

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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

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
(State or Other Jurisdiction of
Incorporation or Organization)

409 Illinois Street
San Francisco, CA
(Address of Principal Executive Offices)

77-0357827
(I.R.S. Employer
Identification No.)

94158
(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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

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

The number of shares of common stock outstanding as of October 31, 2023 was 98,340,219.

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FIBROGEN, INC.
PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 120,914	\$ 155,700
Short-term investments	130,426	266,308
Accounts receivable, net (\$22,916 and \$12,088 from related parties)	31,694	16,299
Inventories	40,696	40,436
Prepaid expenses and other current assets	40,378	14,083
Total current assets	364,108	492,826
Restricted time deposits	2,072	2,072
Long-term investments	—	4,348
Property and equipment, net	14,512	20,605
Equity method investment in unconsolidated variable interest entity	4,534	5,061
Operating lease right-of-use assets	71,248	79,893
Other assets	3,952	5,282
Total assets	\$ 460,426	\$ 610,087
Liabilities, redeemable non-controlling interests and deficit		
Current liabilities:		
Accounts payable	\$ 19,220	\$ 30,758
Accrued and other current liabilities (\$29,157 and \$63,886 to a related party)	170,986	219,773
Deferred revenue (\$5,482 and \$9,259 to related parties)	7,325	12,739
Operating lease liabilities, current	11,884	10,292
Total current liabilities	209,415	273,562
Product development obligations	16,942	16,917
Deferred revenue, net of current (\$4,671 and \$31,044 to a related party)	154,206	185,722
Operating lease liabilities, non-current	70,035	79,593
Senior secured term loan facilities, non-current	71,666	—
Liability related to sale of future revenues, non-current	49,109	49,333
Other long-term liabilities (\$668 and \$0 to a related party)	4,255	6,440
Total liabilities	575,628	611,567
Commitments and Contingencies (Note 12)		
Redeemable non-controlling interests	21,480	—
Stockholders' deficit:		
Preferred stock, \$0.01 par value; 125,000 shares authorized; no shares issued and outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock, \$0.01 par value; 225,000 shares authorized at September 30, 2023 and December 31, 2022; 98,339 and 94,166 shares issued and outstanding at September 30, 2023 and December 31, 2022	983	942
Additional paid-in capital	1,634,459	1,541,019
Accumulated other comprehensive loss	(6,923)	(5,720)
Accumulated deficit	(1,785,688)	(1,557,688)
Total stockholders' deficit attributable to FibroGen	(157,169)	(21,447)
Nonredeemable non-controlling interests	20,487	19,967
Total deficit	(136,682)	(1,480)
Total liabilities, redeemable non-controlling interests and deficit	\$ 460,426	\$ 610,087

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue:				
License revenue (includes \$0, \$0, \$0 and \$22,590 from a related party)	\$ 2,649	\$ —	\$ 9,649	\$ 22,590
Development and other revenue (includes \$2,358, \$1,414, \$5,821, and \$8,419 from a related party)	6,775	2,453	15,825	19,672
Product revenue, net (includes \$26,463, \$14,914, \$68,347 and \$50,873 from a related party)	29,390	17,359	77,439	59,495
Drug product revenue, net (from a related party)	1,320	(4,077)	17,701	4,610
Total revenue	<u>40,134</u>	<u>15,735</u>	<u>120,614</u>	<u>106,367</u>
Operating costs and expenses:				
Cost of goods sold	4,243	4,308	13,441	15,355
Research and development	61,194	75,182	231,158	235,163
Selling, general and administrative	25,573	29,902	91,029	90,722
Restructuring charge	12,606	—	12,606	—
Total operating costs and expenses	<u>103,616</u>	<u>109,392</u>	<u>348,234</u>	<u>341,240</u>
Loss from operations	<u>(63,482)</u>	<u>(93,657)</u>	<u>(227,620)</u>	<u>(234,873)</u>
Interest and other, net				
Interest expense	(5,022)	(84)	(10,464)	(321)
Interest income and other income (expenses), net	4,296	1,798	7,984	6,672
Total interest and other, net	<u>(726)</u>	<u>1,714</u>	<u>(2,480)</u>	<u>6,351</u>
Loss before income taxes	<u>(64,208)</u>	<u>(91,943)</u>	<u>(230,100)</u>	<u>(228,522)</u>
Provision for (benefit from) income taxes	84	114	(77)	250
Investment income in unconsolidated variable interest entity	677	407	2,023	1,293
Net loss	<u>\$ (63,615)</u>	<u>\$ (91,650)</u>	<u>\$ (228,000)</u>	<u>\$ (227,479)</u>
Net loss per share - basic and diluted	\$ (0.65)	\$ (0.98)	\$ (2.35)	\$ (2.43)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	98,245	93,767	96,901	93,431

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)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Net loss	\$ (63,615)	\$ (91,650)	\$ (228,000)	\$ (227,479)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(1,033)	(436)	(3,618)	(28)
Available-for-sale investments:				
Unrealized gain (loss) on investments, net of tax effect	360	20	2,415	(3,155)
Other comprehensive gain (loss), net of taxes	(673)	(416)	(1,203)	(3,183)
Comprehensive loss	<u>(64,288)</u>	<u>(92,066)</u>	<u>(229,203)</u>	<u>(230,662)</u>

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

FIBROGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share data)
(Unaudited)

