	$ 921	$ 1,420,471	$ (4,624)	$ (1,045,766)	$ 19,271	$ 390,273
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

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,	
	2021	2020
Operating activities		
Net loss	$ (71,755)	$ (78,348)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,723	2,868
Amortization of finance lease right-of-use assets	2,616	2,594
Net accretion of premium and discount on investments	131	(143)
Unrealized loss on equity investments	—	21
Investment loss in unconsolidated variable interest entity	240	—
Stock-based compensation	19,384	16,916
Tax benefit on unrealized gain on available-for-sale securities	—	(439)
Realized loss on sales of available-for-sale securities	—	258
Changes in operating assets and liabilities:		
Accounts receivable, net	1,336	(30,085)
Inventories	(4,288)	(1,521)
Prepaid expenses and other current assets	(5,457)	(637)
Other assets	(5,621)	761
Accounts payable	(669)	(3,223)
Accrued and other liabilities	252	(41,224)
Deferred revenue	17,196	47,996
Accrued interest for finance lease liabilities	(29)	(216)
Other long-term liabilities	(1,043)	24,936
Net cash used in operating activities	(44,984)	(59,486)
Investing activities		
Purchases of property and equipment	(518)	(459)
Purchases of available-for-sale securities	(196,243)	(38)
Proceeds from sales of available-for-sale securities	—	10,606
Proceeds from maturities of investments	42	45,900
Net cash provided by (used in) investing activities	(196,719)	56,009
Financing activities		
Repayments of finance lease liabilities	(3,299)	(2,814)
Repayments of lease obligations	(101)	(101)
Cash paid for payroll taxes on restricted stock unit releases	(4,757)	(5,279)
Proceeds from issuance of common stock	6,077	7,004
Net cash used in financing activities	(2,080)	(1,190)
Effect of exchange rate change on cash and cash equivalents	(1,102)	(39)
Net decrease in cash and cash equivalents	(244,885)	(4,706)
Total cash and cash equivalents at beginning of period	678,393	126,266
Total cash and cash equivalents at end of period	$ 433,508	$ 121,560

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”) is 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”) biology, 2-oxoglutarate enzymology, 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 activity that is being commercialized in China (tradename: 爱瑞卓®) for the treatment of anemia caused by chronic kidney disease (“CKD”) in dialysis and non-dialysis patients. EVRENZO® (roxadustat) is also being commercialized in Japan and has been approved in Chile for the treatment of anemia associated with CKD in dialysis and non-dialysis patients.

The Company’s New Drug Application (“NDA”) filing in the United States (“U.S.”) for roxadustat for the treatment of anemia in dialysis and non-dialysis CKD patients was submitted in December 2019 to the U.S. Food and Drug Administration (“FDA”). In December 2020, the FDA extended the review period of the NDA by three months for FibroGen to submit additional analyses of existing roxadustat clinical data, and set a new Prescription Drug User Fee Act goal date of March 20, 2021. On March 1, 2021, the FDA informed us that the Cardiovascular and Renal Drugs Advisory Committee will hold an advisory committee meeting to review the NDA for roxadustat. The date of the advisory committee meeting has been tentatively set for July 15, 2021. In Europe, the Marketing Authorization Application filing for roxadustat for the treatment of anemia in dialysis and non-dialysis CKD patients was accepted for regulatory review by the European Medicines Agency (“EMA”) in May 2020 and Astellas Pharma Inc. (“Astellas”) expects an approval decision by the EMA mid-2021.

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

Pamrevlumab, an anti-CTGF human monoclonal antibody, is in Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis, locally advanced unresectable pancreatic cancer and Duchenne muscular dystrophy.

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. All inter-company transactions and balances have been eliminated in consolidation. For any variable interest entity for which FibroGen is not the primary beneficiary, the Company uses the equity method of accounting. 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, 2020 (“2020 Form 10-K”).

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. The more significant areas requiring the use of management estimates and assumptions include valuation and recognition of revenue, specifically, estimates in variable consideration for drug product sales, and estimates in transaction price per unit for China performance obligation (as defined and discussed under *Significant Accounting Policies* below). 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

Potential common shares that would have the effect of increasing diluted earnings per share are considered to be anti-dilutive and as such, these shares are not included in the calculation of diluted earnings per share. Diluted weighted average shares excluded potential common shares related to stock options, restricted stock units and shares to be purchased under the employee stock purchase plan totaling 7.8 million and 8.7 million, for the three months ended March 31, 2021 and 2020, respectively, as they were anti-dilutive.

Risks and Uncertainties

The Company's business is subject to risks and uncertainties, including those related to COVID-19 and the related shelter-in-place, stay-at-home and other similar governmental orders issued in response to the COVID-19 pandemic.

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, rapid technological change, obtaining second source suppliers, regulatory approval from the FDA or other regulatory authorities, the results of clinical trials and the achievement of milestones, market acceptance of the Company's product candidates, competition from other products and larger companies, protection of proprietary technology, strategic relationships and dependence on key individuals.

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

Recently Issued and Adopted Accounting Guidance

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 was effective for annual reporting periods beginning after December 15, 2020 including interim periods. The Company adopted this guidance on January 1, 2021, and the adoption of this guidance did not have material impact to the Company's condensed consolidated financial statements and related disclosures.

Recently Issued Accounting Guidance Not Yet Adopted

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting* (*"ASU 2020-04"*), which provides companies with optional financial reporting alternatives to reduce the cost and complexity associated with the accounting for contracts and hedging relationships affected by reference rate reform. This guidance is effective as of March 12, 2020 through December 31, 2022. Subsequently in January 2021, the FASB issued ASU 2021-01, *Reference Rate Reform (Topic 848): Scope*, which clarifies ASU 2020-04 and provides certain optional expedients that allow derivative instruments impacted by changes in the interest rate used for margining, discounting or contract price alignment to qualify for certain optional relief. ASU 2021-01 is effective in the same timeframe as ASU 2020-04. The relief offered by this guidance, if adopted, is available to companies for the period March 12, 2020 through December 31, 2022. The Company has certain lease arrangements that are linked to LIBOR. The Company is in the process of evaluating options for transitioning away from LIBOR and expects to complete by the time LIBOR is phased out. The Company did not elect to apply any of the expedients or exceptions as of and for the period ended March 31, 2021 and is currently evaluating the impact on its consolidated financial statements and related disclosures 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 2020 Form 10-K, except for the following:

Product revenue, net

Product revenue, net consists of revenues from sales of roxadustat commercial product to Beijing Falikang Pharmaceutical Co., Ltd. ("Falikang"), and directly to pharmaceutical distributors located in a few provinces in China that are not covered by Falikang. Falikang is jointly owned by AstraZeneca AB ("AstraZeneca") and FibroGen Beijing. The Company is not the primary beneficiary of Falikang for accounting purposes, as AstraZeneca is the final decision maker for all the roxadustat commercialization activities, and the Company lacks the power criterion to direct the activities of Falikang (see Note 3, *Variable Interest Entity*).

Sales to Falikang

Falikang became fully operational in January 2021, at which time FibroGen Beijing began selling roxadustat commercial product to Falikang. Falikang is FibroGen Beijing's primary customer in China and substantially all roxadustat product sales to distributors in China are made by Falikang. Falikang bears inventory risk once it receives and accepts the product from FibroGen Beijing, and is responsible for delivering product to its distributors.

The promises identified under the AstraZeneca China Agreement (as defined in Note 2, *Collaboration Agreements and Revenues*), including the license, co-development services and manufacturing of commercial supplies have been bundled into a single performance obligation ("China performance obligation"). Amounts of the transaction price allocable to this performance obligation under the Company's agreements with AstraZeneca as outlined in Note 2, *Collaboration Agreements and Revenues*, are deferred until control of the manufactured commercial product has begun to transfer to AstraZeneca.

The initiation of roxadustat sales to Falikang marked the beginning of the China performance obligation. Revenue is recognized at a point in time when control of roxadustat commercial product is transferred to Falikang. Revenue is recognized based on the estimated transaction price per unit and actual quantity of product delivered during the reporting period. Specifically, the transaction price per unit is determined based on the overall transaction price over the total estimated sales quantity for the estimated performance period in which the Company believes those sales would occur. The price per unit is subject to reassessment on a quarterly basis, which may result in cumulative catch up adjustments.

The overall transaction price for FibroGen Beijing's product sales to Falikang includes the following elements of consideration:

- Non-refundable upfront license fees; development, regulatory, and commercial milestone payments based on the China Agreement allocated to the China performance obligation;
- Co-development billings resulting from the Company's research and development efforts, which are reimbursable under the China Agreement;
- Interim profit/loss share between FibroGen Beijing and AstraZeneca from April 1, 2020 through December 31, 2020; and

- Net transfer price from product sales to Falikang from January 1, 2021 onwards. The net transfer price includes the following elements:
  - Gross transfer price: The gross transfer price is based on a percentage of Falikang's net sales to its distributors, which takes into account Falikang's operating expenses and its payments to AstraZeneca for roxadustat sales and marketing efforts, capped at a percentage of Falikang's net roxadustat sales.
  - Profit share: The gross transfer price is then adjusted for an estimated amount to achieve the 50/50 profit share from current period roxadustat net sales in China. The adjustments to date have been a reduction to the transfer price and the related accounts receivable from Falikang.

The non-refundable upfront license fees constitute a fixed consideration. The remainder of the above are variable consideration components, which may be constrained, and included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period when the uncertainty associated with the variable consideration is subsequently resolved. The calculation of the above variable consideration includes key estimation areas such as total sales quantity, performance period, gross transfer price and profit share, which require a substantial degree of judgment.

Any net transfer price in excess of the revenue recognized is added to the deferred balance to date, and will be recognized over future periods as the performance obligations are satisfied.

Direct Sales to Distributors

The Company sells roxadustat in China directly to a number of pharmaceutical distributors located in a few provinces in China that are not covered by Falikang. These pharmaceutical distributors are the Company's customers. Hospitals order roxadustat through a distributor and the Company ships the product directly to the distributors. The delivery of roxadustat to a distributor represents a single performance obligation. Distributors are responsible for delivering product to end users, primarily hospitals. Distributors bear inventory risk once they receive and accept the product. Product revenue is recognized when control of the promised good is transferred to the customer in an amount that reflects the consideration to which the Company expects to be entitled to in exchange for the product.

The period between the transfer of control of the promised goods and when the Company receives payment is based on 60-day payment terms. As such, product revenue is not adjusted for the effects of a significant financing component.

Product revenue is recorded at the net sales prices which includes the following estimates of variable consideration:

- Price adjustment: When China's National Healthcare Security Administration releases price guidance for roxadustat under the National Reimbursement Drug List ("NRDL"), any channel inventories that have not been sold through by distributors, or to patients by hospitals and retailors, would be eligible for a price adjustment under the price protection. The price adjustment is calculated based on estimated channel inventory levels;
- Contractual sales rebate: The contractual sales rebate is calculated based on the stated percentage of gross sales by each distributor in the distribution agreement entered between FibroGen and each distributor. The contractual sales rebate is recorded as a reduction to revenue at the point of sale to the distributor;
- Non-key account hospital listing award: A one-time fixed-amount award is offered to a distributor who successfully lists the product with an eligible hospital, and who meets certain requirements. The Company considers this particular award to be an upfront payment to a customer within the definitions of ASC 606. The non-key account hospital listing award is capitalized when the distributor meets eligibility requirements, and amortized as reduction to product revenue over future sales orders made by the distributor until exhausted;
- Other discounts and rebates, including key account hospital sales rebate and transfer fee discount, are generally based on a percentage of eligible gross sales made by the distributor and recorded as a reduction to revenue at the point of sale to the distributor; and
- Sales returns: Distributors can request to return product to the Company only due to quality issues or for product purchased within one year prior to the product's expiration date.

The calculation of the above variable consideration is based on gross sales to the distributor, or estimated utilizing best available information from the distributor, maximum known exposures and other available information including estimated channel inventory levels and estimated sales made by the distributor to hospitals, which involve a substantial degree of judgment.

The above rebates and discounts all together are eligible to be applied against the distributor's future sales order, limited to certain maximums until such rebates and discounts are exhausted. These rebates and discounts are recorded as contract liabilities at the time they become eligible and in the same period that the related revenue is recorded. Due to the distributor's legal right to offset, at each balance sheet date, the liability for rebates and discounts are presented as reductions of gross accounts receivable from the distributor, or as a current liability to the distributor to the extent that the total amount exceeds the gross accounts receivable or when the Company expects to settle the discount in cash. The distributor's legal right of offset is calculated at the individual distributor level.

2. Collaboration Agreements and Revenues

Astellas Agreements

Japan Agreement

In June 2005, the Company entered into a collaboration agreement with Astellas for the development and commercialization (but not manufacture) of roxadustat for the treatment of anemia in Japan ("Japan Agreement"). Under this agreement, Astellas paid license fees and other consideration totaling $40.1 million (such amounts were fully received as of February 2009). Under the Japan Agreement, the Company is also eligible to receive from Astellas an aggregate of approximately $132.5 million in potential milestone payments, comprised of (i) up to $22.5 million in milestone payments upon achievement of specified clinical and development milestone events (such amounts were fully received as of July 2016), (ii) up to $95.0 million in milestone payments upon achievement of specified regulatory milestone events, and (iii) up to approximately $15.0 million in milestone payments upon the achievement of specified commercial sales milestone. The Japan Agreement also provides for tiered payments based on net sales of product (as defined) in the low 20% range of the list price published by Japan's Ministry of Health, Labour and Welfare, adjusted for certain elements, after commercial launch. The aggregate amount of consideration received through March 31, 2021 totals $105.1 million, excluding drug product revenue that is discussed separately below.

In 2018, FibroGen and Astellas entered into an amendment to the Japan Agreement that allows Astellas to manufacture roxadustat drug product for commercialization in Japan (the "Japan Amendment"). Under this amendment, FibroGen would continue to manufacture and supply roxadustat API to Astellas for the roxadustat commercial purposes in Japan. The commercial terms of the Japan Agreement relating to the transfer price for roxadustat for commercial use remain substantially the same, reflecting an adjustment for the manufacture of drug product by Astellas rather than FibroGen. The related drug product revenue, as described in details under *Drug Product Revenue* section below, was $4.0 million for the three months ended March 31, 2021.

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 under the Europe Agreement through March 31, 2021 totals $540.0 million, excluding drug product revenue that is discussed separately below.

Under the Europe Agreement, Astellas has an option to purchase roxadustat bulk drug product in support of commercial supplies. During the three months ended March 31, 2021, the Company entered into an Astellas EU Supply Agreement ("EU Supply Agreement") under the Europe Agreement with Astellas to define general forecast, order, supply and payment terms for Astellas to purchase roxadustat bulk drug product from FibroGen in support of commercial supplies. The Company shipped bulk drug product to Astellas as pre-commercial supply for process validation purposes during the three months ended March 31, 2021. The Company constrained the consideration of $11.8 million from this shipment, as described in details under *Drug Product Revenue* section below.

AstraZeneca Agreements

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

Effective July 30, 2013, the Company entered into a collaboration agreement with 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 (such amounts were fully received as of April 2020), (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 under the U.S./RoW Agreement through March 31, 2021 totals $439.0 million, excluding drug product revenue that is discussed separately below.

In 2020, the Company entered into Master Supply Agreement under the U.S./RoW Agreement with AstraZeneca ("Master Supply Agreement") to define general forecast, order, supply and payment terms for AstraZeneca to purchase roxadustat bulk drug product from FibroGen in support of commercial supplies. The Company shipped bulk drug product to AstraZeneca as commercial supply during the three months ended March 31, 2021 and recognized related drug product revenue of $4.5 million, as described in details under *Drug Product Revenue* section below.

China Agreement

Effective July 30, 2013, the Company (through its subsidiaries affiliated with China) entered into the China Agreement ("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), which was amended under the China Amendment discussed below in the third quarter of 2020, 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 period. The aggregate amount of such consideration received for milestone and upfront payments through March 31, 2021 totals $77.2 million.

China Amendment

In July 2020, FibroGen China and AstraZeneca (together with FibroGen China, the "Parties") entered into the China Amendment, effective July 1, 2020, relating to the development and commercialization of roxadustat in China. While the responsibilities of the Parties under the China Agreement remain largely the same, certain changes were made.

Under the China Amendment, in September 2020, FibroGen Beijing and AstraZeneca completed the establishment of a jointly owned entity, Falikang, which performs roxadustat distribution, as well as conduct sales and marketing through AstraZeneca.

Under the China Amendment, the interim period is defined as the period from April 1, 2020 to the time when Falikang is fully operational. Falikang became fully operational in January 2021. The calculation for profit or loss share related to sales of roxadustat in China has changed for the period from April 1, 2020 onwards. With effect from April 1, 2020, the Parties have changed the method under which commercial expenses incurred by AstraZeneca are calculated and billed. AstraZeneca's co-promotion expenses for their sales and marketing efforts are now subject to a cap of a percentage of net sales. Once AstraZeneca has been fully reimbursed for their sales and marketing costs under the cap, AstraZeneca will bill the co-promotion expenses based on actual costs on a prospective basis. In addition, the China Amendment has allowed for a higher cost of manufacturing incurred by FibroGen Beijing to be included in the profit or loss share calculation, subject to an annual cap, among other changes.

Since Falikang became fully operational in January 2021, substantially all direct roxadustat product sales to distributors in China are made by Falikang, while FibroGen Beijing continues to sell roxadustat product directly in a few provinces in China. FibroGen Beijing manufactures and supplies commercial product to Falikang based on a gross transfer price, which is adjusted for the estimated profit share. In addition, AstraZeneca now bills the co-promotion expenses to Falikang and to FibroGen Beijing, respectively, for its services provided to the respective entity. Development costs continue to be shared 50/50 between the Parties.

During the three months ended March 31, 2021, the Company recognized $10.4 million of net product revenue from the sales to Falikang, as described in details under *Product Revenue, Net* section below.

In addition to sales to Falikang, the Company recognized $5.0 million of net product revenue from sales directly to distributors in a few provinces in China, as described as direct sales in Note 2, *Collaboration Agreements and Revenues*.

License Revenue and Development Revenue Recognized Under the Collaboration Agreements

Amounts recognized as license revenue and development revenue under the Japan Agreement with Astellas were as follows (in thousands):

		Three Months Ended March 31,	
Agreement	**Performance Obligation**	**2021**	**2020**
Japan	License revenue	$ —	$ —
	Development revenue	$ 80	$ 163

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

Japan Agreement	**Cumulative Revenue Through March 31, 2021**	**Deferred Revenue at March 31, 2021**	**Total Consideration Through March 31, 2021**
License	$ 100,347	$ —	$ 100,347
Development revenue	16,430	75	16,505
Total license and development revenue	$ 116,777	$ 75	$ 116,852

The revenue recognized under the Japan Agreement for the three months ended March 31, 2021 included immaterial revenue resulting from changes to estimated variable consideration in the current period relating to performance obligations satisfied or partially satisfied in previous periods. The Company does not expect material variable consideration from estimated future co-development billing beyond the development period in the transaction price related to the Japan Agreement.

Amounts recognized as license revenue and development revenue under the Europe Agreement with Astellas were as follows (in thousands):

		Three Months Ended March 31,	
Agreement	**Performance Obligation**	**2021**	**2020**
Europe	License revenue	$ —	$ —
	Development revenue	$ 3,531	$ 4,574

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

Europe Agreement	**Cumulative Revenue Through March 31, 2021**	**Deferred Revenue at March 31, 2021**	**Total Consideration Through March 31, 2021**
License	$ 487,951	$ —	$ 487,951
Development revenue	252,493	825	253,318
Total license and development revenue	$ 740,444	$ 825	$ 741,269

The revenue recognized under the Europe Agreement for the three months ended March 31, 2021 included an increase in revenue of $0.4 million resulting from changes to estimated variable consideration. The remainder of the transaction price related to the Europe Agreement includes $24.5 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 and China Agreement with AstraZeneca were as follows (in thousands):

Agreement	Performance Obligation	Three Months Ended March 31, 2021	2020
U.S. / RoW and China	License revenue	$ —	$ —
	Development revenue	10,976	14,556
	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 with AstraZeneca, along with any associated deferred revenue as follows (in thousands):

U.S. / RoW and China Agreements	Cumulative Revenue Through March 31, 2021	Deferred Revenue at March 31, 2021		Total Consideration Through March 31, 2021
License	$ 341,844	$ —		$ 341,844
Co-development, information sharing & committee services	565,751	4,449		570,200
China performance obligation *	10,406	142,813		153,219
Total license and development revenue	$ 918,001	$ 147,262	**	$ 1,065,263

* China performance obligation revenue is recognized as product revenue, as described in details under *Product Revenue, Net* section below.

** Contract assets and liabilities related to rights and obligations in the same contract are recorded net on the consolidated balance sheets. As of March 31, 2021, deferred revenue included $143.6 million related to the U.S./RoW and China Agreement, which represents the net of $147.3 million of deferred revenue presented above and a $3.7 million unbilled co-development revenue under the China Amendment with AstraZeneca.

The revenue recognized under the U.S./RoW Agreement for the three months ended March 31, 2021 included a reduction in revenue of $4.2 million resulting from changes to estimated variable consideration. The remainder of the transaction price related to the U.S./RoW Agreement and China Agreement includes $49.5 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. The amount allocated to the U.S./RoW Agreement is expected to be recognized over the remaining development service period. The amount allocated to the China performance obligation is expected to be recognized as the Company transfers control of the commercial products to Falikang.

Product Revenue, Net

Product revenue, net from the sales of roxadustat commercial product in China was as follows (in thousands):

	Three Months Ended March 31, 2021	2020
Direct Sales:		
Gross revenue	$ 5,429	$ 5,372
Discounts and rebates	(562)	(417)
Sales returns	89	—
Direct sales revenue, net	4,956	4,955
Sales to Falikang:		
Gross transfer price	24,401	—
Profit share	(10,064)	—
Net transfer price	14,337	—
Constrained for future recognition	(3,931)	—
Sales to Falikang revenue, net	10,406	—
Total product revenue, net	$ 15,362	$ 4,955

Direct Sales

Product revenue from direct roxadustat product sales to distributors in China is recognized in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those products, net of various sales rebates and discounts. The total discounts and rebates were $0.6 million and $0.4 million for the three months ended March 31, 2021 and 2020, respectively, which primarily consisted of the contractual sales rebate calculated based on the stated percentage of gross sales by each distributor in the distribution agreement entered between FibroGen and each distributor.

The rebates and discounts that the Company's pharmaceutical distributors have earned are eligible to be applied against future sales orders, limited to certain maximums until such rebates and discounts are exhausted. These rebates and discounts are recorded as contract liabilities at the time they become eligible in the same period that the related revenue is recorded. Due to the Company's legal right to offset, at each balance sheet date, the rebates and discounts are presented as reductions to gross accounts receivable from the distributor, or as a current liability to the distributor to the extent that the total amount exceeds the gross accounts receivable or when the Company expects to settle the discount in cash. The Company's legal right to offset is calculated at the individual distributor level. The following table includes a roll-forward of the contract liabilities (in thousands):

	Balance at December 31, 2020	Additions	Deduction	Currency Translation and Other	Balance at March 31, 2021
Product revenue - Direct sales - contract liabilities	$ (15,137)	$ (1,422)	$ 533	$ 47	$ (15,979)

As of March 31, 2021 and December 31, 2020, the total contract liabilities were $16.0 million and $15.1 million, which were included in accrued and other current liabilities in the condensed consolidated balance sheet. There were no rebates and discounts reflected as reductions to gross accounts receivable as of March 31, 2021 as substantially all direct product sales to distributors were transitioned to Falikang. As of December 31, 2020, the total rebates and discounts as reductions to gross accounts receivable was $0.5 million.

Sales to Falikang – China Performance Obligation

Since Falikang became fully operational in January 2021, substantially all direct roxadustat product sales to distributors in China are made by Falikang. FibroGen Beijing manufactures and supplies commercial product to Falikang. The net transfer price for FibroGen Beijing's product sales to Falikang is based on a gross transfer price, which is adjusted to account for the 50/50 profit share for the period.

The roxadustat sales to Falikang marked the beginning of the Company's China performance obligation under the Company's agreements with AstraZeneca. Product revenue is based on the transaction price of the China performance obligation. Revenue is recognized when control of product is transferred to Falikang, in an amount that reflects the allocation of the transaction price to the performance obligation satisfied during the reporting period. Any net transfer price in excess of the revenue recognized is added to the deferred balance to date, and will be recognized over future periods as the performance obligations are satisfied. During the three months ended March 31, 2021, the Company constrained $3.9 million from the net transfer price to Falikang, which was included in the related deferred revenue of China performance obligation.

The following table includes a roll-forward of the related deferred revenue that is considered as a contract liability (in thousands):

	Balance at December 31, 2020	Additions	Recognized as Revenue	Balance at March 31, 2021
Product revenue - AstraZeneca				
China performance obligation - deferred revenue	$ (137,338)	$ (15,881)	$ 10,406	$ (142,813)

Deferred revenue includes amounts allocated to the China performance obligation under the AstraZeneca arrangement as revenue recognition associated with this unit of accounting is tied to the commercial launch of the products within China and to when the control of the manufactured commercial products is transferred to AstraZeneca. As of March 31, 2021, approximately $6.0 million of the deferred revenue related to the China unit of accounting was included in short-term deferred revenue, which represents the amount of deferred revenue associated with the China unit of accounting that is expected to be recognized within the next 12 months, associated with the commercial sales in China.

The reductions to gross accounts receivable related to product revenue to Falikang was $9.2 million as of March 31, 2021.

Drug Product Revenue

Drug product revenue from commercial-grade API or bulk drug product sales to AstraZeneca and Astellas was as follows (in thousands):

	Three Months Ended March 31, 2021
Astellas	$ 4,030
AstraZeneca	4,450
Drug product revenue	$ 8,480

During the three months ended March 31, 2021, the Company recorded $4.0 million drug product revenue related to the API shipments fulfilled under the terms of the Japan Amendment with Astellas in 2018, due to a change in estimated variable consideration. Specifically, the change in estimated variable consideration was based on the API held by Astellas at March 31, 2021 adjusted to reflect the changes in the estimated bulk product strength mix intended to be manufactured by Astellas, estimated cost to convert the API to bulk product tablets, and estimated yield from the manufacture of bulk product tablets, among others. This amount was unbilled to Astellas as of March 31, 2021, and recorded under prepaid expenses and other current assets in the condensed consolidated balance sheet. This amount was billed to Astellas in April 2021.

During three months ended March 31, 2021, the Company shipped bulk drug product to AstraZeneca as commercial supply under the terms of the Master Supply Agreement, and recognized drug product revenue of $4.5 million.

During the three months ended March 31, 2021, the Company shipped bulk drug product from process validation supplies for commercial purposes under the terms of the Europe Agreement and the EU Supply Agreement with Astellas. The Company constrained the consideration of $11.8 million from this shipment due to a high degree of uncertainty associated with the final consideration, which was reflected as deferred revenue as of March 31, 2021. The deferred revenue will be recognized as and when uncertainty is resolved. The following table includes a roll-forward of the related deferred revenue that is considered as a contract liability (in thousands):

	Balance at December 31, 2020	Additions	Recognized as Revenue	Balance at March 31, 2021
Drug product revenue - Astellas - deferred revenue	$ (5,984)	$ (11,759)	$ —	$ (17,743)

3. Variable Interest Entity

Falikang is a distribution entity jointly owned by AstraZeneca and FibroGen Beijing. FibroGen Beijing owns 51.1% of the outstanding shares of Falikang.

