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 June 30, 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 July 31, 2021 was 92,621,941.

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, South Korea, 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 negative vote of the FDA Cardiovascular and Renal Drugs Advisory Committee meeting is expected to have a significant impact on roxadustat's approvability in CKD anemia in the U.S.
- 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 the appropriate amount of 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 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 related 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)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 353,361	$ 678,393
Short-term investments	153,851	8,144
Accounts receivable, net ($13,352 and $4,127 from related parties)	24,266	41,883
Inventories	24,530	16,530
Prepaid expenses and other current assets ($0 and $889 from related parties)	8,458	10,160
Total current assets	564,466	755,110
Restricted time deposits	2,072	2,072
Long-term investments	105,758	244
Property and equipment, net	30,670	33,647
Finance lease right-of-use assets	861	29,606
Equity method investment in unconsolidated variable interest entity	3,083	2,728
Operating lease right-of-use assets	97,091	2,043
Other assets	4,617	1,390
Total assets	$ 808,618	$ 826,840
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable ($0 and $1,118 to a related party)	$ 48,988	$ 24,789
Accrued and other current liabilities ($14 and $24 to a related party)	147,801	118,333
Deferred revenue ($10,699 and $2,907 to a related party)	25,234	6,547
Finance lease liabilities, current	23	12,330
Operating lease liabilities, current	10,718	1,188
Total current liabilities	232,764	163,187
Product development obligations	18,277	18,697
Deferred revenue, net of current ($9,381 and $4,636 to a related party)	152,865	138,474
Finance lease liabilities, non-current	6	25,391
Operating lease liabilities, non-current	94,196	853
Other long-term liabilities	30,659	38,789
Total liabilities	528,767	385,391
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 125,000 shares authorized; no shares issued and outstanding at June 30, 2021, and December 31, 2020	—	—
Common stock, $0.01 par value; 225,000 shares authorized at June 30, 2021, and December 31, 2020; 92,609 and 91,441 shares issued and outstanding at June 30, 2021, and December 31, 2020	926	914
Additional paid-in capital	1,443,975	1,399,774
Accumulated other comprehensive loss	(4,567)	(4,499)
Accumulated deficit	(1,179,754)	(974,011)
Total stockholders' equity	260,580	422,178
Non-controlling interests	19,271	19,271
Total equity	279,851	441,449
Total liabilities, stockholders' equity and non-controlling interests	$ 808,618	$ 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
License revenue	$ —	$ —	$ —	$ —
Development and other revenue (includes $2,645, $4,766, $6,256 and $9,503 from a related party)	19,641	18,957	34,228	38,402
Product revenue, net (includes $11,760, $0, $22,167 and $0 from a related party)	13,371	15,693	28,733	20,648
Drug product revenue (includes $(1,974), $8,238, $2,056 and $8,238 from a related party)	(8,648)	8,238	(168)	8,238
Total revenue	24,364	42,888	62,793	67,288
Operating costs and expenses:				
Cost of goods sold	3,078	3,076	6,479	4,047
Research and development	122,567	61,414	197,243	116,315
Selling, general and administrative	32,554	63,535	63,334	113,138
Total operating costs and expenses	158,199	128,025	267,056	233,500
Loss from operations	(133,835)	(85,137)	(204,263)	(166,212)
Interest and other, net				
Interest expense	(355)	(651)	(856)	(1,284)
Interest income and other income (expenses), net	(363)	644	(817)	3,810
Total interest and other, net	(718)	(7)	(1,673)	2,526
Loss before income taxes	(134,553)	(85,144)	(205,936)	(163,686)
Provision for (benefit from) income taxes	(3)	169	130	(25)
Investment income in unconsolidated variable interest entity	562	—	323	—
Net loss	$ (133,988)	$ (85,313)	$ (205,743)	$ (163,661)
Net loss per share - basic and diluted	$ (1.45)	$ (0.95)	$ (2.24)	$ (1.84)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	92,276	89,451	91,983	88,835

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net loss	$ (133,988)	$ (85,313)	$ (205,743)	$ (163,661)
Other comprehensive income (loss):				
Foreign currency translation adjustments	40	(1,615)	(30)	(1,334)
Available-for-sale investments:				
Unrealized gain (loss) on investments, net of tax effect	17	(1,129)	(38)	520
Other comprehensive income, net of taxes	57	(2,744)	(68)	(814)
Comprehensive loss	$ (133,931)	$ (88,057)	$ (205,811)	$ (164,475)

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 March 31, 2021	92,080,399	$ 921	$ 1,420,471	$ (4,624)	$ (1,045,766)	$ 19,271	$ 390,273
Net loss	—	—	—	—	(133,988)	—	(133,988)
Change in unrealized gain or loss on investments	—	—	—	17	—	—	17
Foreign currency translation adjustments	—	—	—	40	—	—	40
Shares issued from stock plans, net of payroll taxes paid	528,530	5	4,503	—	—	—	4,508
Stock-based compensation	—	—	19,001	—	—	—	19,001
Balance at June 30, 2021	92,608,929	$ 926	$ 1,443,975	$ (4,567)	$ (1,179,754)	$ 19,271	$ 279,851
Balance at March 31, 2020	88,895,630	$ 889	$ 1,319,354	$ 1,183	$ (863,068)	$ 19,271	$ 477,629
Net loss	—	—	—	—	(85,313)	—	(85,313)
Change in unrealized gain or loss on investments	—	—	—	(1,129)	—	—	(1,129)
Foreign currency translation adjustments	—	—	—	(1,615)	—	—	(1,615)
Shares issued from stock plans, net of payroll taxes paid	1,332,663	13	7,914	—	—	—	7,927
Stock-based compensation	—	—	17,644	—	—	—	17,644
Balance at June 30, 2020	90,228,293	$ 902	$ 1,344,912	$ (1,561)	$ (948,381)	$ 19,271	$ 415,143

FIBROGEN, INC.

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

	For The Six Month Period						
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Non Controlling	
	Shares	Amount	Capital	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	—	—	—	—	(205,743)	—	(205,743)
Change in unrealized gain or loss on investments	—	—	—	(38)	—	—	(38)
Foreign currency translation adjustments	—	—	—	(30)	—	—	(30)
Shares issued from stock plans, net of payroll taxes paid	1,168,296	12	5,816	—	—	—	5,828
Stock-based compensation	—	—	38,385	—	—	—	38,385
Balance at June 30, 2021	92,608,929	$ 926	$ 1,443,975	$ (4,567)	$ (1,179,754)	$ 19,271	$ 279,851
Balance at December 31, 2019	87,657,489	$ 877	$ 1,300,725	$ (747)	$ (784,720)	$ 19,271	$ 535,406
Net loss	—	—	—	—	(163,661)	—	(163,661)
Change in unrealized gain or loss on investments	—	—	—	520	—	—	520
Foreign currency translation adjustments	—	—	—	(1,334)	—	—	(1,334)
Shares issued from stock plans, net of payroll taxes paid	2,570,804	25	9,627	—	—	—	9,652
Stock-based compensation	—	—	34,560	—	—	—	34,560
Balance at June 30, 2020	90,228,293	$ 902	$ 1,344,912	$ (1,561)	$ (948,381)	$ 19,271	$ 415,143

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)

	Six Months Ended June 30,	
	2021	**2020**
Operating activities		
Net loss	$ (205,743)	$ (163,661)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	5,242	5,737
Amortization of finance lease right-of-use assets	4,393	5,247
Net accretion of premium and discount on investments	767	(22)
Unrealized loss on equity investments	4	15
Investment loss in unconsolidated variable interest entity	(323)	—
Loss (gain) on disposal of property and equipment	13	—
Stock-based compensation	38,385	34,560
Expense for acquired in-process research and development asset	25,000	—
Tax benefit on unrealized gain on available-for-sale securities	—	(138)
Realized loss on sales of available-for-sale securities	8	258
Changes in operating assets and liabilities:		
Accounts receivable, net	17,868	1,903
Inventories	(7,861)	(2,016)
Prepaid expenses and other current assets	2,231	126,874
Operating lease right-of-use assets	(1,800)	494
Other assets	(3,066)	3,529
Accounts payable	(1,013)	(1,060)
Accrued and other liabilities	27,745	(33,331)
Operating lease liabilities, current	295	(170)
Deferred revenue	33,078	48,117
Accrued interest for finance lease liabilities	(73)	(115)
Operating lease liabilities, non-current	1,388	(359)
Other long-term liabilities	(8,065)	64,317
Net cash provided by (used in) operating activities	(71,527)	90,179
Investing activities		
Purchases of property and equipment	(2,215)	(1,185)
Payment made for investment in unconsolidated variable interest entity	—	(1,419)
Purchases of available-for-sale securities	(266,647)	(38)
Proceeds from sales of available-for-sale securities	4,000	10,606
Proceeds from maturities of investments	10,610	201,900
Net cash provided by (used in) investing activities	(254,252)	209,864
Financing activities		
Repayments of finance lease liabilities	(5,326)	(5,992)
Repayments of lease obligations	(201)	(201)
Cash paid for payroll taxes on restricted stock unit releases	(5,928)	(6,858)
Proceeds from issuance of common stock	11,756	16,510
Net cash provided by financing activities	301	3,459
Effect of exchange rate change on cash and cash equivalents	446	(499)
Net increase (decrease) in cash and cash equivalents	(325,032)	303,003
Total cash and cash equivalents at beginning of period	678,393	126,266
Total cash and cash equivalents at end of period	$ 353,361	$ 429,269

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 (“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 South Korea and Chile for the treatment of anemia associated with CKD in dialysis and non-dialysis patients.

In June 2021, the Committee for Medicinal Products for Human Use of the European Medicines Agency (“EMA”) adopted a positive opinion, recommending the granting of Marketing Authorization Application (“MAA”) for the medicinal product Evrenzo (roxadustat), intended for the treatment of adult patients with symptomatic anemia associated with CKD. Our partner Astellas Pharma Inc. (“Astellas”) expects an approval decision on the MAA for roxadustat by the European Commission in August 2021.

In July 2021, the United States (“U.S.”) Food and Drug Administration (“FDA”) Cardiovascular and Renal Drugs Advisory Committee (“CRDAC”) voted to recommend not approving roxadustat, an oral HIF-PH inhibitor, for the treatment of anemia due to CKD in adult patients. The CRDAC vote was 13 to 1 for non-dialysis dependent CKD patients, and 12 to 2 for dialysis-dependent CKD patients. While the FDA is not required to follow CRDAC's vote, the agency considers CRDAC's non-binding recommendations when making its decision.

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, a human monoclonal antibody targeting CTGF, 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 the 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 11.4 million and 9.2 million for the three months ended June 30, 2021 and 2020, and totaling 9.4 million and 9.0 million for the six months ended June 30, 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 Severe Acute Respiratory Syndrome Coronavirus 2 and the resulting Coronavirus Disease ("COVID-19") and the risk that we may not get approval of roxadustat in the U.S. for CKD anemia given the fact that the CRDAC voted to recommend not approving roxadustat in July 2021.

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.

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 this analysis 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 June 30, 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 is transferred 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 due to changes in estimates.

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 estimates 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 deferred, 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, 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 Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("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.

License Acquisition Agreement

On June 16, 2021, the Company entered into an exclusive license and option agreement with HiFiBiO Therapeutics ("HiFiBiO") ("HiFiBiO Agreement"), pursuant to which the Company exclusively licensed all product candidates in HiFiBiO's Galectin-9 program and will have the sole right to develop them worldwide. The Company has also obtained exclusive options to license all product candidates in HiFiBiO's CXCR5 and CCR8 programs. Under the terms of the HiFiBiO Agreement, the Company will make a $25 million upfront payment to HiFiBiO, as well as payments upon option exercise. In addition, HiFiBiO may receive up to a total of an additional $1.1 billion in future option, clinical, regulatory, and commercial milestone payments across all three programs. HiFiBiO will also be eligible to receive royalties based upon worldwide net sales.

The acquisition of these licenses was accounted for as an asset acquisition. The initial upfront payment of $25.0 million related to the license and options acquisition meets the definition of an in-process research and development asset ("IPR&D asset") under the ASC 730, *Research and Development* ("ASC 730"). It relates to particular research and development projects and is determined to have no alternative future uses and thus have no separate economic value. Therefore, this upfront payment was recorded as a research and development expense during the three months ended June 30, 2021. As of June 30, 2021, this amount was not paid, and was included as accounts payable in the condensed consolidated balance sheet.

Contingent consideration payments will be evaluated and recognized when they become probable and reasonably estimable. The related IPR&D asset will only be capitalized if it has an alternative future use other than in a particular research and development project. Otherwise, amounts allocated to IPR&D asset that have no alternative use will be expensed. As of June 30, 2021, all programs were at the early stage of development and the contingencies related to the milestone payments had not been resolved, therefore no contingent consideration was recognized. The Company will reassess the probability of future option payments and contingent payments on a quarterly basis.

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 June 30, 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 active pharmaceutical ingredient ("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 $(2.0) million and $2.1 million for the three and six months ended June 30, 2021, respectively.

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 June 30, 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 first quarter of 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 first quarter of 2021. The Company recorded the consideration of $11.8 million from this shipment as deferred revenue as of June 30, 2021, 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 June 30, 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 2020, and the first and second quarter of 2021. On July 15, 2021, the FDA CRDAC voted to recommend not approving roxadustat for the treatment of anemia due to CKD in adult patients. While the FDA is not required to follow the CRDAC's vote, the agency considers the CRDAC's non-binding recommendations when making its decision. The Company evaluated the impact of these developments in revising its estimates of variable consideration associated with drug product revenue. As a result, the Company updated the estimated transaction price, and recorded $11.2 million as deferred revenue as of June 30, 2021. See 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 June 30, 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 and six months ended June 30, 2021, the Company recognized $11.8 million and $22.2 million, respectively, 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, during the three and six months ended June 30, 2021, the Company recognized $1.6 million and 6.6 million, respectively, of net product revenue from sales directly to distributors in a few provinces in China, as described as direct sales under *Product Revenue, Net* section below.

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 June 30,		Six Months Ended June 30,	
Agreement	**Performance Obligation**	**2021**	**2020**	**2021**	**2020**
Japan	License revenue	$ —	$ —	$ —	$ —
	Development revenue	$ 99	$ 164	$ 179	$ 327

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 June 30, 2021	Deferred Revenue at June 30, 2021	Total Consideration Through June 30, 2021
License	$ 100,347	$ —	$ 100,347
Development revenue	16,529	30	16,559
Total license and development revenue	$ 116,876	$ 30	$ 116,906

The revenue recognized under the Japan Agreement for the three months ended June 30, 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 June 30,		Six Months Ended June 30,	
Agreement	Performance Obligation	2021	2020	2021	2020
Europe	License revenue	$ —	$ —	$ —	$ —
	Development revenue	$ 2,546	$ 4,602	$ 6,077	$ 9,176

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 June 30, 2021	Deferred Revenue at June 30, 2021	Total Consideration Through June 30, 2021
License	$ 487,951	$ —	$ 487,951
Development revenue	255,039	333	255,372
Total license and development revenue	$ 742,990	$ 333	$ 743,323

The revenue recognized under the Europe Agreement for the three months ended June 30, 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 $10.7 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):

		Three Months Ended June 30,		Six Months Ended June 30,	
Agreement	Performance Obligation	2021	2020	2021	2020
U.S. / RoW and China	License revenue	$ —	$ —	$ —	$ —
	Development revenue	16,993	13,750	27,969	28,305
	China performance obligation	$ —	$ 441	$ —	$ 594

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 June 30, 2021	Deferred Revenue at June 30, 2021		Total Consideration Through June 30, 2021
License	$ 341,844	$ —		$ 341,844
Co-development, information sharing & committee services	582,743	2,309		585,052
China performance obligation *	22,167	149,759		171,926
Total license and development revenue	$ 946,754	$ 152,068	**	$ 1,098,822

* 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 June 30, 2021, deferred revenue included $146.8 million related to the U.S./RoW and China Agreement, which represents the net of $152.1 million of deferred revenue presented above and a $5.3 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 June 30, 2021 included a reduction in revenue of $0.2 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 $34.1 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Direct Sales:				
Gross revenue	$ 2,230	$ 19,833	$ 7,659	$ 25,205
Discounts and rebates	(618)	(4,095)	(1,181)	(4,512)
Sales returns	(1)	(45)	88	(45)
Direct sales revenue, net	1,611	15,693	6,566	20,648
Sales to Falikang:				
Gross transfer price	26,714	—	51,115	—
Profit share	(9,573)	—	(19,636)	—
Net transfer price	17,141	—	31,479	
Increase in deferred revenue	(5,381)	—	(9,312)	
Sales to Falikang revenue, net	11,760	—	22,167	—
Total product revenue, net	$ 13,371	$ 15,693	$ 28,733	$ 20,648

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 $4.1 million for the three months ended June 30, 2021 and 2020, and $1.2 million and $4.5 million for the six months ended June 30, 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 June 30, 2021
Product revenue - Direct sales - contract liabilities	$ (15,137)	$ (883)	$ 2,410	$ (183)	$ (13,793)

As of June 30, 2021 and December 31, 2020, the total contract liabilities were $13.8 million and $15.1 million, which were included in accrued and other current liabilities in the condensed consolidated balance sheet. The rebates and discounts reflected as reductions to gross accounts receivable for direct sales was $0.8 million and $0.5 million as of June 30, 2021 and December 31, 2020, respectively.

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 and six months ended June 30, 2021, following updates to its estimates, the Company deferred $5.4 million and $9.3 million, respectively, from the net transfer price to Falikang, which was included in the related deferred revenue of the 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 June 30, 2021
Product revenue - AstraZeneca				
China performance obligation - deferred revenue	$ (137,338)	$ (34,588)	$ 22,167	$ (149,759)

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 June 30, 2021, approximately $6.3 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 $10.1 million as of June 30, 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Astellas	$ (1,974)	$ 8,238	$ 2,056	$ 8,238
AstraZeneca	(6,674)	—	(2,224)	—
Drug product revenue	$ (8,648)	$ 8,238	$ (168)	$ 8,238

During three months ended June 30, 2021, the Company shipped bulk drug product to AstraZeneca as commercial supply under the terms of the Master Supply Agreement. Based on the above-mentioned FDA CRDAC's vote on July 15, 2021, the Company evaluated the impact of these developments in revising its estimates of variable consideration associated with drug product revenue. As a result, the Company updated the estimated transaction price, and recorded $11.2 million as deferred revenue as of June 30, 2021.

During the three months ended June 30, 2021, the Company recorded a reduction of $2.0 million to the 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 June 30, 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 recorded under deferred revenue in the condensed consolidated balance sheet as of June 30, 2021. During the first quarter of 2021, the Company recorded $4.0 million drug product revenue related to the same API shipments for the change in estimated variable consideration based on the API held by Astellas at March 31, 2021, under the same methodology. This amount was unbilled to Astellas as of March 31, 2021, and was billed and received from Astellas during the second quarter of 2021.

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 recorded the consideration of $11.8 million from this shipment as deferred revenue as of June 30, 2021, due to a high degree of uncertainty associated with the final consideration. The deferred revenue will be recognized as and when uncertainty is resolved.

The following table includes a roll-forward of the above-mentioned deferred revenues that are considered as contract liabilities related to drug product (in thousands):

	Balance at December 31, 2020	Additions	Recognized as Revenue	Balance at June 30, 2021
Astellas - Japan Agreement	$ —	$ (1,974)	$ —	$ (1,974)
Astellas - Europe Agreement	(5,984)	(11,759)	—	(17,743)
AstraZeneca - U.S. Agreement	—	(11,171)	—	(11,171)
Drug product revenue - deferred revenue	$ (5,984)	$ (24,904)	$ —	$ (30,888)

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, *Consolidation* ("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 the 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 Income	Currency Translation	Balance at June 30, 2021
Falikang	51.1%	$ 2,728	$ 323	$ 32	$ 3,083

Falikang is considered 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):

	June 30, 2021			
	Level 1	Level 2	Level 3	Total
Money market funds	$ 220,627	$ —	$ —	$ 220,627
Corporate bonds	—	104,483	—	104,483
Commercial paper	—	72,099	—	72,099
U.S. government bonds	46,568	—	—	46,568
Agency bonds	—	14,284	—	14,284
Asset-backed securities	—	12,490	—	12,490
Foreign government bonds	—	12,151	—	12,151
Equity investments	233	—	—	233
Total	$ 267,428	$ 215,507	$ —	$ 482,935

	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 and six months ended June 30, 2021.

The Company's financial liabilities related to lease obligations as of June 30, 2021 and December 31, 2020 were $0.9 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	June 30, 2021	December 31, 2020
Assets			
Finance:			
Right-of-use assets - cost		$ 2,007	$ 50,477
Accumulated amortization		(1,146)	(20,871)
Finance lease right-of-use assets, net	Finance lease right-of-use assets	861	29,606
Operating:			
Right-of-use assets - cost		100,705	3,934
Accumulated amortization		(3,614)	(1,891)
Operating lease right-of-use assets, net	Operating lease right-of-use assets	97,091	2,043
Total lease assets		$ 97,952	$ 31,649
Liabilities			
Current:			
Finance lease liabilities	Finance lease liabilities, current	$ 23	$ 12,330
Operating lease liabilities	Operating lease liabilities, current	10,718	1,188
Non-current:			
Finance lease liabilities	Finance lease liabilities, non-current	6	25,391
Operating lease liabilities	Operating lease liabilities, non-current	94,196	853
Total lease liabilities		$ 104,943	$ 39,762

The Company's long-term property lease with Alexandria for its corporate headquarters in San Francisco, California, had an initial term of 15 years, scheduled to expire in 2023. The original lease was accounted for as a finance lease upon adoption of ASC 842, *Leases* ("ASC 842"), at January 1, 2019. On June 1, 2021, the Company entered into an amendment with Alexandria to extend the lease to 2028 ("Lease Amendment"). Under the terms of the Lease Amendment, the Company has two optional rights to each extend the lease for an additional five years. The lease contract provides for a fixed annual rent, with scheduled increases of two percent that occur on each anniversary of the rent commencement date through 2023, and with scheduled increases of three percent that occur on each anniversary of the rent commencement date through 2028. This lease requires the Company to pay all costs of ownership, operation, and maintenance of the premises, including without limitation all operating costs, insurance costs, and taxes.

Company determined that the Lease Amendment was a lease modification, effective June 1, 2021, and thus reassessed the lease classification, remeasured the related lease liability using an updated discount rate, and adjusted the related right-of-use asset under the lease modification guidance under the ASC 842. Accordingly, on June 1, 2021, the Company determined that the modified lease be accounted for as an operating lease, and therefore derecognized the previous finance lease right-of-use asset of $24.6 million and the related finance lease liability of $32.6 million, and recognized an operating lease right-of-use asset of $93.2 million and the related operating lease liability of $101.2 million. Starting June 1, 2021, the cash payment related to this lease was classified as an operating activity, the impact of which was approximately $1.1 million to the condensed consolidated statement of cash flow for the six months ended June 30, 2021.

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):

	Statement of Operations Line Item	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Finance lease cost:					
Amortization of right-of-use assets	Cost of goods sold; Research and development; Selling, general and administrative expenses	$ 1,777	$ 2,653	$ 4,393	$ 5,247
Interest on lease liabilities	Interest expense	242	534	627	1,049
Operating lease cost	Cost of goods sold; Research and development; Selling, general and administrative expenses	1,744	255	2,162	564
Sublease income	Selling, general and administrative expenses	(275)	(306)	(575)	(598)
Total lease cost		$ 3,488	$ 3,136	$ 6,607	$ 6,262

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

	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 2,246	$ 433
Operating cash flows from finance leases	628	1,010
Financing cash flows from finance leases	5,326	5,992
Non-cash: Right-of-use assets obtained in exchange for new lease liabilities:		
Finance leases	303	144
Operating leases	3,498	5
Non-cash: Increase (decrease) resulting from lease modification:		
Finance lease right-of-use assets	(24,654)	—
Operating lease right-of-use assets	93,222	—
Finance lease liabilities, current	(12,587)	—
Operating lease liabilities, current	9,221	—
Finance lease liabilities, non-current	(20,009)	—
Operating lease liabilities, non-current	$ 91,943	$ —

Lease term and discount rate were as follows:

	June 30, 2021	December 31, 2020
Weighted-average remaining lease term (years):		
Finance leases	1.3	2.9
Operating leases	7.3	1.8
Weighted-average discount rate:		
Finance leases	4.55%	4.39%
Operating leases	4.75%	4.74%

Maturities of lease liabilities as of June 30, 2021 are as follows (in thousands):

Year Ending December 31,	Finance Leases	Operating Leases
2021 (remaining six month period)	$ 16	$ 7,534
2022	11	15,517
2023	3	13,454
2024	—	16,798
2025	—	18,193
Beyond 2025	—	53,881
Total future lease payments	30	125,377
Less: Interest	(1)	(20,463)
Present value of lease liabilities	$ 29	$ 104,914

6. Balance Sheet Components

Cash and Cash Equivalents

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

	June 30, 2021	December 31, 2020
Cash	$ 130,035	$ 88,046
Commercial paper	2,699	—
Money market funds	220,627	590,347
Total cash and cash equivalents	$ 353,361	$ 678,393

At June 30, 2021 and December 31, 2020, a total of $85.1 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):

	June 30, 2021			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Corporate bonds	$ 104,499	$ 27	$ (43)	$ 104,483
Commercial paper	69,400	—	—	69,400
U.S. government bonds	46,589	—	(21)	46,568
Agency bonds	14,288	2	(6)	14,284
Asset-backed securities	12,489	1	—	12,490
Foreign government bonds	12,151	1	(1)	12,151
Equity investments	118	115	—	233
Total investments	$ 259,534	$ 146	$ (71)	$ 259,609

	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 June 30, 2021, the available-for-sale investments had contractual maturities range from several months to two years. During the three and six months ended June 30, 2021 and 2020, the Company did not recognize any other-than-temporary impairment loss.

Inventories

Inventories consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Raw materials	$ 1,190	$ 2,303
Work-in-progress	15,541	8,114
Finished goods	7,799	6,113
Total inventories	$ 24,530	$ 16,530

The Company capitalizes inventory costs for FibroGen Beijing's production of roxadustat for commercial sales purposes. The Company started capitalizing pre-launch inventory costs in the second quarter of 2020 prior to regulatory approvals in the U.S. and other territories. As of June 30, 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 three and six months ended June 30, 2021 and 2020.

Prepaid expenses and other current assets

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

	June 30, 2021	December 31, 2020
Unbilled contract assets	$ 5,256	$ 2,147
Deferred revenues from associated contracts	(5,256)	(2,147)
Net unbilled contract assets	—	—
Prepaid assets	7,149	8,353
Other current assets	1,309	1,807
Total prepaid expenses and other current assets	$ 8,458	$ 10,160

The unbilled contract assets as of June 30, 2021 of $5.3 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):

	June 30, 2021	December 31, 2020
Leasehold improvements	$ 102,657	$ 102,006
Laboratory equipment	19,247	18,143
Machinery	8,387	8,312
Computer equipment	9,205	9,545
Furniture and fixtures	6,126	6,128
Construction in progress	1,407	760
Total property and equipment	$ 147,029	$ 144,894
Less: accumulated depreciation	(116,359)	(111,247)
Property and equipment, net	$ 30,670	$ 33,647

Accrued and Other Current Liabilities

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

	June 30, 2021	December 31, 2020
Preclinical and clinical trial accruals	$ 65,274	$ 44,113
Payroll and related accruals	18,047	22,800
Contract liabilities to pharmaceutical distributors	13,793	15,137
Accrued co-promotion expenses - current	20,832	11,537
Roxadustat profit share to AstraZeneca	7,007	7,007
Property taxes and other taxes	10,344	5,970
Professional services	7,471	4,869
Other	5,033	6,900
Total accrued and other current liabilities	$ 147,801	$ 118,333

The profit share liability of $7.0 million to AstraZeneca as of June 30, 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):

	June 30, 2021	December 31, 2020
Accrued long-term co-promotion expenses	$ 19,205	$ 27,424
Other long-term tax liabilities	8,985	8,675
Other	2,469	2,690
Total other long-term liabilities	$ 30,659	$ 38,789

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 10,681	$ 10,780	$ 22,903	$ 21,417
Selling, general and administrative	8,320	6,864	15,482	13,143
Total stock-based compensation expense	$ 19,001	$ 17,644	$ 38,385	$ 34,560

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Stock Options				
Expected term (in years)	5.6	5.5	5.7	5.7
Expected volatility	63.4 %	69.2 %	59.4 %	68.4 %
Risk-free interest rate	0.9 %	0.4 %	0.7 %	0.8 %
Expected dividend yield	—	—	—	—
Weighted average estimated fair value	$ 11.91	$ 21.72	$ 25.38	$ 17.75
ESPPs				
Expected term (in years)	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0
Expected volatility	47.5 - 104.2 %	49.5 - 77.1 %	47.5 - 104.2 %	49.5 - 77.1 %
Risk-free interest rate	0.0 - 2.2 %	0.2 - 2.9 %	0.0 - 2.2 %	0.2 - 2.9 %
Expected dividend yield	—	—	—	—
Weighted average estimated fair value	$ 13.60	$ 17.82	$ 14.69	$ 18.11

8. Income Taxes

Provision for (benefit from) income tax for the three and six months ended June 30, 2021 were primarily due to foreign taxes. Provision for (benefit from) income tax for the three and six months ended June 30, 2020 were primarily due to the tax effect arising from other comprehensive income related to available-for-sale securities, and 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 net 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 is considered a related party. The Company recorded revenue related to collaboration agreements with Astellas of $2.6 million and $4.8 million for the three months ended June 30, 2021 and 2020, and $6.3 million and $9.5 million for the six months ended June 30, 2021 and 2020, respectively. The Company also recorded drug product revenue from Astellas of $(2.0) million and $8.2 million for the three months ended June 30, 2021 and 2020, and $2.1 million and $8.2 million for the six months ended June 30, 2021 and 2020, respectively. See Note 2, *Collaboration Agreements and Revenues*, for details.

The Company's expense related to collaboration agreements with Astellas was immaterial for each of the three and six months ended June 30, 2021 and 2020.

As of June 30, 2021 and December 31, 2020, accounts receivable from Astellas were $2.6 million and $4.1 million, respectively.

As of June 30, 2021 and December 31, 2020, total deferred revenue from Astellas was $20.1 million and $7.5 million, respectively.

As of June 30, 2021, the amount due to Astellas was immaterial. As of December 31, 2020, amount due to Astellas was $1.1 million.

Falikang, an entity jointly owned by FibroGen Beijing and AstraZeneca is an unconsolidated VIE 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 and six months ended June 30, 2021, the net product revenue from Falikang was $11.8 million and $22.2 million, respectively. See Note 2, *Collaboration Agreements and Revenues*, for details.

For the three and six months ended June 30, 2021, the investment income in Falikang was $0.6 million and $0.3 million, respectively. As of June 30, 2021 and December 31, 2020, the Company's equity method investment in Falikang was $3.1 million and $2.7 million, respectively. See Note 3, *Variable Interest Entity*, for details.

As of June 30, 2021, accounts receivable, net, from Falikang was of $10.8 million.

As of June 30, 2021, there was no miscellaneous receivables from Falikang. As of December 31, 2020, prepaid expenses and other current assets included miscellaneous receivables from Falikang of $0.9 million.

10. Commitments and Contingencies

Contract Obligations

As of June 30, 2021, the Company had outstanding total non-cancelable purchase obligations of $81.9 million, including $29.6 million for manufacture and supply of roxadustat, $47.3 million for manufacture and supply of pamrevlumab, and $5.0 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. As of June 30, 2021, future milestone payments for research and pre-clinical stage development programs consisted of up to approximately $359.2 million in total potential future milestone payments under the Company's license agreements with HiFiBiO (for Galectin-9), Medarex, Inc. and others. 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 June 30, 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 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 were filed on June 11, 2021 and a hearing on the motion is scheduled for August 19, 2021. Once a lead plaintiff is appointed by the Court, the Company expects to receive an amended consolidated complaint.

On July 30, 2021, a purported shareholder derivative complaint was filed in the U.S. District Court for the Northern District of California. The complaint names as defendants ten of the Company's officers and directors, as well as the Company as nominal defendant, and asserts state and federal claims based on some of the same alleged misstatements as the securities class action complaints. The complaint seeks unspecified damages, attorneys' fees, and other costs. The Company and individual defendants have not yet been served.

The Company believes that the claims are without merit and it intends to vigorously defend against them. However, any litigation is inherently uncertain, and any judgment or injunctive relief entered against FibroGen or any adverse settlement could materially and adversely impact its 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.

11. Subsequent Event

Outcome of FDA Advisory Committee Review

On July 15, 2021, the FDA CRDAC voted to recommend not approving roxadustat for the treatment of anemia due to CKD in adult patients. While the FDA is not required to follow the CRDAC's vote, the agency considers the CRDAC's non-binding recommendations when making its decision.

The Company evaluated this subsequent event and concluded that it required adjustment and disclosure in the condensed consolidated financial statements, specifically to the drug product revenue related the bulk drug product shipments to AstraZeneca as commercial supply under the terms of the Master Supply Agreement. As a result, the Company recorded $11.2 million as deferred revenue as of June 30, 2021. See Note 2, *Collaboration Agreements and Revenues*, for details.

License Agreement with Eluminex

On July 19, 2021, Eluminex Biosciences (Suzhou) Limited ("Eluminex"), an ophthalmology-focused biotechnology company headquartered in Suzhou, China with a US-subsidiary office in San Francisco Bay Area, California, exclusively licensed global rights from FibroGen, Inc. for the development and commercialization of an investigational biosynthetic cornea derived from recombinant human collagen Type III intended to treat patients with corneal blindness.

Under the terms of the agreement, Eluminex will make an $8 million upfront payment to FibroGen. In addition, FibroGen may receive up to a total of $64 million in future manufacturing, clinical, regulatory, and commercial milestone payments for the biosynthetic cornea program, as well as $36 million in commercial milestones for the first recombinant collagen III product that is not the biosynthetic cornea. FibroGen will also be eligible to receive mid single-digit to low double-digit royalties based upon worldwide net sales of cornea products, and low single-digit to mid single-digit royalties based upon worldwide net sales of other recombinant human collagen type III products that are not cornea products.

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 ("2020 Form 10-K").

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 ("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 South Korea and Chile for the treatment of anemia associated with CKD in dialysis and non-dialysis patients.

In June 2021, the Committee for Medicinal Products for Human Use of the European Medicines Agency ("EMA") adopted a positive opinion, recommending the granting of Marketing Authorization Application ("MAA") for the medicinal product Evrenzo (roxadustat), intended for the treatment of adult patients with symptomatic anemia associated with CKD. Our partner Astellas Pharma Inc. ("Astellas") expects an approval decision on the MAA for roxadustat by the European Commission in August 2021.

In July 2021, the United States ("U.S.") Food and Drug Administration ("FDA") Cardiovascular and Renal Drugs Advisory Committee ("CRDAC") voted to recommend not approving roxadustat, an oral HIF-PH inhibitor, for the treatment of anemia due to CKD in adult patients. The CRDAC vote was 13 to 1 for non-dialysis dependent CKD patients, and 12 to 2 for dialysis-dependent CKD patients. While the FDA is not required to follow CRDAC's vote, the agency considers CRDAC's non-binding recommendations when making its decision.

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 ("MDS"). Roxadustat is in Phase 2 clinical development for chemotherapy-induced anemia.