	For The Three Month Period							Redeemable Non-Controlling Interests (Note 3)
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Nonredeemable Non-Controlling Interests	Total Equity (Deficit)	
	Shares	Amount						
Balance at June 30, 2023	98,204,243	\$ 982	\$ 1,625,067	\$ (6,250)	\$ (1,722,073)	\$ 20,487	\$ (81,787)	\$ 21,480
Net loss	—	—	—	—	(63,615)	—	(63,615)	—
Change in unrealized gain or loss on investments	—	—	—	360	—	—	360	—
Foreign currency translation adjustments	—	—	—	(1,033)	—	—	(1,033)	—
Shares issued from stock plans, net of payroll taxes paid	134,880	1	(84)	—	—	—	(83)	—
Stock-based compensation	—	—	9,476	—	—	—	9,476	—
Balance at September 30, 2023	<u>98,339,123</u>	<u>\$ 983</u>	<u>\$ 1,634,459</u>	<u>\$ (6,923)</u>	<u>\$ (1,785,688)</u>	<u>\$ 20,487</u>	<u>\$ (136,682)</u>	<u>\$ 21,480</u>
Balance at June 30, 2022	93,733,034	\$ 937	\$ 1,509,636	\$ (6,930)	\$ (1,399,863)	\$ 19,967	\$ 123,747	\$ —
Net loss	—	—	—	—	(91,650)	—	(91,650)	—
Change in unrealized gain or loss on investments	—	—	—	20	—	—	20	—
Foreign currency translation adjustments	—	—	—	(436)	—	—	(436)	—
Shares issued from stock plans, net of payroll taxes paid	203,306	2	(995)	—	—	—	(993)	—
Stock-based compensation	—	—	15,585	—	—	—	15,585	—
Balance at September 30, 2022	<u>93,936,340</u>	<u>\$ 939</u>	<u>\$ 1,524,226</u>	<u>\$ (7,346)</u>	<u>\$ (1,491,513)</u>	<u>\$ 19,967</u>	<u>\$ 46,273</u>	<u>\$ —</u>

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

	For The Nine Month Period								Redeemable Non-Controlling Interests (Note 3)
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Nonredeemable Non-Controlling Interests	Total Equity (Deficit)		
	Shares	Amount							
Balance at December 31, 2022	94,166,086	\$ 942	\$ 1,541,019	\$ (5,720)	\$ (1,557,688)	\$ 19,967	\$ (1,480)	\$ —	
Net loss	—	—	—	—	(228,000)	—	(228,000)	—	
Consolidation of Fortis (Note 3)	—	—	—	—	—	520	520	21,480	
Change in unrealized gain or loss on investments	—	—	—	2,415	—	—	2,415	—	
Foreign currency translation adjustments	—	—	—	(3,618)	—	—	(3,618)	—	
Issuance of common stock under ATM Program	2,472,090	24	48,383	—	—	—	48,407	—	
Shares issued from stock plans, net of payroll taxes paid	1,700,947	17	3,586	—	—	—	3,603	—	
Stock-based compensation	—	—	41,471	—	—	—	41,471	—	
Balance at September 30, 2023	<u>98,339,123</u>	<u>\$ 983</u>	<u>\$ 1,634,459</u>	<u>\$ (6,923)</u>	<u>\$ (1,785,688)</u>	<u>\$ 20,487</u>	<u>\$ (136,682)</u>	<u>\$ 21,480</u>	
Balance at December 31, 2021	92,880,533	\$ 929	\$ 1,476,414	\$ (4,163)	\$ (1,264,034)	\$ 19,967	\$ 229,113	\$ —	
Net loss	—	—	—	—	(227,479)	—	(227,479)	—	
Change in unrealized gain or loss on investments	—	—	—	(3,155)	—	—	(3,155)	—	
Foreign currency translation adjustments	—	—	—	(28)	—	—	(28)	—	
Shares issued from stock plans, net of payroll taxes paid	1,055,807	10	(1,583)	—	—	—	(1,573)	—	
Stock-based compensation	—	—	49,395	—	—	—	49,395	—	
Balance at September 30, 2022	<u>93,936,340</u>	<u>\$ 939</u>	<u>\$ 1,524,226</u>	<u>\$ (7,346)</u>	<u>\$ (1,491,513)</u>	<u>\$ 19,967</u>	<u>\$ 46,273</u>	<u>\$ —</u>	