Pursuant to the guidance under ASC 810, the Company concluded that Falikang qualifies as a variable interest entity (“VIE”). As Falikang is a distribution entity and AstraZeneca is the final decision maker for all the roxadustat commercialization activities, the Company lacks the power criterion while AstraZeneca meets both the power and economic criteria under ASC 810, to direct the activities of Falikang that most significantly impact its performance. Therefore, the Company is not the primary beneficiary of this VIE for accounting purposes. As a result, the Company accounts for its investment in Falikang under the equity method, and Falikang is not consolidated into the Company’s condensed consolidated financial statements. Accordingly, the Company records its total investments in Falikang as an equity method investment in an unconsolidated variable interest entity in the condensed consolidated balance sheet. In addition, the Company recognizes its proportionate share of the reported profits or losses of Falikang as investment gain or loss in unconsolidated variable interest entity in the condensed consolidated statement of operations, and as an adjustment to its investment in Falikang in the condensed consolidated balance sheet. Falikang has not incurred material profit or loss to date. The Company may provide shareholder loans to Falikang to meet necessary financial obligations as part of its operations. To date, these loans have been immaterial.

The Company’s equity method investment in Falikang was as follows (in thousands):

Entity	Ownership Percentage	Balance at December 31, 2020	Share of Net Loss	Currency Translation	Balance at March 31, 2021
Falikang	51.1%	$ 2,728	$ (240)	$ (5)	$ 2,483

Falikang is considered as a related party to the Company. See Note 9, *Related Party Transactions*, for related disclosures.

4. 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, 2021			
	Level 1	Level 2	Level 3	Total
Money market funds	$ 282,269	$ —	$ —	$ 282,269
Corporate bonds	—	84,538	—	84,538
Commercial paper	—	100,958	—	100,958
U.S. government bonds	30,059	—	—	30,059
Agency bonds	—	14,347	—	14,347
Asset-backed securities	—	12,569	—	12,569
Foreign government bonds	—	12,194	—	12,194
Equity investments	242	—	—	242
Total	$ 312,570	$ 224,606	$ —	$ 537,176

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Bond and mutual funds	$ —	$ 8,144	$ —	$ 8,144
Equity investments	244	—	—	244
Money market funds	590,347	—	—	590,347
Total	$ 590,591	$ 8,144	$ —	$ 598,735

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. There were no transfers of assets between levels during the three months ended March 31, 2021.

The Company's financial liabilities related to lease obligations as of March 31, 2021 and December 31, 2020 were $1.0 million and $1.1 million, respectively. The fair values of the Company's financial liabilities are carried at historical cost that 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.

5. Leases

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

	Balance Sheet Line Item	March 31, 2021	December 31, 2020
Assets			
Finance:			
Right-of-use assets - cost		$ 50,796	$ 50,477
Accumulated amortization		(23,485)	(20,871)
Finance lease right-of-use assets, net	Finance lease right-of-use assets	27,311	29,606
Operating:			
Right-of-use assets - cost		7,340	3,934
Accumulated amortization		(2,264)	(1,891)
Operating lease right-of-use assets, net	Other assets	5,076	2,043
Total lease assets		$ 32,387	$ 31,649
Liabilities			
Current:			
Finance lease liabilities	Finance lease liabilities, current	$ 12,480	$ 12,330
Operating lease liabilities	Accrued and other current liabilities	1,724	1,188
Non-current:			
Finance lease liabilities	Finance lease liabilities, non-current	22,193	25,391
Operating lease liabilities	Other long-term liabilities	3,354	853
Total lease liabilities		$ 39,751	$ 39,762

During the three months ended March 31, 2021, after FibroGen Beijing's previous long-term lease agreement expired, the Company entered into a new lease agreement with the landlord for the same pilot plant located in Beijing Yizhuang Biomedical Park of BDA. The new lease term is five year, scheduled to expire in 2026, and is treated as an operating lease. Accordingly, the Company recorded $3.4 million in the operating right-of-use assets and total operating lease liabilities, respectively. The lease contract provides for fixed quarterly rent payments, and require the Company to pay operating and maintenance costs.

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

		Three Months Ended March 31,	
	Statement of Operations Line Item	2021	2020
Finance lease cost:			
Amortization of right-of-use assets	Cost of goods sold; Research and development; Selling, general and administrative expenses	$ 2,616	$ 2,594
Interest on lease liabilities	Interest expense	385	515
Operating lease cost	Cost of goods sold; Research and development; Selling, general and administrative expenses	418	309
Sublease income	Selling, general and administrative expenses	(300)	(292)
Total lease cost		$ 3,119	$ 3,126

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

	Three Months Ended March 31,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 475	$ 149
Operating cash flows from finance leases	385	517
Financing cash flows from finance leases	3,299	2,814
Right-of-use assets obtained in exchange for new lease liabilities:		
Finance leases	322	9
Operating leases	$ 3,462	$ —

Lease term and discount rate were as follows:

	March 31, 2021	December 31, 2020
Weighted-average remaining lease term (years):		
Finance leases	2.6	2.9
Operating leases	4.0	1.8
Weighted-average discount rate:		
Finance leases	4.39%	4.39%
Operating leases	4.75%	4.74%

Maturities of lease liabilities as of March 31, 2021 are as follows (in thousands):

Year Ending December 31,	Finance Leases	Operating Leases
2021 (remaining nine month period)	$ 10,237	$ 1,425
2022	13,898	1,602
2023	12,535	909
2024	—	768
2025	—	766
Beyond 2025	—	65
Total future lease payments	36,670	5,535
Less: Interest	(1,997)	(457)
Present value of lease liabilities	$ 34,673	$ 5,078

6. Balance Sheet Components

Cash and Cash Equivalents

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

	March 31, 2021	December 31, 2020
Cash	$ 100,735	$ 88,046
Commercial paper	41,419	—
Corporate bonds	9,085	—
Money market funds	282,269	590,347
Total cash and cash equivalents	$ 433,508	$ 678,393

At March 31, 2021 and December 31, 2020, a total of $76.5 million and $66.0 million, respectively, of the Company's cash and cash equivalents were held outside of the U.S. in its foreign subsidiaries to be used primarily for its China operations.

Investments

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

	March 31, 2021			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Corporate bonds	$ 75,503	$ 4	$ (54)	$ 75,453
Commercial paper	59,536	4	(1)	59,539
U.S. government bonds	30,060	2	(3)	30,059
Agency bonds	14,349	1	(3)	14,347
Asset-backed securities	12,573	—	(4)	12,569
Foreign government bonds	12,195	1	(2)	12,194
Equity investments	125	117	—	242
Total investments	$ 204,341	$ 129	$ (67)	$ 204,403

	December 31, 2020			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Bond and mutual funds	$ 8,147	$ —	$ (3)	$ 8,144
Equity investments	125	119	—	244
Total investments	$ 8,272	$ 119	$ (3)	$ 8,388

At March 31, 2021, the available-for-sale investments had contractual maturities range from several months to four years. During the three months ended March 31, 2021, the Company did not recognize any other-than-temporary impairment loss.

Inventories

Inventories consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Raw materials	$ 3,308	$ 2,303
Work-in-progress	9,661	8,114
Finished goods	7,795	6,113
Total inventories	$ 20,764	$ 16,530

The Company capitalizes inventory costs for FibroGen Beijing's productions of roxadustat for commercial sales purposes. The Company started capitalizing pre-launch inventory costs in the U.S. in the second quarter of 2020 prior to regulatory approval. As of March 31, 2021 and December 31, 2020, pre-launch inventory capitalized was 37% and 29% of the total inventory balance, respectively. The provision to write-down excess and obsolete inventory was immaterial for the three months ended March 31, 2021 and 2020.

Prepaid expenses and other current assets

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

	March 31, 2021	December 31, 2020
Unbilled contract assets	$ 7,721	$ 2,147
Deferred revenues from associated contracts	(3,691)	(2,147)
Net unbilled contract assets	4,030	—
Prepaid assets	9,602	8,353
Other current assets	2,523	1,807
Total prepaid expenses and other current assets	$ 16,155	$ 10,160

The unbilled contract assets as of March 31, 2021 included $4.0 million related to a change in estimated variable consideration associated with the API shipments fulfilled under the terms of the Japan Amendment with Astellas in 2018, and $3.7 million related to unbilled co-development revenue under the China Amendment with AstraZeneca. The unbilled contract assets as of December 31, 2020 were related to unbilled co-development revenue under the China Amendment with AstraZeneca. See Note 2, *Collaboration Agreements and Revenues*, for details.

Property and Equipment

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

	March 31, 2021	December 31, 2020
Leasehold improvements	$ 102,265	$ 102,006
Laboratory equipment	18,541	18,143
Machinery	8,231	8,312
Computer equipment	9,107	9,545
Furniture and fixtures	6,195	6,128
Construction in progress	228	760
Total property and equipment	$ 144,567	$ 144,894
Less: accumulated depreciation	(113,634)	(111,247)
Property and equipment, net	$ 30,933	$ 33,647

Accrued and Other Current Liabilities

Accrued and other current liabilities consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Preclinical and clinical trial accruals	$ 39,775	$ 44,113
Payroll and related accruals	15,473	22,800
Contract liabilities to pharmaceutical distributors	15,979	15,137
Accrued co-promotion expenses - current	17,431	11,537
Roxadustat profit share to AstraZeneca	7,007	7,007
Property taxes and other taxes	9,242	5,970
Professional services	5,948	4,869
Other	8,926	8,088
Total accrued and other current liabilities	$ 119,781	$ 119,521

The profit share liability of $7.0 million to AstraZeneca as of March 31, 2021 and December 31, 2020 represented the profit/loss share between FibroGen Beijing and AstraZeneca that was calculated for the interim period pursuant to the China Amendment. This liability correspondingly reduced the deferred revenue related to the performance obligation in accordance with the China Amendment.

Other Long-term Liabilities

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

	March 31, 2021	December 31, 2020
Accrued long-term co-promotion expenses	$ 23,295	$ 27,424
Other long-term tax liabilities	9,025	8,675
Operating lease liabilities, non-current	3,354	853
Other	2,661	2,690
Total other long-term liabilities	$ 38,335	$ 39,642

7. Stock-Based Compensation

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

	Three Months Ended March 31,	
	2021	2020
Research and development	$ 12,221	$ 10,637
Selling, general and administrative	7,163	6,279
Total stock-based compensation expense	$ 19,384	$ 16,916

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,	
	2021	2020
Stock Options		
Expected term (in years)	5.7	5.7
Expected volatility	58.8 %	68.3 %
Risk-free interest rate	0.7 %	0.9 %
Expected dividend yield	—	—
Weighted average estimated fair value	$ 27.46	$ 17.24
ESPPs		
Expected term (in years)	0.5 - 2.0	0.5 - 2.0
Expected volatility	47.5 - 64.4 %	49.5 - 57.7 %
Risk-free interest rate	0.1 - 2.2 %	1.5 - 2.9 %
Expected dividend yield	—	—
Weighted average estimated fair value	$ 16.94	$ 18.57

8. Income Taxes

Provision for income tax for the three months ended March 31, 2021 was primarily due to foreign taxes. The benefit from income taxes for the three months ended March 31, 2020 was primarily due to the tax effect arising from other comprehensive income related to available-for-sale securities, partially offset by foreign taxes.

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

9. 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 $3.6 million and $4.7 million for the three months ended March 31, 2021 and 2020, respectively.

During the three months ended March 31, 2021, the Company also recorded drug product revenue from Astellas of $4.0 million related to the API shipments fulfilled under the terms of the Japan Amendment with Astellas in 2018, due to a change in estimated variable consideration. See Note 2, *Collaboration Agreements and Revenues*, for details.

The Company's expense related to collaboration agreements with Astellas was $0.1 million for each of the three months ended March 31, 2021 and 2020, respectively.

As of March 31, 2021 and December 31, 2020, accounts receivable from Astellas were $17.5 million and $4.1 million, respectively.

As of March 31, 2021 and December 31, 2020, total deferred revenue from Astellas was $18.6 million and $7.5 million, respectively.

As of March 31, 2021 and December 31, 2020, amounts due to Astellas were $0.1 million and $1.1 million, respectively.

As of March 31, 2021, prepaid expenses and other current assets included $4.0 million of unbilled contract assets from Astellas, representing the above mentioned change in estimated variable consideration related to the API shipments fulfilled in 2018. This amount was billed to Astellas in April 2021. See Note 2, *Collaboration Agreements and Revenues*, for details.

In September 2020, FibroGen Beijing and AstraZeneca completed the establishment of a jointly owned entity, Falikang, which was determined to be an unconsolidated VIE. As such, Falikang is accounted for as an equity method investment, and considered as a related party to the Company. FibroGen Beijing owns 51.1% of Falikang's equity. See Note 3, *Variable Interest Entity*, for details.

For the three months ended March 31, 2021, the net product revenue from Falikang was $10.4 million. See Note 2, *Collaboration Agreements and Revenues*, for details.

For the three months ended March 31, 2021, the investment loss in Falikang was $0.2 million. As of March 31, 2021 and December 31, 2020, the Company's equity method investment in Falikang was $2.5 million and $2.7 million, respectively. See Note 3, *Variable Interest Entity*, for details.

As of March 31, 2021, accounts receivable, net, from Falikang was of $15.4 million.

As of March 31, 2021 and December 31, 2020, prepaid expenses and other current assets included miscellaneous receivables from Falikang of $1.0 million and $0.9 million, respectively.

10. Commitments and Contingencies

Contract Obligations

As of March 31, 2021, the Company had outstanding total non-cancelable purchase obligations of $93.9 million, including $30.4 million for manufacture and supply of roxadustat, $57.5 million for manufacture and supply of pamrevlumab, and $6.0 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.

Some of the Company's license agreements provide for periodic maintenance fees over specified time periods, as well as payments by the Company upon the achievement of development, regulatory and commercial milestones. Future milestone payments for research and pre-clinical stage development programs consisted of up to approximately $10.9 million in total potential future milestone payments under the Company's license agreements with Dana-Farber Cancer Institute, University of Miami and Medarex, Inc. These milestone payments generally become due and payable only upon the achievement of certain developmental, clinical, regulatory and/or commercial milestones. The event triggering such payment or obligation has not yet occurred.

Legal Proceedings

From time to time, the Company is a party to various legal actions, both inside and outside the U.S., arising in the ordinary course of its business or otherwise. The Company accrues amounts, to the extent they can be reasonably estimated, that the Company believes will result in a probable loss (including, among other things, probable settlement value), to adequately address any liabilities related to legal proceedings and other loss contingencies. A loss or a range of loss is disclosed when it is reasonably possible that a material loss will incur and can be estimated, or when it is reasonably possible that the amount of a loss, when material, will exceed the recorded provision.

The Company did not have material accruals for any currently active legal action in its condensed consolidated balance sheets as of March 31, 2021, as it could not predict the ultimate outcome of these matters, or reasonably estimate the potential exposure.

In April 2021, three putative securities class action complaints were filed against FibroGen and certain of its current and former executive officers (collectively, the “Defendants”) in the United States District Court for the Northern District of California. The lawsuits allege that Defendants violated the Securities Exchange Act of 1934 by making materially false and misleading statements regarding FibroGen’s Phase 3 clinical studies data and prospects for FDA approval between November 2019 and December 2020. Plaintiffs seek to represent a class of persons or entities that purchased FibroGen securities between November 8, 2019 and April 6, 2021. In May 2021, two additional putative securities class action complaints were filed against Defendants alleging the same claims. One of the lawsuits alleges that Defendants made materially false and misleading statements between October 2017 and December 2020 and seeks to represent a class of persons or entities that purchased FibroGen securities between October 18, 2017 and April 6, 2021. The other lawsuit alleges that Defendants made materially false and misleading statements between December 2018 and February 2020 and seeks to represent a class of persons or entities that purchased FibroGen securities between December 20, 2018 and April 6, 2021. All plaintiffs seek unspecified monetary damages and other relief. Motions for lead plaintiff are due on June 11, 2021. Once a lead plaintiff is appointed by the Court, we expect to receive an amended consolidated complaint. We believe that the claims are without merit and we intend to vigorously defend against them. However, any litigation is inherently uncertain, and any judgment or injunctive relief entered against us or any adverse settlement could materially and adversely impact our business, results of operations, financial condition, and prospects.

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, 2020 filed with the SEC on March 1, 2021.

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 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") biology, 2-oxoglutarate enzymology, 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 (together with HIF, "HIF-PH") activity that is being commercialized in China (tradename: 爱瑞卓®) for the treatment of anemia caused by chronic kidney disease ("CKD") in dialysis and non-dialysis patients. EVRENZO® (roxadustat) is also being commercialized in Japan and has been approved in Chile for the treatment of anemia associated with CKD in dialysis and non-dialysis patients.

Our New Drug Application ("NDA") filing in the United States ("U.S.") for roxadustat for the treatment of anemia in dialysis and non-dialysis CKD patients was submitted for review in December 2019 to the U.S. Food and Drug Administration ("FDA") and in December 2020, the FDA extended the review period of the NDA by three months for FibroGen to submit additional analyses of existing roxadustat clinical data, and set a new Prescription Drug User Fee Act goal date of March 20, 2021. On March 1, 2021, the FDA informed us that the Cardiovascular and Renal Drugs Advisory Committee will hold an advisory committee meeting to review the NDA for roxadustat. The date of the advisory committee meeting has been tentatively set for July 15, 2021. In Europe, the Marketing Authorization Application ("MAA") filing for roxadustat for the treatment of anemia in dialysis and non-dialysis CKD patients was accepted for regulatory review by the European Medicines Agency ("EMA") in May 2020 and Astellas Pharma Inc. ("Astellas") expects an approval decision mid-2021.

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

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

Impact of Severe Acute Respiratory Syndrome Coronavirus 2 and the resulting Coronavirus Disease ("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. The rapid spread has resulted in authorities implementing numerous measures to contain the virus.

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, particularly our Phase 3 IPF program, 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 beyond those effects described above, including any impact on sales of roxadustat, will depend in large part on future developments with the pandemic, 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 roll out of 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, 2021 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,	
	2021	2020
	(in thousands, except for per share data)	
Result of Operations		
Revenue	$ 38,429	$ 24,401
Operating costs and expenses	108,856	105,475
Net loss	(71,755)	(78,348)
Net loss per share - basic and diluted	$ (0.78)	$ (0.89)

	March 31, 2021	December 31, 2020
	(in thousands)	
Balance Sheet		
Cash and cash equivalents	$ 433,508	$ 678,393
Short-term and long-term investments	204,403	8,388
Accounts receivable	$ 40,543	$ 41,883

Our revenue for the three months ended March 31, 2021 included the revenue recognized related to the following:

- $14.6 million of development revenue recognized under our collaboration agreements with our partners Astellas and AstraZeneca AB ("AstraZeneca");
- $15.4 million of net product revenue from roxadustat commercial sales in China; and
- $8.5 million of drug product revenue related to roxadustat bulk drug or active pharmaceutical ingredient ("API") deliveries to AstraZeneca and Astellas.

As a comparison, 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; and
- $5.0 million of net product revenue from roxadustat commercial sales in China.

Operating costs and expenses for the three months ended March 31, 2021 increased compared to the same period a year ago primarily, as a result of the net effect of the following:

- Higher clinical trial expenses associated with Phase 3 trials for pamrevlumab and roxadustat post-approval safety studies;
- Higher employee-related expenses resulting from higher average compensation level and headcount;
- Higher stock-based compensation expense, primarily due to the cumulative impact of stock option grant activities;
- Higher cost of goods sold associated with increased product revenue and drug product revenue; and
- Lower sales and marketing expenses primarily due to a change in the calculation method of co-promotion expenses with AstraZeneca as a result of the China Amendment between FibroGen China and AstraZeneca in the third quarter of 2020. In addition, since Falikang became fully operational in January 2021, substantially all direct product sales to distributors were made by Falikang, while FibroGen Beijing continued to sell product directly in a few provinces in China. AstraZeneca now bills the co-promotion expenses to Falikang and to FibroGen Beijing, respectively, for its services provided to the respective entity. All defined terms referenced in this paragraph that are not already defined, are defined below in *Collaboration Partnerships for Roxadustat*.

During the three months ended March 31, 2021, we had a net loss of $71.8 million, or net loss per basic and diluted share of $0.78, as compared to a net loss of $78.3 million for the same period a year ago, due to an increase in revenue, partially offset by an increase in operating costs and expenses as discussed above.

Cash and cash equivalents, investments and accounts receivable totaled $678.5 million at March 31, 2021, a decrease of $50.2 million from December 31, 2020, 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.

Our collaboration partner AstraZeneca and we continue to expand the commercialization of roxadustat (tradename: 爱瑞卓®) in China where it is approved for the treatment of anemia caused by CKD in non-dialysis and dialysis patients. As of the end of the first quarter of 2021, roxadustat was listed at hospitals that collectively represent approximately 74% of the CKD anemia market opportunity in China and roxadustat had a 27% value share within the segment of erythropoiesis stimulating agents and HIF-PH inhibitors (roxadustat is the only HIF-PH inhibitor currently on the market in China).

In Japan, our partner Astellas continues the commercial launch of EVRENZO® (roxadustat) for the treatment of anemia associated with CKD in both non-dialysis and dialysis patients.

With respect to the U.S., the Cardiovascular and Renal Drugs Advisory Committee will hold an advisory committee meeting to review the NDA for roxadustat for the treatment of anemia due to CKD, tentatively scheduled for July 15, 2021. In addition, ASPEN and DENALI, our two U.S. Phase 3b studies of roxadustat in CKD anemia with large dialysis organizations, have completed enrollment and we expect topline data to be presented at a future medical meeting.

In May 2020, our partner Astellas' MAA for roxadustat for the treatment of anemia in patients with CKD was accepted for regulatory review by the EMA and Astellas expects an approval decision mid-2021.

EVRENZO® (roxadustat) has also been approved for the treatment of anemia in CKD patients on dialysis and patients not on dialysis in Chile. In collaboration with AstraZeneca, applications for marketing approval of roxadustat in CKD anemia have been submitted in Canada, Australia, Mexico, Brazil, Taiwan, South Korea, Philippines, Singapore, India, Colombia, and Thailand.

Roxadustat for the Treatment of Anemia in Myelodysplastic Syndromes

We are continuing to enroll MATTERHORN, our Phase 2/3 placebo controlled, double-blind clinical trial to evaluate the safety and efficacy of roxadustat for treatment of anemia in MDS in the U.S. and Europe. This 160-patient trial is studying roxadustat in transfusion-dependent, lower-risk MDS patients, in which subjects are randomized 3:2 to receive roxadustat or placebo three-times-weekly. The primary endpoint is the proportion of patients who achieve transfusion independence by 28 weeks with secondary endpoints and safety evaluated at 52 weeks. We expect topline data from this study in the first half of 2022.

In China, we are preparing to enroll the randomized, double-blind, placebo-controlled portion of our Phase 3 clinical trial to evaluate the safety and efficacy of roxadustat in non-transfusion dependent, lower-risk MDS patients with anemia. One hundred thirty-five subjects will be randomized 2:1 to receive roxadustat or placebo three-times weekly for 26 weeks. The primary endpoint for this study is percentage of patients achieving a hemoglobin response.

Roxadustat for the Treatment of Chemotherapy-Induced Anemia

We have completed enrollment in WHITNEY, 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 92 patients receiving myelosuppressive chemotherapy treatment for non-myeloid malignancies, with a treatment duration of 16 weeks. We expect topline data from this study in the second half of 2021.

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

Pamrevlumab is our first-in-class antibody developed to inhibit the activity of CTGF, a common factor in fibrotic and fibro-proliferative disorders characterized by persistent and excessive scarring that can lead to organ dysfunction and failure.

In the second quarter of 2021, the FDA granted both Rare Pediatric Disease designation and Fast Track designation for pamrevlumab for the treatment of patients with Duchenne muscular dystrophy (“DMD”). In addition, 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-1, our Phase 3 trial of pamrevlumab in IPF patients, as well as our newly initiated ZEPHYRUS-2, a second IPF Phase 3 study. Both studies are randomized, double-blind, placebo-controlled Phase 3 trials targeting approximately 340 patients, each with a primary U.S. efficacy endpoint of change from baseline in forced vital capacity. The primary efficacy endpoint in Europe for each study is disease progression (defined by a decline in forced vital capacity percent predicted of greater than or equal to 10% or death). Secondary endpoints will include clinical outcomes of disease progression, patient reported outcomes, and quantitative changes in lung fibrosis volume from baseline.

Locally Advanced Unresectable Pancreatic Cancer

We continue to enroll 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 chemotherapy (either FOLFIRINOX or gemcitabine plus nab-paclitaxel). We expect topline resection data from this study in the second half of 2022.

Duchenne Muscular Dystrophy

In the third quarter of 2020, we initiated a Phase 3 clinical trial, LELANTOS-1, evaluating pamrevlumab in combination with systemic corticosteroids as a treatment for DMD. LELANTOS is a double-blind, placebo-controlled trial in approximately 90 non-ambulatory DMD patients. Patients are 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. We expect topline data from this study in the second half of 2022.

In the first quarter of 2021, we initiated a second double-blind, placebo-controlled Phase 3 clinical trial, LELANTOS 2, evaluating pamrevlumab in combination with systemic corticosteroids in approximately 70 ambulatory DMD patients. Patients aged 6-12 will be randomized at a 1:1 ratio to pamrevlumab or placebo and have a treatment period of 52 weeks. The primary efficacy endpoint will assess ambulatory function, measured by the change in North Star Ambulatory Assessment from baseline to Week 52.

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 ("Europe Agreement"). 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 Europe 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. Astellas is responsible for roxadustat commercialization activities in the Astellas territories.

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, 2021 totals $645.1 million.

Additionally, under these agreements, Astellas pays 100% of the commercialization costs in their territories. In Europe, Astellas will pay us a tiered transfer price for our manufacture and supply of roxadustat based on net sales of roxadustat in the low 20% range. In Japan, Astellas pays us a transfer price in the low 20% range of the list price published by Japan's Ministry of Health, Labour and Welfare, adjusted for certain elements.

In 2018, FibroGen and Astellas entered into an amendment to the Japan Agreement that allows Astellas to manufacture roxadustat drug product for commercialization in Japan (the "Japan Amendment"). Under this amendment, FibroGen would continue to manufacture and supply roxadustat API to Astellas for the roxadustat commercial purposes in Japan. The commercial terms of the Japan Agreement relating to the transfer price for roxadustat for commercial use remain substantially the same, reflecting an adjustment for the manufacture of drug product by Astellas rather than FibroGen. The related drug product revenue was $4.0 million for the three months ended March 31, 2021.

Under the Europe Agreement, Astellas has an option to purchase roxadustat bulk drug product in support of commercial supplies. During the three months ended March 31, 2021, we entered into an EU Supply Agreement under the Europe Agreement with Astellas to define general forecast, order, supply and payment terms for Astellas to purchase roxadustat bulk drug product from FibroGen in support of commercial supplies. We shipped bulk drug product to Astellas as pre-commercial supply for process validation purposes during the three months ended March 31, 2021. We constrained the consideration of $11.8 million from this shipment due to a high degree of uncertainty associated to the final consideration, which was included in the related deferred revenue as of March 31, 2021. The deferred revenue will be recognized as and when uncertainty is resolved.

In addition, as of March 31, 2021, 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 a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in China ("China Agreement"). 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, and FibroGen will transfer the U.S. NDA to AstraZeneca upon approval. AstraZeneca will hold the equivalent regulatory filings in the other licensed countries.

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, 2021 totals $516.2 million.

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

Under the China Agreement, which is conducted through FibroGen China Anemia Holdings, Ltd., FibroGen Beijing, and FibroGen International (Hong Kong) Limited (collectively, ("FibroGen China, the commercial collaboration was structured as a 50/50 profit share, which was amended by the China Amendment in the third quarter of 2020, as discussed and defined below in *China Amendment*.

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.

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.

In 2020, we entered into Master Supply Agreement under the U.S./RoW Agreement with AstraZeneca ("Master Supply Agreement") to define general forecast, order, supply and payment terms for AstraZeneca to purchase roxadustat bulk drug product from FibroGen in support of commercial supplies. We shipped bulk drug product to AstraZeneca as commercial supply during the three months ended March 31, 2021 and recognized related drug product revenue of $4.5 million.