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

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 and six months ended June 30, 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(in thousands, except for per share data)			
Result of Operations				
Revenue	$ 24,364	$ 42,888	$ 62,793	$ 67,288
Operating costs and expenses	158,199	128,025	267,056	233,500
Net loss	(133,988)	(85,313)	(205,743)	(163,661)
Net loss per share - basic and diluted	$ (1.45)	$ (0.95)	$ (2.24)	$ (1.84)

	June 30, 2021	December 31, 2020
	(in thousands)	
Balance Sheet		
Cash and cash equivalents	$ 353,361	$ 678,393
Short-term and long-term investments	259,609	8,388
Accounts receivable	$ 24,266	$ 41,883

Our revenue for the three and six months ended June 30, 2021 included the revenue recognized related to the following:

- $19.6 million and $34.2 million of development revenue recognized under our collaboration agreements with our partners Astellas and AstraZeneca AB ("AstraZeneca");
- $13.4 million and $28.7 million of net product revenue from roxadustat commercial sales in China; and
- $(8.6) million and $(0.2) million of drug product revenue primarily resulted from the deferred considerations of roxadustat bulk drug or active pharmaceutical ingredient ("API") deliveries to AstraZeneca and Astellas.

As a comparison, our revenue for the three and six months ended June 30, 2020 included the revenue recognized related to the following:

- $19.0 million and $38.4 million of development revenue recognized under our collaboration agreements with our partners Astellas and AstraZeneca;
- $15.7 million and 20.6 million of net product revenue from roxadustat commercial sales in China; and
- $8.2 million of roxadustat API delivery to Astellas.

Operating costs and expenses for the three and six months ended June 30, 2021 increased compared to the same periods a year ago as a result of the net effect of the following:

- Expense of $25 million for acquired in-process research and development asset from HiFiBiO Therapeutics (“HiFiBiO”);
- Higher clinical trial expenses associated with Phase 3 trials for pamrevlumab and roxadustat post-approval safety studies;
- Higher drug development expenses associated with drug substance and drug product manufacturing activities primarily related to pamrevlumab;
- Higher employee-related expenses resulting from higher average compensation level and headcount; 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*.

For the three and six months ended June 30, 2021, we had net losses of $134.0 million and 205.7 million, respectively, or net loss per basic and diluted share of $1.45 and $2.24, respectively, as compared to a net loss of $85.3 million and $163.7 million for the same periods a year ago, due to decreases in revenue, and increases in operating costs and expenses as discussed above.

Cash and cash equivalents, investments and accounts receivable totaled $637.2 million at June 30, 2021, a decrease of $91.5 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 second quarter of 2021, roxadustat was listed at hospitals that collectively represent approximately 81% of the CKD anemia market opportunity in China and roxadustat had a 32% 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.

In June 2021, the Committee for Medicinal Products for Human Use of the EMA adopted a positive opinion, recommending the granting of MAA for the medicinal product Evrenzo (roxadustat), intended for the treatment of adult patients with symptomatic anemia associated with CKD. Our partner Astellas expects an approval decision on the MAA for roxadustat by the European Commission in August 2021.

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

In July 2021, the FDA CRDAC voted to recommend not approving roxadustat, an oral HIF-PH inhibitor, for the treatment of anemia due to CKD in adult patients. While the FDA is not required to follow CRDAC’s vote, the agency considers CRDAC’s non-binding recommendations when making its decision.

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 between the second half of 2022 and the first half of 2023.

In China, we are enrolling 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 third quarter of 2021.

Pamrevlumab (FG-3019) – Monoclonal Antibody Targeting 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 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. We expect topline data from ZEPHYRUS-1 in mid-2023.

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). Overall survival is the primary endpoint of this study. An interim analysis of event-free survival will be completed in the second half of 2022 for potential accelerated approval.

In June 2021 the Pancreatic Cancer Action Network's (PanCAN) Precision PromiseSM adaptive trial platform included pamrevlumab, with standard of care chemotherapy treatments for pancreatic cancer (gemcitabine and Abraxane®), in its study for patients with metastatic pancreatic cancer. The combination therapy is offered to patients as either a first- or second-line treatment option, marking the first experimental treatment arm to be offered as a first-line treatment in PanCAN’s innovative Precision Promise trial. The objective of Precision Promise is to expedite the study and approval of promising therapies for pancreatic cancer by bringing multiple stakeholders together, including academic, industry and regulatory entities.

Duchenne Muscular Dystrophy

We continue to enroll LELANTOS-1, our Phase 3 clinical trial 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 first half of 2023.

We also continue to enroll our 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.

Licensing Activities

Exclusive License and Option Agreement with HiFiBiO Therapeutics

On June 17, 2021, we announced a partnership with HiFiBiO covering three HiFiBiO programs.

FibroGen exclusively licensed all product candidates in the Galectin-9 program and will have sole right to develop them worldwide. FibroGen has also obtained exclusive options to license all product candidates in HiFiBiO's CXCR5 and CCR8 programs. Each option may be independently exercised following delivery of program-specific data to be generated by HiFiBiO. If an option is exercised, FibroGen will have the sole right to develop products from that program worldwide. Under the terms of the Exclusive License and Option Agreement, dated June 16, 2021 (the "HiFiBiO Agreement"), FibroGen will make a $25 million upfront payment to HiFiBiO, as well as payments upon option exercise. In addition, HiFiBiO may receive up to a total of an additional $1.1 billion in future option, clinical, regulatory, and commercial milestone payments across all three programs. HiFiBiO will also be eligible to receive mid single-digit to low double-digit royalties based upon worldwide net sales. The HiFiBiO Agreement is filed as an exhibit hereto.

Exclusive License with Eluminex Biosciences

On July 19, 2021, we announced an exclusive license of our global rights to investigational biosynthetic cornea derived from recombinant human collagen type III Eluminex Biosciences (Suzhou) Limited ("Eluminex").

Under the terms of the agreement with Eluminex (the "Eluminex Agreement"), Eluminex will make an $8 million upfront payment to FibroGen. In addition, FibroGen may receive up to a total of $64 million in future manufacturing, clinical, regulatory, and commercial milestone payments for the biosynthetic cornea program, as well as $36 million in commercial milestones for the first recombinant collagen III product that is not the biosynthetic cornea. FibroGen will be eligible to receive mid single-digit to low double-digit royalties based upon worldwide net sales of cornea products, and low single-digit to mid single-digit royalties based on worldwide net sale of other recombinant human collagen type III products that are not cornea products. The Eluminex Agreement contains other industry standard license terms including related to exclusivity, sublicensing, manufacturing, milestones, royalties, intellectual property, and termination. The Eluminex Agreement will expire on a product-by-product and country-by-country basis at the end of the applicable royalty term.

The foregoing description of the Eluminex Agreement is not a complete description thereof, and is qualified in its entirety by reference to the actual Agreement that will be filed with the SEC as an exhibit to FibroGen's Quarterly Report on Form 10-Q for the quarter ending September 30, 2021.

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. See Note 2, *Collaboration Agreements and Revenues*, to the condensed consolidated financial statements for details.

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, the aggregate amount of such consideration received through June 30, 2021 totals $645.1 million.

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, the related drug product revenue was $(2.0) and $2.1 million for the three and six months ended June 30, 2021, respectively.

During the first quarter of 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 first quarter of 2021. We recorded the consideration of $11.8 million from this shipment as deferred revenue as of June 30, 2021, due to a high degree of uncertainty associated with the final consideration. The deferred revenue will be recognized as and when uncertainty is resolved.

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 the AstraZeneca agreements, aggregate amount of such consideration received through June 30, 2021 totals $516.2 million.

Under the China Agreement, which is conducted through FibroGen China Anemia Holdings, Ltd., FibroGen (China) Medical Technology Development Co., 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*.

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 2020 and the first and second quarter of 2021. Based on the above-mentioned FDA CRDAC's vote on July 15, 2021, we evaluated the impact of these developments in revising our estimates of variable consideration associated with drug product revenue. As a result, we updated the estimated transaction price, and recorded $11.2 million as deferred revenue as of June 30, 2021.

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").

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.

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 and six months ended June 30, 2021, we recognized net product revenue of $11.8 million and $22.2 million, respectively.

Additional Information Related to Collaboration Agreements

Total cash consideration received through June 30, 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 June 30, 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 June 30,		Change		Six Months Ended June 30,		Change	
	2021	2020	$	%	2021	2020	$	%
	(dollars in thousands)							
Revenue:								
License revenue	$ —	$ —	$ —	— %	$ —	$ —	$ —	— %
Development and other revenue	19,641	18,957	684	4 %	34,228	38,402	(4,174)	(11) %
Product revenue, net	13,371	15,693	(2,322)	(15) %	28,733	20,648	8,085	39 %
Drug product revenue	(8,648)	8,238	(16,886)	(205) %	(168)	8,238	(8,406)	(102) %
Total revenue	$ 24,364	$ 42,888	$ (18,524)	(43) %	$ 62,793	$ 67,288	$ (4,495)	(7) %

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 and six months ended June 30, 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 June 30, 2021, the estimated future non-contingent development periods range from three to 48 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 New Drug Application ("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 decreased $18.5 million, or 43% for the three months ended June 30, 2021 and $4.5 million, or 7% for the six months ended June 30, 2021, compared to the same periods a year ago for the reasons discussed in the sections below.

Development and Other Revenue

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2021	2020	$	%	2021	2020	$	%
	(dollars in thousands)							
Development revenue:								
Astellas	$ 2,645	$ 4,766	$ (2,121)	(45) %	$ 6,256	$ 9,503	$ (3,247)	(34) %
AstraZeneca	16,993	14,191	2,802	20 %	27,969	28,899	(930)	(3) %
Total development revenue	19,638	18,957	681	4 %	34,225	38,402	(4,177)	(11) %

Development and other revenue increased $0.7 million, or 4% for the three months ended June 30, 2021 and decreased $4.2 million, or 11% for the six months ended June 30, 2021, compared to the same periods a year ago.

Co-development billings related to the development of roxadustat under our collaboration agreements with Astellas for the three and six months ended June 30, 2021 decreased as a result of the substantial completion of Phase 3 trials for roxadustat.

Development revenue recognized under our collaboration agreements with AstraZeneca for the three and six months ended June 30, 2021 was impacted by the increase in CKD related co-development billings in the U.S., offset by the extension of the estimated future non-contingent development period when we were notified of the FDA CRDAC meeting to review the NDA for roxadustat.

Product Revenue, Net

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2021	2020	$	%	2021	2020	$	%
	(dollars in thousands)							
Direct Sales:								
Gross revenue	$ 2,230	$ 19,833	$ (17,603)	(89) %	$ 7,659	$ 25,205	$ (17,546)	(70) %
Discounts and rebates	(618)	(4,095)	3,477	(85) %	(1,181)	(4,512)	3,331	(74) %
Sales returns	(1)	(45)	44	(98) %	88	(45)	133	(296) %
Direct sales revenue, net	1,611	15,693	(14,082)	(90) %	6,566	20,648	(14,082)	(68) %
Sales to Falikang:								
Gross transfer price	26,714	—	26,714	100 %	51,115	—	51,115	100 %
Profit share	(9,573)	—	(9,573)	100 %	(19,636)	—	(19,636)	100 %
Net transfer price	17,141	—	17,141	100 %	31,479	—	31,479	100 %
Increase in deferred revenue	(5,381)	—	(5,381)	100 %	(9,312)	—	(9,312)	100 %
Sales to Falikang revenue, net	11,760	—	11,760	100 %	22,167	—	22,167	100 %
Total product revenue, net	$ 13,371	$ 15,693	$ (2,322)	(15) %	$ 28,733	$ 20,648	$ 8,085	39 %

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 $2.3 million and $19.8 million for the three months ended June 30, 2021 and 2020, and $7.7 million and $25.2 million for six months ended June 30, 2021 and 2020, respectively. The total discounts and rebates were $0.6 million and $4.1 million for the three months ended June 30, 2021 and 2020, and $1.2 million and $4.5 million for six months ended June 30, 2021 and 2020, respectively. The discounts and rebates 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, and non-key account hospital listing award that was calculated based on eligible non-key account hospital listing to date achieved by each distributor with certain requirements met during the period. In the second quarter of 2020, we recorded a $2.6 million as a reduction to the revenue related to accounting modifications of non-key account hospital listing award, when we amended the agreement with our pharmaceutical distributors.

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 and six months ended June 30, 2021, the gross transfer price was $26.7 million and $51.1 million respectively, net of the calculated profit share of $9.6 million and $19.6 million respectively. Following updates to our estimates, we deferred $5.4 million and $9.3 million from the sales to Falikang for the three and six months ended June 30, 2021, respectively, which was included in the related deferred revenue of the China performance obligation.

Drug Product Revenue

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2021	2020	$	%	2021	2020	$	%
	(dollars in thousands)							
Drug product revenue:								
Astellas	$ (1,974)	$ 8,238	$ (10,212)	(124) %	$ 2,056	$ 8,238	$ (6,182)	(75) %
AstraZeneca	(6,674)	—	(6,674)	(100) %	(2,224)	—	(2,224)	(100) %
Total drug product revenue:	$ (8,648)	$ 8,238	$ (16,886)	(205) %	$ (168)	$ 8,238	$ (8,406)	(102) %

During the three months ended June 30, 2021, we recorded a reduction of $2.0 million to the 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 June 30, 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. During the first quarter of 2021, the Company recorded $4.0 million drug product revenue related to the same API shipments for the change in estimated variable consideration based on the API held by Astellas at March 31, 2021, under the same methodology.

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 recorded the consideration of $11.8 million from this shipment as deferred revenue as of June 30, 2021, due to a high degree of uncertainty associated to the final consideration, which will be recognized as and when uncertainty is resolved.

During three and six months ended June 30, 2021, we shipped bulk drug product to AstraZeneca as commercial supply under the terms of the Master Supply Agreement. Based on the above-mentioned FDA CRDAC’s vote on July 15, 2021, we evaluated the impact of these developments in revising our estimates of variable consideration associated with drug product revenue. As a result, we updated the estimated transaction price, and recorded $11.2 million as deferred revenue as of June 30, 2021.

Operating Costs and Expenses

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2021	2020	$	%	2021	2020	$	%
	(dollars in thousands)							
Operating costs and expenses								
Cost of goods sold	$ 3,078	$ 3,076	$ 2	— %	$ 6,479	$ 4,047	$ 2,432	60 %
Research and development	122,567	61,414	61,153	100 %	197,243	116,315	80,928	70 %
Selling, general and administrative	32,554	63,535	(30,981)	(49) %	63,334	113,138	(49,804)	(44) %
Total operating costs and expenses	$ 158,199	$ 128,025	$ 30,174	24 %	$ 267,056	$ 233,500	$ 33,556	14 %

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. 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 and six months ended June 30, 2021, some reduction in expenses, such as due to paused or slowed enrollment for trials, were offset by some increased expenses, such as in patient care.

Total operating costs and expenses increased $30.2 million, or 24% for the three months ended June 30, 2021, and $33.6 million, or 14% for the six months ended June 30, 2021, compared to the same periods a year ago, for the reason discussed in the sections below.

Cost of Goods Sold

Cost of goods sold was $3.1 million for each of the three months ended June 30, 2021 and 2020. Cost of goods sold was $6.5 million and $4.0 million for the six months ended June 30, 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 $1.9 million and $2.7 million for the three months ended June 30, 2021 and 2020, and $4.6 million and $3.7 million for the six months ended June 30, 2021 and 2020, respectively, due to the sales to Falikang that started in January 2021, offset by the overall increase in the gross sales.

Cost of goods sold associated with the roxadustat drug product revenue in the U.S. was $1.1 million and $0.4 million for the three months ended June 30, 2021 and 2020, and $1.9 million and $0.4 million for the six months ended June 30, 2021 and 2020, respectively. 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. Research and development expenses also include in-process research and development asset that has no alternative future use other than in a particular research and development project.

The following table summarizes our research and development expenses incurred during the three and six months ended June 30, 2021 and 2020:

		Three Months Ended June 30,		Six Months Ended June 30,	
Product Candidate	Phase of Development	2021	2020	2021	2020
		(in thousands)			
Roxadustat	Phase 3	$ 27,313	$ 34,332	$ 53,641	$ 60,344
Pamrevlumab	Phase 2/3	58,277	23,320	93,523	45,401
Other research and development expenses		36,977	3,762	50,079	10,570
Total research and development expenses		$ 122,567	$ 61,414	$ 197,243	$ 116,315

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 $61.2 million, or 100% for the three months ended June 30, 2021, compared to the same period a year ago, as a result of the net effect of the following:

- Expense of $25.0 million for acquired in-process research and development asset from HiFiBiO;
- Increase of $21.7 million in drug development expenses associated with drug substance and drug product manufacturing activities primarily related to pamrevlumab;
- Increase of $8.3 million in clinical trials costs, primarily due to Phase 3 trials for pamrevlumab and roxadustat post-approval safety studies in China;
- Increase of $3.2 million in employee-related costs primarily due to higher headcount in the research and development functions and higher compensation levels; and
- Increase of $2.4 million in outside services due to higher consulting expenses related to roxadustat in China and higher scientific contract activities related to pamrevlumab Phase 3.

Research and development expenses increased $80.9 million, or 70% for the six months ended June 30, 2021, compared to the same period a year ago, as a result of the net effect of the following:

- Expense of $25.0 million for acquired in-process research and development asset from HiFiBiO;
- Increase of $22.8 million in clinical trials costs, primarily due to Phase 3 trials for pamrevlumab and roxadustat post-approval safety studies in China;
- Increase of $20.0 million in drug development expenses associated with drug substance and drug product manufacturing activities primarily related to pamrevlumab;
- Increase of $7.3 million in employee-related costs primarily due to higher headcount in the research and development functions and higher compensation levels;
- Increase of $3.8 million in outside services due to higher consulting expenses related to roxadustat in China and higher scientific contract activities related to pamrevlumab Phase 3; and
- Increase of $1.5 million in stock-based compensation expense, primarily due to the cumulative impact of stock option grant activities expensed in the normal course.

Selling, General and Administrative Expenses

We started to incur sales and marketing expenses in 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 $31.0 million, or 49% for the three months ended June 30, 2021, compared to the same period a year ago, as a result of the net effect of the following:

- Decrease of $34.9 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;
- Decrease of $1.8 million in legal expenses primarily associated with less patent-related activities in United Kingdom compared to prior year period;

- Increase of $1.7 million in employee-related costs primarily due to higher headcount in the general and administrative functions and higher compensation levels;
- Increase of $1.6 million in facilities-related expense due higher repair and general maintenance expenses; and
- Increase of $1.5 million in stock-based compensation expense, primarily due to the cumulative impact of stock option grant activities expensed in the normal course.

SG&A expenses decreased $49.8 million, or 44% for the six months ended June 30, 2021, compared to the same period a year ago, as a result of the net effect of the following:

- Decrease of $59.5 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;
- Decrease of $1.5 million in legal expenses primarily associated with less patent-related activities in United Kingdom compared to prior year period;
- Increase of $3.9 million in employee-related costs primarily due to higher headcount in the general and administrative functions and higher compensation levels;
- Increase of $2.6 million in facilities-related expense due higher repair and general maintenance expenses.
- Increase of $2.3 million in stock-based compensation expense, primarily due to the cumulative impact of stock option grant activities expensed in the normal course; and
- Increase of $2.2 million in audit and tax expenses.

Interest and Other, Net

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2021	2020	$	%	2021	2020	$	%
	(dollars in thousands)							
Interest and other, net:								
Interest expense	$ (355)	$ (651)	$ 296	(45) %	$ (856)	$ (1,284)	$ 428	(33) %
Interest income and other income (expenses), net	(363)	644	(1,007)	(156) %	(817)	3,810	(4,627)	(121) %
Total interest and other, net	$ (718)	$ (7)	$ (711)	10,157 %	$ (1,673)	$ 2,526	$ (4,199)	(166) %

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 expense decreased $0.3 million, or 45% for the three months ended June 30, 2021, and $0.4 million, or 33% for the six months ended June 30, 2021 compared to the same periods a year ago. The decrease was primarily due to the lease amendment effective June 1, 2021, related to our long-term property lease in San Francisco, was determined as a lease modification and classified as an operating lease, as compared to a finance lease before the lease modification. In addition, the new lease agreement effective in February 2021 for our long-term property lease in China was classified as an operating lease, as compared to a finance lease for the expired lease. The classification for both leases no longer trigger recognition of interest on the lease liabilities separately in the condensed statement of operations. See Note 5, *Leases*, to the condensed consolidated financial statements for details.

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 $1.0 million, or 156% for the three months ended June 30, 2021, and $4.6 million, or 121% for the six months ended June 30, 2021 compared to the same periods a year ago, primarily due to lower interest earned on our cash, cash equivalents and investments associated with the lower average balances and lower interest rates.

In addition, 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 changed resulted in a one-time $1.0 million foreign currency loss during the three and six months ended June 30, 2020.

Income Taxes

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(dollars in thousands)			
Loss before income taxes	$ (134,553)	$ (85,144)	$ (205,936)	$ (163,686)
Provision for (benefit from) income taxes	(3)	169	130	(25)
Effective tax rate	— %	(0.2) %	(0.1) %	— %

Provision for (benefit from) income tax for the three and six months ended June 30, 2021 were primarily due to foreign taxes. Provision for (benefit from) income tax for the three and six months ended June 30, 2020 were primarily due to the tax effect arising from other comprehensive income related to available-for-sale securities, and 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 net deferred tax assets as we do not currently believe that realization of those assets is more likely than not.

Investment income in unconsolidated variable interest entity

Investment income 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 and six months ended June 30, 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 June 30, 2021, we had cash and cash equivalents of $353.4 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 June 30, 2021, we had short-term and long-term investments of $153.9 million and $105.8 million, respectively. As of June 30, 2021, a total of $85.1 million of our cash and cash equivalents was held outside of the U.S. in our foreign subsidiaries, including $63.8 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 are expected to 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):

	Six Months Ended June 30,	
	2021	2020
Net cash provided by (used in):		
Operating activities	$ (71,527)	$ 90,179
Investing activities	(254,252)	209,864
Financing activities	301	3,459
Effect of exchange rate changes on cash and cash equivalents	446	(499)
Net increase (decrease) in cash and cash equivalents	$ (325,032)	$ 303,003

Operating Activities

Net cash used in operating activities was $71.5 million for the six months ended June 30, 2021 and consisted primarily of net loss of $205.7 million adjusted for non-operating cash items of $73.5 million, offset by a net increase in operating assets and liabilities of $60.7 million. The significant non-operating cash items included stock-based compensation expense of $38.4 million, expense for acquired in-process research and development asset from HiFiBiO of $25.0 million, depreciation expense of $5.2 million and amortization of finance lease right-of-use assets of $4.4 million. The significant items in the changes in operating assets and liabilities included the increases resulting from the following:

- Deferred revenue of $33.1 million, primarily related to the above-mentioned $11.8 million and $11.2 million of the deferred considerations of the bulk drug product shipped to Astellas and AstraZeneca, respectively, due to a high degree of uncertainty associated to the final consideration, and $9.3 million of the deferred revenue from the sales to Falikang associated with the 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;
- Accrued and other liabilities of $27.7 million, primarily driven by the timing of invoicing and payment; and
- Accounts receivable of $17.9 million, primarily driven by the timing of the receipt of upfront payments and the recognition of revenues under our collaboration agreements with Astellas and AstraZeneca, as well as the collection from our distributors and Falikang.

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

- Other long-term liabilities of $8.1 million, primarily due to the decrease in the co-promotional expenses with AstraZeneca for its sales and marketing efforts related to the commercial launch of roxadustat in China that are not expected to be paid in the next year; and
- Inventories of $7.9 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 provided by operating activities was $90.2 million for the six months ended June 30, 2020 and consisted primarily of net loss of $163.7 million adjusted for non-operating cash items of $45.7 million, offset by a net increase in operating assets and liabilities of $208.2 million. The significant non-operating cash items included stock-based compensation expense of $34.6 million, depreciation expense of $5.7 million and amortization of finance lease right-of-use assets of $5.2 million. The significant items in the changes in operating assets and liabilities included the increases resulting from the following:

- Prepaid expenses and other current assets of $126.9 million and Deferred revenue of $48.1 million, primarily related to the billing and receipt of $130.0 million in regulatory milestones under the Europe Agreement with Astellas associated with the MAA submission in Europe; and the billing and receipt of $50.0 million regulatory milestone under the U.S./RoW Agreement with AstraZeneca associated with the NDA submission for review in the U.S. These milestones were not billable as of December 31, 2019, and was net of the associated deferred revenues of $4.8 million and $50.0 million, respectively. The change in deferred revenue was also driven by the recognition of revenues under our collaboration agreements with Astellas and AstraZeneca;
- Other long-term liabilities of $64.0 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;
- Other assets of $4.0 million, primarily related to the return and consumption of input value added tax by FibroGen Beijing; and
- Accounts receivable of $1.9 million, primarily driven by the timing of the receipt of upfront payments and the recognition of revenues under our collaboration agreements with Astellas and AstraZeneca;

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

- Accrued and other liabilities of $33.5 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 API delivery; as well as driven by the timing of invoicing and payment; and
- Inventories of $2.0 million, driven by the increased inventory level related to FibroGen Beijing's productions of roxadustat for commercial sales purposes.

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 $254.3 million for the six months ended June 30, 2021 and consisted primarily of $266.6 million of cash used in purchases of available-for-sale securities, partially offset by $10.6 million of proceeds from maturities of investments, and $4.0 million of proceeds from sales of available-for-sale securities.

Net cash provided by investing activities was $209.9 million for the six months ended June 30, 2020 and consisted primarily of $201.9 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 provided by financing activities was $0.3 million for the six months ended June 30, 2021 and consisted primarily of $11.8 million of proceeds from the issuance of common stock upon exercise of stock options and purchases under our Employee Share Purchase Plan (“ESPP”), partially offset by $5.9 million of cash paid for payroll taxes on restricted stock unit releases, and $5.3 million of repayments of finance lease liabilities.

Net cash provided by financing activities was $3.5 million for the six months ended June 30, 2020 and consisted primarily of $16.5 million of proceeds from the issuance of common stock upon exercise of stock options and purchases under our ESPP, partially offset by $6.9 million of cash paid for payroll taxes on restricted stock unit releases, and $6.0 million of repayments of finance lease liabilities.

Off-Balance Sheet Arrangements

During the three and six months ended June 30, 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 June 30, 2021, we had $104.9 million of operating lease liabilities. Our finance lease liabilities were immaterial as of June 30, 2021.

As of June 30, 2021, we had outstanding total non-cancelable purchase obligations of $81.9 million, including $29.6 million for manufacture and supply of roxadustat, $47.3 million for manufacture and supply of pamrevlumab, and $5.0 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. As of June 30, 2021, future milestone payments for research and pre-clinical stage development programs consisted of up to approximately $359.2 million in total potential future milestone payments under our license agreements with HiFiBiO (for Galectin-9), Medarex, Inc. and others. 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 Accounting Guidance

For recently issued accounting guidance, see Note 1, *Significant Accounting Policies*, to the condensed consolidated financial statements.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

There have been no material changes in our critical accounting policies, estimates and judgments during the three and six months ended June 30, 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 is transferred 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 due to changes in estimates.

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 estimates 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 deferred, 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 the 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 and six months ended June 30, 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 June 30, 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 June 30, 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 June 30, 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 two quarters 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 June 30, 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 June 30, 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 were filed on June 11, 2021 and a hearing on the motion is scheduled for August 19, 2021. Once a lead plaintiff is appointed by the Court, the Company expects to receive an amended consolidated complaint.

On July 30, 2021, a purported shareholder derivative complaint was filed in the U.S. District Court for the Northern District of California. The complaint names as defendants ten of the Company's officers and directors, as well as the Company as nominal defendant, and asserts state and federal claims based on some of the same alleged misstatements as the securities class action complaints. The complaint seeks unspecified damages, attorneys' fees, and other costs. The Company and individual defendants have not yet been served.

The Company believes that the claims are without merit and it intends to vigorously defend against them. However, any litigation is inherently uncertain, and any judgment or injunctive relief entered against FibroGen or any adverse settlement could materially and adversely impact its 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, South Korea, 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, South Korea, 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 an independent advisory committee that roxadustat is safe and effective in treating anemia in CKD, myelodysplastic syndromes, or chemotherapy-induced anemia, 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 (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 negative vote of the FDA Cardiovascular and Renal Drugs Advisory Committee meeting is expected to have a significant impact on roxadustat's approvability in CKD anemia in the U.S.*

The Cardiovascular and Renal Drugs Advisory Committee ("CRDAC") of the FDA voted 13 to 1 for non-dialysis dependent patients with CKD, and 12 to 2 for dialysis-dependent CKD patients to recommend not approving roxadustat, an oral hypoxia-inducible factor prolyl hydroxylase ("HIF-PH") inhibitor, for the treatment of anemia due to CKD in adult patients. While the FDA is not required to follow CRDAC's vote, the agency considers CRDAC's non-binding recommendations when making its decision, and there is a high risk roxadustat's NDA will not be approved, or if it is approved, it may be for a more restricted use than the Company has requested. We do not know how long it will take for the FDA to make a decision on our NDA. The FDA may give us a complete response letter (rejecting our NDA) or further delay approval of our NDA if applicable regulatory criteria are not satisfied and/or the FDA requires additional testing or information.

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 the appropriate amount of 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.

In addition, if we are not able to obtain regulatory approval of roxadustat in the U.S. in CKD anemia, we may have excess supply manufactured in anticipation of commercialization. Such excess supply of roxadustat could be wasted, for example, if it expires prior to being used in other clinical trials or prior to being used in other territories where such formulation of roxadustat is approved. 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 sufficient supply agreements in place for our development and commercialization plan, 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. Any 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 "HIF-PH" inhibitors for anemia in CKD indications include GlaxoSmithKline plc ("GSK"), Bayer Corporation ("Bayer"), Akebia Therapeutics, Inc. ("Akebia"), Otsuka Pharmaceutical, 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 ESA (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. The FDA accepted for filing the NDA for the treatment of anemia due to CKD in both adult patients on dialysis and adult patients not on dialysis, with a Prescription Drug User Fee Act (PDUFA) target action date of March 29, 2022.

In July 2021, GSK announced positive headline results from five Phase 3 studies of daprodustat for patients with anemia due to CKD. Full results of the studies are anticipated to be presented at a forthcoming medical meeting later in 2021. 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, Galecto's GB0139, Liminal BioSciences' PBI-4050, and Roche/Promedior, Inc.'s PRM-151. Roche is enrolling patients in a Phase 3 trial evaluating the efficacy and safety of PRM-151, a recombinant human pentraxin-2 (rhPTX-2), compared to placebo in patients with IPF.

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 healthcare providers 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;
- adequate pricing and reimbursement 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 COVID-19

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

The COVID-19 pandemic 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, government-mandated restrictions, the vaccine penetration rate (globally and in the U.S.), and the efficacy of the COVID-19 vaccines in preventing the spread and effects of current and future 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, COVID-19 presents a health risk to our employees, including members of senior management.

We have seen impacts from COVID-19 on all of our clinical trials to varying degrees, but COVID-19 has most heavily impacted our clinical trial timelines in IPF, DMD, and MDS. There is a risk that any or all of our clinical trials will be further delayed, in particular our studies in IPF, DMD and MDS, due to a new outbreak which could 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 business, operating results, and financial condition.

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.

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. To date, at oral proceedings, the Opposition Division of the European Patent Office found the '488 patent did not meet the grounds for novelty. FibroGen plans to appeal this decision once the Written Decision providing the underlying reasoning has been published. 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, South Korea, 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 Risk Evaluation and Mitigation Strategy 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 U.S. Securities and Exchange Commission ("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 June 30, 2021, approximately $63.8 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 June 30, 2021, we had an accumulated deficit of $1.2 billion. As of June 30, 2021, we had capital resources consisting of cash, cash equivalents and short-term investments of $507.2 million plus $105.8 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 to 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 potential 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 July 31, 2021, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 40.91% 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.

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

In a press release on April 6, 2021, the Company clarified that certain previously disclosed cardiovascular safety analyses from the roxadustat Phase 3 program for the treatment of anemia in chronic kidney disease included post-hoc changes to the stratification factors, and provided additional data from the cardiovascular safety analyses with the pre-specified stratification factors. As stated at that time, the Company initiated an internal review to ensure this does not occur in the future. We have now completed that review.

The Company's major findings are as follows:

- The underlying data used for cardiovascular safety analyses are accurate, with no data integrity issues with the data used to generate such analyses.
- In its NDA, the Company calculated accurately and described both sets of analyses, including the statistical methodologies and stratification factors utilized. The statistical analyses using post-hoc stratification factors were designated as "primary" analysis, and the statistical analyses using pre-specified stratification factors as a "sensitivity" analysis.
- We believe a number of elements contributed to the fact that the cardiovascular safety analyses designated as primary included post-hoc stratification factors. These include a complex data set with data from multiple clinical studies conducted by three companies, and a lack of clarity in the pooled cardiovascular safety analysis plans which identified multiple statistical methods and assessment periods.
- In addition, this information was compartmentalized within the organization, which relied on the founder and then-CEO to make key decisions and facilitate internal communication between groups. He unfortunately passed away in August 2019 prior to public disclosure of the detailed pooled safety analyses and the NDA filing.
- Those responsible for the statistical analyses believed that it was a reasonable and valid way to analyze and present the data.

Management is taking steps to ensure the Company's processes are consistent with best practices in all respects. We plan to implement and improve a number of processes and procedures, including independent quality unit oversight of clinical data management, programming, analysis, and reporting.

Those directly responsible for the decision to use post-hoc stratification factors in the primary analyses no longer work for the Company.

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*	Sixth Amendment to the Lease by and between ARE-San Francisco No., 43, LLC and FibroGen, Inc. as of June 1, 2021.	—	—	—	—
10.2*†	Exclusive License and Option Agreement by and between FibroGen, Inc. and HiFiBiO (HK) Limited (D.B.A. HiFiBiO Therapeutics), as of June 16, 2021.	—	—	—	—
21.1*	Subsidiaries of FibroGen, Inc.	—	—	—	—
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 the omitted information is both (i) not material and (ii) the type of information that the Company treats as private or confidential

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: August 9, 2021

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

Dated: August 9, 2021

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

SIXTH AMENDMENT TO LEASE

THIS SIXTH AMENDMENT TO LEASE (this "**Sixth Amendment**") is made as of June 1, 2021 (the "**Effective Date**"), by and between **ARE- SAN FRANCISCO NO. 43, LLC**, a Delaware limited liability company ("**Landlord**"), and **FIBROGEN, INC.**, a Delaware corporation ("**Tenant**").

RECITALS

A. Landlord (as successor-in-interest to X-4 Dolphin LLC) and Tenant are parties to that certain Lease Agreement dated as of September 22, 2006 (the "**Original Lease**"), as amended by that certain First Amendment to Lease dated as of October 10, 2007, and as further amended by that certain letter agreement dated as of March 21, 2008, that certain Second Amendment to Lease dated as of June 29, 2009, that certain Third Amendment to Lease dated as of May 19, 2011 (the "**Third Amendment**"), that certain letter agreement dated as of June 20, 2011, that certain Fourth Amendment to Lease dated as of September 8, 2011, that certain letter agreement dated as of November 15, 2012, that certain Memorandum of Understanding dated as of October 1, 2014, that certain Fifth Amendment to Lease dated as of December 23, 2014, that certain letter agreement dated as of December 23, 2014, that certain letter agreement dated as of December 10, 2015, and that certain letter agreement dated as of April 26, 2016 (as amended, the "**Lease**"). Pursuant to the Lease, Tenant leases certain premises containing approximately 234,249 rentable square feet (the "**Premises**") in that certain building located at 409 Illinois Street, San Francisco, California (the "Building"). The Premises are more particularly described in the Lease. Capitalized terms used herein without definition shall have the meanings defined for such terms in the Lease.