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

FIBROGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2023	2022
Operating activities		
Net loss	\$ (228,000)	\$ (227,479)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	7,653	7,503
Amortization of finance lease right-of-use assets	402	411
Net accretion of premium and discount on investments	(3,654)	1,842
Investment income in unconsolidated variable interest entity	(2,023)	(1,293)
Loss (gain) on disposal of property and equipment	1	(3)
Stock-based compensation	41,471	49,377
Acquired in-process research and development expenses	24,636	—
Non-cash interest expense related to sale of future revenues	5,636	—
Dividend received from unconsolidated variable interest entity	2,255	—
Impairment of investment	1,000	—
Realized loss on sales of available-for-sale securities	271	5
Changes in operating assets and liabilities:		
Accounts receivable, net	(16,283)	983
Inventories	(1,519)	(11,147)
Prepaid expenses and other current assets	(27,393)	8,265
Operating lease right-of-use assets	8,447	7,759
Other assets	962	823
Accounts payable	(14,057)	(5,120)
Accrued and other liabilities	(50,246)	87,167
Operating lease liabilities, current	1,669	715
Deferred revenue	(36,930)	4,509
Accrued interest for finance lease liabilities	(22)	(68)
Operating lease liabilities, non-current	(9,447)	(7,407)
Other long-term liabilities	(1,529)	(10,262)
Net cash used in operating activities	<u>(296,700)</u>	<u>(93,420)</u>
Investing activities		
Purchases of property and equipment	(2,268)	(3,408)
Payment made for acquired in-process research and development asset	—	(35,000)
Proceeds from sale of property and equipment	—	8
Purchases of available-for-sale securities	(157,210)	(97,301)
Cash acquired from consolidation of Fortis	656	—
Proceeds from sales of available-for-sale securities	1,730	7,382
Proceeds from maturities of investments	300,507	216,342
Net cash provided by investing activities	<u>143,415</u>	<u>88,023</u>
Financing activities		
Proceeds from senior secured term loan facilities, net of issuance costs	74,078	—
Cash paid for transaction costs for senior secured term loan facilities	(2,746)	—
Repayments of finance lease liabilities	(128)	(23)
Repayments of lease obligations	(302)	(302)
Cash paid for payroll taxes on restricted stock unit releases	—	(4,562)
Proceeds from issuance of common stock under ATM Program, net of commissions	48,407	—
Proceeds from issuance of common stock under employee stock plans	3,686	2,989
Net cash provided by (used in) financing activities	<u>122,995</u>	<u>(1,898)</u>
Effect of exchange rate change on cash and cash equivalents	(4,496)	(7,968)
Net decrease in cash and cash equivalents	(34,786)	(15,263)
Total cash and cash equivalents at beginning of period	155,700	171,223
Total cash and cash equivalents at end of period	<u>\$ 120,914</u>	<u>\$ 155,960</u>

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 discovering, 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, and connective tissue growth factor to advance innovative medicines for the treatment of anemia and cancer.

Pamrevlumab, a human monoclonal antibody targeting connective tissue growth factor, is in Phase 3 clinical development for the treatment of locally advanced unresectable pancreatic cancer. Pamrevlumab is also in Phase 2/3 development for the treatment of metastatic pancreatic cancer. To date, the Company has retained exclusive worldwide rights for pamrevlumab.

Roxadustat is an oral small molecule inhibitor of HIF prolyl hydroxylase activity. Roxadustat ([®], EVRENZO[™]) is approved in China, Europe, Japan, and numerous other countries for the treatment of anemia in chronic kidney disease for patients who are on dialysis and not on dialysis. Roxadustat is in clinical development for chemotherapy-induced anemia in China.

The Company has a pipeline of late-stage clinical programs as well as preclinical drug candidates at various stages of development that include both small molecules and biologics. FibroGen’s goal is to build a diversified pipeline with novel drugs that will address unmet patient needs with a refined focus in oncology.

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

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

The unaudited condensed consolidated financial statements and related disclosures have been prepared in accordance with accounting principles generally accepted in the United States (“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 for the year ended December 31, 2022, filed on February 27, 2023.

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 and deferred revenue, specifically, estimates in variable consideration for drug product sales, and estimates in transaction price per unit for the China performance obligation. 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.

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 the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed on February 27, 2023, except for the updates to the following:

Asset Acquisition

The Company evaluates acquisitions of entities or assets to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If this screen criteria is met, the transaction is accounted for as an asset acquisition. If not, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs which would meet the definition of a business. The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes transaction costs.

In an asset acquisition, the cost allocated to acquire in-process research and development ("IPR&D") with no alternative future use is charged to research and development expense at the acquisition date. The Company recognizes assets acquired and liabilities assumed in asset acquisitions, including contingent assets and liabilities, and non-controlling interests ("NCI") in the acquired assets at their estimated fair values as of the date of acquisition.

An NCI represents the non-affiliated equity interest in the underlying entity or asset. The Company presents redeemable NCI in its consolidated statements of changes in equity within mezzanine equity. Nonredeemable NCI and redeemable NCI are initially recorded at their fair values. Subsequently, net loss in the underlying entity or asset is only allocated to nonredeemable NCI. Net income in the underlying entity or asset is allocated to nonredeemable NCI and redeemable NCI based on their respective stated rights.

Restructuring Charge

A restructuring charge is recognized when the liability is incurred and accrued in the period in which it is probable that the employees are entitled to the restructuring benefits and the amounts can be reasonably estimated. The restructuring liability accrued but not paid at the end of the reporting period is included in accrued and other current liabilities in the consolidated balance sheets.

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. The Company reported a net loss for each of the three and nine months ended September 30, 2023 and 2022. Therefore, dilutive common shares are not assumed to have been issued since their effect is anti-dilutive for these periods.

Diluted weighted average shares excluded the following potential common shares related to stock options, service-based restricted stock units ("RSUs"), performance-based RSUs ("PRSUs"), total shareholder return ("TSR") awards and shares to be purchased under the 2014 Employee Stock Purchase Plan ("ESPP") for the periods presented as they were anti-dilutive (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Employee stock options	11,293	9,715	10,022	9,794
RSUs, PRSUs and TSR awards	4,596	1,978	3,208	2,066
ESPP	559	50	556	390
	<u>16,448</u>	<u>11,743</u>	<u>13,786</u>	<u>12,250</u>

Risks and Uncertainties

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, the results of clinical trials and the achievement of milestones, research developments, actions by regulatory authorities, market acceptance of the Company's product candidates, competition from other products and larger companies, the liquidity and capital resources of the Company, intellectual property protection for the Company's proprietary technology, strategic relationships, and dependence on key individuals, suppliers, clinical organization, and other third parties.