China Amendment

In July 2020, FibroGen China and AstraZeneca (together with FibroGen China, the "Parties") entered into an amendment, effective July 1, 2020, to the China Agreement, relating to the development and commercialization of roxadustat in China (the "China Amendment"). While the responsibilities of the Parties under the China Agreement remain largely the same, certain changes are being made under the China Amendment.

Under the China Amendment, in September 2020, FibroGen Beijing and AstraZeneca completed the establishment of a jointly owned entity, Beijing Falikang Pharmaceutical Co., Ltd. ("Falikang"), which performs roxadustat distribution, as well as conduct sales and marketing through AstraZeneca.

As Falikang is a distribution entity for roxadustat and AstraZeneca is the final decision maker for all the roxadustat commercialization activities, we lack the power criterion while AstraZeneca meets both the power and economic criteria under ASC 810, to direct the activities of Falikang that most significantly impact its performance. Therefore, we are not the primary beneficiary of Falikang for accounting purposes. As a result, we accounted for our investment in Falikang under the equity method, and Falikang is not consolidated into our condensed consolidated financial statements. In addition, we recognized our proportionate share of the reported profits or losses of Falikang, as investment gain or loss in unconsolidated variable interest entity in the condensed consolidated statement of operations, and as an adjustment to our investment in Falikang in the condensed consolidated balance sheet. Falikang has not incurred material profit or loss to date.

Under the China Amendment, the interim period is defined as the period from April 1, 2020 to the time when Falikang is fully operational, which commenced in January 2021. Under the China Amendment, the calculation for profit or loss share has changed related to sales of roxadustat in China for the period from April 1, 2020 onwards. With effect from April 1, 2020, the Parties have changed the method under which commercial expenses incurred by AstraZeneca are calculated and billed. AstraZeneca's co-promotion expenses for their sales and marketing efforts are now subject to a cap of a percentage of net sales. Once AstraZeneca has been fully reimbursed for their sales and marketing costs under the cap, AstraZeneca will bill the co-promotion expenses based on actual costs on a prospective basis. In addition, the China Amendment has allowed for a higher cost of manufacturing incurred by FibroGen Beijing to be included in the profit or loss share calculation, subject to an annual cap, among other changes.

Since Falikang became fully operational in January 2021, substantially all direct product sales to distributors were made by Falikang, while FibroGen Beijing continued to sell product directly in a few provinces in China. AstraZeneca now bills the co-promotion expenses to Falikang and to FibroGen Beijing, respectively, for its services provided to the respective entity. In addition, FibroGen Beijing manufactures and supplies commercial product to Falikang based on an agreed upon transfer price. Development costs continue to be shared 50/50 between the Parties.

FibroGen Beijing manufactures and supplies commercial product to Falikang based on an agreed upon transfer price, which includes gross transfer price, net of calculated profit share. Revenue is recognized upon the transfer of control of commercial products to Falikang in an amount that reflects the allocation of transaction price of the China manufacturing and supply obligation ("China performance obligation") to the performance obligation satisfied during the reporting period. During the three months ended March 31, 2021, we recognized net product revenue of $10.4 million. FibroGen, Inc. and AstraZeneca concurrently amended the U.S./RoW Agreement to reflect minor changes in the governance structure under the China Agreement.

Additional Information Related to Collaboration Agreements

Total cash consideration received through March 31, 2021 and potential cash consideration, for upfront payments and milestone payments under our collaboration agreements are as follows:

	Cash Received for Upfront Payments and Milestone Payments Through March 31, 2021	Additional Potential Cash Payment for Milestones	Total Potential Cash Payments for Upfront Payments and Milestones
		(in thousands)	
Astellas--related-party:			
Japan Agreement	$ 105,093	$ 67,500	$ 172,593
Europe Agreement	540,000	205,000	745,000
Total Astellas	645,093	272,500	917,593
AstraZeneca:			
U.S. / RoW Agreement	439,000	810,000	1,249,000
China Agreement	77,200	299,500	376,700
Total AstraZeneca	516,200	1,109,500	1,625,700
Total	$ 1,161,293	$ 1,382,000	$ 2,543,293

The above table does not include development cost reimbursement, transfer price payments, and royalties and profit share under our existing collaboration agreements. 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	
	2021	2020	$	%
	(dollars in thousands)			
Revenue:				
License revenue	$ —	$ —	$ —	— %
Development and other revenue	14,587	19,446	(4,859)	(25) %
Product revenue, net	15,362	4,955	10,407	210 %
Drug product revenue	8,480	—	8,480	100 %
Total revenue	$ 38,429	$ 24,401	$ 14,028	57 %

Our revenue to date has been generated substantially from our collaboration agreements with Astellas and AstraZeneca. In addition, we started roxadustat commercial sales in China in 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, 2021 and 2020.

Development 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 we begin to transfer control of the manufactured commercial product to AstraZeneca, which commenced in the first quarter of 2021 and expected to continue through 2028. Other development related services are recognized as revenue over the non-contingent development period based on a proportional performance method. As of March 31, 2021, the estimated future non-contingent development periods range from six to 39 months. Other revenues consist of sales of research and development material and have not been material for any of the periods presented.

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

Drug product revenue includes commercial-grade API or bulk drug product sales to AstraZeneca and Astellas in support of pre-commercial preparation prior to the NDA or MAA approval, and to Astellas for ongoing commercial launch in Japan. Drug product revenue is recognized when we fulfill the delivery obligations. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the drug product revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period when the uncertainty associated with the variable consideration is subsequently resolved. Actual amounts of consideration ultimately received in the future may differ from our estimates, for which we will adjust these estimates and affect the drug product revenue in the period such variances become known. 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 drug 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.

Total revenue increased $14.0 million, or 57% for the three months ended March 31, 2021, 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	
	2021	2020	$	%
	(dollars in thousands)			
Development revenue:				
Astellas	$ 3,611	$ 4,737	$ (1,126)	(24) %
AstraZeneca	10,976	14,709	(3,733)	(25) %
Total development revenue	14,587	19,446	(4,859)	(25) %

Development and other revenue decreased $4.9 million, or 25% for the three months ended March 31, 2021, compared to the same period a year ago.

Development revenue recognized under our collaboration agreements with AstraZeneca for the three months ended March 31, 2021 decreased primarily due to the extension of the estimated future non-contingent development period resulting from the notice received on March 1, 2021 from FDA, that the Cardiovascular and Renal Drugs Advisory Committee will hold an advisory committee meeting to review the NDA for roxadustat.

In addition, co-development billings related to the development of roxadustat under our collaboration agreements with Astellas and AstraZeneca for the three months ended March 31, 2021 decreased as a result of the substantial completion of Phase 3 trials for roxadustat.

Product Revenue, Net

	Three Months Ended March 31,		Change	
	2021	2020	$	%
	(dollars in thousands)			
Direct Sales:				
Gross revenue	$ 5,429	$ 5,372	$ 57	1 %
Discounts and rebates	(562)	(417)	(145)	35 %
Sales returns	89	—	89	100 %
Direct sales revenue, net	4,956	4,955	1	— %
Sales to Falikang:				
Gross transfer price	24,401	—	24,401	100 %
Profit share	(10,064)	—	(10,064)	100 %
Net transfer price	14,337	—	14,337	100 %
Constrained for future recognition	(3,931)	—	(3,931)	100 %
Sales to Falikang revenue, net	10,406	—	10,406	100 %
Total product revenue, net	$ 15,362	$ 4,955	$ 10,407	210 %

In January 2021, Falikang became fully operational and substantially all direct product sales to distributors in China were made by Falikang, while FibroGen Beijing continued to sell product directly in a few provinces in China.

Product revenue from direct sales to distributors is recognized in an amount that reflects the consideration to which we expect to be entitled in exchange for those products, net of various sales rebates and discounts. The gross product revenue from direct sales to distributors was $5.4 million for each of the three months ended March 31, 2021 and 2020, respectively. The total discounts and rebates were $0.6 million and $0.4 million for the three months ended March 31, 2021 and 2020, respectively, which primarily consisted of the contractual sales rebate that were calculated based on the stated percentage of gross sales by each distributor in the distribution agreement entered between FibroGen and each distributor.

FibroGen Beijing manufactures and supplies commercial product to Falikang based on an agreed upon transfer price, which includes gross transfer price, net of calculated profit share. Revenue is recognized upon the transfer of control of commercial products to Falikang in an amount that reflects the allocation of the China performance obligation transaction price to the performance obligation satisfied during the reporting period. The variable consideration components that are included in the transaction price may be constrained, and are included in the product revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period when the uncertainty associated with the variable consideration is subsequently resolved. During the three months ended March 31, 2021, the gross transfer price was $24.4 million, net of the calculated profit share of $10.1 million, and we constrained $3.9 million from the sales to Falikang, which was included in the related deferred revenue of China performance obligation.

Drug Product Revenue

	Three Months Ended March 31, 2021
	(dollars in thousands)
Drug product revenue:	
Astellas	$ 4,030
AstraZeneca	4,450
Total drug product revenue:	$ 8,480

During the three months ended March 31, 2021, we recorded $4.0 million drug product revenue related to the API shipments fulfilled under the terms of the Japan Amendment with Astellas in 2018, due to a change in estimated variable consideration. Specifically, the change in estimated variable consideration was based on the API held by Astellas at March 31, 2021 adjusted to reflect the updated listed price for roxadustat issued by Japan's Ministry of Health, Labour and Welfare and changes in the estimated bulk product strength mix intended to be manufactured by Astellas, estimated cost to convert the API to bulk product tablets, and estimated yield from the manufacture of bulk product tablets, among others.

During the three months ended March 31, 2021, we shipped bulk drug product from process validation supplies for commercial purposes under the terms of the Europe Agreement with Astellas. We constrained the consideration of $11.8 million from this shipment due to a high degree of uncertainty associated to the final consideration, which was included in the related deferred revenue as of March 31, 2021. The deferred revenue will be recognized as and when uncertainty is resolved.

During three months ended March 31, 2021, we shipped bulk drug product to AstraZeneca as commercial supply under the terms of the Master Supply Agreement and recognized drug product revenue of $4.5 million.

Operating Costs and Expenses

	Three Months Ended March 31,		Change	
	2021	2020	$	%
	(dollars in thousands)			
Operating costs and expenses				
Cost of goods sold	$ 3,401	$ 970	$ 2,431	251 %
Research and development	74,676	54,902	19,774	36 %
Selling, general and administrative	30,779	49,603	(18,824)	(38) %
Total operating costs and expenses	$ 108,856	$ 105,475	$ 3,381	3 %

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. However, the overall impact of COVID-19 on our expenses was not significant. During the three months ended March 31, 2021, 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 $3.4 million, or 3% for the three months ended March 31, 2021 compared to the same period a year ago, for the reason discussed in the sections below.

Cost of Goods Sold

Cost of goods sold was $3.4 million and $1.0 million for the three months ended March 31, 2021 and 2020, respectively.

Cost of goods sold, associated with the roxadustat commercial sales in China, consists of direct costs to manufacture commercial product, as well as indirect costs including factory overhead, storage, shipping, quality assurance, idle capacity charges, and inventory valuation adjustments. Cost of goods sold, associated with the roxadustat commercial sales in China, was $2.7 million and $1.0 million for the three months ended March 31, 2021 and 2020, respectively, due to the sales to Falikang that started in January 2021.

Cost of goods sold associated with the roxadustat drug product revenue in the U.S. was $0.7 million for the three months ended March 31, 2021. We expect costs of goods sold to increase in relation to drug product revenue as we deplete inventories that we had expensed prior to receiving regulatory approvals.

Research and Development Expenses

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

The following table summarizes our research and development expenses incurred during the three months ended March 31, 2021 and 2020:

Product Candidate	Phase of Development	Three Months Ended March 31, 2021	2020
		(in thousands)	
Roxadustat	Phase 3	$ 26,524	$ 26,038
Pamrevlumab	Phase 2/3	35,370	22,100
Other research and development expenses		12,782	6,764
Total research and development expenses		$ 74,676	$ 54,902

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 $19.8 million, or 36% for the three months ended March 31, 2021, compared to the same period a year ago, as a result of the net effect of the following:

- Increase of $14.5 million in clinical trials costs, primarily due to Phase 3 trials for pamrevlumab and roxadustat post-approval safety studies in China;
- Increase of $4.1 million in employee-related costs primarily due to higher headcount in the research and development functions and higher compensation levels;
- Increase of $1.6 million in stock-based compensation expense, primarily due to the cumulative impact of stock option grant activities expensed in the normal course;
- Increase of $1.5 million in outside services due to higher consulting expenses related to roxadustat Phase 3 and pamrevlumab Phase 3, and higher scientific contract activities related to pamrevlumab Phase 3; and
- Decrease of $1.8 million in drug development expenses, primarily due to lower drug substance manufacturing activities and supplies related to roxadustat and pamrevlumab, partially offset by higher drug product manufacturing costs related to pamrevlumab, and higher supply chain expenses related to roxadustat and pamrevlumab.

Selling, General and Administrative Expenses

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

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

SG&A expenses decreased $18.8 million, or 38% for the three months ended March 31, 2021, compared to the same period a year ago, as a result of the net effect of the following:

- Decrease of $24.6 million in outside service expenses, due to the above-mentioned change in the calculation of co-promotion expenses with AstraZeneca as a result of the China Amendment between FibroGen China and AstraZeneca in the third quarter of 2020. In addition, since Falikang became fully operational in January 2021, substantially all direct product sales to distributors were made by Falikang, while FibroGen Beijing continued to sell product directly in a few provinces in China. AstraZeneca now bills the co-promotion expenses to Falikang and to FibroGen Beijing, respectively, for its services provided to the respective entity;
- Increase of $2.2 million in employee-related costs primarily due to higher headcount in the general and administrative functions and higher compensation levels; and
- Increase of $1.4 million in audit and tax expenses.

Interest and Other, Net

	Three Months Ended March 31,		Change	
	2021	2020	$	%
	(dollars in thousands)			
Interest and other, net:				
Interest expense	$ (501)	$ (633)	$ 132	(21) %
Interest income and other income (expenses), net	(453)	3,165	(3,618)	(114) %
Total interest and other, net	$ (954)	$ 2,532	$ (3,486)	(138) %

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 Income (Expenses), 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, and other non-operating income and expenses.

Interest income and other, net decreased $3.6 million, or 114% for the three months ended March 31, 2021 compared to the same period a year ago, primarily due to lower interest earned on our cash, cash equivalents and investments associated with the lower average balances.

On April 1, 2020, FibroGen Beijing adopted Renminbi Yuan (“CNY”) as its functional currency based on reassessment of the primary economic environment in which FibroGen Beijing operates, as such environment was mainly associated with its growing manufacturing and product sales activities conducted in CNY. Prior to April 1, 2020, FibroGen Beijing’s functional currency was the U.S. dollar. This change did not result in material impact to unrealized foreign currency gain or loss for the three months ended March 31, 2021 compared to the same period a year ago.

Income Taxes

	Three Months Ended March 31,	
	2021	2020
	(dollars in thousands)	
Loss before income taxes	$ (71,381)	$ (78,542)
Provision for (benefit from) income taxes	134	(194)
Effective tax rate	(0.2)%	0.2%

Provision for income tax for the three months ended March 31, 2021 was primarily due to foreign taxes. The benefit from income taxes for the three months ended March 31, 2020 was primarily due to the tax effect arising from other comprehensive income related to available-for-sale securities, partially offset by foreign taxes.

Based upon the weight of available evidence, which includes our historical operating performance, reported cumulative net losses since inception, 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.

Investment loss in unconsolidated variable interest entity

Investment loss in unconsolidated variable interest entity represented our proportionate share of the reported profits or losses of Falikang, an unconsolidated VIE accounted for under the equity method, and was immaterial for the three months ended March 31, 2021. See Note 3, *Variable Interest Entity*, to the condensed consolidated financial statements for details.

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 collaboration agreements involving license payments, milestones and reimbursement for development services.

As of March 31, 2021, we had cash and cash equivalents of $433.5 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 and marketable equity investments, and stated at fair value, are also available as a source of liquidity. As of March 31, 2021, we had short-term and long-term investments of $110.7 million and $93.7 million, respectively. As of March 31, 2021, a total of $76.5 million of our cash and cash equivalents was held outside of the U.S. in our foreign subsidiaries, including $55.1 million of our cash and cash equivalents is held in China, to be used primarily for our China operations.

Operating Capital Requirements

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

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

Cash Sources and Uses

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

	Three Months Ended March 31,	
	2021	2020
Net cash provided by (used in):		
Operating activities	$ (44,984)	$ (59,486)
Investing activities	(196,719)	56,009
Financing activities	(2,080)	(1,190)
Effect of exchange rate changes on cash and cash equivalents	(1,102)	(39)
Net decrease in cash and cash equivalents	$ (244,885)	$ (4,706)

Operating Activities

Net cash used in operating activities was $45.0 million for the three months ended March 31, 2021 and consisted primarily of net loss of $71.8 million adjusted for non-cash items of $25.1 million, offset by a net increase in operating assets and liabilities of $1.7 million. The significant non-cash items included stock-based compensation expense of $19.4 million, depreciation expense of $2.7 million and amortization of finance lease ROU of $2.6 million. The significant items in the changes in operating assets and liabilities included the increases resulting from the following:

- Deferred revenue of $17.2 million, primarily related to the above-mentioned $11.8 million of the constrained consideration of the bulk drug product shipped to Astellas due to a high degree of uncertainty associated to the final consideration, and $3.9 million of the constrained revenue from the sales to Falikang associated with China performance obligation. The change in deferred revenue was also driven by the extension of the estimated future non-contingent development period and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca. See Note 2, *Collaboration Agreements and Revenues*, to the condensed consolidated financial statements for details.

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

- Other assets of $5.6 million, primarily related to the new operation right-of-use assets in China;
- Prepaid expenses and other current assets of $5.5 million, primarily driven by the above-mentioned $4.0 million unbilled contract asset related to drug product revenue as a change in estimated variable consideration, based on the API held by Astellas at March 31, 2021. See Note 2, *Collaboration Agreements and Revenues*, to the condensed consolidated financial statements for details; and
- Inventories of $4.3 million, driven by the increased inventory level primarily related to FibroGen Beijing's productions of roxadustat for commercial sales purposes and pre-launch inventory cost capitalized in the U.S.

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 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 were 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.

Investing Activities

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

Net cash used in investing activities was $196.7 million for the three months ended March 31, 2021 and consisted primarily of $196.2 million of cash used in purchases of available-for-sale securities.

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.

Financing Activities

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

Net cash used in financing activities was $2.1 million for the three months ended March 31, 2021 and consisted primarily of $4.8 million of cash paid for payroll taxes on restricted stock unit releases, $3.3 million of repayments of finance lease liabilities, partially offset by $6.1 million of proceeds from the issuance of common stock upon exercise of stock options.

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.

Off-Balance Sheet Arrangements

During the three months ended March 31, 2021, 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

As of March 31, 2021, we had $34.7 million of finance lease liabilities and $5.1 million of operating lease liabilities.

As of March 31, 2021, we had outstanding total non-cancelable purchase obligations of $93.9 million, including $30.4 million for manufacture and supply of roxadustat, $57.5 million for manufacture and supply of pamrevlumab, and $6.0 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.

Some of our license agreements provide for periodic maintenance fees over specified time periods, as well as payments by us upon the achievement of development, regulatory and commercial milestones. Future milestone payments for research and pre-clinical stage development programs consisted of up to approximately $10.9 million in total potential future milestone payments under our license agreements with Dana-Farber Cancer Institute, University of Miami and Medarex, Inc. These milestone payments generally become due and payable only upon the achievement of certain developmental, clinical, regulatory and/or commercial milestones. The event triggering such payment or obligation has not yet occurred.

Recently Issued and Adopted Accounting Guidance

In December 2019, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“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 was effective for annual reporting periods beginning after December 15, 2020 including interim periods. We adopted this guidance on January 1, 2021, and the adoption of this guidance did not have material impact to our condensed consolidated financial statements and related disclosures.

Recently Issued Accounting Guidance Not Yet Adopted

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting* ("ASU 2020-04"), which provides companies with optional financial reporting alternatives to reduce the cost and complexity associated with the accounting for contracts and hedging relationships affected by reference rate reform. This guidance is effective as of March 12, 2020 through December 31, 2022. Subsequently in January 2021, the FASB issued ASU 2021-01, *Reference Rate Reform (Topic 848): Scope*, which clarifies ASU 2020-04 and provides certain optional expedients that allow derivative instruments impacted by changes in the interest rate used for margining, discounting or contract price alignment to qualify for certain optional relief. ASU 2021-01 is effective in the same timeframe as ASU 2020-04. The relief offered by this guidance, if adopted, is available to companies for the period March 12, 2020 through December 31, 2022. We have certain lease arrangements that are linked to LIBOR. We are in the process of evaluating options for transitioning away from LIBOR and expects to complete by the time LIBOR is phased out. We did not elect to apply any of the expedients or exceptions as of and for the period ended March 31, 2021 and are currently evaluating the impact on our consolidated financial statements and related disclosures 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, 2021 compared with the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2020, except for the following:

Product revenue, net

Product revenue, net consists of revenues from sales of roxadustat commercial product to Falikang, and directly to pharmaceutical distributors located in a few provinces in China that are not covered by Falikang. Falikang is jointly owned by AstraZeneca and FibroGen Beijing. We are not the primary beneficiary of Falikang for accounting purposes, as AstraZeneca is the final decision maker for all the roxadustat commercialization activities, and we lack the power criterion to direct the activities of Falikang (see Note 3, *Variable Interest Entity*, to the condensed consolidated financial statements).

Sales to Falikang

Falikang became fully operational in January 2021, at which time FibroGen Beijing began selling roxadustat commercial product to Falikang. Falikang is FibroGen Beijing's primary customer in China and substantially all roxadustat product sales to distributors in China are made by Falikang. Falikang bears inventory risk once it receives and accepts the product from FibroGen Beijing, and is responsible for delivering product to its distributors.

The promises identified under the AstraZeneca China Agreement, including the license, co-development services and manufacturing of commercial supplies have been bundled into the China performance obligation. Amounts of the transaction price allocable to this performance obligation under our agreements with AstraZeneca are deferred until control of the manufactured commercial product has begun to transfer to AstraZeneca.

The initiation of roxadustat sales to Falikang marked the beginning of the China performance obligation. Revenue is recognized at a point in time when control of roxadustat commercial product is transferred to Falikang. Revenue is recognized based on the estimated transaction price per unit and actual quantity of product delivered during the reporting period. Specifically, the transaction price per unit is determined based on the overall transaction price over the total estimated sales quantity for the estimated performance period in which we believe those sales would occur. The price per unit is subject to reassessment on a quarterly basis, which may result in cumulative catch up adjustments.

The overall transaction price for FibroGen Beijing's product sales to Falikang includes the following elements of consideration:

- Non-refundable upfront license fees; development, regulatory, and commercial milestone payments based on the China Agreement allocated to the China performance obligation;
- Co-development billings resulting from our research and development efforts, which are reimbursable under the China Agreement;
- Interim profit/loss share between FibroGen Beijing and AstraZeneca from April 1, 2020 through December 31, 2020; and
- Net transfer price from product sales to Falikang from January 1, 2021 onwards. The net transfer price includes the following elements:
    - Gross transfer price: The gross transfer price is based on a percentage of Falikang's net sales to its distributors, which takes into account Falikang's operating expenses and its payments to AstraZeneca for roxadustat sales and marketing efforts, capped at a percentage of Falikang's net roxadustat sales.
    - Profit share: The gross transfer price is then adjusted for an estimated amount to achieve the 50/50 profit share from current period roxadustat net sales in China. The adjustments to date have been a reduction to the transfer price and the related accounts receivable from Falikang.

The non-refundable upfront license fees constitute a fixed consideration. The remainder of the above are variable consideration components, which may be constrained, and included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period when the uncertainty associated with the variable consideration is subsequently resolved. The calculation of the above variable consideration includes key estimation areas such as total sales quantity, performance period, gross transfer price and profit share, which require a substantial degree of judgment.

Any net transfer price in excess of the revenue recognized is added to the deferred balance to date, and will be recognized over future periods as the performance obligations are satisfied.

Direct Sales to Distributors

We sell roxadustat in China directly to a number of pharmaceutical distributors located in a few provinces in China that are not covered by Falikang. These pharmaceutical distributors are our customers. Hospitals order roxadustat through a distributor and we ship the product directly to the distributors. The delivery of roxadustat to a distributor represents a single performance obligation. Distributors are responsible for delivering product to end users, primarily hospitals. Distributors bear inventory risk once they receive and accept the product. Product revenue is recognized when control of the promised good is transferred to the customer in an amount that reflects the consideration to which we expect to be entitled to in exchange for the product.

The period between the transfer of control of the promised goods and when we receive payment is based on 60-day payment terms. As such, product revenue is not adjusted for the effects of a significant financing component.

Product revenue is recorded at the net sales prices which includes the following estimates of variable consideration:

- Price adjustment: When China's National Healthcare Security Administration releases price guidance for roxadustat under the National Reimbursement Drug List, any channel inventories that have not been sold through by distributors, or to patients by hospitals and retailors, would be eligible for a price adjustment under the price protection. The price adjustment is calculated based on estimated channel inventory levels;
- Contractual sales rebate: The contractual sales rebate is calculated based on the stated percentage of gross sales by each distributor in the distribution agreement entered between FibroGen and each distributor. The contractual sales rebate is recorded as a reduction to revenue at the point of sale to the distributor;
- Non-key account hospital listing award: A one-time fixed-amount award is offered to a distributor who successfully lists the product with an eligible hospital, and who meets certain requirements. We consider this particular award to be an upfront payment to a customer within the definitions of ASC 606. The non-key account hospital listing award is capitalized when the distributor meets eligibility requirements, and amortized as reduction to product revenue over future sales orders made by the distributor until exhausted;
- Other discounts and rebates, including key account hospital sales rebate and transfer fee discount, are generally based on a percentage of eligible gross sales made by the distributor and recorded as a reduction to revenue at the point of sale to the distributor; and
- Sales returns: Distributors can request to return product to us only due to quality issues or for product purchased within one year prior to the product's expiration date.

The calculation of the above variable consideration is based on gross sales to the distributor, or estimated utilizing best available information from the distributor, maximum known exposures and other available information including estimated channel inventory levels and estimated sales made by the distributor to hospitals, which involve a substantial degree of judgment.

The above rebates and discounts all together are eligible to be applied against the distributor's future sales order, limited to certain maximums until such rebates and discounts are exhausted. These rebates and discounts are recorded as contract liabilities at the time they become eligible and in the same period that the related revenue is recorded. Due to the distributor's legal right to offset, at each balance sheet date, the liability for rebates and discounts are presented as reductions of gross accounts receivable from the distributor, or as a current liability to the distributor to the extent that the total amount exceeds the gross accounts receivable or when we expect to settle the discount in cash. The distributor's legal right of offset is calculated at the individual distributor level.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

During the three months ended March 31, 2021, we believe there were no material changes to our exposure to market risks as set forth in Part II, Item 7A "Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K for the year ended December 31, 2020.

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 March 31, 2021, 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 our evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of March 31, 2021 because of the material weaknesses in our internal control over financial reporting described below.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

As of September 30, 2020, we have identified a material weakness in the risk assessment component of internal control as we did not appropriately design and maintain an effective risk assessment process at a precise enough level to identify new and evolving risks of material misstatement to the financial statements as a result of changes in our business operation. This material weakness gave rise to the following additional control deficiencies, which we also determined to be material weaknesses. We did not design and maintain effective controls related to the timely identification of shipments associated with drug product revenue, and we did not design and maintain effective controls related to the timely identification of changes in estimated variable consideration related to drug product revenue.

Each of these material weaknesses could result in material misstatements in the drug product revenue, contract asset or contract liability account balances or disclosures in our annual or interim consolidated financial statements that would not be prevented or detected.