B. The Term of the Lease is scheduled to expire on November 19, 2023.

C. Landlord and Tenant desire, subject to the terms and conditions set forth below, to amend the Lease to, among other things, extend the Term of the Lease through November 30, 2028 (the "**Sixth Amendment Expiration Date**").

NOW, THEREFORE, in consideration of the foregoing Recitals, which are incorporated herein by this reference, the mutual promises and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:

1. **Extended Term**. The Term of the Lease is hereby extended beginning on November 20, 2023 (the "**Sixth Amendment Commencement Date**") through the Sixth Amendment Expiration Date (the "**Extended Term**"). Tenant's occupancy of the Premises through the Sixth Amendment Expiration Date shall be on an "as-is" basis and, except as otherwise expressly provided in the work letter attached to this Sixth Amendment as **Exhibit A** (the "**A06 Work Letter**"), Landlord shall have no obligation to provide any tenant improvement allowance or make any alterations to the Premises. With respect to Tenant's surrender obligations under the Lease, all work described in the A06 Work Letter shall be deemed to be "Tenant's Work" as defined in Section 2.17 of the Lease.

2. **Minimum Monthly Base Rent**. Tenant shall continue to pay Minimum Monthly Rent as provided under the Lease through November 19, 2023. Commencing on the Sixth Amendment Commencement Date, Tenant shall pay Minimum Monthly Rent in the amount of $72.00 per rentable square foot of the Premises per year. Commencing on December 1, 2024, and on each subsequent December 1st through the Sixth Amendment Expiration Date (each, a "**Sixth Amendment Adjustment Date**"), Minimum Monthly Rent shall be increased by multiplying the Minimum Monthly Rent payable immediately before such Sixth Amendment Adjustment Date by

3.0% (the "**Rent Adjustment Percentage**") and adding the resulting amount to the Minimum Monthly Rent payable immediately before such Sixth Amendment Adjustment Date. The amounts comprising the Minimum Monthly Rent are set forth Exhibit D entitled, "**A06 Minimum Monthly Rent Schedule**" attached hereto.

In addition to the Minimum Monthly Base Rent payable during the Extended Term, Tenant may be required to also pay "Additional TI Rent," as defined in this paragraph. Landlord shall, subject to the terms of the A06 Work Letter, make available to Tenant the Additional Tenant Improvement Allowance (as defined in the A06 Work Letter). If Tenant elects to draw down all or any portion of the Additional Tenant Improvement Allowance, then, commencing on the Sixth Amendment Commencement Date Tenant shall pay, in addition to the Minimum Monthly Base Rent, that monthly amount (the "**Additional TI Rent**") necessary to fully amortize the portion of the Additional Tenant Improvement Allowance requested by Tenant and actually funded by Landlord (if any), payable in equal monthly payments with interest at a rate of 8% per annum over the Extended Term, which interest shall begin to accrue on the date that Landlord first disburses such Additional Tenant Improvement Allowance or any portion(s) thereof. Any Additional TI Rent remaining unpaid as of the expiration or earlier termination of this Lease shall be paid to Landlord in a lump sum at the expiration or earlier termination of this Lease.

3. **Abatement**. Notwithstanding anything to the contrary contained in the Lease, so long as there exists no Event of monetary Default under the lease after the application of applicable notice and cure periods, for the period commencing on the Sixth Amendment Commencement Date, and ending on January 19, 2024 (the "**Minimum Monthly Rent Abatement Period**"), Tenant shall not be required to pay Minimum Monthly Rent under the Lease. Tenant shall resume paying 100% of the Minimum Monthly Rent required to be paid under the Lease on the date immediately following the expiration of the Minimum Monthly Rent Abatement Period. For the avoidance of doubt, Tenant shall continue during the Minimum Monthly Rent Abatement Period to pay Tenant's Proportionate Share of Operating Costs, Taxes and Insurance Costs (in accordance with the terms of the Lease and without any abatement) and all other amounts due under the Lease.

4. **Operating Costs, Taxes and Insurance Costs**. Tenant shall continue to pay Tenant's Proportionate Share of Operating Costs, Proportionate Share of Taxes and Proportionate Share of Insurance Costs as provided under the Lease during the Extended Term. Notwithstanding the foregoing, during the Extended Term only, (a) in addition to the exclusions set forth in the Lease, (i) the following items shall be excluded from Operating Costs: gross receipts taxes and costs associated with the fitness center, shuttle, vestibule security guard and security (Visentry AI and remote monitoring), and (ii) Operating Costs shall not include any items which have not previously been included within Operating Costs, except to the extent such new Operating Costs are outside of Landlord's reasonable control and/or are consistent with maintaining and/or operating a Class A laboratory/office building in the Mission Bay neighborhood of San Francisco, California, and (b) Tenant's Proportionate Share of Operating Costs for the Parking Garage, Proportionate Share of Taxes for the Parking Garage and Proportionate Share of Insurance Costs for the Parking Garage shall not, taken together, increase by more than 2.0% per annum (i) on the Sixth Amendment Commencement Date over the amount payable immediately prior to the Sixth Amendment Commencement Date, and (ii) on each Sixth Amendment Adjustment Date over the amount payable immediately prior to such Sixth Amendment Adjustment Date. The limitations on increases to Tenant's Proportionate Share of Operating Costs for the Parking Garage, Proportionate Share of Taxes for the Parking Garage and Proportionate Share of Insurance Costs for the Parking Garage set forth in this Section 4 shall not be applicable to the extent any such increase is attributable to Tenant leasing additional parking spaces as a result of leasing space in the 499 Building.

The Calculation and Payment of Additional Rent provisions of Section 6.3 of the Original Lease shall continue to apply during the Extended Term except as specifically provided to the contrary in this Section 4.

Notwithstanding anything to the contrary contained in this Lease, if, at any time prior to the Sixth Amendment Expiration Date, any sale of the Complex is consummated by Landlord, and solely as a result thereof, and to the extent that solely in connection therewith, the Complex is reassessed (the "**Reassessment**") for real estate tax purposes by the appropriate governmental authority pursuant to the terms of Proposition 13, Tenant shall not be obligated with respect to the existing Premises only during the Extended Term to pay the Tax Increase solely in connection therewith. The term "**Tax Increase**" shall mean that portion of the Taxes during the Extended Term which is attributable solely to the Reassessment. Accordingly, the term Tax Increase shall not include (and Tenant shall be required to pay for) any portion of the Taxes which (i) is attributable to assessments which were pending prior to the Reassessment or which would otherwise have occurred unrelated to the sale, or (ii) is attributable to the annual inflationary increase of real estate taxes. In addition, nothing contained in this paragraph is intended to excuse Tenant from paying the full amount of any Taxes (including, without limitation, as a result of reassessments) resulting from any construction and/or improvements made to the Complex by Landlord or Tenant at any time. Notwithstanding anything to the contrary contained herein, the provisions of this paragraph shall not apply to (i) any period prior to the Extended Term or, if Tenant leases the Premises following the Extended Term (i.e. following November 30, 2028), to any period following the Extended Term and/or (ii) any other premises (e.g., Expansion Space, ROFR Space and ROFO Space) that Tenant may lease in the Complex.

5. **Security Deposit**. Commencing on the Effective Date, the Security Deposit shall be reduced from $2,072,481.00 to $1,657,984.80 (the "**Reduced Security Deposit Amount**"). Landlord shall reasonably cooperate with Tenant, at no cost, expense or liability to Landlord, to reduce the Initial Letter of Credit to the Reduced Security Deposit Amount.

6. **Condition of Premises**. Prior to the Sixth Amendment Commencement Date, Landlord shall retain a third party professional (reasonably approved by Tenant) to conduct an inspection of the mechanical, electrical and plumbing systems serving the Building to determine if any such mechanical, electrical and plumbing systems are either beyond their useful life or will then have a remaining useful life of fewer than 5 years (collectively, the "**MEP Replacement Items**"). When each existing MEP Replacement Item requires a capital repair or replacement during the Extended Term, as mutually and reasonably agreed upon by Tenant and Landlord in good faith, Landlord shall be solely responsible for the cost of the capital repair or replacement of such MEP Replacement Item (and with Landlord having the right to approve in its good faith reasonable discretion, the make, model, specifications, cost and contract, as applicable, for such MEP Replacement Item), which work of repair or replacement shall be addressed under the control and management of Tenant, and not included as part of Operating Costs. If Tenant elects to enter into any contract(s) for MEP Replacement Items (rather than have Landlord enter into such contract(s)), Landlord shall be named a third party beneficiary of such contract with the right to enforce all warranties. Once an MEP Replacement Item has been given a capital repair or been replaced pursuant to the immediately preceding sentence, and such MEP Replacement Item would thereafter have a remaining useful life of at least 5 years, any subsequent capital repair or replacement required of such MEP Replacement Item during the Term shall be performed as an Operating Cost, subject to the terms of Section 2.6 of the Original Lease. For avoidance of doubt, Landlord will continue to be able to include amortized Capital Costs in the calculation of Operating Costs, as permitted under Section 2.6 of the Original Lease, to the extent such Capital Costs relate to any capital repairs, improvements, alterations and replacements made by Landlord to the Complex and are not with respect to an MEP Replacement Item.

7. **Amenity Utilities**. Landlord shall review with its asset services team the feasibility of (a) rerouting water and electrical servicing the first-floor amenities located within the Building (Taproot and the fitness center) to originate from 499 Illinois Street, San Francisco, California (the "**499 Building**"), which is also owned by Landlord, or (b) separately metering such first floor amenities. If the cost of such rerouting or separate metering is determined to be reasonable by Landlord, then Landlord, at its sole cost and expense, shall either reroute such water and electrical service or install separate meters for the first floor amenities, prior to the Sixth Amendment Commencement Date.

8. **Right to Extend Term**. Section 34 of the Original Lease shall be replaced with the provision of this Section 8. Tenant shall have the right to further extend the Term of the Lease upon the following terms and conditions:

a. **Extension Right**. Tenant shall have 2 consecutive rights (each, an "**Extension Right**") to extend the term of the Lease for 5 years each (each, an "**Additional Extension Term**") on the same terms and conditions as the Lease (other than with respect to Minimum Monthly Rent, the TI Allowance (as defined in the A06 Work Letter), and any provisions which only apply during the Extended Term) by giving Landlord written notice of its election to exercise each Extension Right at least 18 months prior, and no earlier than 21 months prior, to the then current expiration date of the Lease.

b. Upon the commencement of any Additional Extension Term, Minimum Monthly Rent shall be payable at the Market Rate (as defined below). Minimum Monthly Rent shall thereafter be adjusted on each annual anniversary of the commencement of such Additional Extension Term by a percentage as determined by Landlord and agreed to by Tenant at the time the Market Rate is determined. As used herein, "**Market Rate**" shall mean the rate that comparable landlords of comparable buildings have accepted in current transactions from non-equity (i.e., not being offered equity in the buildings) and nonaffiliated tenants of similar financial strength for space of comparable size, quality (including all Tenant Improvements, Alterations and other improvements) and floor height in Class A laboratory focused buildings in the Mission Bay area of San Francisco, California, for a comparable term, with the determination of the Market Rate to take into account all relevant factors, including tenant inducements, parking costs, available amenities (including any Complex amenities), leasing commissions, allowances or concessions, if any. In addition, Landlord may impose a market rent for the parking rights provided hereunder.

c. If, on or before the date which is 210 days prior to the expiration of the then current Term of the Lease, Tenant has not agreed with Landlord's determination of the Market Rate and the rent escalations during the Additional Extension Term after negotiating in good faith, Tenant shall be deemed to have elected arbitration as described in Section 8.b, below. If Tenant has elected to exercise the Extension Right by delivering notice to Landlord as required in this Section 8.a., Tenant shall have no right thereafter to rescind or elect not to extend the term of the Lease for an Additional Extension Term.

d. **Arbitration**.

(i) Within 10 days of Tenant's notice to Landlord of its election (or deemed election) to arbitrate Market Rate and escalations, each party shall deliver to the other a proposal containing the Market Rate and escalations that the submitting party believes to be correct ("**Extension Proposal**"). If either party fails to timely submit an Extension Proposal, the other party's submitted proposal shall determine the Minimum Monthly Rent and escalations for such Additional Extension Term. If both parties submit Extension Proposals, then Landlord and Tenant shall meet within 7 days after delivery of the last Extension Proposal and make a good faith attempt to mutually appoint a single Arbitrator (defined below) to determine the Market Rate and escalations. If Landlord and Tenant are unable to agree upon a single Arbitrator, then each shall, by written notice delivered to

the other within 10 days after the meeting, select an Arbitrator. If either party fails to timely give notice of its selection for an Arbitrator, the other party's submitted proposal shall determine the Minimum Monthly Rent for the Additional Extension Term. The 2 Arbitrators so appointed shall, within 5 business days after their appointment, appoint a third Arbitrator. If the 2 Arbitrators so selected cannot agree on the selection of the third Arbitrator within the time above specified, then either party, on behalf of both parties, may request such appointment of such third Arbitrator by application to any state court of general jurisdiction in the jurisdiction in which the Premises are located, upon 10 days prior written notice to the other party of such intent.

(ii) The decision of the Arbitrator(s) shall be made within 30 days after the appointment of a single Arbitrator or the third Arbitrator, as applicable. The decision of the single Arbitrator shall be final and binding upon the parties. The average of the two closest Arbitrators in a three Arbitrator panel shall be final and binding upon the parties. Each party shall pay the fees and expenses of the Arbitrator appointed by or on behalf of such party and the fees and expenses of the third Arbitrator shall be borne equally by both parties. If the Market Rate and escalations are not determined by the first day of the Additional Extension Term, then Tenant shall pay Landlord Minimum Monthly Rent in an amount equal to the Minimum Monthly Rent in effect immediately prior to the Additional Extension Term and increased by the Rent Adjustment Percentage until such determination is made. After the determination of the Market Rate and escalations, the parties shall make any necessary adjustments to such payments made by Tenant. Landlord and Tenant shall then execute an amendment recognizing the Market Rate and escalations for the Additional Extension Term.

(iii) An "**Arbitrator**" shall be any person appointed by or on behalf of either party or appointed pursuant to the provisions hereof and: (i) shall be (A) a member of the American Institute of Real Estate Appraisers with not less than 10 years of experience in the appraisal of improved office and high tech industrial real estate in the greater San Francisco, California, metropolitan area, or (B) a licensed commercial real estate broker with not less than 15 years' experience representing landlords and/or tenants in the leasing of high tech or life sciences space in the greater San Francisco, California, metropolitan area, (ii) devoting substantially all of their time to professional appraisal or brokerage work, as applicable, at the time of appointment and (iii) be in all respects impartial and disinterested.

e. **Rights Personal**. Extension Rights are personal to Tenant and are not assignable without Landlord's consent, which may be granted or withheld in Landlord's sole discretion separate and apart from any consent by Landlord to an assignment of Tenant's interest in the Lease.

f. **Exceptions**. Notwithstanding anything set forth above to the contrary, Extension Rights shall, at Landlord's option, not be in effect and Tenant may not exercise any of the Extension Rights:

(i) during the existence of an Event of monetary Default under the Lease (beyond any applicable notice and cure periods); or

(ii) if an Event of monetary Default has existed under the Lease 3 or more times, whether or not the Events of monetary Default are cured, during the 12 month period immediately prior to the date that Tenant intends to exercise the Extension Right.

g. **No Extensions**. The period of time within which any Extension Rights may be exercised shall not be extended or enlarged by reason of Tenant's inability to exercise the Extension Rights.

h. **Termination**. The Extension Rights shall, at Landlord's option, terminate and be of no further force or effect even after Tenant's due and timely exercise of an Extension Right, if, after such exercise, but prior to the commencement date of the Additional Extension Term, (i) Tenant

fails to timely cure any Event of monetary Default by Tenant under the Lease; or (ii) an Event of monetary Default under the Lease has occurred 3 or more times during the period from the date of the exercise of the Extension Right to the date of the commencement of the Additional Extension Term, whether or not such Events of monetary Default are cured. Section 34 of the Original Lease is hereby deleted in its entirety, and Tenant shall have no right to extend the Term of the Lease except as expressly set forth in this Sixth Amendment.

9. **Sublease**. Landlord agrees to not withhold its consent in the event Tenant desires to sublease a portion of the Premises in the Building to The Regents of the University of California (the "**UC Tenant**"), solely based on the fact that the UC Tenant is an existing tenant of the 499 Building. For avoidance of doubt, the immediately prior sentence is only applicable to the Premises located in the Building and is not applicable to any premises that Tenant may lease in the future in the 499 Building. All other requirements with respect to subletting the Premises set forth in the Lease remain in full force and effect.

10. **Right of First Negotiation**. Tenant shall continue to have the rights set forth in Section 35.25 of the Original Lease.

11. **Expansion Right**.

a. **Expansion Right Generally**. Subject to the terms of this Section 11, commencing on the Effective Date and continuing for 12 months thereafter, Tenant shall have the ongoing right, but not the obligation, subject to the terms of this Section 11, to expand the Premises (the "**Expansion Right**") to include the Expansion Space upon the terms and conditions in this Section 11. If Tenant exercises the Expansion Right, Landlord shall not be obligated to deliver the Expansion Space until after the existing tenant in the Expansion Space vacates the Expansion Space at the expiration of the term of the existing lease for the Expansion Space. Landlord agrees to use reasonable available legal rights to cause the existing tenant to vacate the Expansion Space at the expiration of its term. For purposes of this Section 11, "**Expansion Space**" shall mean that certain space located on the 5th floor of the 499 Building, containing approximately 44,000 rentable square feet, as more specifically described on **Exhibit B** attached hereto. For the avoidance of doubt, Tenant shall be required to exercise its right under this Section 11 with respect to all of the Expansion Space. Tenant shall have 12 months following the Effective Date to deliver to Landlord written notification of Tenant's exercise of the Expansion Right ("**Exercise Notice**") with respect to the Expansion Space. If Tenant elects to lease the Expansion Space by delivering the Exercise Notice within the required 12 month period, Tenant shall be deemed to agree to expand the Premises to include the Expansion Space and to lease the Expansion Space on the same general terms and conditions as the Lease (including the TI Allowance). Landlord shall permit Tenant access, at Tenant's sole risk and expense, to the Expansion Space 14 days prior to the commencement date of the lease of the Expansion Space, for the purpose of space planning, construction and moving into the Expansion Space, and, during such early access period, all terms of the Lease shall be in effect with respect to the Expansion Space, except that Tenant shall not be required to pay Minimum Monthly Rent with respect to the Expansion Space, Tenant's Proportionate Share of Operating Costs, Taxes and Insurance Costs with respect to the Expansion Space or the increase in Tenant's Proportionate Share of Operating Costs, Taxes and Insurance Costs with respect to the Parking Garage which are attributable to the Expansion Space during such early access period; provided, however, after such early access period, Tenant shall commence paying Minimum Monthly Rent with respect to the Expansion Space, Tenant's Proportionate Share of Operating Costs, Taxes and Insurance Costs with respect to the Expansion Space and the increase in Tenant's Proportionate Share of Operating Costs, Taxes and Insurance Costs with respect to the Parking Garage which are attributable to the Expansion Space. The term of the Lease with respect to the Expansion Space shall be co-terminus with the Term of the Lease with respect to the then-existing Premises. If Tenant does not deliver an Exercise Notice to Landlord within such 12 month period, then Tenant

shall be deemed to have waived its rights under this Section 11 to lease the Expansion Space, and Landlord shall have the right to lease the Expansion Space to any third party on any terms and conditions acceptable to Landlord. Tenant's failure to timely deliver an Exercise Notice shall not impact Tenant's rights under Sections 12 and 13 below.

b. Amended Lease (Expansion). If: (i) Tenant fails to timely deliver an Exercise Notice, or (ii) after the expiration of a period of 10 days after Landlord's delivery to Tenant of a lease amendment for Tenant's lease of the Expansion Space, no lease amendment for the Expansion Space acceptable to both parties each in their reasonable discretion after using diligent good faith efforts negotiate the same, has been executed, Tenant shall, notwithstanding anything to the contrary contained herein, be deemed to have forever waived its right to lease the Expansion Space.

c. Expansion Right Exceptions. Notwithstanding the above, the Expansion Right shall, at Landlord's option, not be in effect and may not be exercised by Tenant:

(i) during any period of time that there exists an Event of monetary Default under the Lease after the expiration of applicable notice and cure rights; or

(ii) if an Event of monetary Default under the Lease has existed 3 or more times, whether or not the Events of Default are cured, during the 12 month period prior to the date on which Tenant seeks to exercise the Expansion Right.

d. Expansion Right Termination. The Expansion Right shall, at Landlord's option, terminate and be of no further force or effect even after Tenant's due and timely exercise of the Expansion Right, if, after such exercise, but prior to the commencement date of the lease of the Expansion Space, (i) Tenant fails to timely cure any Event of monetary Default under the Lease; or (ii) an Event of monetary Default under the Lease has existed 3 or more times during the period from the date of the exercise of the Expansion Right to the date of the commencement of the lease of the Expansion Space, whether or not such Events of monetary Default are cured.

e. Expansion Rights Personal. The Expansion Right is personal to Tenant and is not assignable without Landlord's consent, which may be granted or withheld in Landlord's sole discretion separate and apart from any consent by Landlord to an assignment of Tenant's interest in the Lease.

f. No Extensions of Expansion Right. The period of time within which the Expansion Right may be exercised shall not be extended or enlarged by reason of Tenant's inability to exercise the Expansion Right.

12. Right of First Refusal.

a. ROFR Generally. Subject to the terms of this Section 12, the first time after the Effective Date that Landlord intends to accept a bona fide written proposal or deliver a counter proposal which Landlord would be willing to accept (the "**Pending Deal**") to lease all or a portion the ROFR Space (as hereinafter defined) to a third party, Landlord shall deliver to Tenant written notice (the "**Pending Deal Notice**") of the existence of such Pending Deal, which Pending Deal Notice shall include the material terms of the Pending Deal. For purposes of this Section 12, "**ROFR Space**" shall mean all space in the 499 Building which is not occupied by a tenant or which is occupied by an existing tenant whose lease is expiring within 12 months or less and such tenant does not wish to renew (whether or not such tenant has a right to renew) its occupancy of such space. For the avoidance of doubt, Tenant shall be required to exercise its right under this Section 12 with respect to all of the space described in the Pending Deal Notice, including, at Landlord's option, any space

in addition to the ROFR Space that is described in the Pending Deal Notice, which additional space shall be deemed to be included as part of the ROFR Space (the "**Identified Space**"). Within 10 days after Tenant's receipt of the Pending Deal Notice, Tenant shall deliver to Landlord written notice (the "**Acceptance Notice**") if Tenant elects to lease the Identified Space. Tenant's right to receive the Pending Deal Notice and election to lease or not lease the Identified Space pursuant to this Section 12 is hereinafter referred to as the "**Right of First Refusal**." If Tenant elects to lease the Identified Space described in the Pending Deal Notice by delivering the Space Acceptance Notice within the required 10 day period, Tenant shall be deemed to agree to expand the Premises to include the Identified Space and to lease the Identified Space on the same general terms and conditions as the Lease except that the terms of the Lease shall be modified to reflect the terms of the Pending Deal Notice for the rental of the Identified Space. If the Identified Space subject to a Pending Deal Notice does not include all of the ROFR Space, Tenant's Right of First Refusal shall continue to apply with respect to any remaining portion of the ROFR Space through the Extended Term (subject to the last sentence of this Section 12(a)). Tenant acknowledges that the term of the Lease with respect to the Identified Space and the Term of the Lease with respect to the existing Premises may not be co-terminus. Notwithstanding anything to the contrary contained herein, in no event shall the A06 Work Letter apply to the Identified Space. If Tenant fails to deliver an Acceptance Notice to Landlord within the required 10 day period, Tenant shall be deemed to have forever waived its rights under this Section 12 to lease the Identified Space. Tenant's Right of First Refusal shall be ongoing during the Extended Term; provided, however that Tenant shall have no right to exercise the Right of First Refusal and the provisions of this Section 12 shall no longer apply after the date that is 18 months prior to the expiration of the Extended Term if Tenant has not exercised its Extension Right pursuant to Section 8 of this Sixth Amendment.

b. **Amended Lease (ROFR)**. If: (i) Tenant fails to timely deliver an Acceptance Notice, or (ii) after the expiration of a period of 10 days after Landlord's delivery to Tenant of a lease amendment for Tenant's lease of the Identified Space, no lease amendment for the Identified Space acceptable to both parties each in their reasonable discretion after using diligent good faith efforts negotiate the same, has been executed, Tenant shall, notwithstanding anything to the contrary contained herein, be deemed to have forever waived its right to lease the ROFR Space.

c. **ROFR Exceptions**. Notwithstanding the above, the Right of First Refusal shall, at Landlord's option, not be in effect and may not be exercised by Tenant:

(i) during any period of time that there exists an Event of monetary Default under the Lease, after the expiration of applicable notice and cure periods; or

(ii) if an Event of monetary Default under the Lease has existed 3 or more times, whether or not the Events of Default are cured, during the 12 month period prior to the date on which Tenant seeks to exercise the Right of First Refusal.

d. **Termination of ROFR**. The Right of First Refusal shall, at Landlord's option, terminate and be of no further force or effect even after Tenant's due and timely exercise of the Right of First Refusal, if, after such exercise, but prior to the commencement date of the lease of the Identified Space, (i) Tenant fails to timely cure any Event of monetary Default under the Lease; or (ii) an Event of Default under the Lease has existed 3 or more times during the period from the date of the exercise of the Right of First Refusal to the date of the commencement of the lease of the Identified Space, whether or not such Events of monetary Default are cured.

e. **ROFR Rights Personal**. The Right of First Refusal is personal to Tenant and is not assignable without Landlord's consent, which may be granted or withheld in Landlord's sole discretion separate and apart from any consent by Landlord to an assignment of Tenant's interest in the Lease.

f. **No Extensions of ROFR**. The period of time within which the Right of First Refusal may be exercised shall not be extended or enlarged by reason of Tenant's inability to exercise the Right of First Refusal.

13. **Right of First Offer**.

a. **ROFO Generally**. Subject to the terms of this Section 13, each time during the Extended Term that all or a portion of the ROFO Space becomes available after the Effective Date, Tenant shall have a right, but not the obligation, subject to the terms of this Section 13, to expand the Premises (the "**Right of First Offer**") to include the ROFO Space upon the terms and conditions in this Section 13. For purposes of this Section 13, "**ROFO Space**" shall mean that certain space on the second floor of the 499 Building containing approximately 25,957 rentable square feet as more particularly shown on **Exhibit C** attached hereto (the "**Second Floor ROFO Space**") and the Expansion Space (if Tenant has not previously exercised its Expansion Right set forth in Section 13 above with respect to the Expansion Space), which is not occupied by a tenant or which is occupied by a then-existing tenant whose lease is expiring within 12 months or less and such tenant does not wish to renew (whether or not such tenant has a right to renew) its occupancy of such space. Each time during the Extended Term that all or a portion of the ROFO Space will become available, Landlord shall, at such time as Landlord shall elect so long as Tenant's rights hereunder are preserved, deliver to Tenant written notice (the "**ROFO Notice**") of the availability of such ROFO Space, together with the terms and conditions on which Landlord is prepared to lease Tenant such ROFO Space. Tenant shall be required to exercise its right under this Section 13 with respect to all of the ROFO Space described in the ROFO Notice (the "**Identified ROFO Space**"). In no event shall the A06 Work Letter apply with respect to the ROFO Space. The Term of the Lease with respect to the ROFO Space must be co-terminus with the Term of the Lease with respect to the then existing Premises. Tenant shall have 10 days following receipt of the ROFO Notice to deliver to Landlord written notification of Tenant's exercise of its Right of First Offer with respect to the Identified ROFO Space ("**ROFO Exercise Notice**"). If Tenant does not deliver a ROFO Exercise Notice to Landlord within such 10 day period, then Landlord shall have the right to lease the Identified ROFO Space to any third party on any terms and conditions acceptable to Landlord. Tenant's Right of First Offer shall be ongoing during the Extended Term; provided, however that Tenant shall have no right to exercise the Right of First Offer and the provisions of this Section 13 shall no longer apply after the date that is 18 months prior to the expiration of the Extended Term if Tenant has not exercised its Extension Right pursuant to Section 8 of this Sixth Amendment.

b. **Amended Lease (ROFO)**. If: (i) Tenant fails to timely deliver a ROFO Exercise Notice, or (ii) after the expiration of a period of 10 days after Landlord's delivery to Tenant of a lease amendment for Tenant's lease of such ROFO Space, no lease amendment for the ROFO Space acceptable to both parties each in their reasonable discretion after using diligent good faith efforts negotiate the same, has been executed, Tenant shall, notwithstanding anything to the contrary contained herein, be deemed to have forever waived its right to lease that specific ROFO Space.

c. **ROFO Exceptions**. Notwithstanding the above, the Right of First Offer shall, at Landlord's option, not be in effect and may not be exercised by Tenant:

(i) during any period of time that there exists an Event of monetary Default under the Lease; or

(ii) if an Event of monetary Default under the Lease has existed 3 or more times, whether or not the Events of Default are cured, during the 12 month period prior to the date on which Tenant seeks to exercise the Right of First Offer.

d. **Termination of ROFO**. The Right of First Offer shall, at Landlord's option, terminate and be of no further force or effect even after Tenant's due and timely exercise of the Right of First Offer, if, after such exercise, but prior to the commencement date of the lease of such ROFO Space, (i) Tenant fails to timely cure any Event of monetary Default under the Lease; or (ii) an Event of Default under the Lease has existed 3 or more times during the period from the date of the exercise of the Right of First Offer to the date of the commencement of the lease of such ROFO Space, whether or not such Events of monetary Default are cured.

e. **ROFO Rights Personal**. The Right of First Offer is personal to Tenant and is not assignable without Landlord's consent, which may be granted or withheld in Landlord's sole discretion separate and apart from any consent by Landlord to an assignment of Tenant's interest in the Lease.

f. **No Extensions of ROFO**. The period of time within which the Right of First Offer may be exercised shall not be extended or enlarged by reason of Tenant's inability to exercise the Right of First Offer.

14. **Third Amendment**. Commencing on the Sixth Amendment Commencement Date, Section 2.6(a)(20) of the Lease relating to "Administrative Rent", as added to the Lease by the Third Amendment shall be deleted in its entirety from the Lease and shall be of no further force or effect.

15. **California Accessibility Disclosure**. For purposes of Section 1938(a) of the California Civil Code, Landlord hereby discloses to Tenant, and Tenant hereby acknowledges, that the Complex has not undergone inspection by a Certified Access Specialist (CASp). In addition, the following notice is hereby provided pursuant to Section 1938(e) of the California Civil Code: "A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises." In furtherance of and in connection with such notice: (i) Tenant, having read such notice and understanding Tenant's right to request and obtain a CASp inspection, hereby elects not to obtain such CASp inspection and forever waives its rights to obtain a CASp inspection with respect to the Premises, Building and/or Complex to the extent permitted by Legal Requirements; and (ii) if the waiver set forth in clause (i) hereinabove is not enforceable pursuant to Legal Requirements, then Landlord and Tenant hereby agree as follows (which constitutes the mutual agreement of the parties as to the matters described in the last sentence of the foregoing notice): (A) Tenant shall have the one-time right to request for and obtain a CASp inspection, which request must be made, if at all, in a written notice delivered by Tenant to Landlord; (B) any CASp inspection timely requested by Tenant shall be conducted (1) at a time mutually agreed to by Landlord and Tenant, (2) in a professional manner by a CASp designated by Landlord and without any testing that would damage the Premises, Building or Complex in any way, and (3) at Tenant's sole cost and expense, including, without limitation, Tenant's payment of the fee for such CASp inspection, the fee for any reports prepared by the CASp in connection with such CASp inspection (collectively, the "**CASp Reports**") and all other costs and expenses in connection therewith; (C) the CASp Reports shall be delivered by the CASp simultaneously to Landlord and Tenant; (D) Tenant, at its sole cost and expense, shall be responsible for making any improvements, alterations, modifications and/or repairs to or within the Premises to correct violations of construction-related accessibility standards including, without limitation, any violations disclosed by such CASp inspection; and (E) if such CASp inspection identifies any improvements, alterations,

modifications and/or repairs necessary to correct violations of construction-related accessibility standards relating to those items of the Building and Complex located outside the Premises that are Landlord's obligation to repair as set forth in the Lease, then Landlord shall perform such improvements, alterations, modifications and/or repairs as and to the extent required by Legal Requirements to correct such violations, and Tenant shall reimburse Landlord for the cost of such improvements, alterations, modifications and/or repairs within 10 business days after Tenant's receipt of an invoice therefor from Landlord.

16. **OFAC**. Tenant is currently (a) in compliance with and shall at all times during the Term of the Lease remain in compliance with the regulations of the Office of Foreign Assets Control ("**OFAC**") of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "**OFAC Rules**"), (b) not listed on, and shall not during the Term of the Lease be listed on, the Specially Designated Nationals and Blocked Persons List maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.

17. **Brokers.** Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "**Broker**") in connection with the transaction reflected in this Sixth Amendment and that no Broker brought about this Sixth Amendment, other than Jones Lang LaSalle. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker, other than Jones Lang LaSalle, claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this Sixth Amendment.

18. **Miscellaneous**.

a. This Sixth Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Sixth Amendment may be amended only by an agreement in writing, signed by the parties hereto.

b. This Sixth Amendment is binding upon and shall inure to the benefit of the parties hereto, their respective agents, employees, representatives, officers, directors, divisions, subsidiaries, affiliates, assigns, heirs, successors in interest and shareholders.

c. This Sixth Amendment may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Sixth Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

d. Except as amended and/or modified by this Sixth Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this Sixth Amendment. In the event of any conflict between the provisions of this Sixth Amendment and the provisions of the Lease, the provisions of this Sixth Amendment shall prevail. Whether or not specifically amended by this Sixth Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Sixth Amendment.

[Signatures are on the next page]

IN WITNESS WHEREOF, Landlord and Tenant have executed this Sixth Amendment as of the day and year first above written.

TENANT:

a Delaware corporation

By: /s/ Enrique Conterno

Its: CEO

LANDLORD:

ARE- SAN FRANCISCO NO. 43, LLC,

a Delaware limited liability company

By:ALEXANDRIA REAL ESTATE EQUITIES, L.P.,

a Delaware limited partnership,

managing member

By:ARE-QRS CORP.,

a Maryland corporation,

general partner

By: /s/ Kristen Childs

Its: SVP of Real Estate Legal Affairs

EXHIBIT A

A06 WORK LETTER

THIS A06 WORK LETTER dated June 1, 2021 (the "**A06 Work Letter**") is incorporated into that certain Lease Agreement dated as of September 22, 2006, as amended by that certain First Amendment to Lease dated as of October 10, 2007, and as further amended by that certain letter agreement dated as of March 21, 2008, that certain Second Amendment to Lease dated as of June 29, 2009, that certain Third Amendment to Lease dated as of May 19, 2011, that certain letter agreement dated as of June 20, 2011, that certain Fourth Amendment to Lease dated as of September 8, 2011, that certain letter agreement dated as of November 15, 2012, that certain Memorandum of Understanding dated as of October 1, 2014, that certain Fifth Amendment to Lease dated as of December 23, 2014, that certain letter agreement dated as of December 23, 2014, that certain letter agreement dated as of December 10, 2015, that certain letter agreement dated as of April 26, 2016, and that certain Sixth Amendment to Lease dated of even date herewith (the "**Sixth Amendment**") (as amended, the "**Lease**"), by and between **ARE- SAN FRANCISCO NO. 43, LLC**, a Delaware limited liability company ("**Landlord**"), and **FIBROGEN, INC.**, a Delaware corporation ("**Tenant**"). Any initially capitalized terms used but not defined herein shall have the meanings given them in the Lease.