2. Collaboration Agreements, License Agreement and Revenues

Astellas Agreements

Astellas Japan Agreement

In June 2005, the Company entered into a collaboration agreement with Astellas Pharma Inc. (“Astellas”) for the development and commercialization (but not manufacture) of roxadustat for the treatment of anemia in Japan (“Astellas Japan Agreement”). Under this agreement, Astellas agreed to pay license fees, other upfront consideration and various milestone payments, totaling \$172.6 million. The Astellas 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 September 30, 2023 totaled \$105.1 million, excluding drug product revenue that is discussed under the *Drug Product Revenue, Net* section below. Based on its current development plans for roxadustat in Japan, the Company does not expect to receive most or all of the additional potential milestones under the Astellas Japan Agreement.

Amounts recognized as license revenue and development revenue under the Astellas Japan Agreement were as follows for the three and nine months ended September 30, 2023 and 2022 (in thousands):

Agreement	Performance Obligation	Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
Astellas Japan Agreement	Development revenue	\$ 36	\$ 45	\$ 164	\$ 156

The transaction price related to consideration received through September 30, 2023 and accounts receivable has been allocated to each of the following performance obligations under the Astellas Japan Agreement (in thousands):

Astellas Japan Agreement	Total Consideration Through September 30, 2023
License	\$ 100,347
Development revenue	17,047
Total license and development revenue	\$ 117,394

There was no license revenue or development revenue resulting from changes to estimated variable consideration in the current period relating to performance obligations satisfied or partially satisfied in previous periods for the three months ended September 30, 2023 under the Astellas Japan Agreement. 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 Astellas Japan Agreement.

In 2018, FibroGen and Astellas entered into an amendment to the Astellas Japan Agreement that allows Astellas to manufacture roxadustat drug product for commercialization in Japan (the “Astellas Japan Amendment”). The related drug product revenue is described under the *Drug Product Revenue, Net* section below.

Astellas 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 (“Astellas Europe Agreement”). Under the terms of the Astellas Europe Agreement, Astellas agreed to pay license fees, other upfront consideration and various milestone payments, totaling \$745.0 million. Under the Astellas Europe Agreement, Astellas committed to fund 50% of joint development costs for Europe and North America, and all territory-specific costs. The Astellas Europe Agreement also provides for tiered payments based on net sales of product (as defined) in the low 20% range.

On March 21, 2022, EVRENZO® (roxadustat) was registered with the Russian Ministry of Health. The Company evaluated the regulatory milestone payment associated with the approval in Russia under the Astellas Europe Agreement and concluded that this milestone was achieved in the first quarter of 2022. Accordingly, the consideration of \$25.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the Astellas Europe Agreement, all of which was recognized as revenue during the first quarter of 2022 from performance obligations satisfied.

The aggregate amount of consideration received under the Astellas Europe Agreement through September 30, 2023 totaled \$685.0 million, excluding drug product revenue that is discussed under the *Drug Product Revenue, Net* section below. Based on its current development plans for roxadustat in Europe, the Company does not expect to receive most or all of the additional potential milestones under the Astellas Europe Agreement.

Amounts recognized as license revenue and development revenue under the Astellas Europe Agreement were as follows for the three and nine months ended September 30, 2023 and 2022 (in thousands):

Agreement	Performance Obligation	Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
Astellas Europe Agreement	License revenue	\$ —	\$ —	\$ —	\$ 22,590
	Development revenue	\$ 2,322	\$ 1,369	\$ 5,657	\$ 8,263

The transaction price related to consideration received through September 30, 2023 and accounts receivable has been allocated to each of the following performance obligations under the Astellas Europe Agreement as follows (in thousands):

Astellas Europe Agreement	Total Consideration Through September 30, 2023
License	\$ 618,975
Development revenue	285,922
Total license and development revenue	\$ 904,897

There was no license revenue or development revenue resulting from changes to estimated variable consideration in the current period relating to performance obligations satisfied or partially satisfied in previous periods for three months ended September 30, 2023 under the Astellas Europe Agreement. The remainder of the transaction price related to the Astellas Europe Agreement includes \$0.8 million of variable consideration from estimated future co-development billing and is expected to be recognized over the remaining development service period.

Under the Astellas 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 EU Supply Agreement with Astellas under the Astellas Europe Agreement (“Astellas EU Supply Agreement”) 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 related drug product revenue is described under the *Drug Product Revenue, Net* section below.

AstraZeneca Agreements

AstraZeneca U.S./Rest of World (“RoW”) Agreement

Effective July 30, 2013, the Company entered into a collaboration agreement with AstraZeneca AB (“AstraZeneca”) for the development and commercialization of roxadustat for the treatment of anemia in the U.S. and all other countries in the world, other than China, not previously licensed under the Astellas Europe and Astellas Japan Agreements (“AstraZeneca U.S./RoW Agreement”). China is covered by a separate agreement with AstraZeneca described below. Under the terms of the AstraZeneca U.S./RoW Agreement, AstraZeneca agreed to pay upfront, non-contingent, non-refundable and time-based payments, and potential milestone payments, totaling \$1.2 billion. AstraZeneca commits to pay the Company tiered royalty payments on AstraZeneca’s future net sales (as defined in the agreement) of roxadustat in the low 20% range. In addition, the Company is entitled to receive a transfer price for shipment of commercial product based on a percentage of AstraZeneca’s net sales (as defined in the agreement) in the low- to mid-single digit range.