The material weaknesses described above did not result in any material misstatements of our consolidated financial statements or disclosures, but did result in immaterial out-of-period adjustments to drug product revenue related to pre-commercial shipments of drug product, contract assets and contract liabilities, and related financial statement disclosures during the quarter ended September 30, 2020.

Remediation Plan and Status

Our Board of Directors and management are committed to maintaining a strong internal control environment. We have developed a detailed remediation plan and are making progress of what will be a multi-step remediation process to fully remediate the material weaknesses described above. Specifically, as of March 31, 2021, we have continued with the remediation steps that were initiated in the fourth quarter of 2020, including, but not limited to, the following:

- We have started a comprehensive annual risk assessment process, and will continue to refine the risk assessment, to identify and design our control activities related to the above mentioned material weaknesses;
- We have identified and designed new controls and procedures associated with drug product revenue, and where applicable implemented new procedures and controls during the fourth quarter of 2020 and the first quarter of 2021, and will continue to implement new procedures and controls in the future; and
- We have hired additional resources to strengthen our accounting and internal audit functions.

In addition, we will continue to assess risks on a continuous basis to timely identify new exposures or risk categories as business practices change, and we plan to conduct a comprehensive review and, as applicable, update our existing internal control framework to ensure that it has identified, developed and deployed the appropriate business process controls to meet the objectives and address the risks identified.

The material weaknesses will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. We believe the measures described above will remediate these material weaknesses and strengthen our internal control over financial reporting. As we continue to evaluate and work to remediate these material weaknesses, we may determine to take additional measures to address these deficiencies or determine to modify certain of the remediation measures described above.

Changes in Internal Control over Financial Reporting

Besides the new procedures and controls implemented to date as described above, there were no changes in our internal control over financial reporting that occurred during the three months ended March 31, 2021 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 a party to various legal actions that arose in the ordinary course of our business. We recognize accruals for any legal action when we conclude that a loss is probable and reasonably estimable. We did not have any material accruals for any currently active legal action in our consolidated balance sheets as of March 31, 2021, as we could not predict the ultimate outcome of these matters, or reasonably estimate the potential exposure.

In April 2021, three putative securities class action complaints were filed against FibroGen and certain of its current and former executive officers (collectively, the "Defendants") in the United States ("U.S.") District Court for the Northern District of California. The lawsuits allege that Defendants violated the Securities Exchange Act of 1934 by making materially false and misleading statements regarding FibroGen's Phase 3 clinical studies data and prospects for FDA approval between November 2019 and December 2020. Plaintiffs seek to represent a class of persons or entities that purchased FibroGen securities between November 8, 2019 and April 6, 2021. In May 2021, two additional putative securities class action complaints were filed against Defendants alleging the same claims. One of the lawsuits alleges that Defendants made materially false and misleading statements between October 2017 and December 2020 and seeks to represent a class of persons or entities that purchased FibroGen securities between October 18, 2017 and April 6, 2021. The other lawsuit alleges that Defendants made materially false and misleading statements between December 2018 and February 2020 and seeks to represent a class of persons or entities that purchased FibroGen securities between December 20, 2018 and April 6, 2021. All plaintiffs seek unspecified monetary damages and other relief. Motions for lead plaintiff are due on June 11, 2021. Once a lead plaintiff is appointed by the Court, we expect to receive an amended consolidated complaint. We believe that the claims are without merit and we intend to vigorously defend against them. However, any litigation is inherently uncertain, and any judgment or injunctive relief entered against us or any adverse settlement could materially and adversely impact our business, results of operations, financial condition, and prospects.

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, 2020.

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 the People's Republic of China ("China"), Japan, and Chile for chronic kidney disease ("CKD") anemia for patients on dialysis and not on dialysis, our partners and we will need to make substantial additional investments in the development and commercialization of roxadustat worldwide and in various indications. Our near-term prospects, including maintaining our existing collaborations with Astellas Pharma Inc. ("Astellas") and AstraZeneca AB ("AstraZeneca"), will depend heavily on successful development and commercialization of roxadustat, including obtaining additional regulatory approvals for the commercialization of roxadustat for anemia associated with CKD.

Our other lead product candidate, pamrevlumab, is currently in clinical development for idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer, and Duchenne muscular dystrophy ("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.

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 with our collaboration partners, our business would be harmed.

We do not have a sales or marketing infrastructure and have limited experience in the sales, marketing or distribution of pharmaceutical products in any country. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish sales and marketing capabilities or make and maintain our existing arrangements with third parties to perform these services at a level sufficient to support our commercialization efforts.

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

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- our inability to effectively manage geographically dispersed commercial 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 commercial 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 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, 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 our marketing, pricing and reimbursement strategies, facilitating adoption by dialysis organizations, health care professionals, recruiting sales and marketing personnel or in building a sales and marketing infrastructure, or if the market perception of roxadustat's safety and efficacy profile is negative, 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, Japan, and Chile, we may be unable to obtain regulatory approval 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 ultimately receive regulatory approval. In addition, our collaboration partners for roxadustat have final control over development decisions in their respective territories and they may make decisions with respect to development or regulatory authorities that delay or limit the potential approval of roxadustat, or increase the cost of development or commercialization. Accordingly, we may be unable to successfully develop or commercialize roxadustat, pamrevlumab, or any of our other product candidates in one or more indications and jurisdictions.

Moreover, for any Phase 3 clinical trial to support an NDA/Biologics License Application submission for approval, the U.S. Food and Drug Administration ("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 clinical research organizations ("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 or the independent advisory committee 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 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 Risk Evaluation and Mitigation Strategy ("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.

The results of the FDA Cardiovascular and Renal Drugs Advisory Committee meeting may affect roxadustat's approvability and label in CKD anemia.*

On March 1, 2021, the FDA informed us that the Cardiovascular and Renal Drugs Advisory Committee will hold an advisory committee meeting to review the NDA for roxadustat. The date of the advisory committee meeting has been tentatively scheduled for July 15, 2021. The advisory committee is a committee of external experts that will provide input on issues relating to benefit, risk, and interpretation of our roxadustat clinical trial data. However, we do not know how long it will take after the committee convenes for the FDA to make a decision on our NDA. The advisory committee may have a different interpretation of our results and their advisory vote or input to the FDA may affect roxadustat's approvability and labeling. The FDA may further delay approval of our NDA if applicable regulatory criteria are not satisfied and/or the FDA requires additional testing or information. The full extent of the delay on an approval decision and impact of the advisory committee is unknown.

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

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 Severe Acute Respiratory Syndrome Coronavirus 2 and the resulting Coronavirus Disease ("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 (particularly for IPF);
- 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 clinical trial development plan becoming longer and more extensive;
- regulatory authorities increasing the data and information required to approve our product candidates and imposing other requirements; and
- our collaboration partners terminating our existing agreements.

The occurrence of any or all of these events may cause the development of our product candidates to be delayed or terminated, which could materially and adversely affect our business and prospects. Refer to "*Business — Overview*" in our Annual Report on Form 10-K for the year ended December 31, 2020 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 our manufacturers or we cannot properly manufacture sufficient product, 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 roxadustat and pamrevlumab, 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. In addition, we may experience delays or technical problems associated with technology transfer of manufacturing processes to any new suppliers.

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

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

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

We may add or change manufacturers for our products. We, our partners, or regulatory authorities may also request or make changes to our manufacturing processes or to our product or packaging specifications, including in order to accommodate changes in regulations, manufacturing equipment or to account for different processes at new or second source suppliers. If any such changes are made with respect to roxadustat or pamrevlumab we may need to demonstrate comparability to the products and processes already approved or in approval by various regulatory authorities, including potentially through the conduct of additional clinical trials. Even if we do demonstrate comparability, a regulatory agency could challenge that result which could delay our development or commercialization progress. Any such changes could also lead to product having an earlier expiration date, shorter shelf life, or failing to meet specifications. Any of these occurrences may materially impact our operations and potential profitability.

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

- costs and challenges associated with scale-up and attaining sufficient manufacturing yields, in particular for biologic products such as pamrevlumab, which is a monoclonal antibody;
- contracting with additional suppliers and validation/qualification of additional facilities to meet growing demand;
- supply chain issues, including coordination of multiple contractors in our supply chain and securing necessary licenses (such as export licenses);
- the timely availability and shelf life requirements of raw materials and supplies, including delays in availability due to the COVID-19 pandemic;
- limited stability and product shelf life;
- 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.

Regulatory authorities will do their own benefit risk analysis and may reach a different conclusion than we or our partners have, 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 sub-populations, or using certain statistical methods of analysis, the FDA and European Medicines Agency ("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 sets of stratification factors and 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. The failure to obtain regulatory approval, or any label, population or other approval limitations in any jurisdiction, may significantly limit or delay 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 boxed warnings on their labels. The safety concerns relating to ESAs may result in labeling for roxadustat containing similar warnings. 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 safety issues associated with ESAs, even if our Phase 3 clinical trials do not themselves raise safety concerns.

We face substantial competition in the discovery, development and commercialization of product candidates.*

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

If roxadustat is approved and launched commercially, competing drugs are expected to include ESAs, particularly in those patient segments where ESAs are used. Currently available ESAs include epoetin alfa (EPOGEN®, marketed by Amgen Inc. in the U.S., Procrit® and Erypo®/Eprex®, marketed by Johnson & Johnson Inc., and Espo® marketed by Kyowa Hakko Kirin in Japan and China), darbepoetin (Amgen/Kyowa Hakko Kirin's Aranesp® and NESP®) and Mircera® marketed by Hoffmann-La Roche ("Roche") outside of the U.S. and by Vifor Pharma, a Roche licensee, in the U.S. and Puerto Rico, as well as biosimilar versions of these currently marketed ESA products. ESAs have been used in the treatment of anemia in CKD for more than 30 years, serving a significant majority of dialysis CKD patients. While non-dialysis CKD patients who are not under the care of nephrologists, including those with diabetes and hypertension, do not typically receive ESAs and are often left untreated, some non-dialysis patients under nephrology or hematology 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 adequately addressed by ESAs. Companies that are currently developing hypoxia-inducible factor ("HIF") prolyl hydroxylase (together with HIF, "HIF-PH") inhibitors for anemia in CKD indications include GlaxoSmithKline plc ("GSK"), Bayer Corporation ("Bayer"), Akebia Therapeutics, Inc. ("Akebia"), Otsuka Pharmaceutical ("Otsuka"), Akebia's partner in the U.S. and Europe, Japan Tobacco, and Zydus Cadila (India) ("Zydus"). Akebia has completed Phase 3 studies in CKD patients on dialysis and not on dialysis in the U.S., as well as a Phase 3b, randomized, open-label, active-controlled trial evaluating the efficacy and safety of oral vadadustat once daily and three times weekly for the maintenance treatment of anemia in hemodialysis subjects converting from ESAs. The study completion date is estimated to be May 2022. Akebia announced an additional Phase 3 study evaluating the efficacy and safety of dose conversion from a long-acting erythropoiesis stimulating agent (Mircera®) to three times weekly oral vadadustat for the maintenance treatment of anemia in hemodialysis subjects. The estimated study start date is February 2021. On March 30, 2021, Akebia submitted an NDA to the FDA for vadadustat for the treatment of anemia due to CKD in patients on dialysis and not on dialysis.

In Japan, Mitsubishi Tanabe Pharmaceutical Corporation, Akebia's collaboration partner, received approval for vadadustat in June 2020 for the treatment of anemia of CKD patients on and not on dialysis. GSK received approval for daprodustat in Japan in June 2020 for the treatment of anemia of CKD patients on and not on dialysis. Price listing for the launch in Japan of both vadadustat and daprodustat occurred in the third quarter of 2020, with pricing in line with roxadustat pricing. 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. Bayer received approval for molidustat in Japan in January 2021 for the treatment of anemia in CKD patients on and not on dialysis, with pricing in line with roxadustat pricing. Japan Tobacco received approval in Japan for enarodustat for the treatment of anemia in CKD patients on dialysis and not on dialysis, to be sold by Torii Pharmaceuticals Ltd as ENAROY®. Japan Tobacco and its partner JW Pharmaceuticals started a Phase 3 study in dialysis patients in Korea in 2019. Zydus started Phase 3 studies in dialysis and non-dialysis CKD patients in India in 2019.

In July 2020, Zydus received approval from the FDA to begin a Phase 1 study of desidustat for the treatment of chemotherapy-induced anemia, which could potentially be competitive with roxadustat within this indication.

Reblozyl® (luspatercept) was approved by the FDA in April 2020 for the treatment of anemia in adults with myelodysplastic syndromes with ring sideroblasts or myelodysplastic/myeloproliferative neoplasms with ring sideroblasts and thrombocytosis who need regular red blood cell transfusions and have not responded well to or cannot receive an ESA. It is the first and only erythroid maturation agent approved in the U.S., Europe, and Canada and is part of a global collaboration between Acceleron Pharma, Inc. and Bristol Myers Squibb.

In addition, we will likely face competition from other companies developing biologic therapies for the treatment of other anemia indications that we may also seek to pursue in the future. 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.

In China, ESA is considered the standard of care for treatment of anemia of CKD, and locally manufactured epoetin alfa is offered by 15 local manufacturers including the market leader EPIAO that is marketed by 3SBio Inc. We may face potential competition from other HIF-PH inhibitors. Companies active in the US such as Akebia, Bayer, and GSK have been authorized by the National Medical Products Administration ("NMPA") to conduct trials in China to support its ex-China regulatory filings. A number of domestic companies, including Jiangsu Hengrui Medicine Co., Ltd., Guandong Sunshine Health Investment Co., Ltd., 3SBio Inc., and Hangzhou Andao Pharmaceutical Co. have been permitted by the NMPA to conduct clinical trials in their locally developed HIF-PH inhibitor investigational compounds for the treatment of anemia in CKD. Domestic companies are also in-licensing global compounds to be developed as domestic drugs, including China Medical System which in-licensed desidustat, a compound that is currently in Phase 3 trials in India, from Zydus for greater China in January 2020. In January 2021, China Medical System Holdings Ltd. was granted approval by the Chinese NMPA to begin trials for desidustat in patients with anemia of CKD, including dialysis and non-dialysis patients. Shenzhen Salubris Pharmaceutical Co., Ltd., a domestic company in China, has in-licensed enarodustat from Japan Tobacco and received NMPA approval in the third quarter of 2020 to initiate Phase 3 studies. We will also face competition from generics who could enter the market after expiry of our patents in China, and two potential market players have already started bioequivalence studies, including Chia Tai-Tiangqing Pharmaceutical Holdings and CSPA Pharmaceutical Group.

The first biosimilar ESA, Pfizer's Retacrit® (epoetin zeta), entered the U.S. market in November 2018. Market penetration of Retacrit and the potential addition of other biosimilar ESAs currently under development may alter the competitive and pricing landscape of anemia therapy in CKD patients on dialysis under the end-stage renal disease bundle. The patents for Amgen's EPOGEN® (epoetin alfa) expired in 2004 in Europe, and the final material patents in the U.S. expired in May 2015. Several biosimilar versions of currently marketed ESAs are available for sale in Europe, China and other territories. In the U.S., a few ESA biosimilars are currently under development. Sandoz, a division of Novartis, markets Binocrit® (epoetin alfa) in Europe and may file a biosimilar Biologics License Application in the U.S.

The majority of the current CKD anemia market focuses on dialysis patients, who visit dialysis centers on a regular basis, typically three times a week, and anemia therapies are administered as part of the visit. Two of the largest operators of dialysis clinics in the U.S., DaVita Healthcare Partners Inc. ("DaVita"), and Fresenius Medical Care AG & Co. KGaA ("Fresenius"), collectively provide dialysis care to more than 80% of U.S. dialysis patients, and therefore have historically executed long-term contracts including rebate terms with Amgen. Successful penetration in this market will likely require our partner AstraZeneca to enter into a definitive agreement with Fresenius, DaVita, or other dialysis organizations, on favorable pricing terms and on a timely basis.

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

Pamrevlumab is a monoclonal antibody that 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 Kadmon Holdings, Inc.'s KD025, Liminal BioSciences' PBI-4050, and Roche/Promedior, Inc.'s PRM-151.

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

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

If approved and launched commercially to treat DMD, pamrevlumab is expected to face competition from drugs that have been approved in major markets such as the U.S., European Union, and Japan. On September 19, 2016, the FDA approved Sarepta Therapeutics Inc.'s ("Sarepta") Exondys 51™ (eteplirsen). 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's Vyondys 53™ (golodirsen) was approved by the FDA in December 2019 for patients with a confirmed genetic mutation that is amenable to exon 53 skipping, which accounts for approximately 8% of the DMD population. Sarepta's Amondys 45™ (casimersen) was approved by the FDA in February 2021 for patients with a confirmed genetic mutation that is amenable to exon 45 skipping, which accounts for approximately 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, Pliant, Galecto, and Sarepta. Pfizer initiated a Phase 3 study with PF-06939926, its AAV9 mini-dystrophin gene therapy for DMD in February 2020. Pliant's PLN-74809 and Galecto's lead candidate GB0139, are in Phase 2 development for IPF.

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

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

Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors, and others in the medical community. Demonstrating safety and efficacy of our product candidates and obtaining regulatory approvals will not guarantee future revenue. The degree of market acceptance of any of our approved product candidates will depend on several factors, including:

- the efficacy of the product candidate as demonstrated in clinical trials;
- the safety profile and perceptions of safety of our product candidates relative to competitive products;
- acceptance of the product candidate as a safe and effective treatment by clinics and patients;
- the clinical indications for which the product candidate is approved;
- the potential and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments;
- the inclusion or exclusion of the product candidate from treatment guidelines established by various physician groups and the viewpoints of influential physicians with respect to the product candidate;
- the cost of the product candidate relative to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third parties and government authorities as described below;
- the relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- any unfavorable publicity relating to the product candidate.

In addition, see the risk factor titled “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” above. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

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 governments and 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, the pricing may be subject to re-negotiations or third-party payors may not establish adequate reimbursement amounts, which may reduce the demand for, or the price of, our products. For example, our current National Reimbursement Drug List reimbursement pricing for China 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 we expect to be lower based upon historical precedents.

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, our partner or we 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, our partner or we may elect not to commercialize our products in such countries, and our business and financial condition could be adversely affected.

Risks Related to Severe Acute Respiratory Syndrome Coronavirus 2 and the Resulting Coronavirus Disease ("COVID-19")

Our business could continue to be adversely affected by the ongoing COVID-19 global pandemic.*

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. While certain COVID-19 vaccines have received regulatory approval and have begun to be distributed and administered to the general population, it is uncertain how quickly and to what extent such actions will contain the virus and normal economic operating conditions will resume. The efficacy of such vaccines in preventing the spread and effects of current and future COVID-19 variants is also a possible unknown.

The extent of the impact on the COVID-19 pandemic on our business and financial results will continue to depend on numerous evolving factors that we are not able to accurately predict and which will vary by market, including the duration and scope of the pandemic, global economic conditions during and after the pandemic, the availability, speed and efficacy of vaccinations around the world, and governmental actions that have been taken, or may be taken in the future, in response to the pandemic, including any COVID-19 variants.

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 other risks from remote work including but not limited to the potential for reduced oversight of third parties we work with, such as manufacturing, CROs, and clinical sites.

China was able to minimize the impact of COVID-19 on the economy in 2020 relative to other major economies. However, if there are any further COVID-19 outbreaks, our partners or we may need to re-institute or tighten restrictions on our operations.

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 further delayed, in particular our studies in IPF, due to a continued or further outbreak which can slow or pause enrollment or site initiation and other 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 our manufacturing partners and we are currently continuing manufacturing operations. However, we only have a limited stockpile of these drug supply products, and therefore, if there is a greater impact from the COVID-19 pandemic than we have expected, or if manufacturing operations are halted again, or if drug product expires due to slowed clinical trials, we could face shortages in our global supply chains. COVID-19 has created increased demand for the limited global biologics manufacturing capacity, and as a result, we have faced competition for manufacturing supplies due to prioritization of COVID-19 related manufacturing. We could face additional competition for such manufacturing supplies, including for vials, reagents, supplements and media, and may face competition to use available capacity at our manufacturing partners. 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. There may be unexpected regulatory delays due to the COVID-19 pandemic including due to travel restrictions impacting pre-approval inspections.

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 were terminated or if Astellas or AstraZeneca were to prioritize other initiatives over their collaborations with us, 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. In addition, each of those agreements provides our respective partners the right to terminate any of those agreements upon written notice for convenience. 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. 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, 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 do not 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 regulatory 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 receives regulatory approval, we will remain substantially dependent on the commercialization strategy and efforts of our collaboration partners, and, our collaboration partners have limited or no experience in commercialization of an anemia drug. If our collaboration partners are unsuccessful in their commercialization efforts, our results will be negatively affected.

With respect to our collaboration agreements for roxadustat, there are additional complexities in that our collaboration partners, Astellas and AstraZeneca, and we must reach consensus on our development programs and regulatory activities, including for the NDA in the U.S. and the Marketing Authorization Application in Europe. In addition, there are aspects of commercial operations that require cooperation among the collaboration partners, including safety data reporting. 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, or both, 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.

If our preclinical and clinical trial contractors do not properly perform their agreed upon obligations, 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 period of time. 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 terminate these agreements or not perform satisfactorily.*

We do not have operating manufacturing facilities at this time other than our roxadustat manufacturing facilities in China, and our current commercial manufacturing plants 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 rely on third parties for distribution, including our collaboration partners and their vendors, except in China where we have established a jointly owned entity with AstraZeneca to manage most of the 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.

We have entered into an initial commercial supply agreement for the manufacture of pamrevlumab with Samsung Biologics Co., Ltd. ("Samsung"). However, we may experience delays or technical problems associated with technology transfer of the manufacturing process to Samsung and the qualification and scale-up thereof. We have made certain manufacturing commitments to Samsung, and there is a risk we will not require the quantities of pamrevlumab we have committed to, particularly if we cease some of our pamrevlumab clinical trials. 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, IRIX and we have entered into several additional service agreements. IRIX has requested in writing that we honor the letter agreement with respect to the single source manufacturing agreement, and if we were to enter into any such exclusive manufacturing agreement, there can be no assurance that IRIX will not assert a claim for right to manufacture roxadustat or that IRIX could manufacture roxadustat successfully and in accordance with applicable regulations for a commercial product and the specifications of our collaboration partners. In 2015, Patheon Pharmaceuticals Inc., a business unit of DPx Holdings B.V., acquired IRIX, and in 2017, ThermoFisher Scientific Inc. acquired Patheon Pharmaceuticals Inc.

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 components of our products are acquired from single-source suppliers or without long-term supply agreements. The loss of these suppliers, or their failure to supply, 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, active pharmaceutical ingredients ("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 proceedings involving our intellectual property initiated by third parties, which proceedings can be associated with significant costs and commitment of management time and attention. As our product candidates continue in development, third parties have attempted and may again 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 are generally considered 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 our licensors or we were the first to make the inventions claimed in our owned and licensed patents or patent applications, or that our licensors or we 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 have, are, and may again become involved in opposition or interference proceedings challenging our patents and patent applications or the patents and patent applications of others, and the outcome of any such proceedings are highly uncertain. An unfavorable outcome in any such proceedings could reduce the scope of or invalidate our patent rights, allow third parties to commercialize our technology and compete directly with us, or result in our inability to manufacture, develop or commercialize our product candidates without infringing the patent rights of others.

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

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

We may consider administrative proceedings and other means for challenging third-party patents and patent applications. An unfavorable outcome in any such challenge could require us to cease using the related technology and to attempt to license rights to it from the prevailing third party, which may not be available on commercially reasonable terms, if at all, in which case our business could be harmed.

We intend, if necessary, to vigorously enforce our intellectual property in order to protect the proprietary position of our product candidates, including roxadustat and pamrevlumab. In addition, our collaboration partners who have been granted licenses to our patents may also have rights related to enforcement of those patents. Active efforts to enforce our patents by us or by our partners may include litigation, administrative proceedings, or both, depending on the potential benefits that might be available from those actions and the costs associated with undertaking those efforts against third parties. We carefully review and monitor publicly available information regarding products that may be competitive with our product candidates and assert our intellectual property rights where appropriate.

Third parties have challenged and may again challenge our patents and patent applications. For example, various challenges against our HIF anemia-related technologies patent portfolio are ongoing in several territories including the U.S., Europe, the United Kingdom, and Japan. Regardless of final outcome, the potential narrowing or revocation of any of the HIF anemia-related technology patents does not affect our exclusivity for roxadustat or our freedom-to-operate with respect to use of roxadustat for the treatment of anemia in these or other territories.

In May 2020, oppositions were filed against our European Patent No. 2872488 (the "`488 Patent"), which claims a crystalline form of roxadustat, and against our European Patent No. 3003284 (the "`284 Patent"), which claims photostable formulations of roxadustat. Final resolution of the opposition proceedings will take time, and we cannot be assured of the breadth of the claims that will remain in the `488 Patent or `284 Patent, or that either or both of the patents will not be revoked in their 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 that we have in place with them. 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.

The cost of maintaining our patent protection is high and requires continuous review and diligence. We may not be able to effectively maintain our intellectual property position throughout the major markets of the world.

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

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

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

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

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

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

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

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

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

Risks Related to Government Regulation

The regulatory approval process is highly uncertain and we may not obtain regulatory approval for 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, Japan, and Chile for patients on dialysis and not 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 current and future relationships with customers, physicians, and third-party payors are subject to healthcare fraud and abuse laws, false claims laws, transparency laws, privacy and security laws, and other regulations. If we are unable to comply with such laws, we could face substantial penalties.

Our current and future relationships with customers, physicians, and third-party payors are subject to health care laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market and distribute any products for which we obtain marketing approval. 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 administrative, 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 on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors 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, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “PPACA”), which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & 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 significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, 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 maintain 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, partners, affiliates, subcontractors, 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.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these, or if we otherwise fail to maintain an effective system of internal control, it may result in material misstatements in our financial statements.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for evaluating and reporting on the effectiveness of our system of internal control. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external reporting purposes in accordance with generally accepted accounting principles. As a public company, we are required to comply with the Sarbanes-Oxley Act and other rules that govern public companies.

As of September 30, 2020, we have identified a material weakness in the risk assessment component of internal control as we did not appropriately design and maintain an effective risk assessment process at a precise enough level to identify new and evolving risks of material misstatement to the financial statements as a result of changes in our business operation. This material weakness gave rise to the following additional control deficiencies, which we also determined to be material weaknesses. We did not design and maintain effective controls related to the timely identification of shipments associated with drug product revenue and we did not design and maintain effective controls related to the timely identification of changes in estimated variable consideration related to drug product revenue. Each of these material weaknesses could result in material misstatements in the drug product revenue, contract asset, or contract liability account balances or disclosures in our annual or interim consolidated financial statements that would not be prevented or detected. The material weaknesses described above did not result in any material misstatements of our consolidated financial statements or disclosures, but did result in immaterial out-of-period adjustments to drug product revenue related to pre-commercial shipments of drug product, contract assets and contract liabilities, and related financial statement disclosures during the quarter ended September 30, 2020.

We have developed a detailed remediation plan and are making progress to improve our related internal control over financial reporting. For further discussion of the material weaknesses identified and our remedial efforts, see Part II, Item 9A, "*Controls and Procedures"* in our Annual Report on Form 10-K for the year ended December 31, 2020.

Remediation efforts place a significant burden on management and add increased pressure on our financial resources and processes. If we are unable to successfully remediate our existing or any future material weaknesses or other deficiencies in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected, our liquidity, our access to capital markets may be adversely affected, we may be unable to maintain or regain compliance with applicable securities laws, and the Nasdaq Stock Market LLC listing requirements, we may be subject to regulatory investigations and penalties, investors may lose confidence in our financial reporting, and our stock price may decline.