1. **General Requirements**.

(a) **Tenant's Authorized Representative**. Tenant designates Catherine Sharpe and Martin Quan (either such individual acting alone, "**Tenant's Representative**") as the only persons authorized to act for Tenant pursuant to this A06 Work Letter. Landlord shall not be obligated to respond to or act upon any request, approval, inquiry or other communication ("**Communication**") from or on behalf of Tenant in connection with this A06 Work Letter unless such Communication is in writing from Tenant's Representative. Tenant may change either Tenant's Representative at any time upon not less than 5 business days advance written notice to Landlord.

(b) **Landlord's Authorized Representative**. Landlord designates Greg Gehlen and Jeanevy Abata (either such individual acting alone, "**Landlord's Representative**") as the only persons authorized to act for Landlord pursuant to this A06 Work Letter. Tenant shall not be obligated to respond to or act upon any request, approval, inquiry or other Communication from or on behalf of Landlord in connection with this A06 Work Letter unless such Communication is in writing from Landlord's Representative. Landlord may change either Landlord's Representative at any time upon not less than 5 business days advance written notice to Tenant.

(c) **Architects, Consultants and Contractors**. The architect (the "**TI Architect**") for the Tenant Improvements (as defined in Section 2(a) below), the general contractor for the Tenant Improvements (the "**General Contractor**"), and any subcontractors for the Tenant Improvements shall be selected by Tenant, subject to Landlord's approval, which approval shall not be unreasonably withheld, conditioned or delayed. Landlord hereby agrees to approve Hathaway Dinwiddie as the General Contractor, if requested to do so by Tenant. Landlord shall be named a third party beneficiary of any contract entered into by Tenant with the A06 TI Architect, any consultant, any contractor or any subcontractor, and of any warranty made by any contractor or any subcontractor.

2. **Tenant Improvements**.

(a) **Tenant Improvements Defined**. As used herein, "**Tenant Improvements**" shall mean all improvements to the Premises desired by Tenant of a fixed and permanent nature. Other than funding the A06 TI Allowance (as defined below) as provided herein, Landlord shall not have any obligation whatsoever with respect to the finishing of the Premises for Tenant's use and occupancy.

(b) **Tenant's Space Plans**. Tenant shall deliver to Landlord schematic drawings and outline specifications (the "**Space Plans**") detailing Tenant's requirements for the Tenant Improvements. Not more than 10 days thereafter, Landlord shall deliver to Tenant the written reasonable objections, questions or comments of Landlord and the TI Architect with regard to the Space Plans. Tenant shall cause the Space Plans to be revised to address such written comments and shall resubmit said drawings to Landlord for approval thereafter. Such process shall continue until Landlord has approved the Space Plans.

(c) **Working Drawings**. Not later than 15 business days following the approval of the Space Plans by Landlord, Tenant shall cause the TI Architect to prepare and deliver to Landlord for review and comment construction plans, specifications and drawings for the Tenant Improvements ("**TI Construction Drawings**"), which TI Construction Drawings shall be prepared substantially in accordance with the Space Plans. Tenant shall be solely responsible for ensuring that the TI Construction Drawings reflect Tenant's requirements for the Tenant Improvements. Landlord shall deliver its written comments on the TI Construction Drawings to Tenant not later than 10 business days after Landlord's receipt of the same; provided, however, that Landlord may not disapprove any matter that is consistent with the Space Plans. Tenant and the TI Architect shall consider all such comments in good faith and shall, within 10 business days after receipt, notify Landlord how Tenant proposes to respond to such comments. Any disputes in connection with such comments shall be resolved in accordance with Section 2(d) hereof. Provided that the design reflected in the TI Construction Drawings is consistent with the Space Plans, Landlord shall approve the TI Construction Drawings submitted by Tenant. Once approved by Landlord, subject to the provisions of Section 4 below, Tenant shall not materially modify the TI Construction Drawings except as may be reasonably required in connection with the issuance of the TI Permit (as defined in Section 3(a) below).

(d) **Approval and Completion**. If any dispute regarding the design of the Tenant Improvements is not settled within 10 business days after notice of such dispute is delivered by one party to the other, Tenant may make the final decision regarding the design of the Tenant Improvements, provided (i) Tenant acts reasonably and such final decision is either consistent with or a compromise between Landlord's and Tenant's positions with respect to such dispute, (ii) that all costs and expenses resulting from any such decision by Tenant shall be payable out of the TI Allowance (as defined in Section 5(d) below), and (iii) Tenant's decision will not affect the base Building, structural components of the Building or any Building systems (in which case Landlord shall make the final decision). Any changes to the TI Construction Drawings following Landlord's and Tenant's approval of same requested by Tenant shall be processed as provided in Section 4 hereof.

3. **Performance of the Tenant Improvements**.

(a) **Commencement and Permitting of the Tenant Improvements**. Tenant shall commence construction of the Tenant Improvements upon obtaining and delivering to Landlord a building permit (the "**TI Permit**") authorizing the construction of the Tenant Improvements consistent with the TI Construction Drawings approved by Landlord. The cost of obtaining the TI Permit shall be payable from the TI Allowance. Landlord shall assist Tenant in obtaining the TI Permit. Prior to the commencement of the Tenant Improvements, Tenant shall deliver to Landlord a copy of any contract with Tenant's contractors (including the TI Architect), subject to commercially reasonable confidentiality requirements, together with a copy of certificates of insurance from any contractor performing any part of the Tenant Improvement evidencing industry standard commercial general liability, automotive liability, "builder's risk", and workers' compensation insurance. Tenant shall cause the General Contractor to provide a certificate of insurance naming Landlord, Alexandria Real Estate Equities, Inc., and Landlord's lender (if any) as additional insureds for the General Contractor's liability coverages required above.

(b) **Selection of Materials, Etc**. Where more than one type of material or structure is indicated on the TI Construction Drawings approved by Tenant and Landlord, the option will be within Tenant's reasonable discretion if the matter concerns the Tenant Improvements, and within Landlord's sole and

absolute subjective discretion if the matter concerns the structural components of the Building or any Building system.

(c) **Tenant Liability**. Tenant shall be responsible for correcting any deficiencies or defects in the Tenant Improvements.

(d) **Substantial Completion**. Tenant shall substantially complete or cause to be substantially completed the Tenant Improvements in a good and workmanlike manner, in accordance with the TI Permit subject, in each case, to Minor Variations and normal "punch list" items of a non-material nature which do not interfere with the use of the Premises ("**Substantial Completion**" or "**Substantially Complete**"). Upon Substantial Completion of the Tenant Improvements, Tenant shall require the TI Architect and the General Contractor to execute and deliver, for the benefit of Tenant and Landlord, a Certificate of Substantial Completion in the form of the American Institute of Architects ("**AIA**") document G704. For purposes of this A06 Work Letter, "**Minor Variations**" shall mean any modifications reasonably required: (i) to comply with all applicable Legal Requirements and/or to obtain or to comply with any required permit (including the TI Permit); (ii) to comport with good design, engineering, and construction practices which are not material; or (iii) to make reasonable adjustments for field deviations or conditions encountered during the construction of the Tenant Improvements.

4. **Changes**. Any material changes estimated by Tenant to cost in excess of $100,000, which are requested by Tenant to the Tenant Improvements after the delivery and approval by Landlord of the Space Plans, shall be requested and instituted in accordance with the provisions of this Section 4 and shall be subject to the written approval of Landlord, which approval shall not be unreasonably withheld, conditioned or delayed.

(a) **Tenant's Right to Request Changes**. If Tenant shall request changes ("**Changes**"), Tenant shall request such Changes by notifying Landlord in writing in substantially the same form as the AIA standard change order form (a "**Change Request**"), which Change Request shall detail the nature and extent of any such Change. Such Change Request must be signed by Tenant's Representative. Landlord shall review and approve or disapprove such Change Request within 2 business days thereafter, provided that Landlord's approval shall not be unreasonably withheld, conditioned or delayed.

(b) **Implementation of Changes**. If Landlord approves such Change, Tenant may cause the approved Change to be instituted. If any TI Permit modification or change is required as a result of such Change, Tenant shall promptly provide Landlord with a copy of such TI Permit modification or change.

5. **Costs**.

(a) **Budget For Tenant Improvements**. Before the commencement of construction of the Tenant Improvements, Tenant shall estimate and deliver to Landlord a Budget for design and construction of the Tenant Improvements (the "**Budget**"). The Budget shall be based upon the TI Construction Drawings approved by Landlord.

(b) **TI Allowance**. Landlord shall provide to Tenant a tenant improvement allowance (collectively, the "**TI Allowance**") as follows:

1. a "**Tenant Improvement Allowance"** in the maximum amount of $25.00 per rentable square foot in the Premises, which is included in the Minimum Monthly Rent payable during the Extended Term; and

2. an "**Additional Tenant Improvement Allowance**" in the maximum amount of $50.00 per rentable square foot in the Premises, which shall, to the extent used, result in Additional TI Rent as set forth in Section 2 of the Sixth Amendment.

In addition to the TI Allowance, Landlord shall pay the TI Architect up to $0.15 per rentable square foot of the Premises for the preparation of test fits.

Before commencing the Tenant Improvements, Tenant shall notify Landlord how much Additional Tenant Improvement Allowance Tenant has elected to receive from Landlord. Such election shall be final and binding on Tenant, and may not thereafter be modified without Landlord's consent, which may be granted or withheld in Landlord's sole and absolute subjective discretion The TI Allowance shall be disbursed in accordance with this Work Letter.

(c) Tenant shall have no right to the use or benefit (including any reduction to Minimum Monthly Rent) of any portion of the TI Allowance not required for the construction of (i) the Tenant Improvements described in the TI Construction Drawings approved pursuant to Section 2(d) or (ii) any Changes pursuant to Section 4. Tenant shall have no right to any portion of the A06 TI Allowance that is not disbursed before the last day of the month that is 18 months after the Sixth Amendment Commencement Date.

(d) **Costs Includable in TI Allowance**. The TI Allowance shall be used solely for the payment of design, permits and construction costs in connection with the construction of the Tenant Improvements, including, without limitation, the cost of electrical power and other utilities used in connection with the construction of the Tenant Improvements, the cost of preparing the Space Plans and the TI Construction Drawings, all costs set forth in the Budget and the cost of Changes (collectively, "**TI Costs**"). Notwithstanding anything to the contrary contained herein, the TI Allowance shall not be used to purchase any furniture, personal property or other non-Building system materials or equipment, including, but not be limited to, Tenant's voice or data cabling, non-ducted biological safety cabinets and other scientific equipment not incorporated into the Tenant Improvements.

(e) **INTENTIONALLY DELETED**.

(f) **Payment for TI Costs**. During the course of design and construction of the Tenant Improvements, Landlord shall reimburse Tenant for TI Costs once a month against a draw request in Landlord's standard form, containing evidence of payment of such TI Costs by Tenant and such certifications, lien waivers (including a conditional lien release for each progress payment and unconditional lien releases for the prior month's progress payments), inspection reports and other matters as Landlord customarily obtains, to the extent of Landlord's approval thereof for payment, no later than 30 days following receipt of such draw request. Upon completion of the Tenant Improvements, Tenant shall deliver to Landlord: (i) sworn statements setting forth the names of all contractors and first tier subcontractors who did the work and final, unconditional lien waivers from all such contractors and first tier subcontractors; (ii) as-built plans (one copy in print format and two copies in electronic CAD format) for such Tenant Improvements; (iii) a certification of substantial completion in Form AIA G704, (iv) a certificate of occupancy for the Premises; and (v) copies of all operation and maintenance manuals and warranties affecting the Premises. Notwithstanding anything to the contrary contained herein, Tenant shall be responsible for the cost of the Tenant Improvements to the extent that the cost of the Tenant Improvements exceed the Tenant Improvement Allowance and any portion of the Additional Tenant Improvement Allowance elected to be used by Tenant

(g) **Tenant Improvement Progress Reports**. Upon periodic request by Landlord, Tenant shall deliver to Landlord a Tenant Improvement progress report in the form of **Schedule 1** completed to provide all of the most up-to-date information regarding the Tenant Improvements.

6. **Miscellaneous**.

(a) **Consents**. Whenever consent or approval of either party is required under this A06 Work Letter, that party shall not unreasonably withhold, condition or delay such consent or approval, except as may be expressly set forth herein to the contrary.

(b) **Modification**. No modification, waiver or amendment of this A06 Work Letter or of any of its conditions or provisions shall be binding upon Landlord or Tenant unless in writing signed by Landlord and Tenant.

(c) **No Default Funding**. In no event shall Landlord have any obligation to fund any portion of the TI Allowance during any period that an Event of Default exists under the Lease.

(d) **Infectious Conditions**. Tenant shall require the General Contractor, TI Architect and any consultants, contractors, subcontractors and all other service and materials providers entering the Complex during the construction of the Tenant Improvements to perform services or provide materials in connection with the Tenant Improvements to comply with all criteria recommended by the Centers for Disease Control and Prevention and applicable governmental authorities).

Schedule 1

Tenant Improvement Progress Report

Building Address: _____

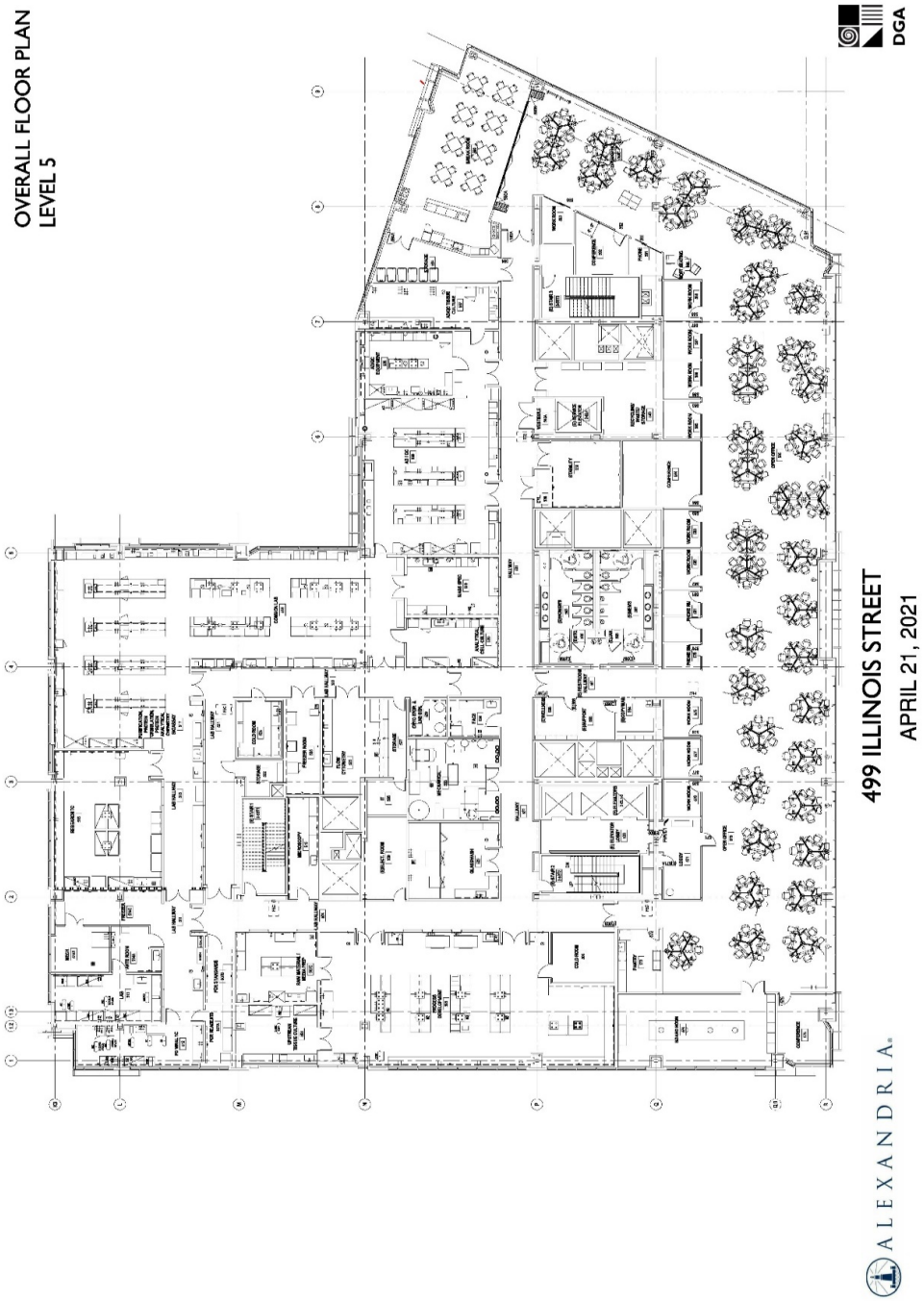
Certification Period: _____

1. Original Project Budget	$_____
2. Net change by Change Orders/Update to budget	$_____
3. Current budget to date (Line 1 ± 2)	$_____
4. Total costs incurred to date	$_____
5. Remaining balance to budget (Line 3 less Line 4)	**$**_____

Certification signature: _____

EXHIBIT B

EXPANSION SPACE



ALEXANDRIA.

EXHIBIT C

SECOND FLOOR ROFO SPACE

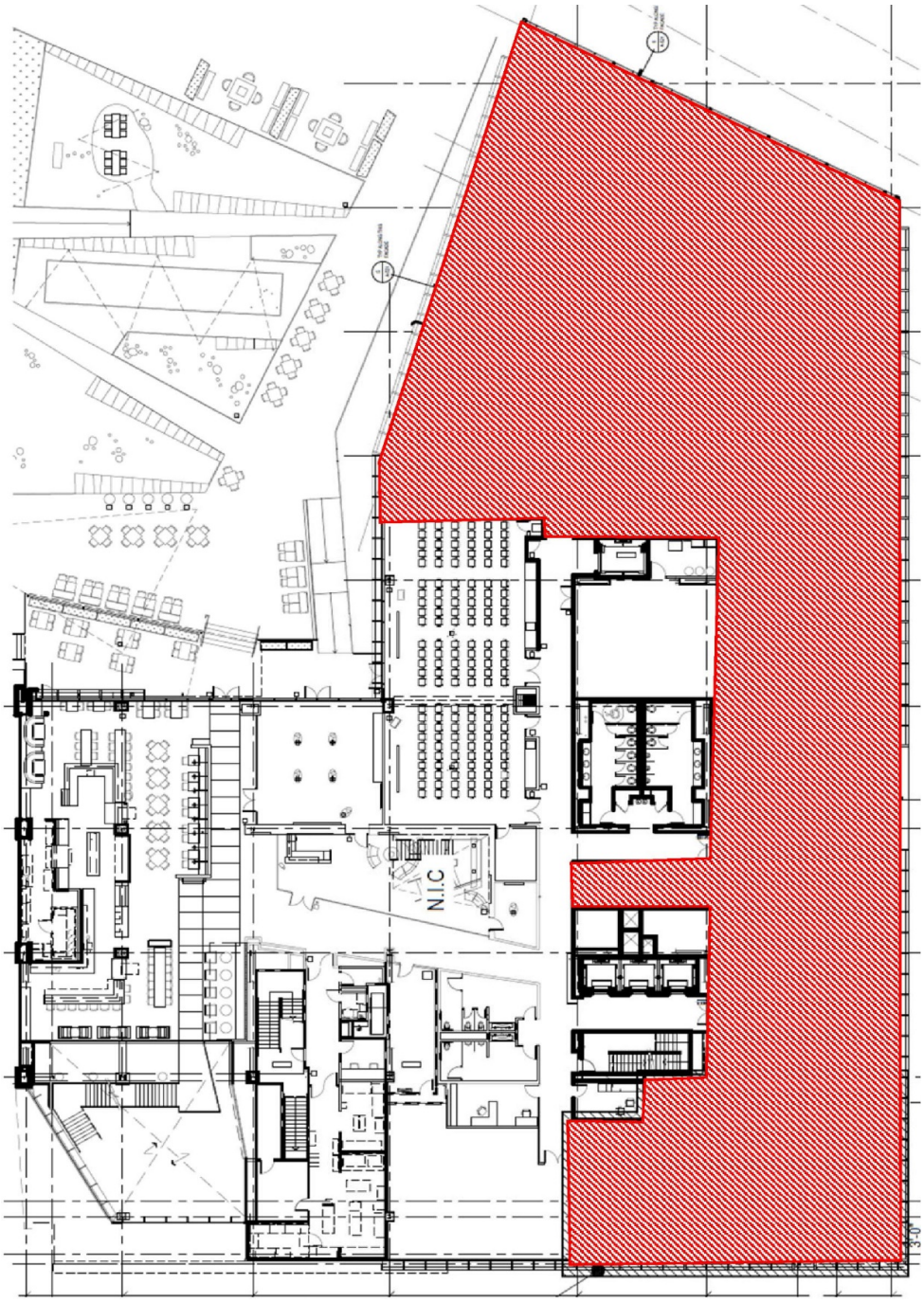


EXHIBIT D

A06 MINIMUM MONTHLY RENT SCHEDULE

A06 Minimum Monthly Rent Schedule		
Months		Monthly Base Rent
1 - 12		$ 1,405,494.00
13 - 24		$ 1,447,658.82
25 - 36		$ 1,491,088.58
37 - 48		$ 1,535,821.24
49 - 60		$ 1,581,895.88

[*] = 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

EXCLUSIVE LICENSE AND OPTION AGREEMENT

BY AND BETWEEN

FIBROGEN, INC.

AND

HIFIBIO (HK) LIMITED (D.B.A. HIFIBIO THERAPEUTICS)

DATED AS OF JUNE 16, 2021

TABLE OF CONTENTS

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[*] = 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.

EXCLUSIVE LICENSE AND OPTION AGREEMENT

THIS EXCLUSIVE LICENSE AND OPTION AGREEMENT (this "**Agreement**") is entered into as of June 16, 2021 (the "**Effective Date**") by and among HiFiBiO (HK) Limited (d.b.a. HiFiBiO Therapeutics), a limited company organized and existing under the laws of Hong Kong, with a registered address at Room 303, Third Floor, St. George's Building, 2 Ice House Street, Central, Hong Kong ("**HFB**"), and **FibroGen, Inc.**, a Delaware corporation having its principal place of business at 409 Illinois St., San Francisco, CA 94158 ("**FibroGen**"). HFB and FibroGen are referred to herein individually as a "**Party**" and collectively as the "**Parties**."

BACKGROUND

WHEREAS, HFB and its Affiliates Control certain Patent Rights and Know-How relating to the Gal-9 Licensed Program;

WHEREAS, HFB and its Affiliates Control certain Patent Rights and Know-How relating to, and are conducting research and Development with respect to, compounds and products directed to CCR8, CXCR5, and other targets.

WHEREAS, HFB desires to grant, and FibroGen desires to receive, an exclusive license under such Patent Rights and Know-How to permit FibroGen to Exploit Licensed Compounds and Licensed Products directed to Gal-9 in the Territory.

WHEREAS, HFB desires to grant, and FibroGen desires to receive, an exclusive option to receive an exclusive license to Exploit (a) Licensed Compounds and Licensed Products directed to CCR8, (b) Licensed Compounds and Licensed Products directed to CXCR5 or, (c) in the event FibroGen does not wish to exercise such option with respect to (a) or (b), Licensed Compounds and Licensed Products that are directed to a target that is the subject of another program Controlled by HFB and selected by the Parties.

NOW THEREFORE, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

1.1 "**Acceptance**" means, (a) with respect to an IND in the United States, the later of (i) the occurrence of [*] following the FDA's receipt of such IND if the FDA does not place a clinical hold with respect to such IND filing in such [*] period or (ii) if the FDA places a clinical hold with respect to such IND during such [*] period, the FDA's notification of the lifting of such clinical hold and (b) with respect to an IND in a country other than the United States, the clearance of such IND in accordance with applicable law such that the Clinical Trial may be Initiated based on such IND in such jurisdiction.

1.2 "**Accounting Standards**" means International Financial Reporting Standards (IFRS) or U.S. Generally Accepted Accounting Principles (GAAP), as generally and consistently applied throughout a Party's organization.

1.3 "**Additional Third Party IP**" has the meaning set forth in Section 2.6 (Third Party In-Licenses).

1.4 "**Affiliate**" means, with respect to a Party, a Person that controls, is controlled by, controlling or is under common control with such Party, but only for so long as such control will continue. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by", "controlling" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.

1.5 "**Agreement**" has the meaning set forth in the Preamble.

[*] = 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.

1.6 "**Alliance Manager**" has the meaning set forth in Section 3.1 (Alliance Manager).

1.7 "**Arbitration Forum**" has the meaning set forth in Section 14.1(b) (Dispute Resolution).

1.8 "**Arising Know-How**" has the meaning set forth in Section 9.2(a)(i) (Arising Technology).

1.9 "**Arising Patent Rights**" has the meaning set forth in Section 9.2(a)(i) (Arising Technology).

1.10 "**Arising Technology**" has the meaning set forth in Section 9.2(a)(i) (Arising Technology).

1.11 "**Bankruptcy Code**" has the meaning set forth in Section 13.4 (Termination for Bankruptcy).

1.12 "**Bankruptcy Event**" means, with respect to a Person, such person makes a general assignment for the benefit of creditors, admits in writing its inability to pay its debts generally as they become due, files or consents to the filing of a petition for bankruptcy or insolvency, the appointment of any receiver, liquidator, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, or files a petition or answer or consent seeking under the laws of any jurisdiction any proceeding for its insolvency, bankruptcy, reorganization, adjustment of debt, arrangement, dissolution, liquidation, or any case or action is taken against such Person by a third person in furtherance of any of the foregoing and such case or action by a third person is not dismissed within [*].

1.13 "**Bankruptcy Laws**" has the meaning set forth in Section 13.4 (Termination for Bankruptcy).

1.14 "**Biosimilar Product**" means, with respect to a particular Licensed Product in a particular country, a product on the market in such country commercialized by any Third Party that is not an Affiliate or Sublicensee of FibroGen and that did not purchase such product in a chain of distribution that included any of FibroGen or its Affiliates or Sublicensees, that (a) is approved by the applicable Regulatory Authority, under any then-existing laws and regulations in the applicable country pertaining to approval of products with no clinically meaningful differences as a "generic", "biosimilar", or "interchangeable" version (or terms of similar meaning) of such Licensed Product, which approval uses such Licensed Product as a reference product and relies on or references any information in the approval application for such Licensed Product, or (b) is otherwise recognized by the applicable Regulatory Authority as a "generic", "biosimilar" or "interchangeable" product (or other term of similar meaning) with no clinically meaningful differences to such Licensed Product.

1.15 "**BLA**" means a Biologics License Application submitted to the FDA pursuant to Section 351 of the Public Health Service Act, 42 U.S.C. § 262, and 21 C.F.R § 601.2 as these provisions may be amended from time-to-time (or its successor statute or regulation), for purposes of obtaining Regulatory Approval for a biological product in the United States, or any equivalent filing in a country or regulatory jurisdiction other than the United States.

1.16 "**Business Day**" means a day other than a Saturday, Sunday, or a day on which banking institutions in San Francisco, CA or Hong Kong are required by applicable law to remain closed.

1.17 "**Calendar Quarter**" means a period of three consecutive months ending on the last day of March, June, September, or December, respectively, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the first to occur of March 31, June 30, September 30 or December 31 after the Effective Date, and the last Calendar Quarter shall end on the last day of the applicable Royalty Term or the Term, as applicable.

1.18 "**Calendar Year**" means a period of 12 consecutive months beginning on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs, and the last Calendar

Year shall commence on January 1 of the year, end on the last day, of the applicable Royalty Term or the Term, as applicable.

1.19 "**CCR8**" means [*].

1.20 "**CCR8 Option Program**" means the program of Development of the Option Compounds and Option Products Directed To CCR8.

1.21 "**cGMP**" means applicable current Good Manufacturing Practices, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the International Conference on Harmonization's Q7 guidelines, and (d) the applicable laws the Territory corresponding to (a) through (c) above, each as may be amended and applicable from time to time.

1.22 "**Chairperson**" has the meaning set forth in Section 3.2(a) (Joint Development Committee).

1.23 "**Change of Control**" means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than 50% of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated that would result in shareholders or equity holders of any Third Party immediately prior to such transaction, owning more than 50% of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (c) there is a sale or transfer to a Third Party of all or substantially all of such Party's consolidated assets taken as a whole, in each of (a) through (c) through one or more related transactions.

1.24 "**Claim**" has the meaning set forth in Section 11.3 (Indemnification Procedures).

1.25 "**Clinical Trial**" means a study in humans to obtain information regarding a product, including information relating to the safety, tolerability, pharmacological activity, pharmacokinetics, dose ranging or efficacy of such product, including a Phase I Clinical Trial, Phase II Clinical Trial, and Phase III Clinical Trial.

1.26 "**CMO**" means a contract manufacturing organization.

1.27 "**Combination Product**" means a Licensed Product that is sold for a single invoice price and is either (a) approved by the applicable Regulatory Authority to be sold in the form of a combination that contains or comprises a Licensed Compound together with one or more other therapeutically active pharmaceutical agents (whether coformulated or copackaged or otherwise sold for a single invoice price), or (b) together with any (i) [*] or (ii) [*] related to a Licensed Compound, but excluding any of (i) or (ii) for which [*] of an independent Licensed Product (such additional therapeutically active pharmaceutical agent and each of (i) and (ii), an "**Other Component**"); or (c) defined as a "combination product" under 21 C.F.R. §3.2(e) or its foreign equivalent.

1.28 "**Commercialization**," "**Commercializing**," or "**Commercialize**" means any and all activities directed to the marketing, promotion, medical affairs, distribution, offering for sale, sale, having sold, importing, having imported, exporting, having exported, or other commercialization of a pharmaceutical or biological product, but excluding activities directed to Manufacturing or Development. "**Commercialize**," "**Commercializing**," and "**Commercialized**" will be construed accordingly.

[*] = 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.

1.29 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by a Party or its Affiliate with respect to any Development or Commercialization objective, obligation, activity, or goal related to a Licensed Product under this Agreement, those efforts and resources that a [*] would normally devote to accomplishing such objective, obligation, activity or goal, based on the specific product and conditions then prevailing and taking into account efficacy, safety, product labeling, profitability, supply chain considerations, the competitiveness of alternative products sold by Third Parties in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval given the regulatory structure involved, and all other relevant factors, including technical, financial, legal, scientific and/or medical factors and, in any case, that such Party shall assign a budget and responsibility for such task or obligation to employees or contractors of such Party who are held accountable for executing such task or obligation and for monitoring such budget and progress on an ongoing basis. [*]

1.30 "**Competitive Activities**" has the meaning set forth in Section 2.8(a) (Exclusivity Covenant).

1.31 "**Competitive Product**" means, with respect to HFB, any [*], and, with respect to FibroGen, any [*], or in the event of the Replacement Option Election, the [*], *provided* that if (i) FibroGen does not provide an Option Exercise Notice in respect of a given Option Program prior to the expiration of the Option Term for such Option Program or (ii) a Licensed Program becomes a Terminated Licensed Program, then "Competitive Products" will cease to include any [*] that is the subject of such Option Program or Terminated Licensed Program.

1.32 "**Confidential Information**" has the meaning set forth in Section 12.1 (Confidentiality; Exceptions).

1.33 "**Continuing Technology Transfer**" has the meaning set forth in Section 2.7(b) (Continuing Technology Transfer).

1.34 "**Control**" or "**Controlled**" means (a) the possession by a Party (whether by ownership, license, or otherwise other than pursuant to this Agreement) of, (i) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms set forth herein, or (ii) with respect to Patent Right, Regulatory Approvals, Regulatory Materials, intangible Know-How, or other intellectual property rights, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Right, Regulatory Approvals, Regulatory Materials, intangible Know-How, or other intellectual property rights on the terms set forth herein, in each case ((i) and (ii)), without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party or incurring any additional payment obligations to a Third Party unless the other Party agrees in writing to be bound by the applicable portion of such payment obligation; and (b) with respect to any product, the possession by a Party of the ability (whether by sole or joint ownership, license or otherwise, other than pursuant to this Agreement) to grant a license or sublicense of Patent Rights that claim such product or proprietary Know-How that is used in connection with the Exploitation of such product. Notwithstanding the foregoing, a Party and its Affiliates will not be deemed to "Control" any Patent Rights, Know-How, or product that, prior to the consummation of a Change of Control of such Party, are owned or in-licensed by a Third Party that becomes an Affiliate of such acquired Party or that merges or consolidates with such Party after the Effective Date as a result of such Change of Control.

1.35 "**Cover**," "**Covering**," or "**Covered**" means, when used to refer to the relationship between a particular Patent Right and particular subject matter, that the manufacture, use, sale, offer for sale, or importation of such subject matter would fall within the scope of one or more claims in, or is otherwise claimed by, such Patent Right.

1.36 "**CPA Firm**" has the meaning set forth in Section 8.7(a) (Books and Records; Audit Rights).

1.37 "**CREATE Act**" means the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. § 103(c)(2)-(c)(3).

1.38 "**CXCR5**" means [*].

1.39 "**CXCR5 Option Program**" means the program of Development of the Option Compounds and Option Products Directed To CXCR5.

1.40 "**Defaulting Party**" has the meaning set forth in Section 13.3(c) (Disputes Regarding Material Breach).

1.41 "**Develop**" or "**Development**" means all internal and external research, development, and regulatory activities related to pharmaceutical or biological products, including (a) research, non-clinical testing, toxicology, testing and studies, non-clinical and preclinical activities, and Clinical Trials, and (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain, support, or maintain Regulatory Approval of a pharmaceutical or biological product and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such pharmaceutical or biological product regarding the foregoing, but excluding activities directed to Manufacturing or Commercialization. Development will include development and regulatory activities for additional forms, formulations, or indications for a pharmaceutical or biological product after receipt of Regulatory Approval of such product (including label expansion), including Clinical Trials initiated following receipt of Regulatory Approval or any Clinical Trial to be conducted after receipt of Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved formulation or indication (such as post-marketing studies, observational studies, implementation and management of registries and analysis thereof, in each case, if required by any Regulatory Authority in any region in the Territory to support or maintain Regulatory Approval for a pharmaceutical or biological product in such region). "**Develop**," "**Developing**," and "**Developed**" will be construed accordingly.

1.42 "**Development Plan**" has the meaning set forth in Section 4.1 (Development Plan).

1.43 "**Diligence Milestone**" has the meaning set forth in Section 4.4 (Development Diligence Obligations).

1.44 "**Directed To**" means, as used with respect to a given compound or product and a given target, [*].

1.45 "**Disclosure Letter**" has the meaning set forth in Section 10.2 (Representations and Warranties by HFB).

1.46 "**Effective Date**" has the meaning set forth in the Preamble.