The aggregate amount of consideration received under the AstraZeneca U.S./RoW Agreement through September 30, 2023 totaled \$439.0 million, excluding drug product revenue that is discussed separately below. Based on its current development plans for roxadustat in the U.S., the Company does not expect to receive most or all of the additional potential milestones under the AstraZeneca U.S./RoW Agreement.

In 2020, the Company entered into a Master Supply Agreement with AstraZeneca under the AstraZeneca U.S./RoW Agreement (“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 related drug product revenue is described under the *Drug Product Revenue, Net* section below.

AstraZeneca China Agreement

Effective July 30, 2013, the Company (through its subsidiaries affiliated with China) entered into a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in China (“AstraZeneca China Agreement”). Under the terms of the AstraZeneca China Agreement, AstraZeneca agreed to pay upfront consideration and potential milestone payments, totaling \$376.7 million. The AstraZeneca China Agreement is structured as a 50/50 profit or loss share (as defined), which was amended under the AstraZeneca China Amendment in 2020 as discussed below, 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 September 30, 2023 totaled \$77.2 million.

On September 18, 2023, the Company received the formal notice, from Beijing Medical Products Administration, of renewal of its right to continue to market Roxadustat in China through 2028. The Company evaluated the regulatory milestone payment associated with this renewal under the AstraZeneca China Agreement and concluded that this milestone was achieved in the third quarter of 2023. Accordingly, the consideration of \$4.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the AstraZeneca U.S./RoW Agreement and the AstraZeneca China Agreement, \$3.5 million of which was recognized as revenue during the third quarter of 2023 from performance obligations satisfied or partially satisfied. As of September 30, 2023, the \$4.0 million milestone was recorded as a contract asset and was fully netted against the contract liabilities (deferred revenue) related to the AstraZeneca U.S./RoW Agreement and AstraZeneca China Agreement.

AstraZeneca China Amendment

In July 2020, FibroGen China Anemia Holdings, Ltd., FibroGen (China) Medical Technology Development Co., Ltd. (“FibroGen Beijing”), and FibroGen International (Hong Kong) Limited and AstraZeneca entered into an amendment to the AstraZeneca China Agreement, relating to the development and commercialization of roxadustat in China (the “AstraZeneca China Amendment”). Under the AstraZeneca China Amendment, in 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 conducts sales and marketing through AstraZeneca.

Substantially all direct roxadustat product sales to distributors in China are made by Falikang, while FibroGen Beijing continues to sell roxadustat product directly in one province 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.

Amounts recognized as license revenue and development revenue under the AstraZeneca U.S./RoW Agreement and AstraZeneca China Agreement were as follows for the three and nine months ended September 30, 2023 and 2022 (in thousands):

Agreement	Performance Obligation	Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
AstraZeneca U.S./RoW Agreement and AstraZeneca China Agreement	License revenue	\$ 2,649	\$ —	\$ 2,649	\$ —
	Development revenue	\$ 3,676	\$ 579	\$ 7,981	\$ 9,750

The transaction price related to consideration received through September 30, 2023 and accounts receivable has been allocated to each of the following performance obligations under the AstraZeneca U.S./RoW Agreement and AstraZeneca China Agreement, along with any associated deferred revenue as follows (in thousands):

AstraZeneca U.S./RoW Agreement and AstraZeneca China Agreement	Cumulative Revenue Through September 30, 2023	Deferred Revenue at September 30, 2023	Total Consideration Through September 30, 2023
License	\$ 344,493	\$ —	\$ 344,493
Co-development, information sharing & committee services	623,619	—	623,619
China performance obligation *	175,081	177,576	352,657
Total license and development revenue	<u>\$ 1,143,193</u>	<u>\$ 177,576</u> **	<u>\$ 1,320,769</u>

* China performance obligation revenue is recognized as product revenue, as described 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 September 30, 2023, deferred revenue included \$151.4 million related to the AstraZeneca U.S./RoW Agreement and AstraZeneca China Agreement, which represents the net of \$177.6 million of deferred revenue presented above and a \$26.2 million unbilled milestone and co-development revenue under the AstraZeneca China Amendment.

There was no license revenue or development revenue resulting from changes to estimated variable consideration in the current period relating to performance obligations satisfied or partially satisfied in previous periods for the three months ended September 30, 2023 under the AstraZeneca U.S./RoW Agreement. The remainder of the transaction price related to the AstraZeneca U.S./RoW Agreement and AstraZeneca China Agreement includes \$2.0 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 China performance obligation is expected to be recognized as the Company transfers control of the commercial drug product to Falikang, and is expected to continue through 2028, which reflects our best estimates.

The net product revenue from the sales to Falikang and the net product revenue from direct sales distributors in China are described under *Product Revenue, Net* section below.