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 End-Stage Renal Disease Prospective Payment System (the "ESRD PPS") 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 or the timing of inclusion. 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 initially be included in the bundle and would instead be eligible for a Transitional Drug Add-on Payment Adjustment ("TDAPA") for a 24-month period. At the 24-month mark, CMS would determine if the TDAPA period should be extended for roxadustat or ended. When the TDAPA period ends, CMS will determine if roxadustat should be included in the bundle and, if so, what changes to the ESRD PPS reimbursement should be made. If roxadustat is included in the ESRD PPS bundle, it may have an impact on roxadustat pricing within dialysis organizations. If roxadustat is not included in the bundle after the TDAPA period, and would therefore be reimbursed outside of the bundle, it may potentially limit further market penetration of roxadustat. We currently expect roxadustat to be granted TDAPA designation one to two calendar quarters after an FDA approval. However, there is a risk that we do not receive TDAPA designation, or when we expect it, in which case, there would be a significant impact on roxadustat revenue from dialysis organizations until TDAPA designation is granted.

In March 2010, 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. 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 eliminated the health insurer tax. Additionally, on December 14, 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. The U.S. Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the U.S. Supreme Court has yet ruled on the constitutionality of the PPACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the PPACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. It is unclear how the U.S. Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration 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 used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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 our partners and us.

Roxadustat is considered a Class 2 substance on the World Anti-Doping Agency Prohibited List. There are enhanced security and distribution procedures we and our collaboration partners and third-party contractors will have to take to limit the risk of loss of product in the supply chain. As a result, our distribution, manufacturing and sales costs for roxadustat, as well as for our partners, will be increased which will reduce profitability. In addition, there is a risk of reduced sales due to patient access to this drug.

Our employees may engage in misconduct or improper activities, which could result in significant liability or 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 or safety laws and regulations, we could incur fines, penalties or other costs.

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 have established operations in China and are seeking approval to commercialize our product candidates outside of the U.S., 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. In recent years, many aspects of pharmaceutical industry regulation have undergone significant reform, and reform may continue. For example, the Chinese government implemented regulations that impact distribution of pharmaceutical products in China, where at most two invoices may be issued throughout the distribution chain, a change that required us to change our distribution paradigm. Any regulatory changes or amendments may result in increased compliance costs to our business or cause delays in or prevent the successful development or commercialization of our product candidates in China. Any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China.

We have limited experience distributing drugs in China.

We have established a jointly owned entity with AstraZeneca in China, one that has a distribution license. It is subject to a new body of regulations pertaining to distribution with which we have limited experience. 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. There are operational risks associated with the jointly owned entity, such as working capital funding requirements and regulatory challenges, which could impact our ability to operate in China, including increasing sales of roxadustat. We have limited experience managing distribution of pharmaceutical products, and this new distribution structure may impose higher costs or limit or delay our ability to sell products to our principal customers, and may limit the near term sales of our products.

We use our own manufacturing facilities in China to produce roxadustat API and drug product. There are risks inherent to operating commercial manufacturing facilities, and with these being our single source suppliers, we may not be able to continually meet market demand.

We have two manufacturing facilities in China, with one located in Beijing and the other in Cangzhou, Hebei.

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, our product suppliers and we 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, and we do not yet have a secondary source supplier for either roxadustat API or drug product 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.

As a company, we have limited experience in pharmacovigilance, medical affairs, and management of the third-party distribution logistics, and cannot assure you we will be able to meet regulatory requirements or operate in these capacities successfully.

We are responsible for commercial manufacturing, pharmacovigilance, medical affairs, and management of the third-party distribution logistics (with AstraZeneca through a jointly owned entity that will perform roxadustat distribution) 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.

Our collaboration partner in China, AstraZeneca, and we may experience difficulties in successfully growing and sustaining sales of roxadustat in China.

AstraZeneca and we have a profit sharing arrangement with respect to roxadustat in China and any difficulties we may experience in growing and sustaining 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 we expect to be lower based upon historical precedents. Sales of roxadustat in China may ultimately 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 retail prices of any product candidates that we develop may be subject to pricing control in China and elsewhere.

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.

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

We plan to conduct all of our business in China through FibroGen China Anemia Holdings, Ltd. and FibroGen Beijing. We may rely on dividends and royalties paid by FibroGen Beijing for a portion of our cash needs, including the funds necessary to service any debt we may incur and to pay our operating costs and expenses. The payment of dividends by FibroGen Beijing is subject to limitations. Regulations in China currently permit payment of dividends only out of accumulated profits as determined in accordance with accounting standards and regulations in China. FibroGen Beijing is not permitted to distribute any profits until losses from prior fiscal years have been recouped and in any event must maintain certain minimum capital requirements. FibroGen Beijing is also required to set aside at least 10.0% of its after-tax profit based on Chinese accounting standards each year to its statutory reserve fund until the cumulative amount of such reserves reaches 50.0% of its registered capital. Statutory reserves are not distributable as cash dividends. In addition, if FibroGen Beijing incurs debt on its own behalf in the future, the agreements governing such debt may restrict its ability to pay dividends or make other distributions to us. As of March 31, 2021, approximately $55.1 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 by complying with certain procedural requirements. However, approval from State Administration of Foreign Exchange 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, our foreign subsidiaries and we 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, governmental, or social conditions could have a material adverse effect on our business.

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.

Risks Related to the Operation of Our Business

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 for anemia in CKD, myelodysplastic syndromes, and chemotherapy-induced anemia, and pamrevlumab for IPF, pancreatic cancer, and 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, 2020, 2019 and 2018 were $189.3 million, $77.0 million and $86.4 million, respectively. As of March 31, 2021, we had an accumulated deficit of $1.0 billion. As of March 31, 2021, we had capital resources consisting of cash, cash equivalents and short-term investments of $544.2 million plus $93.7 million of long-term investments classified as available for sale securities. Despite contractual development and cost coverage commitments from our collaboration partners, AstraZeneca and Astellas, and the potential to receive milestone and other payments from these partners, and despite commercialization efforts in the 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, establish commercialization capabilities 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 our partners and ourselves. 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.

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 business.

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 have to limit commercial operations.

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 2019, and have continued to upgrade these capabilities. 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 and could face a cyber-attack or other breach of these systems.

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 upgraded our disaster data recovery program in March 2019, 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.

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.

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

As of April 30, 2021, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 41.33% 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 acquisitions that could dilute stockholders and harm our business.

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, 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 the determination of these non-income taxes is subject to varying interpretations arising from the complex nature of tax laws and regulations. Therefore, we may have exposure to additional non-income tax liabilities, which could have an adverse effect on our results of operations and financial condition.

Federal and state tax laws impose substantial restrictions on the utilization of net operating loss and credit carryforwards in the event of an “ownership change” for tax purposes, as defined in IRC Section 382. If additional ownership change occurs, the utilization of net operating loss and credit carryforwards could be significantly reduced.

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 could have a material adverse effect on our business.

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 certificate of incorporation designates courts located in Delaware as the sole forum for certain proceedings, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the state and federal courts located in the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated by-laws, or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. If a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

We do not plan to pay dividends. Capital appreciation will be your sole possible source of gain, which may never occur.

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. All proceeds from our initial public offering have been used as planned and described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on November 14, 2014.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of FibroGen, Inc.	8-K	001-36740	3.1	11/21/2014
3.2	Amended and Restated Bylaws of FibroGen, Inc.	S-1/A	333-199069	3.4	10/23/2014
4.1	Form of Common Stock Certificate.	8-K	001-36740	4.1	11/21/2014
4.2	Shareholders' Agreement by and among FibroGen International (Cayman) Limited and certain of its shareholders, dated as of September 8, 2017.	10-Q	001-36740	4.6	11/8/2017
4.3	Common Stock Purchase Agreement by and between FibroGen, Inc. and AstraZeneca AB, dated as of October 20, 2014.	S-1/A	333-199069	4.17	10/24/2014
10.1*+	Transition, Separation, and Consulting Agreement by and between FibroGen, Inc. and K. Peony Yu, dated as of November 27, 2020.	—	—	—	—
10.2*†	Astellas EU Supply Agreement by and between FibroGen, Inc. and Astellas Pharma Europe Ltd, effective as of January 1, 2021.	—	—	—	—
10.3*†	Amendment No. 3 to Master Supply Agreement by and among FibroGen, Inc., Shanghai SynTheAll Pharmaceutical Co., Ltd., and STA Pharmaceutical Hong Kong Limited, dated as of January 12, 2021.	—	—	—	—
21.1	Subsidiaries of FibroGen, Inc.	10-K	001-36740	21.1	03/01/2021
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

† Portions of this exhibit (indicated by asterisks) have been omitted as the Company has determined that (i) the omitted information is not material and (ii) the omitted information would likely cause competitive harm if publicly disclosed

\+ Indicates a management contract or compensatory plan.

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 10, 2021

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

Dated: May 10, 2021

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

Exhibit 10.1

November 27, 2020

K. Peony Yu
Via E-mail

Re: Transition, Separation, and Consulting Agreement

Dear Peony:

This letter sets forth the terms of the transition, separation, and consulting agreement (the "***Agreement***") which you and FibroGen, Inc. (the "***Company***") have agreed in the context of your employment transition.

1. SEPARATION DATE. Subject to the terms and conditions of this Agreement, your employment with the Company will continue through March 15, 2021, which will become your employment termination date (the "***Separation Date***"), unless your employment terminates sooner pursuant to Paragraph 2(c) below. If termination occurs earlier or later than March 15, 2021, the actual date of termination shall become the "***Separation Date***" for purposes of this Agreement. If you do not accept this offer by signing this Agreement, then your employment will terminate on the date that is twenty-one (21) days after the date of this letter Agreement.

2. TRANSITION PERIOD.

a. Title and Duties. You will retain the title of Chief Medical Officer until December 20, 2020, and; thereafter from December 21, 2020 until the Separation Date(such period, the "***Transition Period***"), your title will be Executive Advisor to the CEO, and you will no longer perform your regular duties except for duties agreed with the CEO, and will instead be required to provide transition briefing on matters for which you are knowledgeable, assistance with transitioning your regular duties and responsibilities, and other tasks as requested by the Company from time to time. You acknowledge and agree that the change in your duties during the Transition Period will not constitute Good Reason for your resignation pursuant to Section 9(c) of the Change in Control and Severance Agreement entered into between you and the Company dated December 9, 2019 (the "***Severance Agreement***"). You agree to perform your Transition Period services in good faith and to the best of your abilities. You must continue to comply with all of the Company's policies and procedures and with all of your statutory and contractual obligations to the Company, including, without limitation, your obligations under your Confidential Information, Secrecy and Inventions Agreement (a copy of which is attached hereto as **Exhibit A**), which you acknowledge and agree are contractual commitments that remain binding upon you both during and after the Transition Period.

b. Compensation/Benefits. During the Transition Period, your base salary will remain the same, and you will continue to be eligible for the Company's standard benefits, subject to the terms and conditions applicable to such plans and programs as an employee. Your Company equity awards will continue to vest under the existing terms and conditions set forth in the governing plan documents and option agreement.

c. Termination. Nothing in this Agreement alters your employment at will status. Accordingly, during the Transition Period you are entitled to resign your employment with or without Good Reason and with or without or advance notice, and the Company may terminate your employment with or without Cause (as defined below) or advance notice. If prior to March 15, 2021, the Company terminates your employment without Cause, then you will remain eligible for the Severance Benefits (as defined and described below), *provided that* you have satisfied the conditions for receipt of the Severance Benefits (as set forth below). If prior to March 15, 2021, you resign your employment without Good Reason (as defined in Section 9(c) of the Severance Agreement) or the Company terminates your employment with Cause, then you will no longer be eligible for participation in any Company benefit plans, and you will not be entitled to the Severance Benefits and the Company will not engage you as a consultant pursuant to Section 5, below.

d. Definition of Cause. For purposes of this Agreement, "***Cause***" for termination will mean any one or more of the following: (i) your willful failure to substantially perform your duties and responsibilities to the Company or deliberate violation of a Company policy; (ii) your commission of any act of fraud, embezzlement, dishonesty or any other willful misconduct that has caused or is reasonably expected to result in material injury to the Company; (iii) unauthorized use or disclosure by you of any proprietary information or trade secrets of the Company or any other party to whom you owe an obligation of nondisclosure as a result of your relationship with the Company; or (iv) your willful breach of any of your obligations under any written agreement or covenant with the Company.

3. Accrued Salary And Vacation. On the Separation Date, the Company will pay you all accrued salary and accrued but unused vacation, if any, earned through the last day of your employment, subject to standard payroll deductions and withholdings.

4. Severance Benefits. In full satisfaction of any obligation for the Company to provide you with severance benefits pursuant to the Severance Agreement, if you: (i) allow the releases contained herein to become effective; (ii) comply fully with your obligations hereunder (including without limitation satisfactorily transitioning your duties during the Transition Period); and (iii) within twenty-one (21) days after the Separation Date, execute and return to the Company the release of claims in the form attached hereto as **Exhibit B** (the "***Separation Date Release***") and allow the Separation Date Release to become effective, then the Company will provide you with the following as your sole severance benefits (the "***Severance Benefits***"):

a. Severance Pay. The Company will pay you, as severance, the equivalent of twelve (12) months of your base salary in effect as of the Separation Date (the "***Severance Payment***"). The Severance Payment will be paid in the form of salary continuation payments on the Company's regular payroll schedule, subject to standard payroll deductions and withholdings, with the first salary continuation payment being made on or before the Company's second regularly scheduled payroll pay date that is after the Separation Date Release Effective Date (as defined in the Separation Date Release).

b. Health Insurance.

(i) COBRA. To the extent provided by the federal COBRA law or, if applicable, state insurance laws (collectively, "***COBRA***"), and by the Company's current group health insurance policies, you will be eligible to continue your group health insurance benefits at your own expense. You will be provided with a separate notice describing your rights and obligations under COBRA laws on or after the Separation Date.

(ii) COBRA Premiums. If you timely elect continued coverage under COBRA, the Company will pay your COBRA premiums to continue your coverage (including coverage for eligible dependents, if applicable) ("***COBRA Premiums***") through the period (the "***COBRA Premium Period***") starting on the Separation Date and ending on the earliest to occur of: (i) the date that is twelve (12) months following the Separation Date; (ii) the date you become eligible for group health insurance coverage through a new employer; or (iii) the date you cease to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event you become covered under another employer's group health plan or otherwise cease to be eligible for COBRA during the COBRA Premium Period, you must immediately notify the Company in writing of such event.

(iii) Special Cash Payments in Lieu of COBRA Premiums. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without a substantial risk of violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company instead shall pay to you, on the first day of each calendar month, a fully taxable cash payment equal to the applicable COBRA premiums for that month (including premiums for you and your eligible dependents who have elected and remain enrolled in such COBRA coverage), subject to applicable tax withholdings (such amount, the "***Special Cash Payment***"), for the remainder of the COBRA Premium Period. You may, but are not obligated to, use such Special Cash Payments toward the cost of COBRA premiums. On the thirtieth (30th) day following your Separation from Service, the Company will make the first payment to you under this paragraph, in a lump sum, equal to the aggregate Special Cash Payments that the Company would have paid to you through such date had the Special Cash Payments commenced on the first day of the first month following the Separation from Service through such thirtieth (30th) day, with the balance of the Special Cash Payments paid thereafter on the schedule described above.

c. 2020 Bonus. The Company will pay you a lump sum cash payment of $459,000.00, less payroll deductions and withholdings, which is equal to 150% of your target bonus amount for 2020 pursuant to the Company's Bonus Plan (the "***Bonus Payment***") in recognition of your contributions. You will not be eligible for any other bonus under the Company's Bonus Plan other than the Bonus Payment. The Bonus Payment will be paid to you at the same time as first salary continuation payment under Section 4(a) of this Agreement is paid to you, or such earlier time as determined by the Company.

5. Consulting Agreement. If you: (i) allow the releases contained in this Agreement to become effective; (ii) comply fully with your obligations hereunder (including without limitation satisfactorily transitioning your duties during the Transition Period); and (iii) within twenty-one (21) days after the Separation Date, execute and return to the Company the

Separation Date Release and allow the Separation Date Release to become effective, then the Company will engage you as a consultant under the terms set forth below.

a. Consulting Period. You will serve as a consultant to the Company beginning on March 16, 2021, and ending on September 16, 2021, unless terminated earlier pursuant to Section 5(h), or extended by written agreement by you and the Company (such period of time, the "Consulting Period").

b. Consulting Services. As a consultant, you will be responsible for assisting the Company in any area of your expertise, as reasonably requested by the Company (the "Consulting Services"). Among other things, you will assist the Company with the following: services on the Company's programs, including clinical, regulatory and commercial matters relating to roxadustat and pamrevlumab, and on other matters for which you are knowledgeable as requested by the Company's CEO or his delegate from time to time. It is anticipated that you will provide up to eight (8) hours of Consulting Services per week. You will conduct the Consulting Services at a location of your choosing. You will exercise the highest degree of professionalism and utilize your expertise and creative talents in performing the Consulting Services.

c. Consulting Consideration. Your sole consideration for your services during the Consulting Period will be the continued vesting during the Consulting Period of your outstanding stock options and other equity awards, if any (the "***Stock Awards***") a current list of which is attached hereto as **Exhibit D**.

d. Independent Contractor Status. You agree that during the Consulting Period, (i) you will be an independent contractor to the Company and not an employee of the Company, and (ii) the Company will not make payments for state or federal income tax, FICA (social security and Medicare), make unemployment insurance or disability insurance contributions, or obtain workers' compensation insurance on your behalf.

e. Protection of Information. You agree that during the Consulting Period and thereafter, you will not use or disclose any confidential or proprietary information or materials of the Company that you obtain or develop in the course of performing consulting services for the Company. Any and all work product you create in the course of performing consulting services for the Company will be the sole and exclusive property of the Company. You hereby assign to the Company all right, title, and interest in all inventions, techniques, processes, materials, and other intellectual property developed in the course of performing consulting services for the Company.

f. Limitations on Authority. You will have no responsibilities or authority as a consultant to the Company other than as provided above. You agree not to represent or purport to represent the Company in any manner whatsoever to any third party except with my prior written consent.

g. Standards of Conduct; Noncompetition. You agree not to engage in any conduct during the Consulting Period that is detrimental to the interests of the Company. You further agree during the Consulting Period that you will not, directly or indirectly, as an officer, director, employee, consultant, owner, manager, member, partner, or in any other capacity solicit, perform, or provide, or attempt to perform or provide Conflicting Services in the United States,

nor will you assist another person to solicit, perform or provide or attempt to perform or provide Conflicting Services in the United States. You and the Company agree that for purposes of this Agreement, "Conflicting Services" means any product, service, or process or the research and development thereof, of any person or organization other than the Company that is substantially similar to or competitive with a product, service, or process, including the research and development thereof, of the Company. Notwithstanding the above, you will not be deemed to be engaged directly or indirectly in any Conflicting Services if you participate in any such business solely as a passive investor in up to one percent (1%) of the equity securities of a company or partnership, the securities of which are publicly traded.

h. Termination of Consulting Period. Either you or the Company may terminate the Consulting Period, at any time and for any reason, upon fifteen (15) days written notice to the other party. Upon termination of the Consulting Period by either party, except with respect to any outstanding and unfulfilled Severance Benefit obligations under 4(a)-(c), the Company will have no further obligations to you, and all Stock Awards will immediately cease vesting. Notwithstanding the foregoing, should the Consulting Period end prior to September 16, 2021 for any reason, you will remain eligible for receipt of the Equity Benefits subject to your satisfaction of the conditions for receipt of the Equity Benefits, as described in Section 6, below.

6. EQUITY. Notwithstanding anything to the contrary in this Agreement or the applicable equity documents, if you: (i) comply with all obligations contained in this Agreement, excluding your obligations under the Consulting Agreement set forth in Section 5, and (ii) timely sign and return the Termination of Services Release attached hereto as **Exhibit C** (the "***Termination of Services Release***") the Company will accelerate the vesting of all unvested Stock Awards held by you as of the termination of the Consulting Period with respect to the portion of the shares subject thereto that would have vested during the twelve (12) month period following the termination of the Consulting Period, had you continued to provide services to the Company during such period. Furthermore, should you satisfy the conditions for receipt of the equity acceleration as set forth in the preceding sentence, effective as of the termination of the Consulting Period, your right to exercise any vested Stock Awards shall be extended until the date that is one (1) year following the termination of the Consulting Period (e.g. if the Consulting Period terminates September 16, 2021, the exercise period would be extended until September 16, 2022) (together with the equity acceleration, the "***Equity Benefits***"). You understand that as a result of the extended exercise period described above, applicable tax rules require that any options held by you that qualify for tax purposes as incentive stock options shall automatically be converted to non-statutory stock options for tax purposes as of the Effective Date of this Agreement according to the terms of the applicable equity incentive plan and of the Stock Awards thereunder, and that you shall consult your own tax advisor regarding the extended exercise period and the tax consequences of option transactions. Except as expressly modified herein, your Stock Awards will continue to be governed by the terms of the applicable equity incentive plan and other Stock Award documents, and your rights to exercise any vested Stock Awards shall be as set forth in the applicable equity incentive plan and/or the applicable Stock Award notices and agreements.

7. PROPRIETARY INFORMATION OBLIGATIONS. Both during and after your employment you acknowledge your continuing obligations under your Confidential Information, Secrecy and Inventions Agreement, including your obligations not to use or disclose any

confidential or proprietary information of the Company. A copy of your Confidential Information, Secrecy and Inventions Agreement is attached hereto as **Exhibit A**.

8. No Other Compensation or Benefits. You acknowledge that, except as expressly provided in this Agreement, you have not earned, and will not receive from the Company, any additional compensation, severance, or benefits on or after the Separation Date, with the exception of any vested right you may have under the express terms of a written ERISA-qualified benefit plan (e.g., 401(k) account). By way of example, you acknowledge that you have not earned and are not owed any equity, bonus, incentive compensation, severance benefits, or commissions that are not otherwise provided for in this Agreement.

9. Expense Reimbursements. You agree that, within fifteen (15) days after the Separation Date, you will submit your final documented expense reimbursement statement reflecting all business expenses you incurred through the last day of your employment, if any, for which you seek reimbursement. The Company will reimburse you for reasonable business expenses pursuant to its regular business practice.

10. Return of Company Property. By the Separation Date, you agree to return to the Company all Company documents (and all copies thereof) and other Company property which you have in your possession or control, including, but not limited to, Company files, notes, drawings, records, plans, forecasts, reports, studies, analyses, proposals, agreements, financial information, research and development information, sales and marketing information, customer lists, prospect information, pipeline reports, sales reports, operational and personnel information, specifications, code, software, databases, computer-recorded information, tangible property and equipment (including, but not limited to, computers, printers, mobile telephones, servers), credit cards, entry cards, identification badges and keys; and any materials of any kind which contain or embody any proprietary or confidential information of the Company (and all reproductions thereof in whole or in part); ***provided, however***, that you are permitted to retain any Company property that you and the Company agree is necessary for the performance of your services under the Consulting Agreement, by way of example, your mobile telephone and computer with connection to the company server. You agree that you will make a diligent search to locate any such documents, property and information by the Separation Date. If you have used any personally owned computer, server, or e-mail system to receive, store, review, prepare or transmit any Company confidential or proprietary data, materials or information, within five (5) business days after the Separation Date, you shall provide the Company with a computer-useable copy of such information and then permanently delete and expunge such Company confidential or proprietary information from those systems; and you agree to provide the Company access to your system as requested to verify that the necessary copying and/or deletion is done. Upon termination of the Consulting Period, you agree to return all Company property you retained as necessary for the performance of your services under the Consulting Agreement, as well as any additional Company property you acquired during the Consulting Period, you will have the option of keeping the mobile phone number of the company phone you have been using during current employment, but you will be responsible to set up and pay for mobile phone services after the end of the Consulting Period. **Your timely compliance with this paragraph is a condition precedent to your receipt of the Severance Benefits.**

11. Confidentiality. The provisions of this Agreement will be held in strictest confidence by you and will not be publicized or disclosed in any manner whatsoever; *provided,*

however, that: (a) you may disclose this Agreement to your immediate family; (b) you may disclose this Agreement in confidence to your attorneys, accountants, auditors, tax preparers, and financial advisors; (c) you may disclose this Agreement, and any other documents or information (without notice to the Company) when communicating with the Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal, state or local governmental agency or commission ("***Government Agencies***"), or during the course of an investigation or proceeding that may be conducted by any Government Agency; and (d) you may disclose this Agreement insofar as such disclosure may be necessary to enforce its terms or as otherwise required by law. In particular, and without limitation, you agree not to disclose the terms of this Agreement to any current or former Company employee. Nothing in this provision or this Agreement is intended to prohibit or restrain you in any manner from making disclosures that are protected under the whistleblower provisions of federal or state law or regulation.

12. Mutual Nondisparagement. You agree not to disparage the Company, and the Company's officers, directors, employees, shareholders and agents, in any manner likely to be harmful to them or their business, business reputations or personal reputations. Provided that you remain in compliance with the obligations contained herein, the Company agrees to direct its officers and directors not to disparage you in any manner likely to be harmful to your personal or business reputations. Notwithstanding the foregoing, all parties may respond accurately and fully to any request for information if required by legal process. In addition, nothing in this provision or this Agreement is intended to prohibit or restrain the parties in any manner from making disclosures that are protected under the whistleblower provisions of federal or state law or regulation.

13. No Voluntary Adverse Action; And Cooperation. You agree that you will not voluntarily provide assistance, information or advice, directly or indirectly (including through agents or attorneys), to any person or entity in connection with any proposed or pending litigation, arbitration, administrative claim, cause of action, or other formal proceeding of any kind brought against the Company, its parent or subsidiary entities, affiliates, officers, directors, employees or agents, nor shall you induce or encourage any person or entity to bring any such claims; provided that you may respond accurately and fully to any question, inquiry or request for information when required by legal process (e.g., a valid subpoena or other similar compulsion of law) or as part of a government investigation. In addition, you agree to voluntarily cooperate with the Company if you have knowledge of facts relevant to any existing or future litigation or arbitration initiated by or filed against the Company by making yourself reasonably available without further compensation for interviews with the Company or its legal counsel, for preparing for and providing deposition testimony, and for preparing for and providing trial testimony.

14. No Admissions. The promises and payments in consideration of this Agreement shall not be construed to be an admission of any liability or obligation by either party to the other party, and neither party makes any such admission.

15. Release of Claims.

(a) General Release. In exchange for the consideration provided to you under this Agreement to which you would not otherwise be entitled, you hereby generally and completely

release the Company, and its affiliated, related, parent and subsidiary entities, and its and their current and former directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, insurers, affiliates, and assigns (collectively, the "***Released Parties***") from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to or on the date you sign this Agreement (collectively, the "***Released Claims***").

(b) Scope of Release. The Released Claims include, but are not limited to: (i) all claims arising out of or in any way related to your employment with the Company, or the termination of that employment; (ii) all claims related to your compensation or benefits from the Company, including salary, bonuses, commissions, vacation, paid time off, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership, equity, or profits interests in the Company; (iii) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (iv) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (v) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) (the "***ADEA***"), and the California Labor Code (as amended).

(c) ADEA Waiver. You acknowledge that you are knowingly and voluntarily waiving and releasing any rights you have under the ADEA, and that the consideration given for the waiver and releases you have given in this Agreement is in addition to anything of value to which you were already entitled. You further acknowledge that you have been advised, as required by the ADEA, that: (i) your waiver and release does not apply to any rights or claims that arise after the date you sign this Agreement; (ii) you should consult with an attorney prior to signing this Agreement (although you may choose voluntarily not to do so); (iii) you have twenty-one (21) days to consider this Agreement (although you may choose voluntarily to sign it sooner); (iv) you have seven (7) days following the date you sign this Agreement to revoke this Agreement (in a written revocation sent to me); and (v) this Agreement will not be effective until the date upon which the revocation period has expired, which will be the eighth day after you sign this Agreement provided that you do not revoke it (the "**Effective Date**").