1.47 "**EMA**" means the European Medicines Agency and any successor agency thereto.

1.48 "**Exclusive Target**" means each of (a) Gal-9 and (b) after the Option Exercise Date with respect thereto: (i) CXCR5 Option Program, CXCR5; (ii) CCR8 Option Program, CCR8; and (iii) in the event of the Replacement Option Election, Replacement Option Program, the Replacement Target, except for a target to which a Terminated Licensed Program was Directed To.

1.49 "**Executive Officer**" means (a) in the case of FibroGen, the chief executive officer of FibroGen, and (b) in the case of HFB, the chief executive officer of HFB, neither of whom will be a member of the JSC.

[*] = 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 "**Existing Nondisclosure Agreement**" means the Amended and Restated Mutual Confidential Disclosure Agreement entered into by FibroGen, HFB, and HiFiBiO Inc., effective as of [*].

1.51 "**Existing Patent Rights**" has the meaning set forth in the definition of Licensed Patent Rights.

1.52 "**Exploit**" and "**Exploitation**" means Develop, have Developed, make, have made, use, have used, offer for sale, have offered for sale, sell, have sold, export, have exported, import, have imported, Manufacture, have Manufactured, Commercialize, have Commercialized or otherwise exploit. "**Exploiting**" will be construed accordingly.

1.53 "**FD&C Act**" has the meaning set forth in Section 1.76 (IND).

1.54 "**FDA**" means the U.S. Food and Drug Administration or any successor agency thereto.

1.55 "**FibroGen**" has the meaning set forth in the Preamble.

1.56 "**FibroGen Arising Patent Rights**" has the meaning set forth in Section 9.2(a)(i) (Arising Technology).

1.57 "**FibroGen Background Technology**" has the meaning set forth in Section 9.1 (Background Technology).

1.58 "**FibroGen CMO**" has the meaning set forth in Section 2.7(a) (Initial Technology Transfer).

1.59 "**FibroGen Indemnitees**" has the meaning set forth in Section 11.1 (Indemnification by HFB).

1.60 "**Field**" means any and all uses.

1.61 "**First Commercial Sale**" means, with respect to a Licensed Product in a country or region in the Territory, the first sale to a Third Party of such Licensed Product in such country or region after receipt of Regulatory Approval and, [*]. First Commercial Sale excludes any sale or other distribution of a Licensed Product for promotional or advertising purposes, Clinical Trials, preclinical trials, or other Development purposes, free samples, named patient use, compassionate use, patient assistance, expanded access, or charitable use.

1.62 "**FTE Rate**" means beginning on the Effective Date, [*] per year. The FTE Rate is subject to annual increases beginning on January 1, 2022 to reflect percentage increase in the Consumer Price Index for the US City Average (all items) for the prior Calendar Year and similarly calculated year to year for each subsequent Calendar Year.

1.63 "**Gal-9**" means [*].

1.64 "**Gal-9 Licensed Program**" means the program of Development and Commercialization of the Licensed Compounds and Licensed Products Directed To Gal-9.

1.65 "**GCP**" means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) (the "**ICH Guidelines**") and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 54 (Financial Disclosure of Clinical Investigators), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent applicable laws in the region in the Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that

the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.66 "**GLP**" means all applicable Good Laboratory Practice standards for nonclinical studies, including, as set forth in the then-current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration, as set forth in 21 C.F.R. Part 58, and the equivalent applicable laws in the Territory, each as may be amended and applicable from time to time.

1.67 "**HFB**" has the meaning set forth in the Preamble.

1.68 "**HFB Arising Patent Rights**" has the meaning set forth in Section 9.2(a)(i) (Arising Technology).

1.69 "**HFB Arising Technology**" has the meaning set forth in Section 9.2(a)(i) (Arising Technology).

1.70 "**HFB Background Technology**" has the meaning set forth in Section 9.1 (Background Technology). For clarity, HFB Background Technology includes [*].

1.71 "**HFB Screening Know-How**" means Know-How owned or Controlled by HFB prior to or during the Term relating to HFB's [*].

1.72 "**HFB Screening Patent Rights**" means all Patent Rights owned or Controlled by HFB prior to or during the Term claiming, in whole or in part, any HFB Screening Know-How.

1.73 "**HFB Screening Technology**" means HFB Screening Know-How and HFB Screening Patent Rights.

1.74 "**HFB Indemnitees**" has the meaning set forth in Section 11.2 (Indemnification by FibroGen).

1.75 "[*****]" has the meaning set forth in Section 14.1(b) (Dispute Resolution).

1.76 "**IND**" means (a) an Investigational New Drug Application as defined in the United States Federal Food, Drug and Cosmetic Act, as amended (and any successor regulation) (the "**FD&C Act**") and applicable regulations promulgated thereunder by the FDA, or (b) an equivalent application or other authority pursuant to the laws and regulations of equivalent Regulatory Authority in any other regulatory jurisdiction, which is necessary to initiate or conduct Clinical Trials of a pharmaceutical or biological product in humans in such jurisdiction.

1.77 "**Indemnified Party**" has the meaning set forth in Section 11.3 (Indemnification Procedures).

1.78 "**Indemnifying Party**" has the meaning set forth in Section 11.3 (Indemnification Procedures).

1.79 "**Initial Technology Transfer**" has the meaning set forth in Section 2.7(a) (Initial Technology Transfer).

1.80 "**Initiation**" or "**Initiated**" means, with respect to a Clinical Trial of a product, the first dosing of the first human subject pursuant to the applicable protocol for such Clinical Trial.

1.81 "**Joint Arising Know-How**" has the meaning set forth in Section 9.2(a) (Arising Technology).

1.82 "**Joint Arising Patent Rights**" has the meaning set forth in Section 9.2(a)(i) (Arising Technology).

1.83 "**Joint Arising Technology**" has the meaning set forth in Section 9.2(a)(i) (Arising Technology).

1.84 "**Joint Steering Committee**" and "**JSC**" have the meaning set forth in Section 3.2(a) (Formation; Composition).

1.85 "**Know-How**" means any data, results, and information not generally known to the public of any type whatsoever, in any tangible or intangible form, including trade secrets, practices, techniques, methods, processes, inventions, discoveries, developments, specifications, formulations, formulae,

[*] = 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.

materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, clinical and non-clinical study reports, clinical and non-clinical data, regulatory filings and regulatory submission documents and summaries, technology, test data including pharmacological, biological, chemical, biochemical, toxicological, and clinical test data, analytical and quality control data, stability data, studies and procedures and any other know-how, and any physical embodiments of any of the foregoing.

1.86 "**License Option**" has the meaning set forth in Section 2.9(a) (Grant of Options).

1.87 "**Licensed Compound**" means (a) the compound designated by HFB internally as [*], and any other compound Controlled by HFB or its Affiliates that is Directed To Gal-9, (b) after the Option Exercise Date for each Option Program, all compounds that are Directed To the Exclusive Target that is the subject of such Option Program, and (c) any [*] the compounds set forth in the foregoing clause (a) or (b) that is Directed To the applicable Exclusive Target.

1.88 "**Licensed Know-How**" means [*].

1.89 "**Licensed Patent Rights**" means any and all Patent Rights, [*], Controlled by HFB or any of its Affiliates [*] that are [*] to Exploit any Licensed Compound or Licensed Product in the Field in the Territory, [*]. All Licensed Patent Rights existing [*] are listed on Schedule 1.89 (Existing Patent Rights) (the "**Existing Patent Rights**").

1.90 "**Licensed Product**" means any product that contains a Licensed Compound, alone or in combination with one or more therapeutically active pharmaceutical or biological ingredients, in all forms, presentations, compositions, dosages, and formulations. A Licensed Product will be deemed the same Licensed Product if it contains all the same therapeutically active pharmaceutical or biological ingredients.

1.91 "**Licensed Program**" means the Gal-9 Licensed Program and, after the Option Exercise Date for each Option Program, the CCR8 Option Program, CXCR5 Option Program, and in the event of the Replacement Option Election, the Replacement Option Program, as applicable, but not a Terminated Licensed Program.

1.92 "**Licensed Technology**" means Licensed Know-How, Licensed Patent Rights, and HFB's and its Affiliates' interest in the Joint Arising Technology.

1.93 "**Loss of Market Exclusivity**" means, on a Licensed Product-by-Licensed Product and country-by-country basis, (a) one or more Biosimilar Products for which such Licensed Product is the reference product have obtained Regulatory Approval and are being legally marketed in such country; and (b) such Biosimilar Products sold in such country achieve, on an aggregate basis, at least [*].

1.94 "**Major Market Country**" means any one of the following countries: [*].

1.95 "**Manufacture**" or "**Manufacturing**" means activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, release for distribution, shipping, or storage of any pharmaceutical or biological product (or any components or process steps involving any product or any companion diagnostic), placebo, or comparator agent, as the case may be, including process development, qualification, and validation, scale-up, pre-clinical, clinical, and commercial manufacture and analytic development, product characterization, and stability testing, but excluding activities directed to Development or Commercialization. "**Manufacturing**" will be construed accordingly.

1.96 "**NDA**" means a New Drug Application submitted to the FDA pursuant to section 505(b)(1) of the FD&C Act, 21 U.S.C. 355(B)(1), and 21 C.F.R.§ 314.50 as these provisions may be amended from time-to-time (or its successor statute or regulation), for purposes of obtaining Regulatory Approval for a pharmaceutical product in the United States, or any equivalent filing in a country or regulatory jurisdiction other than the United States.

1.97 "**Net Sales**" means, with respect to a Licensed Product and [*]

For the avoidance of doubt, [*]

In the case of any [*]

If, on a country-by-country basis [*]

If, on a country-by-country basis [*].

1.98 "**New License Agreement**" has the meaning set forth in Section 2.3(b) (Survival of Sublicenses).

1.99 "**Non-Defaulting Party**" has the meaning set forth in Section 13.3(c) (Disputes Regarding Material Breach).

1.100 "**Option Compound**" means (a) any compound Controlled by HFB or its Affiliates Directed To CCR8, (b) any compound Controlled by HFB or its Affiliates Directed To CXCR5, and (c) following the Replacement Option Election, any compound Controlled by HFB or its Affiliates Directed To the Replacement Target.

1.101 "**Option Data Package**" means, with respect to each Option Program, the information and materials set forth on Schedule 1.101 (Option Data Package).

1.102 "**Option Exercise Date**" has the meaning set forth in Section 2.9(e) (Exercise of a License Option).

1.103 "**Option Exercise Notice**" has the meaning set forth in Section 2.9(e) (Exercise of a License Option).

1.104 "**Option Exercise Payment**" has the meaning set forth in Section 8.2 (Option Exercise Payment).

1.105 "**Option Know-How**" [*]

1.106 "**Option Notice**" has the meaning set forth in Section 2.9(c)(i) (Delivery).

1.107 "**Option Notice Delivery Date**" has the meaning set forth in Section 10.2 (Representations and Warranties by HFB).

1.108 "**Option Patent Rights**" has the meaning set forth in Section 10.2(f) (Option Technology).

1.109 "**Option Product**" means any product that contains an Option Compound, alone or in combination with one or more therapeutically active pharmaceutical ingredients, in all forms, presentations, compositions, dosages, and formulations.

1.110 "**Option Program**" means the CCR8 Option Program, CXCR5 Option Program, or following the Replacement Option Election, the elected Replacement Option Program, as applicable.

1.111 "**Option Technology**" means Option Know-How and Option Patent Rights.

1.112 "**Option Term**" has the meaning set forth in Section 2.9(e) (Exercise of a License Option)

1.113 "**Other Component**" has the meaning set forth in Section 1.27 (Other Component).

1.114 "**Party**" and "**Parties**" have the meaning set forth in the Preamble.

1.115 "**Patent Challenge**" means any challenge to the validity or enforceability of a Licensed Patent Right or HFB Screening Patent Right used to generate any Licensed Compound, including by (a) filing a declaratory judgment action in which the applicable Licensed Patent Right or HFB Screening Patent Right is alleged to be invalid or unenforceable, (b) becoming party to an interference with the applicable Licensed Patent Right or HFB Screening Patent Right pursuant to 35 U.S.C. §135 or (c) filing or commencing any re-examination, opposition, cancellation, nullity or similar proceedings against the applicable Licensed Patent Right or HFB Screening Patent Right, or petitioning for any form of administrative or judicial (or arbitration) review of the applicable Licensed Patent Right or HFB Screening Patent Right, including post-grant review, *inter partes* review, or opposition proceedings; *provided* that the term Patent Challenge shall not include a response to a claim or allegation that FibroGen, its Affiliates or Sublicensees infringes or may infringe any Patent Rights owned or Controlled by HFB, any of its Affiliates, or any of their respective successors or assigns, including in *inter partes*, post grant review proceedings, oppositions, nullity proceedings, reissue proceedings, reexamination proceedings, and other similar proceedings before the U.S. Patent & Trademark Office or other agency or tribunal in any jurisdiction, or in any arbitration or litigation.

1.116 "**Patent Right**" means (a) any national, regional, or international patent or patent application, including any provisional patent application, (b) any patent application filed either from such a patent, patent application, or provisional application or from an application claiming priority from any of these, including any divisional, continuation, continuation-in-part, provisional, converted provisional, and continued prosecution application, (c) any patent that has issued or in the future issues from any of the foregoing patent applications ((a) and (b)), including any utility model, petty patent, design patent, and certificate of invention, (d) any extension or restoration by existing or future extension or restoration mechanisms, including any revalidation, reissue, re-examination, and extension (including any supplementary protection certificate and the like) of any of the foregoing patents or patent applications ((a), (b), and (c)), and (e) any similar rights, or any importation, revalidation, confirmation or introduction patent, or registration patent or patent of additions to any such foregoing patent application or patent.

1.117 "**Person**" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Regulatory Authority, or any other entity not specifically listed in this definition.

1.118 "**Phase I Clinical Trial**" means a clinical trial in humans conducted under an IND that generally provides for the first introduction into humans, whether healthy volunteers or patients, of a pharmaceutical or biological product with the primary objectives of evaluating safety, metabolism, pharmacokinetic properties, or clinical pharmacology of such product, in a manner that is generally consistent with 21 C.F.R. § 312.21(a), as amended (or its successor regulation), or, with respect to any other country or region, the equivalent of such a clinical trial in such other country or region.

1.119 "**Phase II Clinical Trial**" means a clinical trial in humans conducted under an IND that is intended to explore the safety, dose ranging, or preliminary efficacy of a pharmaceutical or biological product that is designed to generate sufficient data to commence a Phase III Clinical Trial for a particular indication(s) in patients with the disease or condition for which such product is intended, in a manner that is generally consistent with 21 C.F.R. § 312.21(b), as amended (or its successor regulation), or, with respect to any other country or region, the equivalent of such a clinical trial in such other country or region. Notwithstanding anything to the contrary set forth in this Agreement, treatment of patients as part of [*].

1.120 "**Phase III Clinical Trial**" means a clinical trial in humans of a pharmaceutical or biological product conducted under an IND that is performed to gain evidence with statistical significance of the efficacy of such product for particular indication(s) in patients with the disease or condition for which the product is intended, and to obtain expanded evidence of safety for such product that is needed to evaluate the overall benefit-risk relationship of such product, to form the basis for approval of a BLA by a Regulatory Authority and to provide an adequate basis for physician labeling, in a manner that is generally consistent with 21 C.F.R. § 312.21(c), as amended (or its successor regulation), or, with respect to any other country or region, the equivalent of such a clinical trial in such other country or region. Notwithstanding anything to the contrary set forth in this Agreement, treatment of patients as part of [*].

1.121 "**Pricing and Reimbursement Approval**" means the later of (a) the approval, agreement, determination, or governmental decision establishing a price for a pharmaceutical or biological product that can be legally charged to consumers, if required in a given jurisdiction or country for the Commercialization of such pharmaceutical or biological product in such jurisdiction or country; and (b) the approval, agreement, determination, or governmental decision establishing the level of reimbursement for a pharmaceutical or biological product that will be reimbursed by governmental authorities, in the case of either (a) or (b) if [*] of such pharmaceutical or biological product in such jurisdiction or country.

1.122 "**Product Marks**" has the meaning set forth in Section 9.6 (Trademarks).

1.123 "**Regulatory Approval**" means all approvals necessary for the sale of a product for one or more indications in a country or regulatory jurisdiction, which may include satisfaction of all applicable regulatory and notification requirements. Regulatory Approvals include approvals by Regulatory Authorities of [*], NDAs and BLAs and all [*].

1.124 "**Regulatory Authority**" means, in a particular country or regulatory jurisdiction, any applicable governmental authority involved in granting Regulatory Approval or, to the extent required in such country or regulatory jurisdiction, Pricing and Reimbursement Approval of a product in such country or regulatory jurisdiction.

1.125 "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Licensed Product other than Patent Rights, including rights conferred in the U.S. under the FD&C Act, the Public Health Service Act, and the Biologics Price Competition and Innovation Act, including pediatric exclusivity and orphan drug exclusivity, or rights similar thereto outside the U.S.

1.126 "**Regulatory Materials**" means regulatory applications, submissions, notifications, registrations, or other filings made to or with a Regulatory Authority, and documents and records required by such Regulatory Authority to be maintained or held for inspection, that are necessary in order to Develop, Manufacture, market, sell, or otherwise Commercialize a Licensed Compound or Licensed Product in a particular country or regulatory jurisdiction. Regulatory Materials include INDs, NDAs and BLAs (as applications, but not the approvals with respect thereto).

1.127 "**Replacement Option Election**" has the meaning set forth in Section 2.9(g)(i) (In Connection with FibroGen Non-Exercise).

1.128 "**Replacement Option Program**" has the meaning set forth in Section 2.9(g) (Replacement Option Program).

1.129 "**Replacement Target**" has the meaning set forth in Section 2.9(g) (Replacement Option Program).

1.130 "**Royalty**" has the meaning set forth in Section 8.4 (Royalties).

1.131 "**Royalty and Net Sales Report**" has the meaning set forth in Section 8.4(b) (Reports; Payment).

1.132 "**Royalty Term**" means, on a country-by-country and Licensed Product-by-Licensed Product basis, the period commencing upon the First Commercial Sale of a Licensed Product in a country, and ending upon the later to occur of (a) the expiration in such country of the last to expire of any Valid Claim of a [*] of the Licensed Compound contained in such Licensed Product in such country; (b) [*] after the First Commercial Sale in such country of such Licensed Product; or (c) expiration of [*] for such Licensed Product in such country.

1.133 [*****].

1.134 "**SEC**" has the meaning set forth in Section 12.2(b) (Disclosure to SEC).

1.135 "**Standby Letter**" has the meaning set forth in Section 2.1 (License to FibroGen).

1.136 "**Sublicense Revenue**" means, non-refundable sublicense upfront fees and sublicense milestone payments made by Sublicensees to FibroGen or any of its Affiliates in consideration of a grant of a sublicense under the rights licensed to FibroGen pursuant to Article 2 (Licenses and Exclusivity) hereof. Notwithstanding the foregoing, and for the avoidance of doubt, it is understood and agreed that Sublicense Revenue shall exclude (a) royalties, (b) amounts received from any Third Party for the purchase of equity (except for equity premiums), reimbursement for research and development performed by FibroGen or by FibroGen's subcontractor or delegates (specifically designated in a plan for research and/or development by its agreement with Sublicensee) or by Sublicensee, (c) [*], debt financing, (d) reimbursement for patent costs or other patent related expenses, and (e) [*], (f) [*], and (g)[*].

1.137 "**Sublicensee**" means any Third Party granted a sublicense by FibroGen under the rights licensed to FibroGen pursuant to Article 2 (Licenses and Exclusivity) hereof.

1.138 "**Technology Transfer**" has the meaning set forth in Section 2.7(b) (Continuing Technology Transfer).

1.139 "**Term**" has the meaning set forth in Section 13.1 (Term).

1.140 "**Territory**" means all countries of the world and all territories and possessions thereof.

1.141 "**Termination for Convenience Notice Period**" has the meaning set forth in Section 13.2 (Termination by FibroGen).

1.142 "**Terminated Licensed Product**" has the meaning set forth in Section 13.6 (Effects of Termination).

1.143 "**Terminated Licensed Program**" has the meaning set forth in Section 13.2 (Termination by FibroGen).

1.144 "**Third Party**" means any entity other than HFB or FibroGen or their respective Affiliates.

1.145 "**Third Party License**" has the meaning set forth in Section 2.6 (Third Party In-Licenses).

1.146 "**United States**" or "**U.S.**" means the United States of America and all of its territories and possessions.

1.147 "**Upfront Payment**" has the meaning set forth in Section 8.1 (Upfront Payment).

1.148 "**Upstream License**" means any of that certain Sub-License Agreement [*].

1.149 "**Upstream License Costs**" has the meaning set forth in Section 8.6 (Upstream License Costs).

1.150 "**Valid Claim**" means a claim of (a) an issued, unexpired, and in-force patent, which claim has not been held invalid or unenforceable by a court or other government agency of competent jurisdiction from which no appeal can be or has been taken and has not been held or admitted to be invalid or unenforceable through re-examination, *inter partes* review, post grant review or disclaimer, opposition procedure, nullity suit, or otherwise, or (b) a pending patent application that has not been finally abandoned, finally rejected, or expired; *provided*, *however*, that if a claim of a pending patent application has not issued [*] after the first substantive patent office action considering the patentability of such claim, then such claim will not constitute a Valid Claim for the purposes of this Agreement unless and until a patent issues with such claim.

1.151 "**VAT**" has the meaning set forth in Section 8.8(e) (VAT).

1.152 "**Work Plan**" has the meaning set forth in Section 4.2 (Work Plans).

ARTICLE 2
LICENSES AND EXCLUSIVITY

2.1 **License to FibroGen**. Subject to the terms and conditions of this Agreement, HFB hereby grants to FibroGen an exclusive (even as to HFB and each of its Affiliates), transferable (as permitted in accordance with Section 15.6 (Assignment)) license, with the right to sublicense (as permitted in accordance with Section 2.3 (Sublicensing)), under the Licensed Technology, to Exploit the Licensed Compounds and Licensed Products in the Field in the Territory. FibroGen acknowledges that, subject to and except as set forth in the Standby Letter entered into contemporaneously with this Agreement by and among FibroGen, HFB and [*] (the "**Standby Letter**"), termination of the Upstream License will result in the automatic termination of the license under this Section 2.1 (License to FibroGen) with respect to the Licensed Patent Rights that are licensed to HFB under the Upstream License. FibroGen may, within [*] of termination of the Upstream License, provide written notice to [*] of its willingness to continue Exploiting Licensed Products.

2.2 **License to HFB**. Subject to the terms and conditions of this Agreement, FibroGen hereby grants to HFB, a non-exclusive, non-transferable (except as permitted as permitted in accordance with Section 15.6 (Assignment)) license, with no right to sublicense, under the Licensed Technology, solely to perform the Development activities that are allocated to HFB under each Work Plan, provided that HFB shall have the right to subcontract Development activities as permitted in Section 2.4 (Subcontractors).

2.3 **Sublicensing**.

(a) **Sublicensing Rights**. FibroGen may grant sublicenses of the rights granted to it under Section 2.1 (License to FibroGen) through multiple tiers to any of its Affiliates and to one or more Sublicensees. Within [*] of entering into any sublicense, FibroGen shall provide a fully-executed copy of such sublicense; *provided* that FibroGen may redact confidential terms of such sublicense that are not necessary for HFB to monitor compliance with the terms and conditions of this Agreement. [*]

(b) **Survival of Sublicenses**. Upon termination of this Agreement for any reason, for each Sublicensee not then in breach of its sublicense agreement or the terms of this Agreement applicable to such Sublicensee, HFB will enter into a direct license with such Sublicensee on the same applicable terms as this Agreement, taking into account any difference in

license scope, territory, and duration of sublicense grant (each a "**New License Agreement**"). Under any New License Agreement between HFB and such former Sublicensee, HFB will not have any obligations under the New License Agreement beyond the obligations contained in this Agreement, *provided* that HFB will receive the same amounts in consideration under a New License Agreement as HFB would have otherwise received from FibroGen pursuant to this Agreement based on the former Sublicensee's Exploitation of the Licensed Products.

2.4 **Subcontractors**. Each Party may perform any of its obligations under this Agreement through one or more subcontractors; *provided* that (a) the subcontracting Party will not engage any subcontractor that has been debarred by any Regulatory Authority; (b) the subcontracting Party remains fully responsible for the work allocated to, and payment to, such subcontractors to the same extent it would if it had done such work itself; (c) the subcontractor undertakes in writing obligations of confidentiality and non-use applicable to the Confidential Information that are at least as stringent as those set forth in Article 12 (Confidentiality); (d) the subcontractor agrees in writing to assign or grant a sublicensable license to the subcontracting Party to all Know-How and Patent Rights developed or invented by the subcontractor that are necessary or reasonably useful to Develop, Manufacture, or Commercialize any Licensed Compound or Licensed Product; and (e) the subcontracting Party will be liable for any act or omission of any subcontractor that is a breach of any of the subcontracting Party's obligations under this Agreement as though the same were a breach by the subcontracting Party, and the non-subcontracting Party will have the right to proceed directly against the subcontracting Party without any obligation to first proceed against such subcontractor.

2.5 **No Implied Licenses; Retained Rights**. Except as explicitly set forth in this Agreement, neither Party grants to the other Party any license or other rights, express or implied, under any intellectual property rights (whether by implication, estoppel, or otherwise).

2.6 **Third Party In-Licenses**. During the Term, if either Party identifies any Patent Right or Know-How owned or controlled by a Third Party that it reasonably believes may be necessary or reasonably useful to Exploit any Licensed Compound in the Field in the Territory, or absent a license or agreement with such Third Party to such intellectual property, would be infringed by the Exploitation of any Licensed Compound in the Field in the Territory ("**Additional Third Party IP**"), then it will so notify the other Party. As between the Parties, [*], to enter into an agreement with a Third Party to obtain a license, covenant not to sue, or other similar rights under any such Additional Third Party IP within the Territory (a "**Third Party License**").

2.7 **Technology Transfer**.

(a) **Initial Technology Transfer**.

(i) Gal-9 Licensed Program. Within [*] and in accordance with the Technology Transfer plan to be agreed by the JSC and thereafter automatically deemed to be attached hereto as Schedule 2.7(a) (Initial Technology Transfer), HFB will transfer to FibroGen or, at FibroGen's direction, a CMO designated by FibroGen (a "**FibroGen CMO**"), electronic copies of all material documents, data (including

Manufacturing process data), regulatory correspondence, clinical and pre-clinical data, or other Know-How included within the Licensed Know-How existing as of the Effective Date, including but not limited to documents and information (including any CMC records and information), data (including Manufacturing process data), other Licensed Know-How, or activities, in each case, that are in the possession of HFB, its Affiliates or subcontractors and necessary or reasonably useful to Exploit and Manufacture Licensed Compounds and Licensed Products Directed To Gal-9 and to enable FibroGen or such FibroGen CMO to assume the Manufacturing activities of the Licensed Compounds and Licensed Products Directed To Gal-9.

(ii) Other Licensed Programs. With respect to any Licensed Program other than the Gal-9 Licensed Program, within [*] with respect to such Licensed Program and in accordance with a plan to be agreed between the Parties no later than [*], HFB will transfer to FibroGen and/or, at FibroGen's direction, a FibroGen CMO, electronic copies of all material documents, data, regulatory correspondence, clinical and pre-clinical data, or other Know-How included within the Licensed Know-How with respect to such Licensed Program existing as of the applicable Option Exercise Date, including but not limited to any documents and information (including any CMC records and information), data (including Manufacturing process data), other Licensed Know-How, or activities, in each case, that are in the possession of HFB, its Affiliates or subcontractors and necessary or reasonably useful to Exploit and Manufacture Licensed Compounds and Licensed Products for such Licensed Program and to enable FibroGen or such FibroGen CMO to assume the Manufacturing activities of Licensed Compounds and Licensed Products for such Licensed Program (the transfer described in the foregoing clauses (i) and (ii) with respect to each Licensed Program, the "**Initial Technology Transfer**").

(b) **Continuing Technology Transfer**. [*], HFB will promptly notify FibroGen of and transfer to FibroGen or, at FibroGen's direction, to a FibroGen CMO (if applicable to the Manufacture of Licensed Products) any additional documents, data or other Licensed Know-How, in each case, that is in HFB's possession or Control and has not been previously transferred to FibroGen or a FibroGen CMO and is necessary or reasonably useful to Exploit and Manufacture Licensed Compounds and Licensed Products for such Licensed Program (the "**Continuing Technology Transfer**," and together with the Initial Technology Transfer, the "**Technology Transfer**"). Notwithstanding anything to the contrary in this Section 2.7(b), [*] HFB will provide to FibroGen or its designee any documents, data or other Licensed Know-How, in each case, that is in HFB's possession or Control and has not been previously transferred to FibroGen and [*].

(c) **Technical Assistance and Consultation; Costs of Technology Transfer**. HFB will reasonably cooperate with FibroGen to facilitate the Technology Transfer to FibroGen or a FibroGen CMO (as applicable). In the course of any Technology Transfer, HFB will provide FibroGen or the applicable FibroGen CMO [*] involved in the Development or Manufacture of the Licensed Compounds to provide FibroGen or the FibroGen CMO with a reasonable level of technical assistance and consultation in connection with all Technology Transfers. [*]

(d) **Third Party Vendors or Contractors**. On a Licensed Program-by-Licensed Program basis, at FibroGen's request, HFB will use Commercially Reasonable Efforts to transfer to

FibroGen HFB's relationships with Third Party vendors and contractors that HFB has engaged in the Development or Manufacture of Licensed Compounds and, if any, Licensed Products, by, at FibroGen's request, introducing FibroGen to such vendors or contractors.

2.8 **Exclusivity**.

(a) **Exclusivity Covenant**. Subject to Section 2.8(b) (HFB Change of Control), Section 2.8(c) (FibroGen Change of Control) and Section 2.8(d) (Acquisition by Either Party), during the Term, the Parties will not, and will ensure that its Affiliates do not, independently, or for or with any Third Party, directly or indirectly, Develop, Manufacture, or Commercialize any Competitive Product in the Territory (or license or otherwise authorize any Third Party to do any of the foregoing) (the "**Competitive Activities**") unless agreed in writing by the Parties.

(b) **HFB Change of Control**. If HFB or any of its Affiliates undergoes a Change of Control with a Third Party, and such Third Party is (either directly or through an Affiliate, or in collaboration with another Third Party) [*], then it will not be in breach of the restrictions set forth in Section 2.8(a) (Exclusivity Covenant) due to such Change of Control with such a Third Party, and such Third Party may [*] (ii) HFB and its Affiliates institute [*] technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (i) are met, [*].

(c) **FibroGen Change of Control**. If FibroGen or any of its Affiliates undergoes a Change of Control with a Third Party, and such Third Party is (either directly or through an Affiliate, or in collaboration with another Third Party) [*], and:

(i) [*], such Competitive Products [*], then it will not be in breach of the restrictions set forth in Section 2.8(a) (Exclusivity Covenant) due to such Change of Control with such a Third Party, and such Third Party may continue to [*] after such Change of Control; as long as: (x) [*] and (y) FibroGen and its Affiliates institute [*] technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (x) are met, including [*]; or

(ii) [*], then it will not be in breach of the restrictions set forth in Section 2.8(a) (Exclusivity Covenant) due to such Change of Control with such a Third Party if it does one of following: (x) [*]. FibroGen will notify HFB of its intent to select option (x) or (y) within [*] of such closing of the Change of Control. Until the divestiture or termination is complete, FibroGen shall ensure that (A) [*], and (B) FibroGen and its Affiliates institutes [*] technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (A) are met, including [*].

(iii) For clarity, the same stage of Development means with respect to the Competitive Product and the applicable Licensed Compound or Licensed Product: [*].

(d) **Acquisition by Either Party**. If either Party or any of its Affiliates merges or consolidates with, or otherwise acquires a Third Party (whether such transaction occurs by way of a sale of assets, merger, consolidation, or similar transaction), and at such time such Third Party is [*] or is engaged in activities that would otherwise constitute a breach of Section 2.8(a) (Exclusivity Covenant), then such Party will not be in breach of Section 2.8(a) (Exclusivity Covenant) if it does one of following: (i) divests, or cause its relevant Affiliates to divest,

whether by sale, assignment, exclusive license or otherwise, its interest in such [*] or (ii) terminates any further Competitive Activities with respect to such [*]. Until the divestiture or termination is complete, the acquiring Party shall ensure that (A) [*], and (B) such Party and its Affiliates institutes [*] technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (A) are met, [*].

2.9 **FibroGen License Options.**

(a) **Grant of Options**. HFB hereby grants FibroGen, on an Option Program-by-Option Program basis, the exclusive option during the Option Term for each Option Program to obtain an exclusive license to Exploit the Option Compound and Option Products that are the subject of each Option Program in the Field in the Territory (for each Option Program, a "License Option").

(b) **Data Sharing**. During [*], to assist FibroGen in conducting thorough due diligence to decide whether to exercise the License Option for such Option Program, HFB will provide all material data and results in the possession of HFB, its Affiliates or subcontractors from non-clinical and pre-clinical studies for Option Compounds that are the subject of each Option Program as soon as reasonably practicable [*]. In addition, [*], HFB will provide a summary of all material data and results in the possession of HFB, its Affiliates or subcontractors from all non-clinical and pre-clinical studies for Option Compounds for each Option Program. If reasonably requested by FibroGen, HFB will provide to FibroGen and its representatives an [*] in connection with JSC meetings or more frequently as mutually agreed by the Parties.

(c) **Option Notice**.

(i) **Delivery**. On an Option Program-by-Option Program basis, HFB will deliver to FibroGen [*], and with respect to any Replacement Option Program, [*] pursuant to Section 2.9(g)(ii) (Replacement Option Program Election) (collectively, for each Option Program, an "**Option Notice**"):

(A) the Option Data Package for such Option Program, which shall include the information and materials identified in Schedule 1.101 (Option Data Package) whether or not such information and materials have been previously provided to FibroGen pursuant to Section 2.9(b) (Data Sharing);

(B) electronic copies of all submitted filings to a patent office related to the filing, prosecution and maintenance of any Option Patent Rights;

(C) a Disclosure Letter for such Option Program;

(D) a proposed [*] pursuant to Section 4.2 (Work Plans) for such Option Program;

(E) a list of all Third Party vendors and contractors that HFB has engaged in the conduct of Development or Manufacturing activities for such Option Program; and

(F) [*], the provided information is accurate, and a statement that subject to the disclosures contained in the Disclosure Letter for such Option Program, the representations and warranties of HFB set forth in Section 10.2 (Representations and Warranties of HFB) are [*] with respect to such Option Program [*].

(ii) **Additional Information**.

(A) For [*] following receipt of an Option Notice for an Option Program, FibroGen will have the right to reasonably discuss and request that HFB provide additional data and information pursuant to Section 2.9(c)(i) (Delivery) in its possession with respect to such Option Program. Within [*] following FibroGen's request, HFB will provide FibroGen with such additional data and information. For clarity, the Option Term with respect to each Option Program will expire [*].

(B) During [*], upon FibroGen's request, HFB will provide to FibroGen and its representatives [*], in each case, as FibroGen may reasonably request related to such Option Program to conduct customary and reasonable due diligence of such Option Program.

(iii) **FibroGen Option Decision**. If FibroGen makes a final decision not to exercise a License Option for a given Option Program, FibroGen will provide notice to HFB within [*] of such decision and such option shall terminate pursuant to Section 2.9(f) (Termination of a License Option).