Product Revenue, Net

Product revenue, net from the sales of roxadustat commercial product in China was as follows for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Direct Sales:				
Gross revenue	\$ 3,186	\$ 2,610	\$ 9,853	\$ 8,972
Discounts and rebates	(261)	(166)	(763)	(353)
Sales returns	2	1	2	3
Direct sales revenue, net	<u>2,927</u>	<u>2,445</u>	<u>9,092</u>	<u>8,622</u>
Sales to Falikang:				
Gross transaction price	42,294	32,510	118,696	83,517
Profit share	(18,130)	(12,980)	(51,430)	(31,894)
Net transaction price	24,164	19,530	67,266	51,623
Decrease (increase) in deferred revenue	2,299	(4,616)	1,081	(750)
Sales to Falikang revenue, net	26,463	14,914	68,347	50,873
Total product revenue, net	<u>\$ 29,390</u>	<u>\$ 17,359</u>	<u>\$ 77,439</u>	<u>\$ 59,495</u>

Direct Sales

Product revenue from direct roxadustat product sales to distributors in China is recognized in an amount that reflects the consideration that the Company expects to be entitled to in exchange for those products, net of various sales rebates and discounts. The total discounts and rebates were immaterial for the periods presented.

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 determined at the individual distributor level. The contract liabilities were included in accrued and other current liabilities in the condensed consolidated balance sheet and were immaterial as of September 30, 2023 and December 31, 2022, respectively. The rebates and discounts reflected as reductions to gross accounts receivable for direct sales were immaterial as of September 30, 2023 and December 31, 2022, respectively.

Sales to Falikang – China Performance Obligation

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 the 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 transaction price in excess of the revenue recognized is added to the deferred balance to date, and will be recognized in future periods as the performance obligation is satisfied.

Periodically, the Company updates its assumptions such as total sales quantity, performance period, gross transaction price and profit share and other inputs including foreign currency translation impact, among others. Following updates to its estimates, the Company recognized \$2.3 million and \$1.1 million from the revenue of the China performance obligation during the three and nine months ended September 30, 2023, respectively. The product revenue resulting from changes to estimated variable consideration in the current period relating to performance obligations satisfied in previous periods was immaterial for the three months ended September 30, 2023.

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

	<u>Balance at December 31, 2022</u>	<u>Additions</u>	<u>Recognized as Revenue</u>	<u>Currency Translation and Other</u>	<u>Balance at September 30, 2023</u>
Product revenue - AstraZeneca China performance obligation - deferred revenue	\$ (175,646)	\$ (72,519)	\$ 68,347	\$ 2,242	\$ (177,576)

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 September 30, 2023, approximately \$28.0 million of the above 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.

Due to the Company's legal right to offset, at each balance sheet date, the rebates and discounts, mainly related to profit sharing, are presented as reductions to gross accounts receivable from Falikang, which was \$2.5 million and \$0.5 million as of September 30, 2023 and December 31, 2022, respectively.

Drug Product Revenue, Net

Drug product revenue from commercial-grade active pharmaceutical ingredient (“API”) or bulk drug product sales to Astellas and AstraZeneca was as follows for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Astellas Japan Agreement	\$ 695	\$ (4,313)	\$ 16,236	\$ 3,297
Astellas Europe Agreement	625	236	1,465	1,313
Drug product revenue, net	<u>\$ 1,320</u>	<u>\$ (4,077)</u>	<u>\$ 17,701</u>	<u>\$ 4,610</u>

Astellas Japan Agreement

The Company updates its estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment at each balance sheet date. As a result, the Company recorded an adjustment to the drug product revenue of \$0.7 million for the three months ended September 30, 2023. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect the changes in the estimated bulk product strength mix intended to be manufactured by Astellas, and foreign exchange impacts, among others.

During the three months ended June 30, 2023, the Company fulfilled two shipment obligations under the terms of Astellas Japan Amendment, and recognized related drug product revenue of \$14.4 million in the same period. In addition, the Company updated its estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment and accordingly recorded a reduction to the drug product revenue of \$0.6 million for the three months ended June 30, 2023. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect the changes in the estimated bulk product strength mix intended to be manufactured by Astellas and foreign exchange impacts, among others.

During the three months ended March 31, 2023, the Company updated its estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment, and accordingly recorded an adjustment to the drug product revenue of \$1.7 million. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect the changes in the estimated bulk product strength mix intended to be manufactured by Astellas, and estimated yield from the manufacture of bulk product tablets, among others.

During the three months ended March 31, 2022, the Company fulfilled a shipment obligation under the terms of Astellas Japan Amendment, and recognized related drug product revenue of \$9.8 million in the same period. In addition, the Company updated its estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment, and recorded a reduction to the drug product revenue of \$2.2 million during the first quarter of 2022. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, 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 three months ended September 30, 2022, the Company updated its estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment, and accordingly recorded a reduction to the drug product revenue of \$4.3 million. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect foreign currency translation impact and the changes in the estimated bulk product strength mix intended to be manufactured by Astellas, among others.

As of September 30, 2023, the balances related to the API price true-up under the Astellas Japan Agreement were \$0.6 million in accrued liabilities and \$0.7 million in other long-term liabilities, representing the Company’s best estimate of the timing for these amounts to be paid. As of December 31, 2022, the related balance in accrued liabilities was \$6.5 million.

Astellas Europe Agreement

The Company transferred bulk drug product for commercial purposes under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement in the prior years. The Company recognized the related fully burdened manufacturing costs as drug product revenue in the respective periods and recorded the constrained transaction price in deferred revenue due to a high degree of uncertainty associated with the variable consideration for revenue recognition purposes. The Company updates its estimate of variable consideration related to the bulk drug product transferred in prior years at each balance sheet date.