(d) Waiver of Unknown Claims. In giving the releases set forth in this Agreement, which include claims which may be unknown to you at present, you acknowledge that you have read and understand Section 1542 of the California Civil Code which reads as follows: **"A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party."** You hereby expressly waive and relinquish all rights and benefits under that section and any law or legal principle of similar effect in any jurisdiction with respect to your release of claims herein, including but not limited to the release of unknown and unsuspected claims.

(e) Excluded Claims. Notwithstanding the foregoing, the following are not included in the Released Claims (the "***Excluded Claims***"): (i) any rights or claims for indemnification you may have pursuant to any written indemnification agreement with the

Company to which you are a party or under applicable law; (ii) any rights which cannot be waived as a matter of law, including without limitation claims under the California Fair Employment and Housing Act, to the extent such claims are not waivable as a matter of law with this release; (iii) any rights you have to file or pursue a claim for workers' compensation or unemployment insurance; and (iv) any claims for breach of this Agreement. You hereby represent and warrant that, other than the Excluded Claims, you are not aware of any claims you have or might have against any of the Released Parties that are not included in the Released Claims. You understand that nothing in this Agreement limits your ability to file a charge or complaint with any Government Agency. While this Agreement does not limit your right to receive an award for information provided to the Securities and Exchange Commission, you understand and agree that, to maximum extent permitted by law, you are otherwise waiving any and all rights you may have to individual relief based on any claims that you have released and any rights you have waived by signing this Agreement.

16. Representations. You hereby represent that you have been paid all compensation owed and for all hours worked, you have received all the leave and leave benefits and protections for which you are eligible pursuant to the federal Family and Medical Leave Act, the California Family Rights Act, or otherwise, and you have not suffered any on-the-job injury for which you have not already filed a workers' compensation claim.

17. Dispute Resolution. You acknowledge and agree that any claims arising from this Agreement or its exhibits shall be subject to final and binding arbitration pursuant to the FibroGen Arbitration Agreement entered into between you and the Company dated January 3, 2020 (the "***Arbitration Agreement***"), which is hereby incorporated herein by reference.

18. Miscellaneous. This Agreement, together with its exhibits, constitutes the complete, final and exclusive embodiment of the entire agreement between you and the Company with regard to the subject matter hereof. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other agreements, promises, warranties or representations concerning its subject matter, including, without limitation, the Severance Agreement and the Arbitration Agreement. This Agreement may not be modified or amended except in a writing signed by both you and a duly authorized officer of the Company. This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement, or rights hereunder, shall be in writing and shall not be deemed to be a waiver of any successive breach or rights hereunder. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of California, as applied to contracts made and to be performed entirely within California, without regard to conflicts of law principles. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination shall not affect any other provision of this Agreement and the provision in question shall be modified so as to be rendered enforceable in a manner consistent with the intent of the parties insofar as possible under applicable law. This Agreement may be executed in counterparts which shall be deemed to be part of one original, and facsimile and electronic signatures shall be equivalent to original signatures.

[*Signature page to follow*]

If this Agreement is acceptable to you, please sign and date below within twenty-one (21) days, and send me the fully signed Agreement. The Company's offer contained herein will automatically expire if we do not receive the fully signed Agreement within this timeframe.

We wish you the best in your future endeavors.

Sincerely,

FIBROGEN, INC.

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

Exhibit A: Confidential Information, Secrecy and Inventions Agreement
Exhibit B: Separation Date Release
Exhibit C: Termination of Services Release
Exhibit D: List of Outstanding Stock Awards

UNDERSTOOD, ACCEPTED AND AGREED:

/s/ K. Peony Yu
K. Peony Yu

Nov 27, 2020
Date

Exhibit A

CONFIDENTIAL INFORMATION, SECRECY, AND INVENTIONS AGREEMENT

EXHIBIT B

SEPARATION DATE RELEASE

(To be signed and returned to the Company on or within twenty-one (21) days after the Separation Date)

In exchange for the consideration to be provided to me pursuant to that certain letter transition, separation, and consulting agreement between me and FibroGen, Inc. (the "***Company***") dated November 27, 2020 (the "***Agreement***"), I hereby provide the following Separation Date Release. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Agreement.

I hereby represent that: (i) I have been paid all compensation owed and have been paid for all hours worked for the Company through the Separation Date; (ii) I have received all the leave and leave benefits and protections for which I am eligible pursuant to the federal Family and Medical Leave Act or otherwise; and (iii) I have not suffered any on-the-job injury for which I have not already filed a claim.

I hereby generally and completely release the Company, and its affiliated, related, parent and subsidiary entities, and its and their current and former directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, insurers, affiliates, and assigns (collectively, the "***Released Parties***") from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to or on the date I sign this Agreement (collectively, the "***Released Claims***").

The Released Claims include, but are not limited to: (i) all claims arising out of or in any way related to my employment with the Company, or the termination of that employment; (ii) all claims related to my compensation or benefits from the Company, including salary, bonuses, commissions, vacation, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership, equity, or profits interests in the Company; (iii) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (iv) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (v) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) (the "***ADEA***"), the California Labor Code (as amended), the California Fair Employment and Housing Act (as amended), and any other laws, statutes, or regulations of the state in which I reside and/or work.

I acknowledge that I am are knowingly and voluntarily waiving and releasing any rights I may have under the ADEA (the "***Release ADEA Waiver***"). I also acknowledge that the consideration given for this waiver is in addition to anything of value to which I was already entitled. I further acknowledge that I have been advised by this writing, as required by the ADEA, that: (a) this waiver does not apply to any rights or claims that arise after the date I sign this Separation Date Release; (b) I should consult with an attorney prior to signing this Separation Date Release; (c) I

have had twenty-one (21) days to consider this Separation Date Release; (d) I have seven (7) days following the date I sign this Separation Date Release to revoke (in a written revocation sent to the Company's CEO); and (e) this Separation Date Release will not be effective until the date upon which the revocation period has expired, which will be the eighth day after I sign this Separation Date Release (the "***Separation Date Release Effective Date***").

In giving the general release of claims herein, which includes claims that may be unknown to me at present, I acknowledge that I have read and understand Section 1542 of the California Civil Code, which reads as follows: **"A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party."** I hereby expressly waive and relinquish all rights and benefits under that section and any law of any other jurisdiction of similar effect with respect to my release of any claims hereunder.

Notwithstanding the foregoing, I acknowledge and understand that the following are not included in the Released Claims (the "***Excluded Claims***"): (i) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company to which I am a party or under applicable law; (ii) any rights related to vested securities of the Company that were granted to me during the course of my employment with the Company, or any shares of capital stock or other securities of the Company that I purchased other than pursuant to Company's Plan or the Equity Benefit that arise after the date of this Separation Date Release; or (iii) any rights which are not waivable as a matter of law; and (iv) any claims for breach of this Agreement. I hereby represent and warrant that, other than the Excluded Claims, I am not aware of any claims I have or might have against any of the Released Parties that are not included in the Released Claims. I understand that nothing in this Agreement limits my ability to file a charge or complaint with any Government Agency. I further understand this Agreement does not limit my ability to communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. While this Agreement does not limit my right to receive an award for information provided to the Securities and Exchange Commission, I understand and agree that, to maximum extent permitted by law, I am otherwise waiving any and all rights I may have to individual relief based on any claims that I have released and any rights I have waived by signing this Agreement.

"Plan" collectively refers to (i) Company's Amended and Restated 2005 Stock Plan, adopted by the Board on February 17, 2005, as amended from time to time, (ii) Company's 2014 Equity Incentive Plan, adopted by the Board on September 9, 2014, as amended from time to time, and (iii) any preceding and succeeding plans thereto.

This Separation Date Release, together with the Agreement and its exhibits, constitutes the entire agreement between me, and the Company with respect to the subject matter hereof. I am not relying on any representation not contained herein or in the Agreement.

UNDERSTOOD, ACCEPTED AND AGREED:

K. Peony Yu	Date

EXHIBIT C

Termination of Services Release

(To be signed and returned to the Company within five (5) days after the termination of the Consulting Period)

In exchange for the consideration to be provided to me pursuant to that certain letter transition, separation, and consulting agreement between me and FibroGen, Inc. (the "**Company**") dated November 27, 2020 (the "**Agreement**"), I hereby provide the following Termination of Services Release. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Agreement.

I confirm that I have returned to the Company all Company confidential and proprietary information and other property that I received in the course of my service with the Company, and agree to abide by all of my continuing obligations under the Agreement and the Confidential Information, Secrecy and Inventions Agreement I signed during my employment with the Company, including my obligation to keep all Company confidential and proprietary information in strict confidence.

I represent and warrant that I have been paid all amounts owed to me as a result of my relationship with the Company, and have been reimbursed for all reimbursable business expenses incurred in connection with such service.

I hereby forever release the Company, its affiliated, related, parent, and subsidiary entities, and their current and former directors, officers, employees, shareholders, partners, agents, contractors, vendors, attorneys, predecessors, successors, insurers, affiliates, and assigns, from any and all claims, liabilities, demands, causes of action, attorneys' fees, damages, or obligations of every kind and nature, whether known or unknown, arising from or in any way related to my service with the Company through and including the date I sign this Agreement. This general release includes, but is not limited to, all claims related to or arising from my work for the Company and/or the termination of that my relationship with the Company, as well as all federal and state statutory and common law claims, and claims for breach of contract or other promise, fraud, misrepresentation, discrimination, harassment, retaliation, emotional distress, compensation, commissions, benefits, or equity interests (except for any equity interests promised to me in the Agreement).

In giving the general release of claims herein, which includes claims that may be unknown to me at present, I acknowledge that I have read and understand Section 1542 of the California Civil Code, which reads as follows: **"A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party."** I hereby expressly waive and relinquish all rights and benefits under that section and any law of any other jurisdiction of similar effect with respect to my release of any claims hereunder.

Notwithstanding the foregoing, I acknowledge and understand that the following are not included in the claims being released hereunder: (i) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company to which I am a party or under applicable law; (ii) any rights related to vested securities of the Company that were granted to me during the course of my employment with the Company, or any shares of capital stock or other securities of the Company that I purchased other than pursuant to Company's Plan or the Equity Benefit that arise after the date of this Termination of Services Release; or (iii) any rights which are not waivable as a matter of law; and (iv) any claims for breach of this Agreement.

"Plan" collectively refers to (i) Company's Amended and Restated 2005 Stock Plan, adopted by the Board on February 17, 2005, as amended from time to time, (ii) Company's 2014 Equity Incentive Plan, adopted by the Board on September 9, 2014, as amended from time to time, and (iii) any preceding and succeeding plans thereto.

I understand and agree that the promises and payments in consideration of this Agreement shall not be construed to be an admission of any liability or obligation by the Company to me or to any other person, and the Company makes no such admission.

This Termination of Services Release, together with the Agreement and its exhibits, constitutes the entire agreement between me, and the Company with respect to the subject matter hereof. I am not relying on any representation not contained herein or in the Agreement.

UNDERSTOOD AND AGREED:

_____

K. Peony Yu Date

EXHIBIT D
List of Outstanding Awards

Grant Number	Grant Date	Shares Granted	Price Per Share
004128	**03/04/2015**	**4,618**	**$ 29.66**
005650	**03/08/2017**	**5,011**	**$ 25.40**
006399	**03/04/2018**	**1,860**	**$ 53.75**
007237	**02/05/2019**	**1,744**	**$ 57.33**
008170	**03/17/2020**	**3,786**	**$ 26.41**
007238	**02/05/2019**	**53,456**	**$ 57.33**
008171	**03/17/2020**	**71,214**	**$ 26.41**
NQ3406	**11/13/2014**	**52,500**	**$ 18.00**
NQ4128	**03/04/2015**	**59,518**	**$ 29.66**
NQ4695	**02/22/2016**	**56,250**	**$ 19.39**
NQ5650	**03/08/2017**	**64,989**	**$25.40**
NQ6399	**03/14/2018**	**53,140**	**$ 53.75**
R05928	**03/08/2017**	**41,176**	**$ 0.00**
R06698	**03/14/2018**	**32,000**	**$ 0.00**
R07555	**02/05/2019**	**33,100**	**$ 0.00**
R08544	**03/17/2020**	**45,000**	**$ 0.00**

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Exhibit 10.2

ASTELLAS EU SUPPLY AGREEMENT

This Astellas EU Supply Agreement (the "**Agreement**") is effective as of **January 1, 2021** (the "**Effective Date**"), by and between: **FibroGen, Inc**., a Delaware corporation with offices located at 409 Illinois Street, San Francisco, California 94158 U.S.A. ("**FibroGen**"); and **Astellas Pharma Europe Ltd**, an English corporation with offices located at 300 Dashwood Lang Road, Bourne Business Park, Addlestone, Surrey, KT15 2NX England ("**Astellas**"). Astellas and FibroGen may be referred to individually as a "**Party**", and collectively as the "**Parties**". Astellas and each of its Affiliates shall collectively be referred to herein as "**Astellas**". FibroGen and each of its Affiliates shall collectively be referred to herein as "**FibroGen**".

RECITALS

WHEREAS, FibroGen owns or controls certain technology and intellectual property relating to the compound known as roxadustat (or FG-4592);

WHEREAS, an Affiliate of Astellas, namely Astellas Pharma Inc., and FibroGen are parties to that certain Anemia License and Collaboration Agreement, dated as of April 28, 2006, as amended (the "**EU Collaboration Agreement**"), under which FibroGen granted to Astellas the right to develop and commercialize roxadustat in the Territory (as defined below);

WHEREAS, as contemplated in the EU Collaboration Agreement, Astellas and FibroGen now desire to memorialize terms under which FibroGen will supply roxadustat as Bulk Product (defined below) to Astellas for Astellas' use in commercialization of products containing roxadustat, on the terms set forth below.

AGREEMENT

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

ARTICLE 1
DEFINITIONS

The following capitalized terms, whether used in the singular or plural, shall have the meanings ascribed to them below for purposes of this Agreement:

1.1 "**Actual Price Per Tablet**" has the meaning set forth in **Exhibit B**.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

1.2 "**Actual Weighted Average Net Selling Price Per Tablet**" has the meaning set forth in **Exhibit B**.

1.3 "**Affiliate**" means, with respect to either Party, any other corporation or business entity that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, the term "control" means direct or indirect ownership of more than fifty percent (50%) of the outstanding voting securities or other ownership interests or the power to direct or cause the direction of the management or policies of such entity, whether through the ownership of voting securities, by contract, or otherwise.

1.4 "**API**" means the active pharmaceutical ingredient (ie, Roxadustat) used in the manufacture of the Bulk Product(s).

1.5 "**Applicable Law(s)**" means all laws, rules, and regulations applicable to Manufacturing Services including, as applicable, cGMP and other regulatory standards or requirements of Regulatory Authorities.

1.6 "**Astellas Japan**" means Astellas Pharma Inc. with its registered address at 2-5-1, Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8411, Japan.

1.7 "**Batch(es)**" means a specific quantity defined in **Exhibit A** of Bulk Product that is intended to have uniform character and quality, within specified limits.

1.8 "**Bulk Package(ing)**" means the bulk packaging as agreed by the Parties in writing.

1.9 "**Bulk Product**" means drug product, containing API, supplied by FibroGen to Astellas as a bulk formulated and through the Manufacturing Processes made into finished drug (such as in a form of, including, but not limited to a tablet formulation) in Bulk Packaging only.

1.10 "**Business Day**" a day (other than a Saturday, Sunday or public holiday) when banks in the United Kingdom and the United States of America are open for business.

1.11 "**Certificate of Analysis**" means a document certifying that a particular Batch of Bulk Product was tested and conforms to the Specifications. Unless otherwise agreed to in a signed writing by both Parties, the Certificate of Analysis shall be in the English language.

1.12 "**Certificate of Compliance**" means a document that states a particular Batch of Bulk Product was manufactured in compliance with the Quality Agreement and: (a) lists the manufacturing date, unique Batch number, Bulk Product number, and quantity of Bulk Product in such Batch; (b) certifies that such Batch was manufactured in accordance with all Applicable Laws, including cGMP; and (c) certifies all excursions and investigations associated with the Batch have been closed and found not to impact the Batch. The Parties shall from time to time agree upon a format or formats for the Certificate of Compliance to be used under this Agreement. Unless otherwise agreed to in a signed writing by both Parties, the Certificate of Compliance shall be in the English language.

1.13 "**Change of Control**" means, with respect to a Party, (i) any transaction or series of related transactions to which such Party is a party in which more than fifty percent (50%) of such Party's

voting power is transferred to a single Third Party, or a group (including but not limited to the meaning of Section 13(d) of the United States Securities Exchange Act of 1934) of Third Parties; or (ii) any consolidation or merger of such Party with or into any other corporation or other entity or person, or any other corporate reorganization, in which the stockholders of such Party immediately prior to such consolidation, merger or reorganization, hold less than fifty percent (50%) of the voting power of the surviving entity (or, if the surviving entity is a wholly owned subsidiary, its parent) immediately after such consolidation, merger or reorganization.

1.14 "**cGMP**" means the current Good Manufacturing Practices for medicinal products promulgated by the Regulatory Authority (hereafter defined) in the Territory, which shall include, but not limited to, the EU-GMP (i.e. EUDRALEX Volume 4) and 21 C.F.R. Parts 210 and 211, In case the Bulk Product is distributed from FibroGen warehouse to an Astellas warehouse or logistic service provider under FibroGen's responsibility, the scope of GMP also includes the requirements of the Guidelines for Good Distribution Practices (GDP) 2013/C 343/01, as applicable to the performed activities and amended from time to time; and/or any and all current Good Manufacturing Practices applicable to the manufacture, testing and/or any other processing of pharmaceutical products in other countries and territories worldwide where the respective Finished Products are sold or otherwise marketed from time to time provided that FibroGen is informed about such other Good Manufacturing Practices by Astellas in accordance with Quality Agreement and FibroGen confirms in writing that it will comply with such other Good Manufacturing Practices within a reasonable time so as not to delay release of the Finished Product, provided, however, that Astellas provides FibroGen with advanced notice as set forth in Section 10.1 of this Agreement.

1.15 "**Confidential Information**" with respect to a Party to this Agreement, all information that is proprietary to such Party and/or that is maintained in confidence by such Party and that is disclosed by or on behalf of such Party or its Affiliates to the other Party or its Affiliates pursuant to this Agreement, whether disclosed orally, visually, in writing or in any tangible or electronic form or media and whether marked confidential or not. Notwithstanding the foregoing, the term "Confidential Information" shall not include specific information which, in each case as demonstrated by written proof:

(a) at the time of disclosure, is already available or known to the public;

(b) after disclosure, becomes available or known to the public through no fault of the receiving Party or its Affiliates, or by their respective directors, officers, employees and agents;

(c) is in the receiving Party's possession at the time of the disclosure under this Agreement and/or any Purchase Order without obligations of confidentiality; or

(d) is received by the receiving Party from a Third Party that has the right to disclose the same without any confidentiality obligation directly or indirectly to the disclosing Party or otherwise developed by the receiving Party without reference to any information or materials disclosed by or on behalf of the disclosing Party.

1.16 "**Conforming**" means, with respect to Bulk Product, that such Bulk Product conforms to all of the requirements and acceptance criteria of this Agreement, including all Applicable Laws, the Specifications, Quality Agreement, and warranties set forth in Section 12.3, as applicable.

1.17 "**Control**" or "**Controlled**" means possession of the right to grant a license or sublicense as provided for herein without violating (a) any law or governmental regulation applicable to such license or sublicense, or (b) the terms of any agreement or other arrangement with any Third Party that exists as of the Effective Date, or if such right is acquired after the Effective Date, as of the date the Party first gained possession of such right.

1.18 "**Calendar Quarter**" means any period of three (3) months commencing on January 1, April 1, July 1, and October 1 of each Calendar Year.

1.19 "**Calendar Year**" means any period of twelve (12) calendar months commencing on January 1.

1.20 "**Delivery Year**" means the Calendar Year in which FibroGen will be supplying Bulk Product, as may be further set forth in **Exhibit B**.

1.21 "**Drug Product Blend**" means drug product in "Drug Product Blend" refers to a mixture that contains API, excipients and is lubricated and ready for compression into different strengths of Bulk Product.

1.22 "**EMA**" means the European Medicines Agency or any successor agency thereto.

1.23 "**Executed Batch Record(s)**" means the collection of records that provides a traceable history of how a Batch of Bulk Product was produced.

1.24 [*]

1.25 "**Expected Quantity Per Batch**" has the meaning set forth in **Exhibit A**.

1.26 "**Facility(ies)**" means the facility(ies) as described in Section 4.1 hereto.

1.27 "**Finished Product**" means Bulk Product after primary and secondary packaging and labeling in its final market form (performed by Astellas).

1.28 "**Forecast(ing)**" has the meaning set forth on Section 3.1.

1.29 "**Fully Burdened Cost**" [*].

1.30 "**Government Officials**" has the meaning set forth in Section 12.4(a).

1.31 **"Indirect Taxes"** means any value added tax ("**VAT**"), goods or services tax, sales, use, consumption taxes or other similar taxes imposed in any jurisdiction that is payable on or in respect of any supply made (or deemed to be made) by one Party to another Party in connection with the Agreement but does not include any related penalty, fine or interest thereon.

1.32 "**Intellectual Property**" means all Patents, copyrights, Trade Marks, trade secrets, know-how, inventions, and all other intellectual property rights that are owned or Controlled by a Party (whether patentable or not), including all applications and registrations with respect thereto.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

1.33 "**Latent Defects**" has the definition set forth in Section 5.2.

1.34 "**Lead Time**" means the time between receipt of the Purchase Order by FibroGen for Bulk Product and release of the Bulk Product for Transfer to Astellas, which shall be [*] in compliance with this Agreement unless otherwise agreed to by the Parties in writing.

1.35 "**Joint Steering Committee**" or "**JSC**" has the meaning set forth in the EU Collaboration Agreement.

1.36 "**Major Regulatory Authority**" means each of the following Regulatory Authorities: FDA (for the USA); MHRA (for the UK); and EMA (for the EU).

1.37 "**Manufacturing Processes**" means the production processes for the manufacture of Bulk Product.

1.38 "**Manufacturing Services**" has the meaning set forth in Section 2.1.1.

1.39 "**Marketing Approval**" has the meaning set forth in the EU Collaboration Agreement.

1.40 "**Net Sales**" has the meaning set forth in the EU Collaboration Agreement.

1.41 "**Non-Conforming**" means with respect to Bulk Product, Bulk Product that fails to conform to all of the requirements and acceptance criteria of the Specifications and the warranties set forth in Section 12.3 (excluding warranty (12.3(c)), as applicable).

1.42 "**Order Acceptance**" has the meaning set forth in Section 3.4(c).

1.43 "**Patents**" means, with respect to an invention, any patent or patent application, and any patent issuing therefrom, together with any extensions, reissues, reexaminations, substitutions, renewals, divisions, continuations, continuations-in-part, and foreign equivalents thereof, and any patent or patent application claiming priority to any application in common with any such patent containing a disclosure substantially similar to that of any such patent, all to the extent the foregoing contain claims covering such invention.

1.44 "**Preliminary Price Per Tablet**" has the meaning set forth in **Exhibit B**.

1.45 "**Preliminary Price Per Tablet Schedule**" has the meaning set forth in **Exhibit B**.

1.46 "**Promotional Samples**" means samples used by Astellas for the promotion of the Finished Product in the Territory.

1.47 "**Purchase Order**" has the meaning set forth in Section 3.2.

1.48 "**Quality Agreement**" has the meaning given to in Section 10.1.

1.49 "**Quality Matters**" has the meaning set forth in Section 10.1 of this Agreement.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

1.50 "**Raw Material**" means all Bulk Product excipients, components, labels, and Bulk Packaging required to perform the Manufacturing Services, and shall exclude Special Packaging and Finished Product labeling or packaging for sale to end users in the Territory.

1.51 "**Reasonable Efforts**" means, with respect to a given goal, the efforts, consistent with the practice of comparable pharmaceutical companies with respect to pharmaceutical products of comparable market potential, that a reasonable person in the position of the promiser would use so as to achieve that goal as expeditiously and practicably as possible.

1.52 "**Regulatory Authority(ies)**" means the EMA, or other applicable, national, multi-national, state, regional or local regulatory agency, department, bureau, body or other government entity involved in or responsible for regulation of the relevant subject, as the context requires in this Agreement.

1.53 "**Regulatory Filing**" means any or all applications submitted to Regulatory Authorities for the purpose of registering the Bulk Product, the Manufacturing Process, and/or Finished Product as required by statute or regulation, and any amendments or supplements thereto, and any other filings required by the Regulatory Authorities relating to the manufacture, testing, sale or distribution of Bulk Product and/or Finished Product (as applicable).

1.54 "**Shelf Life**" shall mean [*].

1.55 "**Shipping Requirements**" means FibroGen's methods of packaging, monitoring and shipping any and all Bulk Product, or as specified in a given Purchase Order in accordance with this Agreement.

1.56 "**Specifications**" means the Specifications as defined in the Quality Agreement.

1.57 "**Special Packaging**" mean packaging instructions or materials that are not Bulk Packaging. Special Packaging may include: custom or particular containers, metal drums, special tape, serialized seals, and temperature/humidity monitoring devices.

1.58 "**Subcontractor**" means any independent entity that FibroGen contracts to perform any Manufacturing Services or meet any obligations that are required under the terms and conditions of this Agreement, as further described in this Agreement including in Section 4.7.

1.59 "**Supply Failure**" means any failure by FibroGen [*] ordered by Astellas under the terms of this Agreement.

1.60 "**Taxes**" means all compulsory charges – except Indirect Taxes – imposed pursuant to the authority of the relevant country, or political subdivision thereof (including states, and political subdivisions having jurisdiction), to levy taxes or fees on an entity or activity. Taxes include, but are not limited to income taxes, employment taxes and business taxes. For the avoidance of doubt, social contributions are not included in this definition.

1.61 "**Territory**" has the meaning set forth in the EU Collaboration Agreement.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

1.62 "**Third Party**" means any party other than Astellas, FibroGen and their respective Affiliates.

1.63 "**Trade Marks**" means the trade marks, logos or trade names owned or used by either Party including those used on or in relation to such Party's pharmaceutical products and company name.

1.64 "**Transfer Range**" has the meaning set forth on Section 2.1.1.

1.65 "**Transfer**" shall mean the Bulk Product that is made available to Astellas or its nominated Third Party pursuant to Section 5.3 of this Agreement.

1.66 "**Transfer Date**" means the date specified for delivery of Bulk Product pursuant to a Purchase Order in accordance with this Agreement including Section 5.3 hereof, which shall, for the avoidance of doubt, take into account the Lead Time.

1.67 "**Unit Losses**" means [*].

1.68 "**Withholding Tax**" means any fee, tax charge or deduction imposed by the fiscal authorities in the country of tax residence of Astellas on any sum payable by Astellas to FibroGen for the fees under the Agreement. For the avoidance of doubt, this does not include social security contributions.

ARTICLE 2
SUPPLY ARRANGEMENT

2.1 Supply.

2.1.1 General Supply. Subject to the terms and conditions of this Agreement, FibroGen hereby agrees, either directly or through one or more Third Party Subcontractors, to manufacture and supply Astellas with the amounts of Bulk Product ordered by Astellas in accordance with (and consistent with) the Purchase Order, this Agreement, the applicable Lead Time and all previous Forecasts. Notwithstanding anything in this Agreement to the contrary, any Transfer Date within [*] of the delivery of the first Forecast must be agreed upon by the Parties. The manufacture and supply of Bulk Product (collectively, the "Manufacturing Services") shall be performed in a professional manner by FibroGen or its Third Party Subcontractors consistent with industry standards including but not limited to cGMP and in compliance with the terms and conditions of this Agreement, the Quality Agreement, the Specifications, and all Applicable Laws. Notwithstanding anything to the contrary herein, [*]. [*] Should Astellas produce Finished Product from Bulk Product supplied under this Agreement, the packaging and labeling to be distributed commercially by Astellas shall contain clearly visible acknowledgement that the Finished Product is licensed from FibroGen and that the Finished Product Trade Mark is a registered Trade Mark of FibroGen where permitted by the relevant Regulatory Authorities in the Territory. For the avoidance of doubt, where a Regulatory Authority: (i) does not permit the above acknowledgement to be included but changes this position Astellas shall include the acknowledgement as soon as possible [*]; and (ii) where a Regulatory Authority does permit the acknowledgement to be included but changes this position Astellas shall remove the acknowledgement as soon as possible [*].