(d) **Restrictions**. During [*], other than with the prior written consent of (i) FibroGen, which may be withheld in its sole discretion, HFB will not grant to any Third Party any right to Exploit any Option Compound that is the subject of such Option Program in a manner that would conflict with the License Option granted to FibroGen hereunder and (ii) HFB, which may be withheld in its sole discretion, FibroGen and its Affiliates will not engage in any [*] that would conflict with the exclusivity set forth in Section 2.8 (Exclusivity), with respect to such Option Program or the rights granted to FibroGen if FibroGen were to exercise such License Option.

(e) **Exercise of a License Option**. FibroGen may exercise the License Option for a given Option Program [*] following delivery of an Option Notice with respect to such Option Program, or that the Parties mutually agree upon (the "**Option Term**"), by (i) providing HFB with written notice of its exercise with respect thereto (each, an "**Option Exercise Notice**") and (ii) paying to HFB the applicable Option Exercise Payment set forth in Section 8.2 (Option Exercise Payment) [*]. From and after the Option Exercise Date for an Option Program, all Option Compounds and Option Products that are the subject of such Option Program will thereafter become Licensed Compounds and Licensed Products, as applicable, for all purposes under this Agreement.

(f) **Termination of Option**. If FibroGen (i) provides written notice to HFB pursuant to Section 2.9(c)(iii) (FibroGen Option Decision) or (ii) does not provide an Option Exercise Notice prior to the expiration of the Option Term, in each case, in respect of a given Option Program, then FibroGen's right to exercise the License Option for such Option Program will terminate. Following termination of any Option Program, including pursuant to

Section 13.2 (Termination by FibroGen) or 13.3(b) (By HFB), HFB will have no further obligations to FibroGen with respect to such Option Program and this Agreement will terminate with respect to such Option Program, including all Option Compounds and Option Products.

(g) **Replacement Option Program**.

(i) **In Connection with FibroGen Non-Exercise**. Notwithstanding Section 2.9(f) (Termination of Option), if FibroGen, in its sole discretion, elects not to provide an Option Exercise Notice with respect to either the CCR8 Option Program or the CXCR5 Option Program, then upon FibroGen's written request prior to the expiration of the later of the CXCR5 Option Term or CCR8 Option Term ("**Replacement Option Election**"), the Parties will work in good faith to identify one additional program of a [*] that is Controlled by HFB or its Affiliates for inclusion as an Option Program under this Agreement. For clarity, FibroGen may elect [*] for inclusion as an Option Program under this Agreement pursuant to this Section 2.9(g)(i) (FibroGen Non-Election) [*].

(ii) **Replacement Option Program Election**. Any program identified by the Parties pursuant to Section 2.9(g)(i) (FibroGen Non-Election) and elected by FibroGen pursuant to the Replacement Option Election for inclusion as an Option Program under this Agreement will automatically become an Option Program for all purposes under this Agreement (each such Option Program, a "**Replacement Option Program**", and the target to which any compounds or products under such program are directed, a "**Replacement Target**").

(h) **[*] HFB Screening Technology**. Notwithstanding anything in this Section 2.9 (FibroGen License Options) or otherwise in this Agreement to the contrary, after the Effective Date, [*], any HFB Screening Know-How, HFB Screening Patent Rights, or any Confidential Information relating thereto.

ARTICLE 3
GOVERNANCE

3.1 **Alliance Manager**. Within [*] of the Effective Date, each Party will appoint an individual (from the Party or from any Affiliate of such Party) who possesses a general understanding of Development issues regarding pharmaceutical and biological products to act as the facilitator of the meetings of the JSC and the first point of contact between the Parties with regard to questions relating to this Agreement or the overall business relationship and related matters between the Parties (each, an "**Alliance Manager**"). Each Party may replace its Alliance Manager at any time upon written notice to the other Party.

3.2 **Joint Steering Committee**.

(a) **Formation; Composition**. No later than after [*] after the Effective Date, the Parties will establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**") comprised of an equal number of representatives from each Party (or appointed representatives of any Affiliate of such Party) with sufficient seniority within the applicable Party to make decisions arising within the scope of the JSC's responsibilities. The JSC may change its size from time to time by mutual consent of its members, *provided* that the JSC

will consist at all times of an equal number of representatives of each of HFB and FibroGen. Each Party may replace its JSC representatives at any time upon written notice to the other Party. If agreed by the JSC on a case-by-case basis, the JSC may invite non-members to participate in the discussions and meetings of the JSC, *provided* that such participants will have no voting authority at the JSC and are bound by written obligations of confidentiality, non-disclosure, and non-use provisions at least as restrictive or protective of the Parties as those set forth in this Agreement. The JSC will be chaired by an HFB representative prior to the first Option Exercise Date with respect to any Option Program, and thereafter by a representative of FibroGen (each, a "**Chairperson**"). The role of the Chairperson will be to convene and preside at meetings of the JSC. The Chairperson will have no additional powers or rights beyond those held by the other JSC representatives. The Alliance Managers will work with the Chairperson to prepare and circulate agendas and to ensure the preparation of minutes.

(b) **Specific Responsibilities**. The JSC will:

(i) facilitate the provision and exchange of information between the Parties with respect to the Development of the Licensed Compounds and Licensed Products;

(ii) oversee the identification and Development of Option Compounds and Option Products;

(iii) oversee development of the Option Notice (and all components thereof) for each Option Program;

(iv) review, discuss, and determine whether to approve any Technology Transfer plan pursuant to Section 2.7(a) (Initial Technology Transfer) or Work Plan pursuant to Section 4.2 (Work Plans);

(v) review, discuss, and determine whether to approve any update or amendment to a Work Plan pursuant to Section 4.2(b) (Work Plans);

(vi) review and discuss any Development reports provided by HFB pursuant to Section 4.7 (Development Reports);

(vii) establish such additional subcommittees as it deems necessary to achieve the objective and intent of this Agreement, including as necessary to manage the preparation and prosecution of Joint Arising Technology pursuant to Section 9.3(c) (Joint Arising Patent Rights); and

(viii) perform such other functions as appropriate, to further the purposes of this Agreement, in each case as agreed in writing by the Parties.

(c) **Meetings**. During the Term, the JSC will meet on at least a [*] basis, [*] the JSC will meet on at least a [*] basis, unless otherwise agreed to by the JSC. No later than [*] prior to any meeting of the JSC, the Alliance Managers will jointly prepare and circulate an agenda for such meeting; *provided*, *however*, that either Party may propose additional topics to be included on such agenda, either prior to or in the course of such meeting. Either Party may also call a special meeting of the JSC (by videoconference, teleconference or in person) by providing at least [*] prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, in which event such Party will work with the Chairperson of the JSC to provide the members of the JSC no later than [*] prior to the special meeting with an agenda for the

meeting and materials reasonably adequate to enable an informed decision on the matters to be considered. The JSC may meet in person, by videoconference or by teleconference. In-person JSC meetings will be held at locations agreed upon by HFB and by FibroGen. Each Party will bear the expense of its respective JSC members' participation in JSC meetings. Meetings of the JSC will be effective only if at least [*] are present or participating (including by videoconference or teleconference) in such meeting. The Alliance Managers will be responsible for preparing reasonably detailed written minutes of all JSC meetings that reflect material decisions made and action items identified at such meetings. The Alliance Managers will send draft meeting minutes to each member of the JSC for review and approval within [*] after each JSC meeting. Such minutes will be deemed approved unless [*] members of the JSC objects to the accuracy of such minutes within [*] of receipt.

(d) **Decision-Making**. The representatives from each Party on the JSC will have, collectively, [*] vote on behalf of that Party, and all decision making will be by consensus. Disputes at the JSC will be handled in accordance with Section 3.3 (Resolution of JSC Disputes).

3.3 **Resolution of JSC Disputes**.

(a) **Within the JSC**. All decisions within the JSC will be made by consensus. If the JSC is unable to reach consensus on any issue for which it is responsible within [*] days after a Party affirmatively states that a decision needs to be made, then either Party may elect, by written notice to the other Party, to submit such issue to the Parties' Executive Officers, in accordance with Section 3.3(b) (Referral to Executive Officers).

(b) **Referral to Executive Officers**. If a Party makes an election under Section 3.3(a) (Resolution of JSC Disputes; Within the JSC) to refer a matter to the Executive Officers, then the Executive Officers will use good faith efforts to resolve promptly such matter, which good faith efforts will include at least [*] in-person, video or telephonic meeting between such Executive Officers within [*] after the submission of such matter to them.

(c) **Final Decision-Making Authority**. If the Executive Officers are unable to reach consensus on any such matter within [*] days after its submission to them, then:

(i) **No Changes**. Neither Party will have final decision-making authority with respect to approval of a Work Plan pursuant to Section 4.2(a) (Work Plans).

(ii) **HFB Decisions**. HFB will have final decision-making authority with respect to any such matter relating to an Option Program prior to the Option Exercise Date with respect to such Option Program.

(iii) **FibroGen Decisions**. FibroGen will have final decision-making authority with respect to any such matter [*], *provided* that FibroGen cannot require HFB to perform any activities or incur any costs or expenses that are not included in an approved Work Plan (including any amendments made in accordance with this Agreement). For clarity, such final decision-making authority does not apply to any technology transfer pursuant to Section 2.7 (Technology Transfer).

(iv) **Limitations on Decision-Making**. Without the other Party's prior written consent, neither Party may unilaterally make a decision (in exercise of its final decision-making authority on any such matters) that (A) amends, modifies or waives

compliance with any term or condition of this Agreement, or expands such Party's contractual rights or reduces such Party's contractual obligations under this Agreement, (B) conflicts with this Agreement, or would be reasonably likely to result in a violation of applicable law, the requirement of any Regulatory Authorities, or result in the infringement or misappropriation of intellectual property rights of any Third Party, or (C) is stated to require the agreement or consent of the Parties under Section 3.3(c)(i) (No Changes).

3.4 **Dissolution of JSC**. The JSC and any subcommittees shall be dissolved on a program-by-program basis upon: (a) with respect to any Licensed Program, the date on which [*] with respect to such Licensed Program, (b) with respect to any Option Program, the expiration of the Option Term for such Option Program without an exercise of the License Option for such Option Program. The JSC and any subcommittees shall be dissolved in their entirety upon FibroGen's election in accordance with Section 15.7 (Change of Control of HFB). Once the JSC is disbanded with respect to any program, the JSC will have no further obligations under this Agreement with respect to such program and, thereafter, the Alliance Managers will be the points of contact for the exchange of information between the Parties under this Agreement and any references in this Agreement to decisions of the JSC will automatically become references to decisions by and between the Parties in writing, subject to the other terms of this Agreement and consistent with the terms of Section 3.3(c) (Final Decision-Making Authority).

ARTICLE 4
DEVELOPMENT

4.1 **Development Plans**. An outline of all major Development activities to be conducted by FibroGen with respect to the Gal-9 Licensed Program is attached hereto as Schedule 4.1 (Development Plan). Following the Option Exercise Date with respect to any Option Program, FibroGen will provide an updated Development Plan to HFB reflecting all major Development activities to be conducted by FibroGen with respect to the applicable Licensed Program. Additionally, prior to the first Regulatory Approval of a Licensed Product for each Licensed Program in a Major Market Country, FibroGen will provide an updated Development Plan with respect to such Licensed Program to HFB within [*] of each anniversary of the Effective Date based on the currently available information.

4.2 **Work Plans**.

(a) **Initial Work Plan**. HFB will conduct certain Development activities until IND filing with respect to each Licensed Program in accordance with a written plan that includes [*]. [*] prior to the approximate delivery date of an Option Notice with respect to each Option Program, HFB will submit to the JSC a proposed Work Plan to become effective upon the Option Exercise Date for such Option Program. The JSC will review and discuss, and determine whether to approve any such Work Plan in accordance with Section 3.3(c) (Final Decision-Making Authority).

(b) **Updating Work Plan**. At least [*] (or more frequently as may be required) prior to dissolution of the JSC with respect to any Licensed Program, the JSC will review and update HFB's activities under each Work Plan based on the currently available

information. Each such update to a Work Plan will become effective and will supersede the previous version of such Work Plan upon approval thereof by the JSC. Additionally, from time to time prior to dissolution of the JSC, either Party may provide to the JSC a proposed amendment to any then-current Work Plan. The JSC will review and discuss, and determine whether to approve any proposed amendment to the Work Plan in accordance with Section 3.3(c) (Final Decision-Making Authority).

4.3 **FibroGen Development Responsibilities**. During the Term, FibroGen will have the sole right and responsibility for, and will have sole control and authority over, at its sole cost and expense, the Development of the Licensed Compounds and any Licensed Products.

4.4 **Development Diligence Obligations**. FibroGen will use Commercially Reasonable Efforts to Develop in accordance with the Development Plan, and obtain and maintain Regulatory Approval for, [*] Licensed Product Directed To each Licensed Program in the Field in [*] Major Market Countries. FibroGen shall use Commercially Reasonable Efforts to [*] (each of the events as provided in the foregoing (i) through (iii) are a "**Diligence Milestone**"). If FibroGen makes a final decision to permanently cease Development of all Licensed Products for a Licensed Program, FibroGen shall give HFB written notice within [*] of such decision and such Licensed Program shall be a Terminated Licensed Program pursuant to Section 13.6 (Effects of Termination).

4.5 **HFB Development Responsibilities**. Subject to the terms of this Agreement, on an Option Program-by-Option Program basis prior to the Option Exercise Date with respect to such Option Program, HFB will conduct the Development activities with respect to each Option Program, [*]. On a Licensed Program-by-Licensed Program basis, HFB will conduct solely those Development activities allocated to it under the applicable Work Plan for such Licensed Program, [*], subject to any agreed budget set forth in such Work Plan.

4.6 **Development Records**. Each Party will, and will cause its Affiliates, Sublicensees, and subcontractors to, maintain reasonably complete, current, and accurate records of all Development activities conducted by or on behalf of it and its Affiliates, Sublicensees, and subcontractors, respectively, pursuant to this Agreement. Each Party will maintain all such records relating to the Development of Licensed Compounds and Licensed Products for a period of [*]. HFB will document all non-clinical and preclinical studies in formal written study reports in accordance with GLP, cGMP, and GCP in compliance with ICH Guidelines, as applicable, and in compliance with applicable law. Upon FibroGen's reasonable request, HFB will, and will cause its Affiliates, Sublicensees, and subcontractors to, allow FibroGen to access, review, and copy such records (including access to relevant databases).

4.7 **Development Reports**. At each JSC meeting for [*] during which either Party is performing, or having performed, Development activities for any Option Compound, Option Product, Licensed Compound or Licensed Product in the Territory, such Party will provide a report to the other Party (through the JSC) summarizing such Development activities performed during the period since the preceding JSC meeting, such Development activities as are in process, including a summary of the data and results of such Development activities.

Following dissolution of the JSC pursuant to Section 3.4 (Dissolution of JSC), FibroGen will provide to HFB a Development report no later than [*] during the Term summarizing the Development activities performed by or on behalf of FibroGen and its Affiliates and Sublicensees in the Territory for the Licensed Products since the prior such report provided by FibroGen or, in the case of the first such report, since [*] prior to the date upon which the JSC was dissolved pursuant to Section 3.4 (Dissolution of JSC). HFB will have [*] following receipt of such [*] report to reasonably request additional information and a reasonable and prompt opportunity to discuss. Such reports and any additional information provided by a Party regarding Development activities for the Licensed Compounds and Licensed Products, in each case, will be the Confidential Information of the providing Party and subject to the terms of Article 12 (Confidentiality).

ARTICLE 5
REGULATORY

5.1 **Regulatory Responsibilities**. During the Term, FibroGen will have sole responsibility for, and sole decision-making authority over, all regulatory activities and associated costs and expenses for all Licensed Compounds and all Licensed Products in the Field in the Territory.

5.2 **Regulatory Filings; Ownership**. FibroGen will lead and have sole control over and decision-making authority with respect to preparing and submitting all regulatory filings related to the Licensed Compounds and Licensed Products in the Territory, including all applications for Regulatory Approval in the Territory. FibroGen will own any and all Regulatory Approvals and Regulatory Materials related to the Licensed Compounds and Licensed Products in the Territory, which will be held in the name of FibroGen or its designees. FibroGen will keep HFB informed of receipt of any Regulatory Approvals with respect to any Licensed Products in the Territory. HFB will reasonably cooperate with FibroGen in its efforts to prepare and submit any regulatory submissions to obtain, support, or maintain Regulatory Approvals for the Licensed Products in the Territory and all regulatory activities related to the Exploitation of the Licensed Products in the Territory.

5.3 **Interactions with Regulatory Authorities**. FibroGen will have the sole right to conduct all communications with Regulatory Authorities in the Territory related to the Licensed Compounds and Licensed Products, including all meetings, conferences, and discussions (including advisory committee meetings).

5.4 **Option Programs**. During the Option Term for any Option Program, HFB will not submit any regulatory filings related to the Option Compounds or Option Products for such Option Program or conduct any communications with Regulatory Authorities in the Territory related to such Option Compounds or Option Products, in each case, [*].

ARTICLE 6
MANUFACTURING

6.1 **Manufacturing**. During the Term, FibroGen will have the exclusive right to Manufacture and supply the Licensed Compounds and Licensed Products itself or through one or more Affiliates or FibroGen CMOs for Exploitation in the Field in the Territory.

[*] = 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.

ARTICLE 7
COMMERCIALIZATION

7.1 **Commercialization Responsibilities**. FibroGen will have sole control over and decision-making authority with respect to the Commercialization of all Licensed Products in the Territory, including the right to determine the price of the Licensed Products sold in the Territory.

7.2 **Commercialization Diligence Obligations**. [*]. If, with respect to any Licensed Program, FibroGen ceases all Commercially Reasonable Efforts to Commercialize all Licensed Products within such Licensed Program for [*], such Licensed Program shall be a Terminated Licensed Program and all applicable Licensed Products shall become Terminated Licensed Products; *provided that* (a) if such cessation is a result of a safety concern, regulatory issue, clinical hold, Force Majeure, or injunction or other operation of law, such [*] period will be extended for [*] any of the foregoing listed in this clause (a) caused [*] and FibroGen is diligently seeking to remedy such issue, such [*] period will be [*] as is reasonably necessary to resolve the [*]. If FibroGen makes a [*] Commercialization of all Licensed Products for a Licensed Program, FibroGen shall give HFB written notice within [*] of such decision and such Licensed Program shall be a Terminated Licensed Program pursuant to Section 13.6 (Effects of Termination).

7.3 **Commercialization Report**. Within [*], FibroGen will provide to HFB a report summarizing the Commercialization activities performed by or on behalf of FibroGen and its Affiliates and Sublicensees in the Territory for the Licensed Products since the prior such report provided by FibroGen or, in the case of the first such report, since [*] prior to the date upon which the first Regulatory Approval for a Licensed Product in the Territory was granted. HFB will have [*] following receipt of such report to reasonably request additional information and a reasonable opportunity to discuss at a time mutually agreeable to the Parties. Such reports will be Confidential Information of FibroGen and subject to the terms of Article 12 (Confidentiality). FibroGen will provide updates to any such report at each meeting of the JSC.

ARTICLE 8
FINANCIALS

8.1 **Upfront Payment**. No later than [*] after receipt of an invoice from HFB, which invoice may be provided beginning on the Effective Date, FibroGen will pay to HFB a one-time, non-refundable, non-creditable payment in the amount of twenty-five million dollars ($25,000,000) (the "**Upfront Payment**") [*].

8.2 **Option Exercise Payment**. No later than [*] after receipt of an invoice from HFB, which invoice shall be provided as soon as reasonably practicable after FibroGen's delivery of the Option Exercise Notice for a given License Option for an Option Program, FibroGen will pay to HFB the corresponding one-time, non-refundable, non-creditable payment for

such Option Program set forth in Table 8.2 (each, an "**Option Exercise Payment**"):

Table 8.2 – Option Exercise Payments			
	CCR8 Option Program	***CXCR5 Option Program***	***Replacement Option Program***
Option Exercise Payment	[*]	[*]	[*]

8.3 **Milestone Payments.**

(a) **R&D and Regulatory Milestones**. FibroGen will make the one-time milestone payments set forth in Table 8.3(a) upon the first achievement by FibroGen or its Affiliates or Sublicensees of the corresponding milestone event by the first Licensed Product for each Licensed Program.

Table 8.3(a) – R&D and Regulatory Milestones for each program		
No.	***Milestone Event***	***Milestone Payment***
1	[*]	[*]
2	[*]	[*]
3	[*]	[*]
4	[*]	[*]
5	[*]	[*]
	Maximum total milestone payments per program	[*]
	Total Maximum	[*]

(b) **Sales Milestones**. FibroGen will make the one-time milestone payments set forth in Table 8.3(b) upon the first achievement by FibroGen or its Affiliates or Sublicensees of the corresponding milestone event by the first Licensed Product for each Licensed Program.

Table 8.3(b) – Sales Milestones for each program		
No.	***Milestone Event***	***Milestone Payment***
1	[*]	[*]
2	[*]	[*]
3	[*]	[*]
	Maximum total milestone payments per program	[*]

Each milestone payment under this Section 8.3 (Milestone Payments) is non-refundable and non-creditable and payable only once for each Licensed Program, upon the first achievement by FibroGen or its Affiliate or Sublicensee for a Licensed Product Directed To an Exclusive Target in the Territory that is the subject of each such Licensed Program, notwithstanding whether a Licensed Product achieves the milestone event more than once or whether more than one Licensed Product Directed To an Exclusive Target achieves a milestone event. If any of R&D and regulatory milestones events 2 through 5 are achieved by a given Licensed Product prior to achievement of any of the preceding R&D and regulatory milestone events 1 through 4 for such Licensed Product, all preceding milestone events not previously achieved for such Licensed Product shall be deemed to be achieved and payable upon achievement of the applicable R&D

and regulatory milestone events for such Licensed Product. If [*] events are achieved in the same Calendar Quarter or the same Calendar Year, then [*].

FibroGen will provide HFB with written notice of the achievement of the milestone event in this Section 8.3(a) (R&D and Regulatory Milestones) no later than [*] after the achievement of the applicable milestone event by FibroGen or any of its Affiliates, or within [*] after FibroGen has knowledge of the achievement of the applicable milestone event by a Sublicensee. HFB will invoice FibroGen following receipt of such written notice as soon as reasonably practicable and FibroGen will pay the associated milestone payment no later than [*] after the receipt of such invoice. Such payment will be made by wire transfer of immediately available funds into an account designated by HFB.

8.4 **Royalties**.

(a) **Royalty Rates**. On a Licensed Product-by-Licensed Product and country-by-country basis, FibroGen will pay HFB royalties on aggregate annual Net Sales of each Licensed Product in the Territory in a Calendar Year at the royalty rates set forth in Table 8.4(a) until the expiration of the Royalty Term for such Licensed Product on a country-by-country basis ("**Royalties**").

Table 8.4(a) – Royalty Rates for Licensed Products

Calendar Year Aggregate Net Sales of a Licensed Product in the Territory	***Royalty Rate***
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

[*].

(b) **Reports; Payment**. FibroGen will deliver a written report to HFB showing a calculation of the Royalties and whether a Sales Milestone has been achieved, providing Net Sales in sufficient detail to allow HFB to verify Royalties and achievement of Sales Milestones due in a given Calendar Quarter no later than [*] after the end of each Calendar Quarter (each, a "**Royalty and Net Sales Report**"). All Royalty payments will be payable concurrently with the delivery of the Royalty and Net Sales Report for the applicable Calendar Quarter. All payments under this Agreement will be payable, in full, in U.S. dollars, regardless of the country(ies) in which such sales are made. For purposes of computing the Royalty of any Licensed Product that is sold in a currency other than United States dollars, such currency will be converted into United States dollars at the median of the buying rate and the selling rate of exchange reported by the Wall Street Journal on the last day for the month in which such sales were recorded.

(c) **Reductions**.

(i) **Reduction for Loss of Market Exclusivity**. If, on a Licensed Product-by-Licensed Product and country-by-country basis, a Loss of Market Exclusivity for a Licensed Product in any country has occurred [*], then the Royalties due to HFB pursuant to Section 8.4(a) (Royalty Rates) with respect to such Licensed Product in such country will be reduced by [*] of the applicable Royalties that would otherwise be owed on the Net Sales of such Licensed Product in such country under Section 8.4(a) (Royalty Rates) in such Calendar Quarter.

(ii) **Reduction for Additional Third Party IP**. With respect to any Third Party License entered into after the Effective Date pursuant to which FibroGen is granted rights under any Additional Third Party IP that is necessary to Exploit a Licensed Product in a country or jurisdiction in the Territory, FibroGen will be entitled to deduct from any Royalties due to HFB pursuant to Section 8.4(a) (Royalty Rates) with respect to that country or other jurisdiction [*] of royalties or other amounts paid to such Third Party under such Third Party License to the extent necessary to Develop and Commercialize a Licensed Compound and allocable or specific to the Licensed Products.

(iii) **Cumulative Reductions Floor**. In no event will the Royalties due to HFB under this Agreement in a Calendar Year be reduced by more [*] due to HFB pursuant to Section 8.4(a) (Royalty Rates) that would otherwise be due in such Calendar Year for the Licensed Products as a result of the foregoing reductions.

8.5 **Sublicense Revenue**. FibroGen will pay to HFB [*] of any Sublicense Revenue received by FibroGen under any sublicense to the extent the sublicense is directed to a Licensed Program for which [*]. No Sublicense Revenue will be owed to HFB by FibroGen with respect to any sublicense to the extent such sublicense is directed to a Licensed Program for which [*]. Notwithstanding anything to the contrary set forth in this Agreement, to the extent that any payment is made to FibroGen under a sublicense in consideration for both (a) a sublicense under the Licensed Technology and (b) a license or sublicense under intellectual property rights or materials not licensed to FibroGen under this Agreement, [*]. The Parties will discuss in good faith any dispute by HFB with respect to such [*] and will resolve any issues in accordance with Article 14 (Dispute Resolution).

8.6 **Upstream License Costs**. [*] responsible for all upfront payments, milestone payments, royalties, or other payments due to the licensor under the Upstream License, as well as any rewards, remuneration, or other amounts payable with respect to inventions and technical achievements required by applicable law to be paid to any Persons for the development or invention of any Licensed Technology (collectively, "**Upstream License Costs**"). Without limiting the foregoing, if [*] fails to pay any Upstream License Costs or otherwise fails to maintain the Upstream License as required by Section 10.3(b) (Upstream License) and [*].

8.7 **Books and Records; Audit Rights**.

(a) HFB will have the right to engage, at its own cost and expense, subject to this Section 8.7 (Books and Records; Audit Rights), an independent nationally recognized public accounting firm in the United States chosen by HFB and reasonably acceptable to FibroGen (which accounting firm will not be the external auditor of HFB, will not have been hired or paid on a contingency basis, and will have experience auditing pharmaceutical companies) (a "**CPA Firm**") to conduct an audit of FibroGen for the purposes of confirming FibroGen's compliance with the payment provisions of this Agreement.

(b) The CPA Firm will be given access to and will be permitted to examine such books and records of FibroGen as it will reasonably request, upon [*] prior written notice having been given by HFB, during regular business hours, for the sole purpose of determining compliance with the payment provisions of this Agreement. Prior to any such examination taking place, the CPA Firm will enter into a confidentiality agreement reasonably

acceptable to FibroGen with respect to the Know-How to which they are given access and will not contain in its report or otherwise disclose to HFB or any Third Party any information labeled by FibroGen as being confidential customer information regarding pricing or other competitively sensitive proprietary information.

(c) HFB and FibroGen will be entitled to receive a full written report of the CPA Firm with respect to its findings and HFB will provide, without condition or qualification, FibroGen with a copy of the report, or other summary of findings, prepared by such CPA Firm promptly following HFB's receipt of same. No other information will be provided to HFB. In the event of any dispute between HFB and FibroGen regarding the findings of any such inspection or audit, the Parties will initially attempt in good faith to resolve the dispute amicably between themselves, and if the Parties are unable to resolve such dispute within [*] after delivery to both Parties of the CPA Firm's report, each Party will [*] internationally recognized independent certified public accounting firm which will resolve the dispute, and such accounting firm's determination will be binding on both Parties, absent manifest error by such accounting firm.

(d) Within [*] after completion of the CPA Firm's audit, FibroGen will pay to HFB any deficiency in the payment amount determined by the CPA Firm and, if the deficiency is at least [*] of the total payment amount, then FibroGen shall pay all costs and expenses associated with the CPA Firm's audit and any dispute thereof pursuant to Section 8.7(c) (Books and Records; Audit Rights). If the report of the CPA Firm shows that FibroGen overpaid, then FibroGen will be entitled to off-set such overpayment against any Royalty then owed to HFB. If no Royalty is then owed to HFB, then HFB will remit such overpayment to FibroGen.

(e) HFB's exercise of its audit rights under this Section 8.7 (Books and Records; Audit Rights) may not (i) be conducted for any Calendar Quarter [*] after the end of such Calendar Quarter to which such books and records pertain, (ii) be conducted more than [*] in any a Calendar Year period (unless a previous audit during such period revealed a material underpayment with respect to such period), or (iii) be repeated for any [*].

8.8 **Taxes**.

(a) **Taxes on Net Income**. Each Party will be solely responsible for the payment of any and all taxes levied on such Party's net income.

(b) **Tax Withholding**. The amounts payable pursuant to this Agreement will not be reduced on account of any taxes, unless required by applicable law. If applicable law requires the withholding of taxes on a payment by FibroGen to HFB under this Agreement, then FibroGen will pay the amount of such taxes to the proper governmental authority in a timely manner and will [*]. FibroGen will promptly (as soon as reasonably available) submit to HFB appropriate proof of FibroGen's payment of the withheld taxes as well as the official receipts in respect thereof. Notwithstanding the foregoing, to the extent there is an increase in the applicable rate of withholding tax on any payments by FibroGen to HFB, which increase is solely as a result of a change in form or domicile of FibroGen, FibroGen shall pay HFB an amount so that after any such additional withholding tax has been taken into account (including as a result of any withholding tax imposed on the additional amounts payable pursuant to this sentence), HFB shall have received an amount from FibroGen equal to the payment HFB would have received had no such additional withholding tax applied. If HFB delivers to FibroGen or the appropriate governmental

authority in the applicable jurisdiction the prescribed forms necessary to reduce the applicable rate of withholding or to relieve FibroGen of its obligation to withhold taxes, FibroGen will [*], as the case may be, *provided* that FibroGen is in receipt of evidence, in a form reasonably satisfactory to FibroGen (*e.g.*, HFB's delivery of all applicable documentation) prior to the time that the applicable payments are due.

(c) **Tax Cooperation**. The Parties shall cooperate and exercise their reasonable best efforts to ensure that any withholding taxes imposed on payments to HFB are reduced as far as possible under the provisions of any applicable law (including any applicable income tax treaty). If withholding of tax is required from any payment, both parties shall use reasonable efforts to provide sufficient time for the Parties to review the applicable law and establish any available reduction or exemption from such withholding. For purposes of properly determining its withholding tax obligations (if any) in respect of payments to HFB based on sales (such as royalties), FibroGen covenants to maintain records, available for HFB's review, that support the apportionment of such payments to U.S. sources or non-U.S. sources, as determined for U.S. federal income tax purposes, and as otherwise may be required under the income sourcing rules of other jurisdictions that may impose withholding obligations in respect of such payments. Each Party will cooperate and exercise their reasonable best efforts to enable the recovery, as permitted by applicable law, of withholding taxes, VAT, or similar tax obligations that were paid in respect of payments made under this Agreement, such recovery to be for the benefit of the Party that bore the economic burden of such withholding tax or VAT. Furthermore, the Parties shall reasonably cooperate and provide each other with such forms and information as reasonably may be needed to comply with any applicable tax reporting obligations.

(d) **Certain U.S. Tax Matters.** The Parties intend that, for U.S. federal income tax purposes, the license under this Agreement (and the rights transferred upon exercise of the options under this Agreement) represent a sale of intellectual property (i.e., a transfer of all substantial rights in respect of intellectual property as determined for U.S. federal income tax purposes). [*]

(e) **VAT**. The Parties agree to cooperate with one another and use reasonable efforts to ensure that any value added tax, sales tax or similar payment ("**VAT**") (in respect of any payments made by FibroGen to HFB under this Agreement) does not represent an unnecessary cost in respect of payments made under this Agreement, including use of available VAT exemptions, zero-ratings, reduced-ratings, suspensions or other reliefs. All sums payable under this Agreement will be exclusive of VAT. If any VAT is owing in any jurisdiction with respect to any such payment, then FibroGen will pay such VAT and HFB will provide to FibroGen tax invoices showing the amount of VAT in respect of such payment in addition to any amounts otherwise payable by FibroGen under this Agreement. Where the prevailing legislation requires the recipient to self-account for VAT (for example, but not limited to, the reverse charge mechanism), then FibroGen covenants it will correctly account for VAT in respect of the transactions under this Agreement upon which VAT is due. HFB agrees that it will raise a tax invoice (or equivalent document) to support the charge to VAT.

8.9 **Late Payments**. Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement will bear interest at a rate equal to the lesser of: (a) [*] in which such payments are overdue; or (b) the maximum rate permitted by applicable law; [*].

8.10 **No Other Compensation**. Other than as explicitly set forth (and as applicable) in this Agreement, neither FibroGen nor any of its Affiliates will be obligated to pay any additional fees, milestone payments, royalties or other payments of any kind to or on behalf of HFB or any of its Affiliates under this Agreement.

8.11 **Other Amounts Payable**. With respect to any amounts owed under this Agreement by a Party to the other Party for which no other invoicing and payment procedure is specified in this Agreement, the payee Party will provide an invoice, together with reasonable supporting documentation, to the paying Party for such amounts owed. The paying Party will pay any undisputed amounts no later [*] after receipt of the invoice, and will pay any disputed amounts owed by the paying Party no later than [*] after resolution of the dispute.

ARTICLE 9
INTELLECTUAL PROPERTY

9.1 **Background Technology**. As between the Parties, (a) HFB will retain all rights, title, and interest in and to any Patent Rights, Know-How, and other intellectual property rights owned or Controlled by HFB or any of its Affiliates as of the Effective Date or generated or obtained by or on behalf of HFB or any of its Affiliates during the Term outside of the scope of performance of activities under this Agreement (the "**HFB Background Technology**"), and (b) FibroGen will retain all rights, title, and interest in and to any Patent Rights, Know-How, and other intellectual property rights owned or Controlled by FibroGen or any of its Affiliates as of the Effective Date or generated or obtained by or on behalf of FibroGen or any of its Affiliates during the Term outside of the scope of performance of activities under this Agreement (the "**FibroGen Background Technology**"). Other than as set forth in Sections 9.3(e) (Licensed Patent Rights) and 9.5 (Enforcement), each Party has the sole right, responsibility, and discretion to file, prosecute (including the defense of any oppositions, interferences, reissue proceedings, re-examinations, and other post-grant proceedings originating in a patent office), maintain, and enforce all of their background Patent Rights as follows: (i) FibroGen shall control the Patent Rights within the FibroGen Background Technology, [*] and (ii) HFB shall control Patent Rights within the HFB Background Technology, including HFB Screening Patent Rights, [*].

9.2 **Ownership**.

(a) **Arising Technology**.