During 2022, the Company updated its estimate of variable consideration related to the bulk drug product transferred in prior years. Specifically, the change in estimated variable consideration was based on the bulk drug product held by Astellas at the period end, adjusted to reflect the changes in the estimated transfer price, forecast information, shelf-life estimates and other items. As a result, the Company reclassified the related deferred revenue to accrued liabilities during the year ended December 31, 2022. As of December 31, 2022, the related balance was \$57.4 million in accrued liabilities, which was paid to Astellas during the second quarter of 2023. Further for the nine months ended September 30, 2023, the Company reclassified \$28.7 million from the related deferred revenue to accrued liabilities. As of September 30, 2023, the balances related to the bulk drug product price true-up under the Astellas Europe Agreement and the Astellas EU Supply Agreement were \$28.6 million in accrued liabilities, representing the Company's best estimate that these amounts will be paid within the next 12 months.

The Company recognized royalty revenue of \$0.6 million and \$1.5 million as drug product revenue from the deferred revenue under the Astellas Europe Agreement during the three and nine months ended September 30, 2023, respectively. It is the Company's best estimate that the remainder of the deferred revenue will be recognized as revenue when uncertainty is resolved, based on the performance of roxadustat product sales in the Astellas territory.

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, 2022	Additions	Recognized as Revenue	Reclassified to Accrued Liability / Accounts Payable	Balance at September 30, 2023
Drug product revenue - deferred revenue:					
Astellas Europe Agreement	<u>\$ (40,303)</u>	<u>\$ —</u>	<u>\$ 1,465</u>	<u>\$ 28,685</u>	<u>\$ (10,153)</u>

AstraZeneca U.S./RoW Agreement

There was no shipment of bulk drug product to AstraZeneca as commercial supply under the terms of the AstraZeneca Master Supply Agreement during the periods presented.

During the first quarter of 2022, the Company evaluated the current developments in the U.S. market, and updated its estimates of variable consideration associated with bulk drug product shipments to AstraZeneca in prior years as commercial supply. As a result, the Company reclassified \$11.2 million from the related deferred revenue to accrued liabilities during the year ended December 31, 2022, which remained unchanged as of September 30, 2023 and December 31, 2022, representing the Company's best estimate that this amount will be paid within the next 12 months.

Eluminex Agreement

In July 2021, FibroGen exclusively licensed to Eluminex Biosciences (Suzhou) Limited (“Eluminex”) global rights to its investigational biosynthetic cornea derived from recombinant human collagen Type III.

Under the terms of the agreement with Eluminex, as amended and restated, Eluminex made an \$8.0 million upfront payment to FibroGen during the first quarter of 2022, which was recognized as license revenue for the performance obligation satisfied during 2021. In addition, FibroGen may receive up to a total of \$64.0 million in future manufacturing, clinical, regulatory, and commercial milestone payments for the biosynthetic cornea program, as well as \$36.0 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.

In April 2023, FibroGen and Eluminex entered into an Amended and Restated Exclusive License Agreement (“A&R Eluminex Agreement”) in order to add to the license rights to recombinant human collagen Type I (in addition to the rights to collagen Type III that were already licensed). The A&R Eluminex Agreement included additional total upfront payments of \$1.5 million.

During the three months ended September 30, 2023, the Company recognized a \$0.5 million upfront payment related to patent transfer under the A&R Eluminex Agreement. During the three months ended June 30, 2023, the Company recognized a \$1.0 million upfront payment. During the three months ended March 31, 2023, the Company recognized a \$3.0 million milestone payment based on Eluminex implanting a biosynthetic cornea in the first patient of its clinical trial in China, and a \$3.0 million manufacturing related milestone payment.

During the first quarter of 2022, FibroGen and Eluminex entered into a separate contract manufacturing agreement, under which the Company is responsible for supplying the cornea product at cost plus 10% of its product manufacturing costs until its manufacturing technology is fully transferred to Eluminex. The related contract manufacturing revenue was recorded as other revenue and included in development and other revenue in the condensed consolidated statement of operations.

Amounts recognized as revenue under the Eluminex were as follows for the three and nine months ended September 30, 2023 and 2022 (in thousands):

Agreement	Performance Obligation	Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
Eluminex	License revenue	\$ —	\$ —	\$ 7,000	\$ —
	Other revenue - patent transfer	500	—	500	—
	Other revenue - contract manufacturing	\$ 241	\$ 460	\$ 723	\$ 1,502

3. Exclusive License and Option to Acquire Fortis Therapeutics

On May 5, 2023 (the “Option Acquisition Date”), the Company entered into an exclusive option agreement to acquire Fortis Therapeutics (“Fortis”) with its novel Phase 1 antibody-drug conjugate, FOR46 (now referred to as “FG-3246”), that targets a novel epitope on CD46 preferentially expressed on certain cancer cells. FG-3246 is in development for the treatment of metastatic castration-resistant prostate cancer with potential applicability in other solid tumors and hematologic malignancies.

Pursuant to an evaluation agreement entered into with Fortis concurrent with the option agreement (together the “Fortis Agreements”), FibroGen has exclusively licensed FG-3246 and will control and fund future research, development, including a Phase 2 clinical study sponsored by FibroGen, and manufacturing of FG-3246 during the up-to four-year option period. As part of the clinical development strategy, FibroGen will continue the work to develop a PET-based biomarker utilizing a radiolabeled version of the targeting antibody for patient selection.