2.1.2 Affiliates and Third Party Subcontractors. FibroGen shall procure that and be [*] responsible for its Affiliates and its Subcontractors complying, at all times, with FibroGen's obligations under this Agreement.

2.1.3 Exclusive Arrangement. Subject to the terms and conditions of this Agreement, Astellas agrees to purchase from FibroGen, and FibroGen agrees to manufacture and provide to Astellas, all of Astellas' requirements for Bulk Product in the Territory, subject to Astellas' right of termination set forth in Section 18.1 (Termination) herein below. FibroGen shall be free to supply Bulk Product to any Third Party worldwide subject to the exclusive rights granted to Astellas pursuant to the EU Collaboration Agreement.

ARTICLE 3
FORECASTS AND PURCHASE ORDERS

3.1 Forecasts.

3.1.1 On [*] during the term of this Agreement, Astellas shall give FibroGen a rolling Forecast of its anticipated requirements for Bulk Product [*] to be Transferred in each of the following [*] ("Forecast"). Upon receipt of a Forecast, FibroGen shall provide acceptance or rejection of the Forecast within [*] to Astellas. In the event FibroGen rejects the Forecast the Parties shall discuss in good faith a revised forecast. If such good faith forecast is not agreed within [*], the Parties shall follow the conflict resolution procedure in Section 20.8 of this Agreement.

3.1.2 The [*] of each such Forecast shall be binding and reflect the current and any previously submitted Purchase Orders for Bulk Product [*]. For the avoidance of doubt, the remaining months shall be non-binding for Bulk Product purchases, subject to Section 3.1.3 and Article 18.

3.1.3 The Parties agree that FibroGen may rely on the [*] Forecasts indicated hereinabove to initiate manufacture of API and/or intermediates to meet Astellas Forecasted requirements, and therefore Astellas understands that [*]. [*].

3.1.4 Furthermore, [*].

3.2 Purchase Orders. This Agreement allows the Parties to contract for the manufacturing and supply of Bulk Product by FibroGen to Astellas through the execution of written purchase orders ("Purchase Orders"). Each Purchase Order complying with the requirements of this Article 3 shall be valid and binding upon the acceptance of such Purchase Orders by FibroGen. Each Purchase Order shall become part of and incorporated into this Agreement; and each Purchase Order shall be subject to all of the terms and conditions of this Agreement and the Quality Agreement.

3.3 Astellas shall place formal Purchase Orders, specifying:

(a) [*]

(b) The requested Transfer Date(s);

(c) Shipping Requirements;

(d) The US dollar value of ordered Bulk Product by strengths, that is determined pursuant to Article 6 and Exhibit B;

(e) Astellas's Purchase Order reference number;

(f) Astellas's and FibroGen's stock keeping unit[s] (SKU); and

(g) For the purpose of clarity, the total quantity in a Purchase Order may not, unless agreed otherwise by the Parties in writing, exceed the previously agreed Forecasted in Section 3.1.1.

3.4 [*]

(a) [*]

(b) [*]

(c) Not later than [*] after receipt of a Purchase Order, FibroGen shall confirm in writing its receipt of the Purchase Order ("**Order Acceptance**") and the proposed Transfer Date(s), which will be [*] of the requested date, to Astellas in writing.

(d) FibroGen will use its [*] to manufacture any additional amounts of Bulk Product ordered by Astellas outside of the parameters set forth above.

(e) [*] (for the avoidance of doubt any changes to Product Specification and/or any other aspect of manufacture, including the Facilities, equipment, processes, Raw Materials, Subcontractors, vendors, or record-keeping procedures as a result of such change in Bulk Product Manufacturer will be agreed in accordance with Article 10 of this Agreement), [*].

3.5 FibroGen shall at all times maintain (i) sufficient manufacturing capacity at the Facilities and (ii) sufficient stocks of Raw Materials, in each case enabling FibroGen to manufacture [*] of the quantities of Bulk Product set forth in the Forecast.

3.6 Shortfalls in Supply. In the case of a Supply Failure, FibroGen shall use [*] to cure such failure as soon as practicable. During such Supply Failure, FibroGen shall promptly inform Astellas in writing and provide Astellas with a reasonably detailed explanation why the Lead Time cannot be met and an indication when delivery of the Purchase Order is expected. [*]. If any Supply Failure continues in effect [*], FibroGen and Astellas shall meet and work together reasonably and in good faith to seek a prompt and commercially reasonable solution to the problem causing the Supply Failure, and [*]. For clarity, a Supply Failure will not be deemed to occur if (and to the extent that) (i) such failure is caused by a force majeure event as set out in ARTICLE 19 (ii) such failure is due to the Parties' good faith dispute as to whether the Bulk Product conforms to the Specifications or is Non-Conforming, or (iii) Astellas is not in compliance in all material respects with its obligations under the Agreement.

ARTICLE 4
OTHER MANUFACTURING OBLIGATIONS

4.1 Permits. FibroGen or its Subcontractors shall be responsible for obtaining and maintaining all permits, licenses, and scheduling related to the manufacturing facilities at which any Manufacturing Services are performed by or for FibroGen (the "**Facilities**") and for ensuring that the operation of such Facilities are, at all times, in compliance with all Applicable Law, including cGMP. FibroGen shall provide Astellas with copies of all permits and licenses related to the Facilities and any Regulatory Filing information upon Astellas' reasonable request.

4.2 Raw Materials.

(a) Procurement. Unless specifically stated otherwise in the applicable Purchase Order, FibroGen, either directly or through one or more Third Party Subcontractors, shall be responsible for the sourcing and procurement (including bearing all costs and expenses associated therewith) (in accordance with the applicable Specifications) of all Raw Materials necessary for the manufacture and supply of Bulk Product.

(b) Raw Materials Compliance. All Raw Materials used in the Manufacturing Processes shall comply with the applicable Specifications, and Quality Agreement, unless otherwise agreed in a signed writing by the Parties. FibroGen or a Subcontractor shall perform all testing and evaluation of Raw Materials necessary to ensure that all Bulk Products Transferred under the terms of this Agreement meet the foregoing obligations. All Raw Material and Bulk Products shall be stored at the Facilities, handled and transported in due compliance with the Quality Agreement and Applicable Laws.

(c) Retention and Reserve Samples. FibroGen shall retain (or have retained) certain reserve samples of all Raw Materials and in-process material production samples generated during production of Batches as set forth in the Quality Agreement, the applicable standard operating procedures and Applicable Laws, or as otherwise agreed in a signed writing by FibroGen and Astellas.

4.3 Pass-Through Costs. The Parties agree that costs for Manufacturing Services related to this Agreement which are passed-through to FibroGen by its suppliers, shall be pass-through costs under this Agreement. For the avoidance of doubt, pass-through costs shall apply to the extent such costs are not considered Fully Burdened Costs. Such pass-through costs may only be related to: (a) Special Packaging, (b) to the extent not included in Fully Burdened Costs, storage of Bulk Product (as described in Section 5.4), (c) regulatory inspections by Regulatory Authorities that are not a Major Regulatory Authority, and other compliance related costs; (d) audits and inspection associated with Astellas audits, including those requested by Astellas to be performed by Third Parties, such as industry groups or accrediting organizations, to the extent any such audits are in excess of the free of charge routine biennial audits and "**for cause**" audits as contemplated by and agreed to by the Parties in the Quality Agreement. Technology transfer agreed on or requested by Astellas, special analytical work, stability work and other costs shall occur only as required in a change control pursuant to Section 10.1(a). For each passed-through cost under this Section 4.3, FibroGen shall provide Astellas with evidence of such costs as reasonably requested by Astellas. Notwithstanding the foregoing, while performing Manufacturing Services, FibroGen may incur additional and unforeseeable pass-through costs that are not covered by

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the terms of this Agreement or contemplated by an applicable Purchase Order. In such a circumstance, FibroGen shall promptly notify Astellas of such additional pass-through costs and expenses, and obtain Astellas' written approval, which approval shall not be unreasonably withheld.

4.4 Manufacturing Standards. FibroGen, either directly or through one or more Third Party Subcontractors, shall manufacture all Bulk Product in a professional manner and in accordance with Applicable Law including all applicable cGMPs, Marketing Approvals or Regulatory Filings (as applicable), and industry standards, and in compliance with the terms and conditions of the applicable Purchase Order, this Agreement, and the Quality Agreement.

4.5 Documentation for Manufacture of Bulk Product. FibroGen shall keep complete, accurate accounts, data and records pertaining to the manufacture of the Bulk Product, including without limitation (a) Executed Batch Records for Bulk Product manufactured in accordance with cGMP, and (b) any other records required to be maintained under the Quality Agreement or Applicable Laws. For the avoidance of doubt, if Astellas reasonably requests any additional documentation not covered under this Section 4.5, FibroGen shall provide such documentation to Astellas at Astellas' expense.

4.6 Analytical Testing. FibroGen, or a designated Subcontractor, shall perform the analytical testing on Raw Materials, and Bulk Products as set forth in the Specifications, and/or in the Quality Agreement.

4.7 Subcontracting. FibroGen shall have the right to subcontract some or all of the Manufacturing Services to Third Parties following Astellas' written approval of such Third Party Subcontractor, with Astellas' approval not to be unreasonably withheld. Reasonable grounds to withhold approval include, but are not limited to, disbarment, breach of applicable anti-bribery laws or any other reasonable grounds as determined by the JSC. Notwithstanding anything else in this Agreement to the contrary, FibroGen shall be responsible for all acts or omissions of each of its Affiliates and Subcontractors as if any such breach was caused by FibroGen.

4.8 [*]

4.9 Product Security/Tripartite Agreement. The Parties agree to comply with relevant Product security requirements.

ARTICLE 5
ACCEPTANCE/REJECTION; TRANSFER

5.1 Evaluation of Bulk Product; Acceptance; Complaint Procedures.

(a) Documentation Review. FibroGen shall deliver at the point of the Bulk Product Transfer: (i) a Certificate of Analysis; (ii) Certificate of Compliance; (iii) any documents detailed in the Quality Agreement; and (iv) following receipt of the Bulk Product by Astellas in accordance with the EXW (2020 Incoterms), an invoice. In accordance with the EU Collaboration Agreement's "***Manufacturing & Supply***" section on page 20, the terms and conditions of the JDCA's Section 12.4-12.12 apply, including the JDCA's Section 12.7 (Inspection of Shipment/Right to Reject), wherein Astellas must promptly inspect each shipment and in the event any portion thereof is Non-Conforming,

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Astellas shall notify FibroGen within [*] of Transfer by Astellas in accordance with EXW (2020 Incoterm); otherwise, such Bulk Product shall be deemed "**Accepted**". Should Astellas, within such [*] period, make a determination that there is Non-Conforming Bulk Product, Astellas shall notify FibroGen of such determination, that a Batch is otherwise Non-Conforming and provide a sample of the alleged Non-Conforming Bulk Product (a "**Complaint**").

(b) Cooperation in Investigations. In the event Astellas does not accept Bulk Product under Section 5.1(a), Astellas shall [*].

(c) Disposition of Non-Conforming Bulk Product. In the event that the Parties do not agree on whether any Bulk Product is Conforming, the Parties shall promptly meet to discuss the Bulk Product that Astellas determines as Non-Conforming. The Parties shall discuss, in good faith to determine the origin of the Non-Conforming Bulk Product, including by review of any applicable reserve samples of the applicable Batch retained at FibroGen, as well as the procedures, including but not limited to, those used to generate and test such Bulk Product. If, after [*] of such discussion, the Parties are still unable to agree on whether such Bulk Product is Conforming or Non-Conforming, the Parties shall submit the Bulk Product in question to a mutually agreed independent Third Party expert that has the capability of testing the Bulk Product to determine whether the Bulk Product is Conforming or Non-Conforming. The determination by such independent Third Party expert is final, absent a clear error in numerical calculation or analysis. FibroGen shall bear all costs and expenses related to such testing if the Bulk Product is deemed by such Third Party expert to be Non-Conforming due to FibroGen's negligence or willful misconduct, and Astellas' sole remedy for such Non-Conforming Bulk Product shall be: [*] Astellas shall bear all costs and expenses related to the testing if the Third Party expert determines such Bulk Product is Conforming and shall pay FibroGen in full for all such ordered products. In all other circumstances, the costs and expenses shall be shared equally by the Parties.

5.2 Latent Defects. The Parties recognize that some Bulk Product may be Non-Conforming, but that such nonconformity cannot reasonably be discovered [*] ("**Latent Defects**"). If Astellas discovers that Bulk Product contains a Latent Defect during [*], and Astellas promptly notifies FibroGen of the details of such Latent Defect and provides a sample of the alleged Latent Defect to FibroGen [*], Astellas shall have the right to bring a Complaint to FibroGen for the Bulk Product as Non-Conforming pursuant to the Complaint procedures indicated hereinabove.

5.3 Transfer, Transfer Date, and Shipping Terms; Storage. Unless otherwise set forth on the applicable Purchase Order, shipment of Bulk Product shall be made EXW (Incoterms 2020) at the applicable Facility(ies) ("**Transfer**"), [*] ("**Transfer Date**"), and thereafter FibroGen will not be responsible for the Bulk Product including for insurance, transport fee, and any risks associated with transit/customs delays, storage and handling. FibroGen or its subcontractor may as a convenience assist Astellas in physically loading the Bulk Product onto the relevant Astellas carrier. Astellas shall bear the costs of such carrier, including the costs of insurance of the shipment, and all customs, import formalities, import duties, sales taxes and other governmental charges related to the importation and sales of Bulk Product and Finished Product. FibroGen or its agent shall Transfer each shipment of Bulk Product by the confirmed Transfer Date.

5.4 Storage. If Astellas fails to take possession of Bulk Product on any scheduled Transfer Date [*], FibroGen shall, through its manufacturer, store such Bulk Product (in accordance with the

Specifications and Applicable Laws) and have the right to invoice Astellas monthly following such scheduled Transfer for any reasonable administration, handling and storage costs actually incurred by FibroGen as pass-through cost. Storage costs shall be approximately [*].

5.5 [*]

5.6 If FibroGen requires Astellas to return any packaging materials to FibroGen, that fact must be clearly stated on the delivery note accompanying the relevant shipment of Bulk Product, and any such returns of Bulk Product shall be at FibroGen's sole cost and expense.

ARTICLE 6
PAYMENTS; INVOICING

6.1 Payments for Transfer. Pursuant to the "***Manufacturing & Supply***" section as set forth on pages 19-20 of the EU Collaboration Agreement, and the "***Cost of Supply; Transfer Price Payments***" sections as further set out on pages 20– 22 of the EU Collaboration Agreement, FibroGen will supply to Astellas (or its designated Affiliate) Bulk Product for commercial use, and Astellas will pay FibroGen at a Transfer price equal to [*] of annual Net Sales up to $[*] USD per Calendar Year in the Territory, and [*] on annual Net Sales above $[*] USD per Calendar Year in the Territory, as further set forth below. All invoices, credit notes and other payments hereunder shall be in U.S. Dollars (USD).

6.2 Estimated Payments. Within [*] of each Delivery Year of supply of Bulk Product used for commercial purposes, as set forth in **Exhibit B,** Astellas will provide the Preliminary Price Per Tablet. For the avoidance of doubt, in the first Delivery Year, Astellas shall only be required to provide the Preliminary Price Per Tablet [*].

6.3 Invoicing. FibroGen will invoice Astellas upon Transfer of each shipment of Bulk Product [*]. Astellas will pay FibroGen within [*] after its receipt of such invoice. [*]. For the avoidance of doubt, Astellas will pay any undisputed invoices received from FibroGen within [*] and any credit notes from FibroGen will be applied against future product invoices or paid within [*] by FibroGen if there are no invoices available to apply against.

6.4 Annual Determination for Fully Burdened Costs and Reconciliation. Within [*], FibroGen will provide the estimated costs basis for calculation of the Fully Burdened Cost to be applied in the following Delivery Year ("**Estimated Fully Burdened Costs Basis**"); and [*], FibroGen will reconcile the Estimated Fully Burdened Costs Basis with the actual amount of costs incurred in that Delivery Year (**"Actual Costs for Fully Burdened Costs**") and provide such Actual Costs for Fully Burdened Costs to Astellas. [*]

6.5 Actual Price Per Tablet and Preliminary Price Per Tablet Reconciliation and Payments. Within [*], Astellas will calculate the Actual Price Per Tablet, as further described in Exhibit B. [*] For the avoidance of doubt, Astellas will pay any undisputed invoices received from FibroGen within [*] and any credit notes from FibroGen will be applied against future product invoices or paid within [*] by FibroGen if there are no invoices available to apply against.

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6.6 Pass-through costs. Pass through costs described in Section 4.3 shall be invoiced separately. In the event of ad hoc invoices, Astellas will pay FibroGen within [*] after its receipt of such invoice quoting an Astellas purchase order number.

6.7 Reporting and Audit Rights. FibroGen shall provide all such evidence as Astellas may reasonably request in order to verify invoices submitted by FibroGen. In addition, FibroGen shall, on request, allow Astellas to inspect and take copies of (or extracts from) all relevant records and materials of FibroGen relating to the supply of the Bulk Products, including for the avoidance of doubt, the Fully Burdened Costs, as may be reasonably required in order to verify such matters in accordance with the relevant provisions concerning "***Reporting and Audit Rights***" on pages 23-24 of the EU Collaboration Agreement.

6.8 Quarterly Reporting. Within [*], Astellas shall report to FibroGen its aggregate Net Sales and the number of tablets sold of Finished Product [*] in the Territory. [*]. Within [*] following the end of each Calendar Year, Astellas shall report to FibroGen an updated estimate of the quarterly report provided above. [*].

6.9 Currency. The aggregate Net Sales provided by Astellas to FibroGen shall be provided in EUR. All currency exchanges shall be performed in good faith according to standard operating procedures. The Fully Burdened Cost will be provided to Astellas by FibroGen in USD. [*].

6.10 Astellas Manufacture. Terms pertaining to (a) in the event Astellas manufactures Bulk Product/Finished Product; (b) in the event both Parties manufacture; and (c) determination of royalty reduction rates are set out in the "Cost of Supply; Transfer Price Payments" sections as further set out on pages 20– 22 of the EU Collaboration Agreement.

6.11 Purchase Order Reference. Invoices provided by either Party shall reference the relevant purchase order number provided by the Party receiving such invoice.

6.12 Validation Batch Development Costs. For the avoidance of doubt, Astellas Japan has, prior to the signing of this Agreement, already paid to FibroGen certain sums for the development costs for the EU validation batches and upon payment pursuant to Section 6.13 below, FibroGen will reimburse Astellas Japan for such costs agreed upon both Parties.

6.13 Validation Batch Delivery. The Parties agree that Astellas will raise a Purchase Order for the delivery of the EU validation batches manufactured by FibroGen. Prior to the exchange of Bulk Product, Astellas will deliver a Purchase Order, and FibroGen shall issue an invoice with the shipment, Astellas shall pay for such validation batches pursuant to Sections 6.1 (Payments for Transfer), 6.2 (Estimated Payments), 6.3 (Invoicing), and 6.5 (Actual Price Per Tablet and Preliminary Price Per Tablet Reconciliation and Payments).

6.14 Adjustment for Generic Entry. The Transfer price payments set forth under this Agreement will be adjusted, and, in certain circumstances, FibroGen shall have the right to renegotiate or terminate this Agreement as set forth on page 21 of the EU Collaboration Agreement under the "Cost of Supply; Transfer Price Payments" section.

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ARTICLE 7
TAX RESPONSIBILITIES AND INDEMNITY

7.1 Mutual Assistance. FibroGen and Astellas shall reasonably work together with respect to any audits, disputes or requests for information with respect to Taxes in connection with or as a result of this Agreement or to enable each Party to accurately determine its own Tax liability. This commitment shall include the provision of all relevant information, documents and reasonable support and it shall survive the termination of this Agreement.

7.2 Own Taxes Each Party shall be responsible for Tax based on, imposed on or calculated by reference to:

(a) the net income or any profits or gains received or receivable (including any sum deemed to be received or receivable) by that Party;

(b) any employees employed by that Party;

(c) any assets or property owned or leased by that Party;

(d) the gross income received or receivable (including any sum deemed to be received or receivable) by that Party;

(e) its assets or its assets and liabilities; and

(f) its (net) equity or share capital.

Each Party shall be responsible for Taxes incurred, imposed or calculated on transactions between and amongst that Party and members of its group in respect of this Agreement.

7.3 Indirect Tax. All payments and credits to be made pursuant to the terms of this Agreement, are stated exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of such payments, the Party making the payment shall pay such Indirect Taxes at the applicable rate following the receipt where applicable of an Indirect Taxes invoice in the appropriate form issued. Each Party shall issue valid invoices for all amounts payable under this Agreement consistent with all applicable Laws and irrespective of whether such amounts may be netted for settlement purposes. The Parties shall cooperate in accordance with applicable law to minimize Indirect Taxes.

7.4 Withholding Tax.

(a) Astellas shall deduct or withhold from the payments any Taxes that it is required by applicable law to deduct or withhold. In determining the applicability of any Withholding Tax the provision of any relevant bilateral income tax treaties or regulatory instrument or document shall be taken into account. Astellas should use all reasonable efforts to obtain from FibroGen any Tax forms or appropriate governmental authorization that may be reasonably necessary in order for Astellas to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable

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laws and regulations, of Withholding Taxes resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such Withholding Tax.

(b) To the extent Astellas is required by applicable law or regulations concerning Withholding Taxes on any payment to FibroGen, Astellas shall pay the amounts of such Taxes to the proper Governmental Authority in a timely manner and promptly transmit to FibroGen an official tax certificate or other evidence of such withholding sufficient to enable FibroGen to claim such payment of such Taxes as soon as reasonably practicable (and in any event within [*]).

(c) In the event that Astellas is required by applicable law or regulations to withhold taxes or make similar deductions when making a payment to FibroGen, the provisions set forth on page 23 of the EU Collaboration Agreement under the ***"Net Payment"*** section shall apply. For the avoidance of doubt, references to "Upfront Payments and Milestone Payments" in the ***"Net Payment"*** section of the EU Collaboration Agreement shall be understood to refer to the Transfer price when applied to this Agreement.

7.5 The obligations contained in this Article 7 shall continue notwithstanding the completion or termination of the Agreement.

ARTICLE 8
REGULATORY OBLIGATIONS

8.1 Regulatory Matters Generally. The Parties' respective rights and obligations with respect to Regulatory Filings, communications with Regulatory Authorities, Finished Product recalls, and other regulatory matters relating to the Bulk Product and/or Finished Product (as applicable) are set forth in the EU Collaboration Agreement and/or the Quality Agreement.

ARTICLE 9
HAZARDS AND REPORTING

9.1 Accident Reports/Adverse Event Reporting. Responsibilities with respect to pharmacovigilance and the reporting of adverse events and accident reports shall be set forth in a safety data exchange agreement to be agreed by the Parties prior to the first prescription of Finished Product by Astellas.

ARTICLE 10
QUALITY ASSURANCE

10.1 Quality Agreement. Not later than [*] Purchase Order for Bulk Product placed by Astellas, the Parties will enter into a quality agreement governing the tasks and the division of responsibilities of the Parties with respect to the manufacture, supply, release and quality assurance of Bulk Product(s) (the "Quality Agreement" or "QA"), such QA may be amended by written agreement of the Parties from time to time. The Quality Agreement shall set forth the responsibilities of the Parties with respect to release, quality assurance, notification obligations and procedures related to document retention, audit and inspection rights, and similar matters with respect to the manufacture of Bulk Product including Finished Product recalls, returned goods, and authorization for Finished Product recalls

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("Quality Matters"). The Parties agree that the Quality Agreement shall be amended prior to the inclusion of Finished Product intended to be manufactured for markets other than Territory. Astellas agrees to provide FibroGen with notification at least [*] prior to Astellas' filing of Regulatory Filings (including marketing authorization applications) in such other markets. As set forth in Section 20.8 hereof, in the event of any conflict between this Agreement and the QA relating to Quality Matters, the terms of the QA shall prevail with respect to such Quality Matters, for all other matters this Agreement shall take precedence.

(a) Cost of Changes.

i) [*].

ii) In the event Astellas requests a change or adjustment of the Specifications and/or any aspect of manufacture, including the facilities, equipment, processes, Raw Materials, vendors, Subcontractors or record keeping procedures, the Parties shall discuss such changes [*].

iii) [*]

10.2 Responsibility for Quality Assurance and Quality Control. Responsibility for quality assurance and quality control of Bulk Product and Finished Product (as applicable) shall be allocated between Astellas and FibroGen as set forth in the Quality Agreement. For the avoidance of doubt, FibroGen shall be solely responsible for the costs and expenses of quality assurance and quality control of the Bulk Product during the Manufacturing Processes and prior to Transfer.

10.3 Audits. Astellas shall carry out audits pursuant to the Quality Agreement.

10.4 FibroGen shall ensure that all Bulk Products are packaged in accordance with the Specifications and any other agreed written instructions including, for the avoidance of doubt the Bulk Packaging Requirements.

10.5 FibroGen shall comply with all applicable laws, enactments, orders, rules and regulations relating to the manufacture, packing, packaging, marking, storage, handling, transportation and Transfer of the Bulk Products.

10.6 If, following an inspection, Astellas considers that the Bulk Products are not or are not likely to be as warranted under Section 12.3, Astellas shall inform FibroGen in writing and FibroGen shall take such reasonable action as is necessary to ensure that the Bulk Products are or will be as warranted under Section 12.3. [*]

ARTICLE 11
OWNERSHIP OF INTELLECTUAL PROPERTY AND MATERIALS

11.1 Intellectual Property. This Agreement shall not affect the ownership of any Intellectual Property owned by or licensed to either Party or any rights granted in the EU Collaboration Agreement with respect to such Intellectual Property. Any Intellectual Property rights developed, conceived, generated or derived by either Party under this Agreement shall be owned in accordance with the relevant provisions concerning "***Intellectual Property Rights***" on pages 24-28 in the EU Collaboration Agreement.

ARTICLE 12
REPRESENTATIONS AND WARRANTIES

12.1 Astellas. Astellas hereby represents and warrants to FibroGen that, as of the Effective Date:

(a) Power and Authority. Astellas is duly formed and validly existing under the laws of its jurisdiction of formation and has all requisite corporate power and authority to execute and enter into this Agreement and to perform its obligations hereunder.

(b) Execution, Delivery and Performance of the Agreement. Astellas has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement. This Agreement has been duly executed and delivered on behalf of Astellas, and constitutes a legal, valid, binding obligation, enforceable against Astellas and its successors and assigns in accordance with its terms and conditions.

12.2 FibroGen. FibroGen hereby represents and warrants to Astellas that, as of the Effective Date:

(a) Power and Authority. As of the Effective Date, FibroGen is duly formed and validly existing under the laws of its jurisdiction of formation and has all requisite corporate power and authority to execute and enter into this Agreement and to perform its obligations hereunder.

(b) Execution, Delivery and Performance of Agreement. FibroGen has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement. This Agreement has been duly executed and delivered on behalf of FibroGen, and constitutes a legal, valid, binding obligation, enforceable against FibroGen in accordance with its terms. The execution, delivery and performance of this Agreement does not breach, conflict with, violate, contravene or constitute a default under any contracts, arrangements or commitments to which FibroGen is a party or by which it is bound nor does the execution, delivery and performance of this Agreement by FibroGen violate any order, law or regulation of any court or Regulatory Authority having authority over it.