(i) Ownership will follow inventorship for (A) any and all Know-How developed, created, conceived, or reduced to practice during the Term solely by or on behalf of a Party or any of its Affiliates in a Party's performance of activities under this Agreement with respect to a Licensed Program ("**Arising Know-How**") and (B) any Patent Right claiming, in whole or in part, any such Know-How described in clause (A) (the "**Arising Patent Rights**" and the Arising Know-How and Arising Patent Rights, the "**Arising Technology**"), with inventorship being determined in accordance with United States patent laws (regardless of where the applicable activities occurred). Arising Know-How invented solely by or on behalf of HFB or any of its Affiliates, and all Arising Patent Rights claiming any such Arising

[*] = 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.

Know-How (the "**HFB Arising Patent Rights**") will be solely owned by HFB or any of its Affiliates ("**HFB Arising Technology**"). Arising Know-How invented solely by or on behalf of FibroGen or any of its Affiliates, and all Arising Patent Rights claiming, in whole or in part, any such Arising Know-How (the "**FibroGen Arising Patent Rights**"), [*] will be solely owned by FibroGen or any of its Affiliates ("**FibroGen Arising Technology**"). Arising Know-How invented jointly by HFB or any of its Affiliates and FibroGen or any of its Affiliates ("**Joint Arising Know-How**"), and all Arising Patent Rights claiming, in whole or in part, any such Arising Know-How (the "**Joint Arising Patent Rights**") will be jointly owned by both Parties ("**Joint Arising Technology**").

(ii) HFB will promptly disclose to FibroGen any (A) HFB Arising Technology that is Licensed Technology or (B) Joint Arising Technology, as applicable, developed, created, conceived, or reduced to practice by or on behalf of HFB or any of its Affiliates during the Term. FibroGen will promptly disclose to HFB any FibroGen Arising Technology or Joint Arising Technology, as applicable, developed, created, conceived, or reduced to practice by or on behalf of FibroGen or any of its Affiliates during the Term.

(iii) Each Party will have an undivided one-half (1/2) interest in and to the Joint Arising Technology. Each Party may exercise its ownership rights in and to such Joint Arising Technology, including the right to license and sublicense or otherwise to exploit, transfer, or encumber its ownership interest, without an accounting or obligation to, or consent required from, the other Party, but subject to the licenses hereunder and the other relevant terms and conditions of this Agreement. Each Party hereby [*] is required to effect the foregoing regarding Joint Arising Technology. Each Party, for itself and on behalf of any of its Affiliates, licensees, and Sublicensees, and employees, subcontractors, consultants, and agents of any of the foregoing, hereby assigns (and to the extent such assignment can only be made in the future, hereby agrees to assign), to the other Party (and the other Party hereby accepts such assignment) a joint and undivided interest in and to all Joint Arising Technology.

(b) Notwithstanding any provision to the contrary set forth in this Agreement, neither Party may invoke this Agreement as a "joint research agreement" pursuant to the Cooperative Research and Technology Enhancement Act, 35 U.S.C. § 102(c) without the prior written consent of the other Party.

9.3 **Prosecution, Maintenance & Enforcement**.

(a) **FibroGen Arising Patent Rights**. FibroGen will have the sole right, responsibility, and discretion to file, prosecute (including the defense of any oppositions, interferences, reissue proceedings, re-examinations, and other post-grant proceedings originating in a patent office), and maintain all FibroGen Arising Patent Rights and at its sole cost and expense.

(b) **HFB Arising Patent Rights**. HFB will have the sole right, responsibility and discretion to file, prosecute (including the defense of any oppositions, interferences, reissue proceedings, re-examinations and other post-grant proceedings originating in a patent office), and maintain all HFB Arising Patent Rights at its sole cost and expense, *provided*, that (i) any HFB Arising Patent Rights that are Option Patent Rights will be subject to

Section 9.3(d) (Option Patent Rights) and any HFB Arising Patent Rights that are Licensed Patent Rights will be subject to Section 9.3(e) (Licensed Patent Rights).

(c) **Joint Arising Patent Rights**. FibroGen will have the first right, responsibility, and discretion to file, prosecute (including the defense of any oppositions, interferences, reissue proceedings, re-examinations, and other post-grant proceedings originating in a patent office), and maintain all Joint Arising Patent Rights, in the Territory using counsel mutually agreed by the Parties (such agreement not to be unreasonably withheld by either Party), which may [*]. The Parties will use good faith efforts to agree on a mutually acceptable strategy and will coordinate with each other for the prosecution and maintenance of all Joint Arising Patent Rights. If FibroGen decides it is no longer interested in the prosecution or maintenance of a particular Joint Arising Patent Right in any country the Territory, or [*], then it will promptly provide written notice to HFB of such decision. HFB may, upon written notice to FibroGen, assume the prosecution and maintenance of such Patent Rights in such country in the Territory.

(d) **Option Patent Rights**. [*], HFB will have the sole right, responsibility and discretion to file, prosecute (including the defense of any oppositions, interferences, reissue proceedings, re-examinations and other post-grant proceedings originating in a patent office), and maintain all Option Patent Rights [*], *provided*, that, HFB will provide to FibroGen [*] provided by FibroGen with respect thereto. HFB will provide to FibroGen electronic copies of all submitted filings related to any Option Patent Rights as part of the Option Notice in accordance with Section 2.9(c)(i) (Delivery). For the avoidance of doubt, upon the Option Exercise Date with respect to an Option Program, the Option Patent Rights with respect to such Option Program will automatically become Licensed Patent Rights for all purposes under this Agreement, including without limitation Section 9.3(e) (Licensed Patent Rights).

(e) **Licensed Patent Rights**.

(i) [*] If FibroGen declines to file for, prosecute, or maintain (including defending or prosecuting office actions, prosecutions or interferences) any Licensed Patent Right in the Territory, then it will give HFB reasonable notice thereof and thereafter, HFB may, upon written notice to FibroGen and at HFB's sole cost, control the filing for, prosecution and maintenance of such Licensed Patent Right in the Territory thereafter in accordance with this Section 9.3(e)(i) (Licensed Technology), *mutatis mutandis*.

(ii) No later than [*], HFB will (A) provide FibroGen, [*], with electronic copies of documents (including file histories and then current dockets) for the applicable Licensed Patent Rights that are in the file maintained by HFB's in-house or outside patent counsel for such Patent Rights in the Territory or otherwise available to HFB, including any communications, filings and drafts as well as written notice of any pending deadlines or communications for such Licensed Patent Rights (*provided*, *however*, that HFB will provide notice of pending deadlines as promptly as possible after the Effective Date so as to ensure adequate time and coordination with respect to such deadlines), and (B) execute and deliver any legal papers reasonably requested by FibroGen to effectuate transfer of control of the filing, prosecution, and maintenance of the Licensed Patent Rights in the Territory. In the event HFB assumes control of the preparation of, filing for, and prosecution and maintenance (including the defense of any oppositions, interferences, reissue

proceedings, re-examinations and other post-grant proceedings originating in a patent office) in the Territory with respect to any Licensed Patent Rights pursuant to Section 9.3(e)(i) (Licensed Patent Rights), then FibroGen will (1) provide HFB with electronic copies of any relevant communications, filings, drafts, and documents not previously provided to HFB as well as written notice of any pending deadlines or communications applicable thereto (including file histories and then current dockets), and (2) execute and deliver any legal papers reasonably requested by HFB to effectuate transfer of control of the filing, prosecution, and maintenance of such Licensed Patent Rights.

(iii) Each Party will reasonably cooperate with the other Party in the filing, prosecution, defense, and maintenance of the Licensed Patent Rights. Such cooperation includes promptly executing all documents, requiring inventors to be reasonably available to discuss and review applications and other filings, and requiring inventors, subcontractors, employees and consultants and agents of such Party and any of its Affiliates, and for the prosecuting Party and any of its Affiliates and Sublicensees (with respect to FibroGen), to execute all documents, as reasonable and appropriate so as to enable the prosecution and maintenance of any such Licensed Patent Rights.

9.4 **Defense and Settlement of Third Party Claims**. From and after the Effective Date, if a Third Party asserts that a Patent Right or other right owned by it is infringed by the Exploitation of any Licensed Compound or Licensed Product in the Field in the Territory. Each Party will give the other Party prompt written notice of any allegation by any Third Party that a Patent Right or other right owned by it is infringed by the Exploitation of any Licensed Compound or Licensed Product in the Territory and then the Parties shall confer. FibroGen will have the first right, but not the obligation, to defend against any such assertions at FibroGen's sole cost or elect to settle such claims (except as set forth below). FibroGen will promptly inform HFB if it elects not to exercise its first right under this Section 9.4 (Defense and Settlement of Third Party Claims) to defend against such assertion and, following discussion with FibroGen, [*], HFB will have the second right, but not the obligation, to defend against any such assertions at HFB's sole cost. The other Party and any of its Affiliates will assist the defending Party and cooperate in any such litigation at the defending Party's request. The other Party may join any defense pursuant to this Section 9.4 (Defense and Settlement of Third Party Claims), with its own counsel, [*]. The defending Party or any of its Affiliates may settle or consent to the entry of any judgment in any enforcement action hereunder without the other Party's prior consent; *provided*, *however*, that any such settlement or consent judgment will not, without the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed), impose any liability or obligation on the other Party or any of its Affiliates.

9.5 **Enforcement**.

(a) **Enforcement and Cooperation**. If in the Territory, (i) HFB or FibroGen becomes aware of any actual or suspected infringement of any Licensed Patent Right or Joint Arising Patent Right, or (ii) any such Licensed Patent Right or Joint Arising Patent Right is challenged in any action or proceeding (other than any interferences, oppositions, reissue proceedings or re-examinations, which are addressed in Section 9.3(e) (Licensed Patent

Rights)), then such Party will notify the other Party promptly, and following such notification, the Parties will confer. FibroGen will have the first right, but will not be obligated, to defend any such action or proceeding in the Territory or bring an infringement action with respect to such infringement in the Territory [*]. FibroGen will promptly inform HFB if it elects not to exercise its first right under this Section 9.5(a) (Enforcement and Cooperation) to defend any such action in the Territory or proceeding or to bring an infringement action, and HFB will thereafter have the second right, but will not be obligated, to defend any such action or proceeding in the Territory or bring an infringement action with respect to such infringement in the Territory [*]. HFB will keep FibroGen reasonably informed of all developments in any action or proceeding. Regardless of which Party exercises its right this Section 9.5(a) (Enforcement and Cooperation), the other Party and its Affiliates will reasonably assist such enforcing Party in any action or proceeding being defended or prosecuted if so requested, and will agree to be named in the filing or join in such action or proceeding if requested by such enforcing Party. If the other Party elects to be represented by legal counsel, then the enforcing Party will bear all of such Party's related and reasonable legal costs and expenses if the other Party is required to be named in the filing or joined in such action or proceeding or is joined in such action or proceeding at the enforcing Party's request.

(b) **Damages**. In the event that either Party exercises the rights conferred in this Section 9.5 (Enforcement) and recovers any damages, payments, or other sums in such action or proceeding or in settlement thereof, then such damages or other sums recovered will first be applied to all out-of-pocket costs and expenses incurred by such enforcing Party in connection therewith (including attorney's fees). [*]

9.6 **Trademarks**. FibroGen will have the sole right to brand the Licensed Products in the Territory using trademarks, logos, and trade names that it determines appropriate, which may vary by region or within a region (the "**Product Marks**"). FibroGen will solely own all rights, title, and interest in and to any Product Marks adopted for use with the Licensed Products in the Territory, and will be responsible for the registration, filing, maintenance, and enforcement thereof at its own cost and expense.

9.7 **CREATE Act**. Notwithstanding anything to the contrary in this Article 9 (Intellectual Property), neither Party will have the right to make an election under the CREATE Act when exercising its rights under this Article 9 (Intellectual Property) without the prior written consent of the other Party, which will not be unreasonably withheld, conditioned or delayed. With respect to any such permitted election, the Parties will use reasonable efforts to cooperate and coordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the CREATE Act. Notwithstanding the foregoing, HFB's consent under this Section 9.7 (CREATE Act) will not be required in connection with an obviousness-type double patenting rejection in any patent application filed by FibroGen or its Affiliate claiming a Licensed Compound, Licensed Product, or uses thereof. In the event of an obviousness-type double patenting rejection in any patent application filed by FibroGen or its Affiliate claiming a Licensed Compound or Licensed Product where such rejection is due to any Patent Right within the HFB Background Technology, HFB will discuss and consider [*] such Patent Right to FibroGen.

9.8 **Patent Right Extensions; Regulatory Exclusivity**.

(a) **Patent Right Term Extension**. If elections with respect to obtaining patent term extension or supplemental protection certificates or their equivalents in any country in the Territory with respect to any Licensed Product becomes available, upon Regulatory Approval or otherwise, then FibroGen will have the sole right to file for patent term extension or supplemental protection certificates or their equivalents and to determine which issued patent to extend. HFB and any of its Affiliates will reasonably cooperate with FibroGen so as to enable FibroGen to exercise its rights under this Section 9.8(a) (Patent Right Term Extension). Such cooperation includes promptly executing all documents, requiring inventors to be available to discuss and review any filings, and requiring inventors, subcontractors, employees, consultants, and agents of HFB or any of its Affiliates to execute all documents, as reasonable and appropriate so as to enable FibroGen to exercise its rights under this Section 9.8(a) (Patent Right Term Extension).

(b) **Regulatory Exclusivity**. With respect to Regulatory Exclusivity periods (such as orphan drug exclusivity and any available pediatric extensions), FibroGen will have the sole right to seek and maintain all such Regulatory Exclusivity periods that may be available for the Licensed Products in the Field in the Territory.

ARTICLE 10
REPRESENTATIONS, WARRANTIES, AND COVENANTS

10.1 **Mutual Representations, Warranties, and Covenants**. Each Party hereby represents and warrants to the other Party as of the Effective Date, and covenants, as applicable, as a material inducement for such other Party's entry into this Agreement, as follows:

(a) **Corporate Existence and Power**. It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder.

(b) **Authority and Binding Agreement**. (i) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

(c) **No Conflict**. It is not a party to and will not enter into any agreement that would prevent it from granting the rights or exclusivity granted or intended to be granted to the other Party under this Agreement or performing its obligations under this Agreement.

(d) **Consents**. All consents, approvals, and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained.

[*] = 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.

(e) **Bankruptcy; Insolvency**. It and its Affiliates are not subject to any action or petition, pending or otherwise, for bankruptcy or insolvency in any state, country, or other jurisdiction, and it is not aware of any facts or circumstances that could result in such Party or any of its Affiliates becoming or being declared insolvent, bankrupt, or otherwise incapable of meeting its obligations under this Agreement as they become due in the ordinary course of business.

(f) **No Debarment**. Neither it nor any of its employees nor to its knowledge, any of the agents performing hereunder, has ever been, is currently, or is the subject of a proceeding that could lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity, or Excluded Individual or a Convicted Entity or Convicted Individual. For purposes of this Agreement, the following definitions will apply:

(i) A "**Debarred Individual**" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a person that has an approved or pending drug or biological product application.

(ii) A "**Debarred Entity**" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or Affiliate of a Debarred Entity.

(iii) An "**Excluded Individual**" or "**Excluded Entity**" is (A) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (B) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

(iv) A "**Convicted Individual**" or "**Convicted Entity**" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.–.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

10.2 **Representations and Warranties by HFB**. HFB further represents and warrants to FibroGen (I) with respect to the Gal-9 Licensed Program, [*], except as set forth in Schedule 10.2 and (II) on an Option Program-by-Option Program basis, [*] in accordance with Section 2.9(c) (Option Notice) (the "**Option Notice Delivery Date**"), except as set forth in the disclosure letter delivered to FibroGen [*] (the "**Disclosure Letter**"), as follows:

(a) **No Conflicts**. Neither HFB nor any of its Affiliates has entered into any agreement (other than agreements with subcontractors) granting any right, interest or claim in or to, any Licensed Technology or Option Technology to any Third Party that would conflict with the licenses and other rights granted to FibroGen under this Agreement. The Licensed Technology constitutes all intellectual property rights Controlled by HFB and any of its Affiliates that are necessary or reasonably useful for the Exploitation of the Licensed Compounds in the Field in the Territory. All Existing Patent Rights are exclusively owned or exclusively licensed by HFB or any of its Affiliates, and are free and clear of any (i)

liens, charges, security interests, and encumbrances or licenses and (ii) claims or covenants, in each case that would conflict with or limit the scope of any of the rights or licenses granted to FibroGen hereunder, or would give rise to any Third Party claims for payment against FibroGen or any of its Affiliates. HFB is entitled to grant the license granted to FibroGen under Section 2.1 (License to FibroGen), and HFB has taken all appropriate measures under all applicable laws to grant such licenses.

(b) **No Notice of Infringement or Misappropriation**. (i) Neither HFB nor any of its Affiliates have received or is aware of any written notice from any Third Party asserting or alleging that any Exploitation of any Licensed Technology, any Licensed Compound, any Option Technology, or any Option Compound has infringed or misappropriated, or would infringe or misappropriate, the intellectual property rights of any Third Party, and (ii) no claim is pending, and HFB and any of its Affiliates and, to HFB's knowledge, any Third Party collaborator, has not received from a Third Party notice of a claim or threatened claim to the effect that any granted Patent Right rights within the Licensed Technology licensed to FibroGen under this Agreement, or the Option Technology, is invalid or unenforceable. To HFB's knowledge, the Exploitation of the Licensed Compound, and Option Compound as contemplated hereunder will not infringe, misappropriate, or otherwise violate the intellectual property rights of any Third Party. Additionally, to HFB's knowledge, there is no unauthorized use, infringement or misappropriation of any Licensed Technology or Option Technology by any Third Party as of the Effective Date.

(c) **No Misappropriation**. To HFB's knowledge, no employee, consultant, agent or independent contractor of HFB, any of its Affiliates, or Third Party, has misappropriated any Licensed Technology or Option Technology.

(d) **Licensed Technology**. All Existing Patent Rights are listed on Schedule 1.89 (Existing Patent Rights). All Existing Patent Rights have been and are being diligently prosecuted in the respective patent offices in the Territory in accordance with applicable law, have been and are being filed and maintained properly, and all applicable fees have been paid on or before the due date for payment, and the Existing Patent Rights that have issued are subsisting and not invalid or unenforceable, in whole or in part. The Existing Patent Rights represent all Patent Rights Controlled by HFB and any of its Affiliates that are necessary or reasonably useful for the Exploitation of the Licensed Compounds in the Territory.

(e) **Option Programs**. (i) HFB has the right to use all Option Technology to Exploit the Option Compounds in the Territory as contemplated under this Agreement; and (ii) the Development, Commercialization, or other Exploitation of the Option Compounds as contemplated herein will not conflict with any other license or agreement to which HFB or any of its Affiliates is a party.

(f) **Option Technology**. (i) Schedule 10.2(f) (Option Patent Rights) sets forth a complete and accurate list of all Patent Rights existing as of [*] that are Controlled by HFB or any of its Affiliates that are necessary or reasonably useful to Develop, Manufacture, Commercialize, or otherwise Exploit any Option Compound in the Territory (the "**Option Patent Rights**") and (ii) HFB does not own or hold rights to any Patent Rights that would otherwise fall within the foregoing clause (i) but for the fact that it does not Control such Patent Rights, HFB exclusively owns or exclusively licenses all rights, title, and interests in and to all Option Patent Rights.

(g) **Licensed Compound**. HFB has disclosed to FibroGen all compounds that HFB or any of its Affiliates owns or in-licenses that are the subject of the Gal-9 Licensed Program or each Option Program, as applicable.

(h) **HFB Assignment**. For the Existing Patent Rights that are owned by HFB or its Affiliates, all employees, consultants, contractors, and other Persons who have contributed to the development, creation, conception or invention of any of the Existing Patent Rights have executed a written agreement assigning to HFB or any of its Affiliates all rights to such developments, creations, conceptions or inventions, or Existing Patent Rights, and neither HFB nor any of its Affiliates has received any written communication challenging HFB's ownership or right to the Existing Patent Rights.

(i) **All Material Information Furnished**. HFB has furnished or made available to FibroGen or its agents or representatives (i) all [*] requested by FibroGen, (ii) all material safety and efficacy data, (iii) all material regulatory filings and other correspondence with Regulatory Authorities, and (iv) [*], in each case ((i) through (iv)), concerning the Licensed Compounds, the Option Compounds, the Licensed Technology and the Option Technology. All such material information and data, regulatory filings and other correspondence with Regulatory Authorities is [*].

(j) **Conduct of Research and Development**. HFB and its Affiliates have conducted all Development of Licensed Compound and Option Compound in accordance with all Applicable Law.

(k) **Upstream License**. The Upstream License represents a complete and accurate list of all written agreements pursuant to which any Third Party (other than pursuant to Section 10.2(h) (Representations and Warranties by HFB)) has a license, covenant not to sue, option or other similar right that would be necessary or reasonably useful with respect to the Exploitation of any Licensed Compound, but not including [*]. The Upstream License remains in full force and effect. HFB is in compliance with all material terms of the Upstream License, and no circumstances exist which could reasonably be expected to result in a breach or default of any Upstream License. All consents or approvals required under the Upstream License in order for HFB to grant the rights granted to FibroGen under this Agreement have been obtained. Subject to and except as set forth in the Standby Letter, this Agreement is consistent in all material respects with the terms and condition, and meets all material requirements of, the Upstream License. HFB has provided FibroGen with a complete and correct copy of the Upstream License. HFB has not waived any of its material rights under the Upstream License, and, to its knowledge, no such material rights have lapsed or otherwise expired or been terminated.

(l) **Government Funding**. (i) To HFB's knowledge, no Licensed Technology that is licensed to HFB under the Upstream License is subject to any funding agreement with any government or governmental agency, and (ii) no Licensed Technology owned by HFB or any of its Affiliates is subject to any funding agreement with any government or governmental agency.

(m) **Downstream Licenses**. Neither HFB nor any of its Affiliates have granted to any Third Party a license, covenant not to sue, option, or other right with respect to any Licensed Compound, or Option Compound in the Territory.

(n) **Consents**. Without limitation to Section 10.1(d) (Consents), each Party and its Affiliates have obtained all consents, approvals, and authorizations from all governmental authorities

[*] = 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.

required to be obtained by such Party or its Affiliates in connection with this Agreement and, as between the Parties, the Party responsible for obtaining any such consent, approval or authorization will be [*] to any governmental authority for the failure by such Party or its Affiliates to obtain any such consent, approval or authorization.

10.3 **HFB Covenants**.

(a) **No Conflicting Grants**. Following the Effective Date, HFB will not, and will cause its Affiliates not to, enter into any agreement with any Affiliate or Third Party that materially conflicts with or contradicts the terms and conditions set forth in this Agreement, including any agreement that would limit the grant of licenses or rights hereunder to the Licensed Technology or Option Technology.

(b) **Upstream License**. During the Term, HFB shall fulfill its obligations under the Upstream License and will not, [*]. HFB will provide FibroGen promptly with notice of the occurrence of any breach, amendment or termination (or HFB's receipt of notice of an allegation of any such breach or termination, and a copy thereof) of the Upstream License, and if HFB fails to cure such breach in a timely manner, will permit FibroGen to cure such breach on HFB's behalf. HFB shall furnish FibroGen with copies of all notices and correspondence that HFB receives in connection with the Upstream License related to FibroGen's rights or obligations under this Agreement or that could reasonably be expected to adversely affect FibroGen's right or obligations under this Agreement, [*].

(c) **Control of Licensed Technology**. HFB and its Affiliates will (a) maintain (i) ownership or Control of all Licensed Technology owned by HFB or its Affiliates at any time during the Term and (ii) Control of all Licensed Technology in-licensed by HFB or its Affiliates at any time during the Term, and (b) not assign, transfer, encumber, or otherwise grant any Third Party any rights with respect thereto, in the case of either (a) or (b) that would conflict with, limit the scope of, or materially adversely affect the rights granted to FibroGen under this Agreement;

(d) **Control of Option Technology**. HFB and its Affiliates will (a) maintain (i) ownership or Control of all Option Technology owned by HFB or its Affiliates at any time during the Option Term for each Option Program and (ii) Control of all Option Technology in-licensed by HFB or its Affiliates at any time during the Option Term for each Option Program, and (b) not assign, transfer, encumber, or otherwise grant any Third Party any rights with respect thereto, in the case of either (a) or (b), that would conflict with, limit the scope of, or materially adversely affect the rights granted to FibroGen under this Agreement.

(e) **Negative Events**. During the Term, [*] will provide prompt written notice to [*] if [*] reasonably believes that any of the events set forth in Schedule 10.3(e) (Negative Events) have occurred or are reasonably likely to occur. Upon occurrence of any of the events set forth in Schedule 10.3(e) (Negative Events), (i) the Parties will cooperate and exercise their commercially reasonable efforts to agree on and carry out remediation plans with respect to such events and (ii) except to the extent required by applicable law, [*] will not take any action that conflicts with, limits the scope of, or materially adversely affects or diminishes the rights [*] under this Agreement. This Section 10.3(e) (Negative Events) is without limitation to any other remedy available [*] under this Agreement.

10.4 **Mutual Covenants**.

(a) **Compliance with Applicable Law**. Each Party will comply, and will ensure that its Affiliates, Sublicensees, and subcontractors will comply, with the applicable law, including as applicable GLP, GCP, and cGMP and any applicable anti-corruption or anti-bribery laws or regulations of any governmental authority with jurisdiction over the activities performed by or on behalf of such Party or its Affiliates, Sublicensees, and subcontractors in each case, in the course of performing its obligations or exercising its rights pursuant to this Agreement. Neither Party nor its Affiliates, Sublicensees, and subcontractors will knowingly engage any agent to perform activities under this Agreement that has ever been, is currently, or is the subject of a proceeding that could lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual, or a Convicted Entity or Convicted Individual.

(b) **Assignment of Inventions**. Each Party will ensure, and will ensure that its Affiliates, Sublicensees, and subcontractors ensure that, any and all Persons involved in or performing any activities under this agreement by or on behalf of such Party have an obligation to assign such Persons' rights, title, and interests in and to any Know-How and Patent Rights to such Party prior to any such person performing such activities. As between the Parties, each Party, Sublicensees, and subcontractors will be solely responsible for the payment of, and such will pay, any rewards, remuneration, or other amounts payable with respect to inventions and technical achievements required by applicable law to be paid to its and its Affiliates', Sublicensees', and subcontractors' employees, consultants, contractors, or other Persons for the development or invention of any Know-How or Patent Rights; and

(c) **Debarment**. In the performance of activities under this Agreement, each Party will not knowingly employ or use any Person that: (i) has ever been debarred or is subject to debarment or convicted of a crime for which an entity or person could be a Debarred Entity or Debarred Individual; or (ii) has ever been under indictment for a crime for which a person or entity could be so debarred. Each Party will inform the other Party in writing immediately if it or any Person that is performing activities under this Agreement is debarred or is subject to debarment or is the subject of a conviction described in Section 306 of the FD&C Act, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or threatened, relating to the debarment or conviction of such Party or any Person or entity used in any capacity by such Party or any of its Affiliates, Sublicensees, and subcontractors with respect to this Agreement or the performance of its other obligations or exercise of its rights under this Agreement.

(d) **Consents**. In the event that either Party determines that HFB would have been, [*] in breach of Section 10.2(n), but for the [*], such Party will notify the other in writing and provide all relevant information with respect thereto. The Parties will thereafter work together promptly in good faith, [*] to take all steps necessary in order to remedy such breach (including, if required, obtaining all consents, approvals and authorizations from all government authorities and paying any amounts required by applicable law to be paid to any governmental authority for the failure by such Party or its Affiliates to obtain any such consent, approval or authorization).

10.5 **NO OTHER REPRESENTATIONS OR WARRANTIES**. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 10 (REPRESENTATIONS, WARRANTIES AND COVENANTS), NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL MATERIALS ARE PROVIDED "AS-IS." EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

[*] = 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.

ARTICLE 11
INDEMNIFICATION

11.1 **Indemnification by HFB**. Subject to the remainder of this Article 11 (Indemnification), HFB will defend, indemnify, and hold FibroGen, its Affiliates, and its and their respective officers, directors, employees, and agents (the "**FibroGen Indemnitees**") harmless from and against any and all liabilities, losses, costs, damages, fees, expenses, or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such FibroGen Indemnitees, all to the extent resulting from claims, suits, proceedings, or causes of action brought by or on behalf of such Third Party against such FibroGen Indemnitees that arise from or relate to: (a) the [*] of any Licensed Compound, Licensed Product, Option Compound, or Option Product by or on behalf of HFB or any of its Affiliates [*] with respect to such Licensed Compound, Licensed Product, Option Compound, or Option Product, (b) any activities performed by or on behalf of HFB or any of its Affiliates under this Agreement; (c) a breach of any of HFB's representations, warranties, or Development or other obligations under this Agreement; (d) the willful misconduct or grossly negligent acts of HFB or any of its Affiliates; (e) violation of applicable law by any HFB Indemnitee; or (f) any claim or demand from any employee, consultant, contractor of HFB or its Affiliate or other Person who is an inventor of any Licensed Know-How or Licensed Patent Right with respect to the ownership thereof; excluding, in each case ((a), (b), (c), (d), (e) and (f)), any damages or other amounts for which FibroGen has an obligation to indemnify any HFB Indemnitee pursuant to Section 11.2 (Indemnification by FibroGen).

11.2 **Indemnification by FibroGen**. Subject to the remainder of this Article 11 (Indemnification), FibroGen will defend, indemnify, and hold HFB, its Affiliates, and each of their respective officers, directors, employees, and agents (the "**HFB Indemnitees**") harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such HFB Indemnitees, all to the extent resulting from any claims, suits, proceedings, or causes of action brought by such Third Party against such HFB Indemnitees that arise from or relate to: (a) the Exploitation of Licensed Compound or Licensed Products by FibroGen or any of its Affiliates or Sublicensees in the Territory [*]; (b) a breach of any of FibroGen's representations, warranties, or obligations under this Agreement; (c) the willful misconduct or grossly negligent acts of FibroGen or any of its Affiliates; (d) violation of applicable law by any FibroGen Indemnitee or (e) any claim or demand from any employee,

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consultant, contractor of FGEN or its Affiliate or Sublicensee who is an inventor of any Patent Right with respect to the ownership thereof; excluding, in each case ((a), (b), (c), (d), and (e)), any damages or other amounts for which HFB has an obligation to indemnify any FibroGen Indemnitee pursuant to Section 11.1 (Indemnification by HFB).

11.3 **Indemnification Procedures**. The Party claiming indemnity under this Article 11 (Indemnification) (the "**Indemnified Party**") will give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of the claim, suit, proceeding or cause of action for which indemnity is being sought ("**Claim**"). The Indemnifying Party's obligation to defend, indemnify, and hold harmless pursuant to Section 11.1 (Indemnification by HFB) or Section 11.2 (Indemnification by FibroGen), as applicable, will be reduced to the extent the Indemnified Party's delay in providing notification pursuant to the previous sentence results in actual prejudice to the Indemnifying Party; *provided*, *however*, that the failure by an Indemnified Party to give such notice or otherwise meet its obligations under this Section 11.3 (Indemnification Procedures) will not relieve the Indemnifying Party of its indemnification obligation under this Agreement. At its option, the Indemnifying Party may assume the defense and have exclusive control, at its own expense, of any Claim for which indemnity is being sought by giving written notice to the Indemnified Party within thirty (30) days after receipt of the notice of the Claim. The assumption of defense of the Claim will not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify any Indemnified Party in respect of the Claim, nor will it constitute waiver by the Indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. The Indemnified Party will provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; *provided*, *however*, the Indemnifying Party will have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party will not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. The Indemnified Party will not settle any such Claim without the prior written consent of the Indemnifying Party, which consent will not be unreasonably withheld, conditioned or delayed. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnified Party reserves any right it may have under this Article 11 (Indemnification) to obtain indemnification from the Indemnifying Party.

11.4 **Limitation of Liability**. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, EXEMPLARY, OR INDIRECT DAMAGES OF ANY KIND ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT OR ANY CLAIMS ARISING HEREUNDER, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY

(WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE), REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.4 (LIMITATION OF LIABILITY) IS INTENDED TO OR WILL LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 11.1 (INDEMNIFICATION BY HFB) OR SECTION 11.2 (INDEMNIFICATION BY FIBROGEN), (B) DAMAGES AVAILABLE IN THE CASE OF A PARTY'S FRAUD, GROSS NEGLIGENCE, OR INTENTIONAL MISCONDUCT, OR (C) DAMAGES AVAILABLE TO A PARTY FOR A BREACH BY THE OTHER PARTY OF THE CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 12 (CONFIDENTIALITY), MISAPPROPRIATION OR INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS, OR THE OTHER PARTY'S BREACH OF ITS OBLIGATIONS UNDER SECTION 2.8 (EXCLUSIVITY).

11.5 **Insurance**. Each Party will maintain during the Term and [*] of any Licensed Product for which it is responsible hereunder, and at its cost, reasonable insurance with a reputable solvent insurer against liability and other risks associated with its activities contemplated by this Agreement in an amount appropriate for its business and products of the type that are the subject of this Agreement, and for its obligations under this Agreement; *provided*, *however*, that at a minimum, each Party will maintain, in force beginning at least [*] prior to enrollment of the first subject in a Clinical Trial, product liability insurance policy providing coverage of at least [*]. Each Party will furnish to the other Party evidence of such insurance upon request. Notwithstanding the foregoing, such obligation may be satisfied by a program of self-insurance.

ARTICLE 12
CONFIDENTIALITY

12.1 **Confidentiality; Exceptions**. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, during the Term and for [*] thereafter, the Parties agree that the receiving Party will keep confidential and will not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any information and materials furnished to it by or on behalf of the other Party or any of its Affiliates or generated pursuant to this Agreement (collectively, "**Confidential Information**"). For any Confidential Information that constitutes a trade secret of either Party, the foregoing non-disclosure obligations will continue for as long as such Confidential Information remains a trade secret. Confidential Information of a Party or any of its Affiliates will include all information and materials disclosed by such Party or any of its Affiliates or their respective designees that (a) is marked as "Confidential," "Proprietary," or with similar designation at the time of disclosure or (b) by its nature can reasonably be expected to be considered Confidential Information by the recipient. Know-How disclosed orally will not be required to be identified as such to be considered Confidential Information. The terms of this Agreement and all Licensed Know-How will be deemed to be the Confidential Information of both Parties. All reports delivered by FibroGen to HFB hereunder will be the Confidential Information of FibroGen. On an Option Program-by-Option Program basis, all information and data regarding Option Compounds or Option Products with respect to

an Option Program whether generated before or after the Effective Date, including pursuant to activities contemplated by this Agreement, will be considered Confidential Information of both Parties, with both Parties deemed to be the receiving Party of such Confidential Information during the applicable Option Term, and the exceptions set forth in clauses (a), (d) and (e) below will not apply to such information and data during the Option Term. For the avoidance of doubt, Notwithstanding the foregoing, Confidential Information will not include any information to the extent that it can be established by written documentation by the receiving Party that such information (a) was already known to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), at the time of disclosure, (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party, (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement, (d) was independently developed by the receiving Party as demonstrated by written documentation prepared contemporaneously with such independent development, or (e) was disclosed to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), by a Third Party who had no obligation not to disclose such information to others.

12.2 **Authorized Disclosure**.

(a) **Permitted Disclosure**. Except as expressly provided otherwise in this Agreement, each Party may use and disclose Confidential Information of the other Party solely as follows: (i) under appropriate confidentiality provisions substantially as protective or equivalent to those in this Agreement (but of shorter duration of no less than five (5) years from termination or expiration of the Agreement; provided, that in the case of the Third Parties described in the following clause (C), such terms of confidentiality need extend for no more than two years from the date of disclosure): (A) in connection with the performance of its obligations or as necessary or reasonably useful in the exercise of its rights under this Agreement, including the right to grant licenses or sublicenses as permitted hereunder, (B) to the extent such disclosure is reasonably necessary or reasonably useful in conducting Clinical Trials under this Agreement, or (C) to actual or *bona fide* potential (sub)licensees, acquirers or assignees, collaborators, investment bankers, investors or lenders (including in connection with any royalty factoring transaction), or; (ii) to the extent such disclosure is to a governmental authority as reasonably necessary in filing or prosecuting Patent Right, copyright, and trademark applications in accordance with this Agreement, prosecuting or defending litigation related to this Agreement, complying with applicable governmental regulations with respect to performance under this Agreement (including any disclosure to any securities exchange), obtaining Regulatory Approval or fulfilling post-approval regulatory obligations for the Licensed Compound or Licensed Products, or otherwise required by applicable law; *provided*, *however*, that if a Party is required by applicable law or the rules of any securities exchange or automated quotation system to make any such disclosure of the other Party's Confidential Information then it will, except where impracticable for necessary disclosures (for example, in the event of medical emergency),

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give reasonable advance notice to the other Party of such disclosure requirement and, in each of the foregoing, will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed and will only disclose that Confidential Information that is required to be disclosed; (iii) to advisors (including lawyers and accountants) on a need to know basis, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement, or (iv) to the extent agreed to by the Parties.

(b) **SEC Filings and Other Disclosures**. Either Party may disclose the terms of this Agreement to the extent required to comply with applicable law, including the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent governmental agency in any country in the Territory; *provided*, that such Party will provide the other Party a reasonable opportunity to review such disclosure and reasonably consider the other Party's comments regarding confidential treatment sought for such disclosure, including redaction of financial terms and milestone events. The Parties will use Commercially Reasonable Efforts to conform their respective disclosures made pursuant to this Section 12.2(b) (SEC Filings and Other Disclosures) to the extent allowed under applicable law and the rules of any applicable securities exchange.

(c) **Press Release**. The Parties shall issue the mutually agreed press release set forth on Schedule 12.2(c) hereto (Initial Press Release) on a mutually agreed upon date following the Effective Date. Other than public disclosure permitted by Section 12.2(a) (Permitted Disclosures), Section 12.2(b) (Disclosure to SEC), this Section 12.2(c) (Press Release), and disclosures required by applicable law, the Parties agree that the portions of any other news release or other public announcement relating to this Agreement or the performance hereunder that would disclose information that is not already in the public domain, must first be reviewed and approved by both Parties (with such approval not to be unreasonably withheld or delayed). After a disclosure or other public announcement has been reviewed and approved by both Parties under this Section 12.2 (Authorized Disclosure), either Party may make subsequent public disclosures reiterating such information without having to obtain the other Party's prior consent and approval, so long as the information in such disclosure or other public announcement remains true, correct, and the most current information with respect to the subject matters set forth therein.

12.3 **Prior Agreement**. This Agreement supersedes the Existing Nondisclosure Agreement. All confidential information exchanged between the Parties under the Existing Nondisclosure Agreement will be deemed Confidential Information of the disclosing Party and will be subject to the terms of this Agreement.

12.4 **Residual Knowledge**. Notwithstanding any provision to the contrary set forth in this Agreement, use or disclosure by an authorized representative of a receiving Party of Confidential Information that is knowledge, technique, experience, or Know-How retained in the unaided memory of such authorized representative of the receiving Party that had authorized access to such Confidential Information ("**Residual Knowledge**") will not violate the confidentiality, non-use and non-disclosure obligations set forth in this Agreement, *provided* that such authorized representative did not intentionally memorize such Confidential Information for use outside of this Agreement. Any use made by the receiving Party of any such Residual Knowledge is on an "as is, where is" basis, with all

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faults and all representations and warranties disclaimed and at its sole risk.

12.5 **Publications**. FibroGen will be the exclusive owner of any publication rights with respect to the Licensed Compounds and Licensed Products in the Territory, and will have the sole and exclusive right to publish on such Licensed Compounds and Licensed Products in the Territory without the prior consent of HFB, *provided* that no such publication may include the Confidential Information of HFB. Prior to [*] with respect to an Option Program, neither Party will make any academic, scientific or medical publication or academic, scientific or medical public presentation related to such Option Program, any Option Compound or Option Product with respect to such Option Program or any activities conducted pursuant to this Agreement with respect to such Option Program, in each case, without the JSC's prior written consent.

ARTICLE 13
TERM AND TERMINATION

13.1 **Term**. This Agreement will commence on the Effective Date and, unless earlier terminated pursuant to this Article 13 (Term and Termination), will expire on a Licensed Product-by-Licensed Product and country-by-country basis at the end of the applicable Royalty Term (the "**Term**"). Following the end of the Term for the Licensed Products and in such country by expiration (but not termination), the license granted to FibroGen under Section 2.1 (License to FibroGen) will become perpetual, irrevocable, fully paid-up, and royalty-free.

13.2 **Termination by FibroGen**. FibroGen will have the right for any or no reason to terminate this Agreement in its entirety or on a Licensed Program-by-Licensed Program basis ("**Terminated Licensed Program**"), which for the avoidance of doubt, terminates FibroGen's license and rights for any Licensed Products Directed to the applicable Exclusive Target, upon [*] prior written notice to HFB ("**Termination for Convenience Notice Period**"). Effective upon receipt by HFB of such written notice to terminate from FibroGen and upon written notice to FibroGen, HFB may elect in their sole discretion to have such termination be effective on a Licensed Program-by-Licensed Program basis at any time during the Termination for Convenience Notice Period.

13.3 **Termination for Cause**.

(a) **By FibroGen**. In the event of a material breach of this Agreement by HFB, which material breach remains uncured for [*] measured from the date of written notice of such material breach by FibroGen that identifies the material breach and the actions or conduct that FibroGen considers would be an acceptable cure of such material breach, FibroGen may terminate this Agreement in whole or with respect to those Licensed Programs (and all Licensed Products that include such Licensed Compound) to which such material breach relates at any time during the Term of this Agreement by written notice of termination to HFB.

(b) **By HFB**. In the event of a material breach of this Agreement by FibroGen, which material breach remains uncured for [*] measured from the date of written notice of such material breach by HFB that identifies the material breach and the actions or conduct that it considers would be an acceptable cure of such material breach, HFB may terminate this

Agreement in part with respect to those Licensed Programs (and all Licensed Products that include such Licensed Compound) to which such material breach relates or the Agreement as a whole at any time during the Term of this Agreement by written notice of termination to FibroGen.

(c) **Disputes Regarding Material Breach**. In case the Party (the "**Defaulting Party**") alleged by the other Party (the "**Non-Defaulting Party**") to have committed a material breach under Section 13.3(a) (By FibroGen) or Section 13.3(b) (By HFB) disputes occurrence of such material breach, then the issue of whether the Non-Defaulting Party may properly terminate this Agreement on expiration of the applicable cure period will be resolved in accordance with Article 14 (Dispute Resolution). If as a result of such dispute resolution process, it is determined that the Defaulting Party committed a material breach of this Agreement by a final written determination of the arbitrators, then such termination will be effective as of such final determination. If the Parties in good faith dispute whether a material breach has been cured prior to the final written determination of the arbitrators, then such dispute will also be determined in such arbitration in accordance with Article 15 (Dispute Resolution). This Agreement will remain in full force and effect during the pendency of any such dispute resolution proceeding and the cure periods set forth in Section 13.3(a) (By FibroGen) or Section 13.3(b) (By HFB), as applicable, will be [*], such proceeding will not suspend any obligations of either Party hereunder, and each Party will use reasonable efforts to mitigate any damage. If as a result of such dispute resolution proceeding it is determined that the Defaulting Party did not commit such material breach (or such material breach was cured in accordance with this Section 13.3 (Termination for Cause)), then no termination will be effective, and this Agreement will continue in full force and effect.

13.4 **Termination for Bankruptcy**.

(a) **Bankruptcy**. Either Party may terminate this Agreement in its entirety upon providing written notice to the other Party upon a Bankruptcy Event of the other Party.

(b) **Bankruptcy Laws**. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code, as amended (the "**Bankruptcy Code**"), or similar laws of any applicable state, the U.S., or foreign jurisdiction (collectively, the "**Bankruptcy Laws**"), licenses of rights to "intellectual property" as defined under the Bankruptcy Laws and are to include trademarks and trade names. In the event the Bankruptcy Laws in a jurisdiction outside the US do not have provisions similar to those in Section 365(n) of the Bankruptcy Code, the Parties acknowledge and agree that it is the intention of the Parties to incorporate such rights and remedies herein and the non-bankrupt Party may elect for this Agreement to be treated in accordance with Section 365(n) of the Bankruptcy Code in such jurisdiction.

(c) If a Bankruptcy Event occurs with respect to a Party during the Term under any Bankruptcy Laws:

(i) unless and until this Agreement is rejected as provided pursuant to such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee under the Bankruptcy Code or other applicable Bankruptcy Laws) shall perform all of the obligations in this Agreement intended to be performed by such Party.

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(ii) if this Agreement is rejected as provided for under the Bankruptcy Laws, and the non-bankrupt Party elects to retain its rights hereunder as provided for under the Bankruptcy Laws, then the Party subject to such Bankruptcy Event (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee under the Bankruptcy Code or other applicable Bankruptcy Laws), shall provide to the non-bankrupt Party copies (or complete access to, as appropriate) of all Patent Rights and other information necessary for the non-bankrupt Party to prosecute, maintain and enjoy its rights under the terms of this Agreement. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Laws) in a Bankruptcy Event of the Party under the Bankruptcy Laws. In particular, it is the intention and understanding of the Parties to this Agreement that the rights granted to the Parties under this Section 13.4 (Termination for Bankruptcy) are essential to the Parties' respective businesses and the Parties acknowledge that damages are not an adequate remedy. The Parties acknowledge and agree that the payments made under Section 8.4 (Royalties) shall (A) constitute royalties within the meaning of Section 365(n) of the Bankruptcy Code or any analogous provisions under other Bankruptcy Laws, and (B) relate to licenses of Intellectual Property. In the event that this Agreement is rejected or deemed rejected under the Bankruptcy Laws, the Party subject to such Bankruptcy Event (or its Representative, assignee or trustee in such case or proceeding) shall provide written notice thereof to the other Party. The Parties waive all rights to object to the application of Section 365(n) of the Bankruptcy Code or similar provisions under Bankruptcy Laws.

13.5 **Termination for Patent Challenge**. If FibroGen, its Affiliates or Sublicensees directly or indirectly and voluntarily commences or participates in any Patent Challenge, HFB shall have the right to give a written "**Patent Challenge Notice**" to FibroGen. Within [*] following FibroGen's receipt of the Patent Challenge Notice, and, unless FibroGen or its applicable Affiliate or Sublicensee withdraws or causes to be withdrawn all such Patent Challenges within such [*] following receipt of the Patent Challenge Notice, at HFB's sole discretion, HFB may convert the licenses granted pursuant to Section 2.1 (Licenses to FibroGen) with respect to such Licensed Program to non-exclusive licenses and terminate FibroGen's obligations under Section 2.8 (Exclusivity) with respect to such Licensed Program, or terminate this Agreement with respect to such Licensed Program, if permitted by applicable law.

13.6 **Effects of Termination**. Upon termination of this Agreement with respect to a Licensed Product or, with respect to a Licensed Program, all Licensed Compounds and Licensed Products that are the subject of such Licensed Program (each a "**Terminated Licensed Product**") shall terminate, and (in addition to any other rights and obligations under this Article 13 (Term and Termination)):

(a) **Licenses and Options**. As of the effective date of termination of this Agreement with respect to a Terminated Licensed Program, all licenses and all other rights granted by HFB to FibroGen under Section 2.1 (License to FibroGen) with respect to such Terminated Licensed Program will terminate. In the event of termination of an Option Program, all

outstanding License Options granted by HFB to FibroGen under Section 2.9(a) (Grant of Options) for such Option Program will terminate and, if this Agreement is terminated in the entirety, all outstanding License Options shall terminate pursuant to Section 2.9(f) (Termination of Option).

(b) **Reversion Rights**. At HFB's written request, FibroGen hereby agrees to [*] which FibroGen will and hereby does as of the effective date of termination:

(i) grant HFB, with respect to each Terminated Licensed Product, a non-exclusive, royalty-bearing, worldwide license (with the right to sublicense in multiple tiers) to all FibroGen Arising Technology (with reasonable and customary comment and step-in rights for HFB), and FibroGen's rights in the Joint Arising Technology, [*] for the Exploitation of such Terminated Licensed Product and, if not terminated by HFB for FibroGen's material breach in accordance with Section 13.3(b) (By HFB), [*];

(ii) effect a technology transfer to facilitate HFB's practice of such license;

(iii) [*]

(iv) [*]

[*]

In addition, if HFB reasonably believes that HFB requires a non-exclusive license under FibroGen Background Technology in order to Exploit such Terminated Licensed Product and provides a written request to FibroGen, FibroGen shall (to the extent it is permitted to do so) negotiate in good faith with HFB for commercially reasonable terms under which FibroGen will grant to HFB such license.

(c) **Ongoing Clinical Trials**.

(i) **Transfer to HFB**. If, as of the effective date of termination of this Agreement with respect to a Licensed Product, FibroGen or its Affiliates are conducting any Clinical Trials for such Licensed Product, then, at HFB's election on a Clinical Trial-by-Clinical Trial basis, FibroGen will either (A) reasonably cooperate, and ensure that its Affiliates reasonably cooperate, with HFB to transfer the conduct of such Clinical Trial (including any data, trial master files and clinical and safety databases) to HFB or its designees, or (B) subject to FibroGen's approval, continue to conduct such Clinical Trial, at HFB's cost (unless this Agreement is terminated by HFB pursuant to Section 13.3 (Termination for Cause) [*] for the conduct of such transferred Clinical Trial for such Licensed Products after the transfer date.

(ii) **Wind-Down**. If HFB does not elect to assume control of any such Clinical Trials for any Licensed Product, then FibroGen will, in accordance with accepted pharmaceutical industry norms and ethical practices, wind-down the conduct of any such Clinical Trial in an orderly manner. FibroGen will be responsible for any costs and expenses associated with such wind-down (unless this Agreement is terminated by FibroGen pursuant to Section 13.3 (Termination for Cause), in which case HFB will bear all such costs and expenses).

(d) **Return of Confidential Information**. As of the effective date of termination of this Agreement with respect to each Licensed Program, each Party will promptly return to the other Party (or as directed by such other Party destroy and certify to such other Party in writing as to such destruction) all of such other Party's Confidential Information relating to such Terminated Licensed Program and the Exclusive Target to which such Terminated Licensed Program was Directed To provided by or on behalf of such other Party hereunder that is in the possession or control of such Party (or any of its Affiliates, Sublicensees or subcontractors), except that such Party will have the right to retain one copy of intangible Confidential Information of such other Party for legal purposes. Notwithstanding any provision to the contrary set forth in this Agreement, the receiving Party of any Confidential Information will not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information.

(e) **Other Remedies**. Termination or expiration of this Agreement for any reason will not release either Party from any liability or obligation that already has accrued prior to such expiration or termination, nor affect the survival of any provision hereof to the extent it is expressly stated to survive such termination. Termination or expiration of this Agreement for any reason will not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder or that may arise out of or in connection with such termination or expiration.

13.7 **Survival**. Termination or expiration of this Agreement will not affect rights or obligations of the Parties under this Agreement that have accrued prior to the effective date of termination or expiration of this Agreement. Notwithstanding any provision to the contrary, the following provisions will survive and apply after expiration or termination of this Agreement in its entirety: Article 1 (Definitions), Section 4.6 (Development Records), Section 8.4 (Royalties) (but only with respect to Net Sales made during the Term), Section 8.7 (Books and Records; Audit Rights) (but only with respect to payment obligations accruing during the Term and only for a period of three years after expiration or termination), Section 8.9 (Late Payments) (but only with respect to payment obligations accruing during the Term), Section 9.1 (Background Technology), Section 9.2 (Ownership), Section 10.5 (No Other Representations or Warranties), Article 11 (Indemnification), Article 12 (Confidentiality), Section 13.1 (Term), Section 13.6 (Effects of Termination), Section 13.6(e) (Other Remedies), this Section 13.7 (Survival), Article 14 (Dispute Resolution), and Article 15 (Miscellaneous). In addition, the other applicable provisions of Article 8 (Financials) will survive such expiration or termination of this Agreement in its entirety to the extent required to make final reimbursements, reconciliations or other payments incurred or accrued prior to the date of termination or expiration. For any surviving provisions requiring action or decision by the JSC or an Executive Officer, each Party will appoint representatives to act as its JSC members or Executive Officer, as applicable. All provisions not surviving in accordance with the foregoing will terminate upon the effective date of expiration or termination of this Agreement and be of no further force and effect.

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ARTICLE 14
DISPUTE RESOLUTION

14.1 **Dispute Resolution**.

(a) In the event of any dispute between the Parties under this Agreement, the Parties will first attempt in good faith to resolve such dispute by negotiation and consultation between themselves. In the event that such dispute is not resolved on an informal basis within fifteen (15) Business Days, either Party may refer the matter to the Executive Officers of the Parties for attempted resolution, whereupon the Executive Officers will confer and attempt in good faith to resolve such dispute by negotiation and consultation for a thirty (30) day period following such referral.

(b) If the Executive Officers do not resolve such dispute within such thirty (30) day period, either Party may at any time thereafter proceed within thirty (30) days thereafter to binding arbitration in accordance with this Section 14.1 (Dispute Resolution). If a Party so proceeds, it shall submit such dispute to arbitration with [*] (the "**Arbitration Forum**"), and notify the other Party, in writing, of such dispute. Prior to the arbitrators being selected, each Party may seek from any court having jurisdiction a temporary injective or provisions relief necessary to protect the rights of the Party. The right and obligation to arbitrate under this Section 14.1(b) (Dispute Resolution) shall extend to any claims by or against the Parties and their respective Affiliates and any agents, principals, officers, directors, or employees of either of the Parties or their respective Affiliates. Within thirty (30) days after receipt of such notice, the Parties will each designate in writing an arbitrator to resolve the dispute. Both of the designated arbitrators will elect a third arbitrator; *provided*, *however*, that if the designated arbitrators cannot agree on a third arbitrator within twenty (20) days after both arbitrators have been designated, the third arbitrator will be selected by the Arbitration Forum. Each arbitrator will be an individual with biotechnology and/or pharmaceutical industry legal experience, and will not be and will never have been an Affiliate, employee, consultant, officer, director or stockholder of any Party.

(c) Within thirty (30) days after the designation of the arbitrators, the arbitrators and the Parties will meet, at which time the Parties will be required to set forth in writing all disputed issues and a proposed ruling on the merits of each such issue. The Parties will have the right to be represented by counsel. Except as provided herein, the arbitration will be governed by the [*] Arbitration Rules. The arbitration proceedings will be conducted in English.

(d) The arbitrators will use their best efforts to rule on each disputed issue within thirty (30) days after the completion of any hearings associated with the arbitration. Either party may apply to the arbitrators seeking injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. The arbitrators may enter early or summary disposition of some or all issues, after the Parties have made reasonable submissions on those issues. The determination of the arbitrators as to the resolution of any dispute will be binding and conclusive upon all Parties and their respective Affiliates and any agents, principals, officers, directors, or employees of either of the Parties and their respective Affiliates. The arbitrators will issue a written award that contains a reasoned opinion setting forth the findings of fact and conclusions upon which the award is based, including the

calculation of any damages awarded. A judgment on any award rendered by the arbitrators may be entered in any court having jurisdiction thereof.

(e) The (i) attorneys' fees of the Parties in any arbitration, (ii) fees of the arbitrators and (iii) costs and expenses of the arbitration will be allocated among the Parties as determined by the arbitrators, who shall have discretion to make this determination equitably, taking into account (A) which party prevailed, in the view of the arbitrators, (B) whether any party caused unnecessary delay, burden or expense, and (C) the reasonability of the attorneys' fees, costs, and expenses requested.

(f) Any arbitration pursuant to this Section 14.1 (Dispute Resolution) will be conducted in [*].

(g) The Parties intend that each award by an arbitrators in an arbitration pursuant to this Section 14.1 (Dispute Resolution) will be rendered in accordance with the United Nations Convention on the Recognition and Enforcement of Arbitral Awards and will be enforceable in accordance therewith.

(h) The arbitrators will take appropriate actions to prevent, remediate, and/or sanction abusive conduct or other actions that threaten to undermine the fair, speedy and cost-effective resolution of the matter.

(i) Except to the extent necessary to confirm an award or as may be required by law, neither Party nor an arbitrator may disclose the existence, content, or results or any arbitration without the prior written consent of both Parties.

(j) In addition, during the pendency of any dispute under this Agreement initiated before the end of any applicable cure period under Section 13.3 (Termination for Cause), (i) this Agreement will remain in full force and effect, (ii) the provisions of this Agreement relating to termination for material breach will not be effective, (iii) the time periods for cure under 13.3 (Termination for Cause) as to any termination notice given prior to the initiation of the proceeding will be tolled, and (iv) neither Party will issue a notice of termination pursuant to this Agreement based on the subject matter of the proceeding (and no effect will be given to previously issued termination notices), until the arbitrators have confirmed the existence of the facts claimed by a Non-Defaulting Party to be the basis for the asserted material breach.

14.2 **Injunctive Relief**. Nothing in this Article 14 (Dispute Resolution) will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any proceeding if necessary to protect the interests of such Party or to preserve the status quo pending the proceeding. Therefore, in addition to its rights and remedies otherwise available at law, including the recovery of damages for breach of this Agreement, upon an adequate showing of material breach, and without further proof of irreparable harm other than this acknowledgement, such Non-Defaulting Party will be entitled to seek (a) immediate equitable relief, specifically including both interim and permanent restraining orders and injunctions, and (b) such other and further equitable relief as the court may deem proper under the circumstances. For clarity, nothing in this Section 14.2 (Injunctive Relief) will otherwise limit a Defaulting Party's opportunity to cure a material breach as permitted in

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accordance with 13.3 (Termination for Cause).

ARTICLE 15
MISCELLANEOUS

15.1 **Entire Agreement; Amendment**. This Agreement, including the Schedules hereto, set forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings between the Parties existing as of the Effective Date with respect to the subject matter hereof, including the Existing Nondisclosure Agreement as set forth in Section 12.3 (Prior Agreement). In the event of any inconsistency between any plan hereunder and this Agreement, the terms of this Agreement will prevail. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement will be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

15.2 **Force Majeure**. Neither Party will be held liable to the other Party nor be deemed to have breached this Agreement for failure or delay performing any obligation under this Agreement to the extent that such failure or delay is caused by or results from acts of God, embargoes, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotions, strikes, lockouts, or other labor disturbances (other than strikes, lockouts, or labor disturbances involving a Party's own employees), government actions, fire, earthquakes, floods, epidemics, pandemics, or quarantines ("**Force Majeure**") and for so long as such failure or delay continues to be caused by or result from such Force Majeure event. The Parties agree the effects of the COVID-19 pandemic that is ongoing as of the Effective Date may be invoked as a Force Majeure for the purposes of this Agreement even though the pandemic is ongoing to the extent those effects are not reasonably foreseeable by the Parties as of the Effective Date. The affected Party will notify the other Party in writing of any Force Majeure circumstances that may affect its performance under this Agreement as soon as reasonably practical, will provide a good faith estimate of the period for which its failure or delay in performance under the Agreement is expected to continue based on currently available information, and will undertake reasonable efforts necessary to mitigate and overcome such Force Majeure circumstances and resume normal performance of its obligations hereunder as soon a reasonably practicable under the circumstances. If the Force Majeure circumstance continues, then the affected Party will update such notice to the other Party [*], to provide updated summaries of its mitigation efforts and its estimates of when normal performance under the Agreement will be able to resume.

15.3 **Notices**. Any notice required or permitted to be given under this Agreement will be in writing, will specifically refer to this Agreement, and will be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 15.3 (Notices), and will be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by a reputable

international expedited delivery service, (b) five (5) Business Days after mailing, if mailed by first class certified or registered mail, postage prepaid, return receipt requested, or (c) by email, if confirmed by the intended recipient. This Section 15.3 (Notices) is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

If to HFB:	HiFiBiO Therapeutics Room 303, Third Floor, St. George's Building 2 Ice House Street, Central, Hong Kong Attention: [*] Email: [*]
With a copy to (which will not constitute notice):	HiFiBiO Therapeutics 237 Putnam Avenue Cambridge, MA, 02139 Attention: [*] Email: [*]
and:	Foley Hoag Seaport West 155 Seaport Boulevard Boston, Massachusetts 02210-2600 Attention: [*] Email: [*]
If to FibroGen:	FibroGen, Inc. 409 Illinois Street San Francisco, CA 94158 Attention: [*] Email: [*]
With a copy to (which will not constitute notice):	FibroGen, Inc. 409 Illinois Street San Francisco, CA 94158 Attention: [*] Email: [*]
and:	Ropes & Gray 1900 University Avenue, 6th Floor East Palo Alto, CA 94303 Attention: [*] Email: [*]

[*] = 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.

15.4 **No Strict Construction; Headings**. This Agreement has been prepared jointly and will not be strictly construed against either Party. Ambiguities, if any, in this Agreement will not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

15.5 **Interpretation**. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation," (c) the word "will" will be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person or entity will be construed to include the person's or entity's successors and assigns, (f) the words "herein," "hereof," and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Schedules will be construed to refer to Sections or Schedules of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or," and (l) references to any Sections include Sections and subsections that are part of the related Section (*e.g.*, a section numbered "Section 2.2" would be part of "Section 2", and references to "Section 2.2" would also refer to material contained in the subsection described as "Section 2.2(a)"). Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation

of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.

15.6 **Assignment**. Neither this Agreement nor any interest hereunder will be assignable by either Party without the prior written consent of the other Party, *provided* that (and notwithstanding anything in this Agreement to the contrary) either Party may, without such consent, assign this Agreement and its rights and obligations hereunder in whole to (a) to the successor in connection with a Change of Control of such Party, or (b) to a Third Party that acquires, by or otherwise in connection with a merger, sale of assets, or otherwise, all or substantially all of the business of the assigning Party related to the subject matter of this Agreement. Additionally, FibroGen may, without such consent, assign this Agreement and its rights and obligations hereunder in whole to any Affiliate of FibroGen. Each Party will promptly notify the other Party of any assignment or transfer under the provisions of this Section 15.6 (Assignment). This Agreement will be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein will be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.6 (Assignment) will be null, void and of no legal effect.

15.7 **Change of Control**. Each Party will notify the other Party in writing promptly (and in any event within [*] following the execution of a definitive agreement by the Party, its Affiliates or its equity holders that results in a Change of Control of the Party. Notwithstanding anything to the contrary in this Agreement, if during the Term HFB undergoes a Change of Control with a Third Party, and at such time such Third Party is [*] or is engaged in activities that would otherwise constitute a breach of Section 2.8(a) (Exclusivity Covenant), following the effective date of such Change of Control, at FibroGen's election, the JSC and any subcommittees shall be dissolved (to the extent then in-effect).

15.8 **Performance by Affiliates**. Each Party may perform any obligations and exercise any right hereunder through any of its Affiliates, *provided* that such Party will remain primarily responsible for the other Party hereunder. Each Party hereby guarantees the performance by any of its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement will be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

15.9 **Further Actions**. Each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

15.10 **Severability**. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by the arbitrators or by any court of competent jurisdiction from which no

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appeal can be or is taken, then the provision will be considered severed from this Agreement and will not serve to invalidate any remaining provisions hereof. The Parties will make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering into this Agreement may be realized.

15.11 **No Waiver**. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

15.12 **Independent Contractors**. Each Party will act solely as an independent contractor, and nothing in this Agreement will be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein will be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

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

15.14 **Choice of Law**. This Agreement will be governed by, and enforced and construed in accordance with, the laws of the State of Delaware, without regard to its conflicts of law provisions.

[Signature Page Follows]

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IN WITNESS WHEREOF, the Parties have executed this Agreement by their duly authorized representatives as of the Effective Date.

HIFIBIO (HK) LIMITED (D.B.A. HIFIBIO THERAPEUTICS)	**FIBROGEN, INC.**
By:/s/ Liang Schweizer	By:/s/ Enrique Conterno
Name:Liang Schweizer, Ph. D.	Name:Enrique Conterno
Title:Chief Executive Officer	Title:Chief Executive Officer

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SCHEDULE 1.87

[*]

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SCHEDULE 1.89

Licensed Patent Rights

[*]

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SCHEDULE 1.101

Option Data Package

- [*]

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Option Package for Replacement Program

To be determined by the parties in reasonable. [*].

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SCHEDULE 2.7(a)

Initial Technology Transfer

[*]

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SCHEDULE 4.1

Development Plan

[*]

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SCHEDULE 4.2

Work Plans

[*]

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SCHEDULE 10.2

Disclosure Schedule

- [*]

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SCHEDULE 10.3(e)

Negative Events

[*]

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SCHEDULE 12.2(c)

Initial Press Release

FibroGen and HiFiBiO Announce Transformative Partnership to Advance Next-Generation Therapies for Patients with Cancer and Autoimmune Disease

- *FibroGen Exclusively Licenses HiFiBiO's Galectin-9 Program, and Obtains an Exclusive Option to their CXCR5 and CCR8 Programs*
- *Transformative Transaction for FibroGen's Early-stage Pipeline*
- *HiFiBiO to Receive $25 Million Upfront, and Up to a Total of $1.1B in Additional Milestone Payments Across All Three Programs, Plus Royalties*

SAN FRANCISCO, CA and CAMBRIDGE, MA, June 17, 2021 (GLOBE NEWSWIRE) – FibroGen, Inc. (Nasdaq: FGEN) and HiFiBiO Therapeutics, a private, multinational clinical-stage biotherapeutics company with expertise in immune modulation and single cell science announced a partnership covering three HiFiBiO programs.

"We are very pleased to add the HiFiBiO drug candidates to our pre-clinical development pipeline," said Enrique Conterno, Chief Executive Officer, FibroGen. "With the addition of up to three programs in the immuno-oncology and autoimmune space, we have the potential to transform our early development pipeline."

"The FibroGen partnership represents significant validation of our Drug Intelligent Science (DIS™) approach and deep expertise in disease biology and translation science," said Liang Schweizer, Ph.D., Chief Executive Officer, HiFiBiO. "As another successful showcase of our open innovation approach, we look forward to working closely with FibroGen, an exciting, growing biopharmaceutical company."

Under the terms of the agreement, FibroGen will make a $25 million upfront payment to HiFiBiO, as well as payments upon option exercise. In addition, HiFiBiO may receive up to a total of an additional $1.1B in future option, clinical, regulatory, and commercial milestone payments across all three programs. HiFiBiO will also be eligible to receive royalties based upon worldwide net sales.

FibroGen exclusively licensed all products in the Galectin-9 program and will have sole right to develop them worldwide. The lead product candidate in the Galectin-9 program is expected to enter clinical development in the first quarter of 2023. FibroGen has also obtained exclusive options to license all product candidates in HiFiBiO's CXCR5 and CCR8 programs. Each option may be independently exercised following delivery of program-specific data to be generated by HiFiBiO. If an option is exercised, FibroGen will have the sole right to develop products from that program worldwide. The lead product candidates from the CXCR5 and CCR8 programs are expected to enter clinical development by the middle of 2023.

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“We look forward to a productive partnership with HiFiBiO, a leader in the field of single-cell science for antibody discovery and translational medicine,” said Mark Eisner, M.D, M.P.H, Chief Medical Officer, FibroGen. “We are excited to bring the Galectin-9 antibody program into the FibroGen portfolio. As Galectin 9 plays a role in suppressing the anti-tumor immune response in both myeloid malignancies and solid tumors, we believe this antibody candidate from HiFiBiO can advance the treatment of cancer in combination with chemotherapy or other immuno-oncology agents. The exclusive option to access projects directed to CXCR5 and CCR8 provides additional opportunities to expand our therapeutic area focus on oncology and immunology. These are both important biological targets playing clear roles in autoimmune disease and cancer.”

About FibroGen
FibroGen, Inc. is a biopharmaceutical company committed to discovering, developing, and commercializing a pipeline of first-in-class therapeutics. The Company applies its pioneering expertise in hypoxia-inducible factor (HIF) and connective tissue growth factor (CTGF) biology to advance innovative medicines for the treatment of unmet needs. The Company is currently developing and commercializing roxadustat, an oral small molecule inhibitor of HIF prolyl hydroxylase activity, for anemia associated with chronic kidney disease (CKD). Roxadustat is also in clinical development for anemia associated with myelodysplastic syndromes (MDS) and for chemotherapy-induced anemia (CIA). Pamrevlumab, an anti-CTGF human monoclonal antibody, is in clinical development for the treatment of locally advanced unresectable pancreatic cancer (LAPC), Duchenne muscular dystrophy (DMD), and idiopathic pulmonary fibrosis (IPF). For more information, please visit www.fibrogen.com.

About HiFiBiO Therapeutics
HiFiBiO Therapeutics is transforming the field of immunotherapy by combining proprietary single-cell profiling technologies with advanced data intelligence and deep knowledge of immune system biology. This approach enables the development of novel antibody therapies that are paired with biomarkers to predict patient response. HiFiBiO Therapeutics is working actively to address unmet medical needs around the world through its own innovative pipeline programs and open-innovation partnerships with world-renowned industry and academic researchers. The company’s strong global footprint features cutting-edge laboratories on three continents, in Cambridge, Mass., Paris, Shanghai, and Hong Kong. To learn more, please visit www.hifibio.com.

Forward-Looking Statements
This release contains forward-looking statements regarding our strategy, future plans and prospects, including statements regarding the development and commercialization of the company’s product candidates, the potential safety and efficacy profile of our product candidates, our clinical programs and regulatory events, and those of our partners. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as “may,” “will”, “should,” “on track,” “could,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “continue” and similar words, although some forward-looking statements are expressed differently. Our actual results may differ materially from those indicated in these forward-looking statements due to risks and

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uncertainties related to the continued progress and timing of our various programs, including the enrollment and results from ongoing and potential future clinical trials, and other matters that are described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and our Quarterly Report on Form 10-Q for quarter ended March 31, 2021 filed with the Securities and Exchange Commission (SEC), including the risk factors set forth therein. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and we undertake no obligation to update any forward-looking statement in this press release, except as required by law.

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Exhibit 21.1

List of Subsidiaries of FibroGen, Inc.

Subsidiaries	**Incorporation**
Beijing Falikang Pharmaceutical Co., Ltd.	China
FibroGen (China) Medical Technology Development Co., Ltd.	China
FibroGen China Anemia Holdings, Ltd.	Cayman Islands
FibroGen Europe Oy	Finland
FibroGen International (Cayman) Limited	Cayman Islands
FibroGen International (Hong Kong) Limited	Hong Kong
FibroGen INTL LLC	Delaware, USA
Skin Sciences, Inc.	Delaware, USA

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: August 9, 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: August 9, 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 June 30, 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: August 9, 2021

In Witness Whereof, the undersigned have set their hands hereto as of the 9th day of August 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.