12.3 Bulk Product Warranty. FibroGen hereby represents and warrants to Astellas that at time of Transfer each Batch of Bulk Product: (a) will have been manufactured and analyzed in conformance

with the Quality Agreement, the Specifications and cGMPs; (b) will be transferred free and clear of any liens or encumbrances of any kind to the extent arising through or as a result of the acts or omissions of FibroGen; and (c) comply with Applicable Laws.

12.4 Anti-Corruption. Each Party represents, warrants and covenants to the other Party that:

(a) neither it nor its Affiliates or any of its or their directors, officers, employees, agents, partners or owners/shareholders shall directly or indirectly offer, promise, give or authorise the giving of any financial or other advantage, or anything else of value to any official or employee of any government, government department or agency, enterprise owned in whole or in part by any government or government department or agency, public international organisation, political party, public (governmental) hospital or other healthcare institution, pharmacy or formulary or any other organisation that may prescribe, administer, recommend, purchase, pay for, reimburse, authorise, approve or supply a medicine or medical device or any other product or service sold by Astellas or manufactured by FibroGen, in connection with this Agreement (the persons covered by this provision are referred to in this Agreement as "***Government Officials***") or to any other person or entity at the request of or with the assent or acquiescence of a Government Official, for the purpose of (a) securing any an improper advantage for such Party or (b) influencing any act or decision by a Government Official in his or her official capacity, in each case in order to assist such Party in obtaining or retaining business for or with, or directing business to, any person in connection with the activities contemplated by this Agreement;

(b) neither Party nor its Affiliates or any of its or their directors, officers, employees, agents, partners or owners/shareholders shall directly or indirectly offer, promise, give or authorise the giving of any financial or other advantage, or anything else of value to any person including an officer, employee, agent, or representative of another company or organization to induce such person or another person to breach a duty to his or her employer or improperly perform any work related activity or reward such person or another person for breaching a duty to his or her employer or improperly performing any work related activity;

(c) neither Party nor its Affiliates or any of its or their directors, officers, employees, agents, partners or owners/shareholders (i) has made prior to the date of this Agreement any payment, authorisation, promise or gift as described in Sections 12.4 (a) or 12.4 (b) above, (ii) is a Government Official or (iii) will become a Government Official without prior written notice to the other Party;

(d) to each Party's knowledge, no Government Official will own directly or indirectly without prior written notice to and approval by the other Party any shares or other beneficial interest in it or its Affiliates.

(e) Each Party shall ensure that its Affiliates and its subcontractors comply with its obligation under this Section.

(f) Each Party shall at all times maintain true, accurate, complete and current books and records in relation to all of its activities under this Agreement during the term and for a period of no less than four (4) years following expiration or termination of this Agreement.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Notwithstanding any other provision of this Agreement, either Party is entitled to terminate this Agreement pursuant to Section 18.2(a) if the other Party is in breach of this Section 12.4.

12.5 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES NO AND EXPRESSLY DISCLAIMS ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OF OTHERWISE WITH RESPECT TO THE PRODUCTS OR CONCERNING THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF FIBROGEN TECHNOLOGY, PATENTED OR UNPATENTED, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, ARE HEREBY SPECIFICALLY EXCLUDED AND DISCLAIMED.

ARTICLE 13
INDEMNIFICATION

13.1 Indemnification by Astellas. Subject to Section 13.2 and ARTICLE 14, Astellas shall indemnify, defend and hold FibroGen, and FibroGen's directors, officers, employees and agents (the "**FibroGen Indemnitee(s)**") harmless from and against all losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys' fees and expenses) (collectively, the "Losses") incurred by FibroGen Indemnitees to the extent such Losses arise out of or result from any claim, lawsuit or other action or threat by a Third Party arising out of Astellas' gross negligence, willful misconduct, failure to comply with applicable law, or material breach of this Agreement (including all representations, warranties and covenants set forth herein), the Quality Agreement and/or any Purchase Orders hereunder that result from a willful act or omission by an Astellas Indemnitee, except to the extent any such Loss arises out of or results from a FibroGen Indemnitee's gross negligence, willful misconduct, or breach of this Agreement (including all representations, warranties and covenants set forth herein), the Quality Agreement and/or any Purchase Orders hereunder.

13.2 Indemnification by FibroGen. Subject to Section 13.1 and ARTICLE 14, FibroGen shall indemnify, defend and hold Astellas, and Astellas' directors, officers, employees and agents (the "**Astellas Indemnitee(s)**") harmless from and against all Losses incurred by Astellas Indemnitees to the extent such Losses: arise out of or result from any claim, lawsuit or other action or threat by a Third Party arising out of (a) the gross negligence, willful misconduct, failure to comply with applicable law, or material breach of this Agreement (including, all representations, warranties and covenants set forth herein) the Quality Agreement and/or any Purchase Orders hereunder that result from a willful act or omission by a FibroGen Indemnitee, [*] in each case except to the extent any such Loss arises out of or results from an Astellas Indemnitee's gross negligence, willful misconduct, or breach of this Agreement (including all representations, warranties and covenants set forth herein), the Quality Agreement and/or any Purchase Orders hereunder.

13.3 Indemnification Procedures.

(a) Identification of Indemnitor and Indemnitee. An "**Indemnitor**" means the indemnifying Party. An "**Indemnitee**" means the indemnified Party and their respective directors, officers, employees and agents.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

(b) Indemnification Procedures. An Indemnitee which intends to claim indemnification under Section 13.1 or Section 13.2 hereof shall promptly notify the Indemnitor in writing of any claim, lawsuit or other action in respect of which the Indemnitee or any of their respective directors, officers, employees and agents intend to claim such indemnification. The Indemnitee shall permit, and shall cause their respective directors, officers, employees and agents to permit, the Indemnitor, at its discretion, to settle any such claim, lawsuit or other action and agrees to the complete control of such defense or settlement by the Indemnitor; provided, however, that such settlement shall not adversely affect the Indemnitee's rights under this Agreement or impose any obligations on the Indemnitee in addition to those set forth herein. Indemnitor shall not settle any claim that does not fully and unconditionally release the Indemnitee. No such claim, lawsuit or other action shall be settled without the prior written consent of the Indemnitor and the Indemnitor shall not be responsible for any legal fees or other costs incurred other than as provided herein. The Indemnitee and their respective directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any claim, lawsuit or other action covered by this indemnification, all at the reasonable expense of the Indemnitor. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and expense.

ARTICLE 14
LIMITATION OF LIABILITY

14.1 Disclaimer of Consequential Damages. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, LOSS OF BUSINESS OR LOSS OF GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH THIS AGREEMENT, WHETHER IN CONTRACT OR IN TORT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

14.2 Subject to Section 14.1, each Party's total liability arising under or in connection with this Agreement, whether arising in contract, tort (including negligence) or restitution, or for breach of statutory duty or misrepresentation, or otherwise, shall be limited to [*]. For the avoidance of doubt, in the [*], the limit on each Party's liability shall be limited to [*]. Such limits set out in this Section 14.2 apply except to the extent arising out of: [*]

For clarity, this Section 14.2 does not limit either Parties' liabilities under the EU Collaboration Agreement (or any other agreement between the Parties) and does not limit Astellas' obligation to pay undisputed amounts due under ARTICLE 6 (Payments; Invoicing).

ARTICLE 15
INSURANCE

15.1 Insurance. During the term and [*], FibroGen shall maintain, at its own cost and expense, in force the following insurance policies with reputable insurance companies against the liability referred to in this Agreement. In the event that any of the required polices of insurance are written on a claims

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made basis, then such policies shall be maintained during the term of this Agreement and for [*] following the expiration or termination of this Agreement:

(a) Products and Completed Operations Liability Insurance with a per occurrence limit of not less than [*] per occurrence and [*] in the aggregate.

(b) Commercial General Liability Insurance for not less than [*] per occurrence and [*] in the aggregate (plus a [*] excess umbrella) for claims arising from any single event.

15.2 On Astellas' written request, FibroGen shall provide Astellas with copies of the insurance policy certificates and details of the cover provided.

15.3 [*]

15.4 FibroGen shall notify Astellas if any policy is (or will be) cancelled or its terms are (or will be) subject to any material change.

15.5 [*]

15.6 If FibroGen fails or is unable to maintain insurance in accordance with Section 15.1 or fails to provide evidence that it has paid the current year's premiums in accordance with Section 15.2, Astellas may so far as it is able, purchase such alternative insurance covers as it deems to be reasonably necessary and shall be entitled to recover all reasonable costs and expenses it incurs in doing so from FibroGen.

15.7 For the avoidance of doubt, Astellas shall self-insure itself for the purposes of this Agreement.

ARTICLE 16
CONFIDENTIALITY

16.1 The Parties acknowledge that they expect to exchange certain Confidential Information in the course of, and for the purpose of, the Parties' respective performance under this Agreement. Any such Confidential Information is shared subject to the terms and conditions of this Article 16 and to the exceptions set forth in the definition of such term in Section 1.15 of this Agreement.

16.2 Each Party receiving Confidential Information from the other Party under this Agreement expressly acknowledges the other Party's sole legal title to such Confidential Information.

16.3 Each Party agrees:

(a) to hold in strict confidence all such Confidential Information and not to disclose it to any Third Party without the prior written consent of the disclosing party;

(b) to solely use such Confidential Information for exercising its rights and/or performing its obligations under this Agreement (the "**Purpose**");

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

(c) to take all reasonable precautions necessary or prudent to prevent material in its possession or control that contains or refers to such Confidential Information and from being lost, discovered, used, intercepted or copied by any Third Party; and

(d) to disclose such Confidential Information only to such of its directors, officers, and employees, and those of its Affiliates and external consultants, on a "need to know" basis, who are required by their duties to have knowledge of the Confidential Information for the Purpose, on the condition that each such person (x) is informed that the disclosed information is confidential and is subject to the terms of confidentiality of this Agreement; and (y) has agreed in writing to be bound by similar obligations of confidentiality and restrictions of use as those set forth herein and not to disclose the Confidential Information to any person or to use such information except for the Purpose. It is understood that the receiving Party shall be liable for any breach by each such person of the obligations of confidentiality and restrictions of use hereunder.

16.4 Notwithstanding the foregoing, a Party shall be entitled to disclose Confidential Information to the extent required by applicable law or court order provided that, to the extent permissible under applicable law or order, such Party furnishes the other Party with written notice that the Confidential Information is proposed to be disclosed sufficiently in advance of the proposed disclosure so as to provide the other Party with reasonable opportunity to seek to prevent the disclosure of or to obtain a protective order for the Confidential Information.

16.5 Upon expiration or termination for any reason whatsoever of this Agreement, each Party shall, at the other Party's option, return or destruct and confirm the destruction in writing all Confidential Information of the other Party, except that one (1) copy of such Confidential Information may be kept by the receiving Party in its confidential files for compliance with its regulatory requirements and applicable laws only. Return or destruction of the Confidential Information shall not release either Party of its ongoing obligations of confidentiality and use hereunder.

16.6 The terms of this Agreement shall be considered Confidential Information of both Parties and any press release or other disclosure with respect to the execution of this Agreement and/or any activities pursued hereunder shall be subject to both Parties' mutual agreement.

16.7 The Parties obligations of confidentiality and restricted use under this Article 16 shall survive the expiration or termination for any reason whatsoever of this Agreement and shall remain in effect for a period of [*] following the expiration or termination thereof.

ARTICLE 17
PRESS RELEASES; USE OF NAMES

17.1 Press Releases. Neither Party shall issue nor disclose any press release, publicity or other form of public written disclosure related to this Agreement and/or Manufacturing Services for Astellas without receiving the other Party's prior written consent, which consent shall not be unreasonably withheld.

17.2 Use of Names. Neither Party shall make use of the name of the other Party nor any Affiliate of the other Party, nor any of their respective officers, directors, employees, or agents, in any

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advertising or promotional material, or otherwise, in connection with this Agreement or any related agreements, without the prior written consent of such other Party, which consent shall not be unreasonably withheld.

ARTICLE 18
TERM; TERMINATION

18.1 Term. Unless sooner terminated pursuant to Section 18.2 or extended by the mutual written agreement of the Parties, the term of this Agreement shall commence on the Effective Date and shall continue until expiration or cancellation of the EU Collaboration Agreement, except to the extent the EU Collaboration Agreement specifically requires this Agreement to continue. In addition, in the event that, pursuant to the EU Collaboration Agreement, Astellas determines to manufacture Bulk Product for the Territory, whether directly or through Affiliates or Third Parties, Astellas shall provide FibroGen with not less than [*] prior written notice, or such other notice as reasonably required to comply with FibroGen's obligations to Third Party manufacturers, provided, however, that in the case of FibroGen's material failure to supply Astellas' commercial requirements set forth under the binding Forecast(s) under this Agreement, Astellas may initiate the process of taking over manufacturing its own requirements after reasonable notice to FibroGen and a reasonable opportunity to cure. In the event that Astellas determines to manufacture Bulk Products for the Territory hereunder, FibroGen shall provide to Astellas such information (including know-how, processes, procedures, formulas and protocols), consultation and assistance as is reasonably necessary for Astellas and/or its contract manufacturer to set and implement manufacturing operations for the Bulk Product and to manufacture Bulk Products for the Territory (at Astellas' expense unless resulting from FibroGen's material and uncured breach of its manufacture and supply obligations under this Agreement, provided, that, a Force Majeure Event shall not be considered a material breach of the obligation to supply under this Agreement).

18.2 Termination. This Agreement may be terminated as follows:

(a) Material Breach. Either Party may terminate this Agreement upon written notice to the other Party, for any material breach of this Agreement, Purchase Order, or Quality Agreement by the other Party, if such breach is not cured within [*] after the breaching Party receives written notice of such breach from the non-breaching Party. Such termination shall be effective upon expiration of such cure period.

(b) Insolvency. Either Party may terminate this Agreement upon notice to the other Party, upon (a) the dissolution, termination of existence, liquidation or business failure of the other Party; the appointment of a custodian or receiver for the other Party who has not been terminated or dismissed within [*] of such appointment; or (c) the institution by the other Party of any proceeding under national, federal or state bankruptcy, reorganization, receivership or other similar laws affecting the rights of creditors generally or the making by such Party of a composition or any assignment for the benefit of creditors under any national, federal or state bankruptcy, reorganization, receivership or other similar law affecting the rights of creditors generally, which proceeding is not finally dismissed within [*] of filing.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

18.3 Cumulative Remedies. Any right to terminate this Agreement shall be in addition to and not in lieu of all other rights or remedies that the Party giving notice of termination may have at law or in equity or otherwise.

18.4 Consequences of Termination.

18.4.1 Generally. If Astellas terminates this Agreement pursuant to Section 18.1or either Party terminates in accordance with Section 18.2, FibroGen shall use [*] to wind-down all Manufacturing Services applicable to the terminated Purchase Order, or the Agreement generally, in accordance with its responsibilities under applicable laws, and [*]. Notwithstanding the foregoing, and except for costs specifically related to a breach by FibroGen in the event of termination by Astellas pursuant to Section 18.2, [*]. FibroGen shall promptly deliver or shall procure the delivery to Astellas of all Bulk Product and Astellas property (including for the avoidance of doubt, any non-Astellas property required for Astellas to meet its cGMP and other regulatory obligations and those listed in the Quality Agreement), including all Confidential Information belonging to Astellas, then in FibroGen's possession or control and all copies of the same, whatever their state of development at that time, and all materials and information reasonably required by Astellas to complete and/or related to such Products and shall certify in writing to Astellas that the same has been done.

18.4.2 Accrued Rights. Except as otherwise expressly set forth herein, any termination or expiration of this Agreement shall be without prejudice to any right which shall have accrued to the benefit of either Party and shall not relieve either Party of any obligation which has accrued prior to the effective date of such termination or expiration, which obligations shall remain in full force and effect for the period provided therein or, if no period is provided therein, then such obligations shall remain in full force and effect indefinitely.

18.5 Surviving Rights. Article 1; Article 4; Article 5; Sections 7.1, 8.1, and 9.1;and Articles 10, 11, 12, 13, 14, 15, 16, and 17 and the rights and obligations contained therein shall survive the termination or expiration of this Agreement.

ARTICLE 19
FORCE MAJEURE

19.1 Force Majeure. Neither Party shall be liable hereunder for any failure in performance if such delay or failure is caused by fire, flood, pandemic, explosion, storm, acts of God, acts of any government or government agency or other causes beyond such party's reasonable control, provided that, upon the occurrence of any event of force majeure, (a) the Party whose performance is thereby affected shall promptly notify the other Party of the force majeure event and the circumstances so surrounding and of the expected duration thereof and shall take all reasonable steps to mitigate such delay or failure to perform and (b) if the delay or failure to perform continues for more than [*], the Parties will in good faith confer about adjustments to address the force majeure event and work towards amicable resolution, then the unaffected Party may terminate this Agreement upon [*] prior written notice to the affected Party. Upon cessation of such force majeure event, the affected Party shall promptly resume performance under this Agreement as soon as it is possible for the Party to do so.

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ARTICLE 20
MISCELLANEOUS

20.1 Notices. Any notice required or permitted to be given under this Agreement by any Party shall be in writing and shall be (a) delivered personally, (b) sent by registered mail, return receipt requested, postage prepaid, or (c) sent by an internationally-recognized courier service guaranteeing reasonable international delivery timeframes, charges prepaid, to the addresses of the other Party set forth below, or at such other addresses as may from time to time be furnished by similar notice by any Party. The effective date of any notice under this Agreement shall be the date of receipt by the receiving Party.

If to FibroGen:

FibroGen, Inc.
409 Illinois Street
San Francisco, California 94158
United States of America
Attn: Legal Department

If to Astellas:

Astellas Pharma Europe Limited
300 Dashwood Lang Road
Bourne Business Park
Addlestone
Surrey
KT15 2NX United Kingdom
Attn: Legal Department and Director of Global CMM

20.2 Governing Law; Dispute Resolution. This Agreement shall be governed by, construed and interpreted in accordance with the governing law provisions set forth in the EU Collaboration Agreement. The Parties shall negotiate in good faith and use Reasonable Efforts to settle any dispute in accordance with the EU Collaboration Agreement.

20.3 Headings. All headings in this Agreement are for convenience of reference only and shall not affect the interpretation of this Agreement.

20.4 Assignment. Neither Party may assign or transfer the Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment without the other Party's consent to such Party's Affiliate or to a successor to all or substantially all of the assets or business of such Party to which this Agreement pertains, whether by asset sale, stock sale, merger, acquisition, or otherwise. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. Any purported assignment that is not in conformance with this Section 20.4

shall be null, void and of no legal effect. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the successors and assigns of the Parties.

20.5 Change of Control. In the event of a Change of Control of FibroGen, FibroGen shall give written notice to Astellas of such Change of Control and provide Astellas with all reasonably necessary information [*]. After such Change of Control notice, Astellas shall have [*] to decide (and notify FibroGen of its decision) whether to terminate this Agreement, with such termination to be a minimum of [*]. [*].

20.6 Severability. If any part of this Agreement shall be found to be invalid or unenforceable under applicable law in any jurisdiction, such part shall be ineffective only to the extent of such invalidity or unenforceability in such jurisdiction, without in any way affecting the remaining parts of this Agreement in that jurisdiction or the validity or enforceability of the Agreement as a whole in any other jurisdiction. In addition, the part that is ineffective shall be reformed in a mutually agreeable manner so as to as nearly approximate the intent of the Parties as possible.

20.7 Independent Contractors. Each of the Parties is an independent contractor and nothing herein contained shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between the Parties. Neither Party shall at any time enter into, incur, or hold itself out to Third Parties as having authority to enter into or incur, on behalf of the other Party, any commitment, expense, or liability whatsoever.

20.8 Conflict. This Agreement is subject to the EU Collaboration Agreement. In the event of conflict between this Agreement and the EU Collaboration Agreement, the EU Collaboration Agreement shall govern. The terms and conditions of the body of this Agreement shall prevail in the event of a conflict between or among the provisions of the body of this Agreement and any Purchase Order or the Quality Agreement. Notwithstanding the foregoing, the Quality Agreement shall control with respect to Quality Matters as defined in Section 10.1 hereto. If there is any material conflict between a Purchase Order or an Order Acceptance and the terms and conditions of this Agreement, this Agreement prevails and such conflicting terms are rejected and of no effect, unless the Parties mutually agree otherwise in writing in a separate document or such wording is specifically stated in the Purchase Order as an amendment to this Agreement.

20.9 Waiver. No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition or of any other term, provision or condition of this Agreement.

20.10 No Solicitation of Employees. During [*], each of the Parties agrees not to seek to induce or solicit any employee of the other Party or its Affiliates to discontinue his or her employment with the other Party or such Affiliate in order to become an employee or an independent contractor of the soliciting Party or its Affiliates; provided, however, that neither Party shall be in violation of this Section as a result of making a general solicitation for employees or independent contractors. For the avoidance of doubt, the publication of an advertisement, including without limitation advertisements posted on the internet or in trade journals, shall not constitute solicitation or inducement.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

20.11 Entirety; Amendments. This Agreement, including any ancillary documents attached hereto or referenced herein, constitutes the full understanding of the Parties and a complete and exclusive statement of the terms of their agreement with respect to the specific subject matter hereof except for the EU Collaboration Agreement, and no terms, conditions, understandings or agreements purporting to modify or vary the terms thereof shall be binding unless hereafter made in a written instrument referencing this Agreement and signed by each of the Parties.

20.12 Counterparts. This Agreement and any amendment hereto may be executed in any number of counterparts, each of which shall for all purposes be deemed an original and all of which shall constitute the same instrument.

20.13 Electronic Signature. The Parties agree that execution of this Agreement shall be by e-Signatures (as defined below), and when so executed, shall have the same legal force and effect as the exchange of original signatures. Pursuant to this Agreement, "**e-Signatures**" shall mean a signature that consists of one or more letters, characters, numbers or other symbols in digital form incorporated in, attached to or associated with the electronic document, that (a) is unique to the person making the signature; (b) the technology or process used to make the signature is under the sole control of the person making the signature; (c) the technology or process can be used to identify the person using the technology or process; and (d) the electronic signature can be linked with an electronic document in such a way that it can be used to determine whether the electronic document has been changed since the electronic signature was incorporated in, attached to or associated with the electronic document. For purposes of this Agreement, the Parties have agreed to execute via Docusign e-Signatures.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date.

FIBROGEN, INC.	**ASTELLAS PHARMA EUROPE LTD.**
By: /s/ Michael Martinelli	By: /s/ Adam Pearson
Name: Michael Martinelli, PhD	Name: Adam Pearson
Title: VP, Pharmaceutical Development Manufacturing and Technical Operations	Title: SVP, Head of Corporate Planning
Date: 1/12/2021	Date: 1/13/2021

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Exhibit A

[*]

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EXHIBIT B

Pricing Calculations

[*]

EXHIBIT C

PRODUCT RECONCILIATION TRACKING EXAMPLE

Reconciliation Example: [*]		
[*]	**[*]**	**[*]**
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	**[*]**	**[*]**
[*]		
[*]	[*]	[*]
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[*]	[*]	[*]
[*]	**[*]**	**[*]**
[*]		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	**[*]**	**[*]**

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Exhibit 10.3

AMENDMENT NO. 3 TO MASTER SUPPLY AGREEMENT

THIS AMENDMENT NO. 3 (the "**Third Amendment**") is entered into as of **January 12, 2021**, and effective as of October 1, 2020 (the "**Third Amendment Effective Date**") by and among: FibroGen, Inc. and its Affiliates (collectively, "**FibroGen**"); and Shanghai SynTheAll Pharmaceutical Co., Ltd (d/b/a "上海合全药业有限公司") ("**Shanghai STA**"); and STA Pharmaceutical Hong Kong Limited (d/b/a "合全药业香港有限公司") ("**STA Hong Kong**") (STA Hong Kong, Shanghai STA, and each of their Affiliates are collectively referred to as "**STA**"). This Third Amendment amends the Master Supply Agreement entered into by and between STA and FibroGen on March 2, 2020 (the "**Master Supply Agreement**"), as amended by Amendment No. 1 on May 11, 2020 and Amendment No.2 on July 24, 2020 (collectively, the "**Prior Amendments**"). STA and FibroGen shall be referred to individually herein as a "**Party**", and collectively as, the "**Parties**". The Master Supply Agreement, the Prior Amendments, and this Third Amendment are collectively, the "**Agreement**".

WHEREAS, the Parties desire to amend the Master Supply Agreement to provide for updated shipping and storage terms; and

WHEREAS, the Parties desire to continue the relationship as set forth under the Master Supply Agreement as amended by this Third Amendment.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

(1) Unless otherwise defined herein, all capitalized terms and phrases used in this Third Amendment shall have the meaning ascribed to them in the Master Supply Agreement.

(2) Sect. 3.2.4(a) (FibroGen Materials) is hereby deleted in its entirety and replaced with the following:

> "(a) Pursuant to the Manufacturing Services described under a particular FibroGen forecast or order, FibroGen (or its designee) may provide FibroGen Materials to STA for use in the performance of Manufacturing Services. Any such delivery shall be made [*] (Incoterms 2020) [*], and all risk of loss and damage shall transfer to STA upon [*]. Notwithstanding the foregoing delivery terms, title to FibroGen Materials shall remain with FibroGen at all times."

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

(3) Sect. 4.5 of the Master Supply Agreement is hereby deleted in its entirety and replaced with the following:

> "4.5 Delivery Terms; Storage. Following FibroGen's acceptance of Product pursuant to this Article 4, STA shall either store, ship, or otherwise dispose of such Product as requested by FibroGen in writing. Shipment of Product shall be made [*] (Incoterms [2020]) [*], and legal title and risk of all loss shall transfer to FibroGen [*]. If the Binding Forecast, Stockpile Order or Work Order does not specify disposition of Product, then STA or its Subcontractor shall store such Product in accordance with the storage requirements (as defined in this Agreement, the Specifications and the MBR as applicable) until such time as FibroGen request shipment or other disposition or use of such Product. For any Product that is placed into storage as agreed hereunder, FibroGen shall pay a storage fee in accordance with Section 4.6. [*]. STA shall be solely responsible for [*]. STA shall assist FibroGen [*]. Shipping Requirements shall be approved by FibroGen in writing. No later than [*] ([*]) months before the Delivery Date unless Product is Stockpiled, FibroGen shall provide Shipping Instructions to STA."

(4) The Parties intend for, and all Products have been shipped [*] (Incoterms 2020) [*] as of the Effective Date of the Third Amendment, and legal title with all risk of loss and damage transferring to FibroGen upon [*].

(5) This Third Amendment, together with the Master Supply Agreement as amended by the Prior Amendments, contains the entire understanding of the Parties with respect to the subject matter hereof. Except as otherwise provided herein, the Master Supply Agreement has not been modified or amended and remains in full force and effect. All express or implied agreements and understandings, either oral or written, heretofore made with respect to subject matter herein are expressly superseded in this Third Amendment.

(6) This Third Amendment may be executed in counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Counterparts may be signed and delivered by facsimile and/or via portable document format (pdf), each of which shall be binding when sent.

IN WITNESS WHEREOF, the Parties have executed this Third Amendment to the Master Supply Agreement as of the Third Amendment Effective Date.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

STA PHARMACEUTICAL HONG KONG LIMITED

By: /s/ Xiaoyong Fu

Name: Xiaoyong Fu

Title: SVP

Date: 1/13/2021

FIBROGEN, INC.

By: /s/ Michael Martinelli

Name: Michael Martinelli

Title: SVP Tech Dev

Date: 1/14/2021

SHANGHAI SYNTHEALL PHARMACEUTICAL CO., LTD.

By: /s/ Xiaoyong Fu

Name: Xiaoyong Fu

Title: SVP

Date: 1/13/2021

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the company if publicly disclosed.

Exhibit 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 10, 2021

/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 10, 2021

/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, 2021, 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 10, 2021

In Witness Whereof, the undersigned have set their hands hereto as of the 10th day of May 2021.

/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.