Pursuant to the guidance under Accounting Standards Codification (“ASC”) 810, *Consolidation* (“ASC 810”), the Company determined that Fortis is a VIE and that the Company is the primary beneficiary of Fortis, as through the Fortis Agreements the Company has the power to direct activities that most significantly impact the economic performance of Fortis. Therefore, the Company consolidated Fortis starting from the Option Acquisition Date, and continues to consolidate as of September 30, 2023. The transaction was accounted for as an asset acquisition under ASC 805, *Business Combinations*, as substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable IPR&D asset.

The fair value of the consideration transferred was zero. If FibroGen exercises the option to acquire Fortis, it will pay Fortis an option exercise payment of \$80.0 million, and thereafter, legacy Fortis shareholders would be eligible to receive from FibroGen up to \$200.0 million in contingent payments associated with the achievement of various regulatory approvals. If FibroGen acquires Fortis, it would also be responsible to pay UCSF, an upstream licensor to Fortis, development milestone fees and a single digit royalty on net sales of therapeutic or diagnostic products arising from the licensing arrangement between Fortis and UCSF. If FibroGen chooses not to acquire Fortis, its exclusive license to FG-3246 would expire.

Additionally, the Company is obligated to make four quarterly payments totaling \$5.0 million to Fortis in support of its continued development obligations. The Company determined that these payments should not be included in the purchase consideration, as those payments are payable to Fortis rather than to its shareholders.

Fortis has authorized and issued common shares and Series A preferred shares. As of the Option Acquisition Date and September 30, 2023, the Company owned approximately 2% of Fortis' Series A preferred shares, which was acquired previously and carried at zero cost. The NCI attributable to the common shares is classified as nonredeemable NCI, as it is 100% owned by third party shareholders. The NCI attributable to the approximately 98% of Series A preferred shares owned by other investors are classified as redeemable NCI in temporary equity, as the preferred shares are redeemable by the non-controlling shares holders upon occurrence of certain events out of the Company's control.

Subsequent to the Option Acquisition Date, Fortis' net income is allocated to its common shares and preferred shares based on their respective stated rights. Fortis' net loss is allocated to its common shares only as the holders of preferred shares do not have a contractual obligation to absorb such losses.

The following table represents the allocation of purchase consideration based on estimated fair values of the acquired assets (in thousands):

	Estimated Fair Value as of the Option Acquisition Date
Purchase consideration	\$ —
Assets	
Cash and cash equivalents	656
Prepaid expenses and other current assets	82
IPR&D assets	24,400
Total assets	25,138
Liabilities	
Accounts payable	2,671
Accrued and other current liabilities	703
Total liabilities	3,374
Redeemable non-controlling interests	21,480
Nonredeemable non-controlling interests	520
Net identifiable assets, liabilities and non-controlling interests	\$ (236)
Loss on asset acquisition	\$ (236)

The Company used a third party valuation specialist to determine the fair value of the IPR&D assets using a risk-adjusted net present value discounted cash flow model (the "rNPV") with the following key assumptions: (i) estimated cash flow forecasts of peak sales, sales penetration, remaining IPR&D related product development costs, and other related general and administrative costs; (ii) probabilities of technical success of future underlying Phase II and Phase III clinical trials and ensuing probability of regulatory approval related to the IPR&D assets; and (iii) estimate of a risk-adjusted discount rate of 16.5%. The acquired IPR&D assets were determined to have no alternative future use. Accordingly, the Company expensed fair value of the acquired IPR&D assets of \$24.4 million as research and development expense in the condensed consolidated statements of operations for the nine months ended September 30, 2023.

The fair value of Fortis (enterprise value) and the fair value of nonredeemable NCI and redeemable NCI were determined based on the above-mentioned option exercise payment of \$80.0 million and contingent payments up to \$200.0 million, weighted with probability and expected timing of the underlying events consistent with the assumptions under the rNPV, and discounted by the Company's estimated market level cost of debt.

As of September 30, 2023, total assets and liabilities of Fortis were immaterial. For the period from the Option Acquisition Date to September 30, 2023, Fortis' net income (losses) was immaterial.

4. Equity method investment - Variable Interest Entity

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

Pursuant to the guidance under ASC 810, the Company concluded that Falikang qualifies as a 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. The Company records its total investments in Falikang as an equity method investment in an unconsolidated VIE 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 VIE 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, there has been no such loans. During the three months ended September 30, 2023, the Company received \$2.3 million of dividend distribution from Falikang.

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

Entity	Ownership Percentage	Balance at December 31, 2022	Share of Net Income	Dividend Received	Currency Translation	Balance at September 30, 2023
Falikang	51.1%	\$ 5,061	\$ 2,023	\$ (2,255)	\$ (295)	\$ 4,534

Falikang is considered a related party to the Company. See Note 11, *Related Party Transactions*, for related disclosures.

5. Fair Value Measurements

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

	September 30, 2023			
	Level 1	Level 2	Level 3	Total
Money market funds	\$ 22,016	\$ —	\$ —	\$ 22,016
Corporate bonds	—	11,910	—	11,910
Commercial paper	—	78,800	—	78,800
U.S. government bonds	18,834	43,831	—	62,665
Agency bonds	—	4,967	—	4,967
Total	\$ 40,850	\$ 139,508	\$ —	\$ 180,358

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Money market funds	\$ 19,881	\$ —	\$ —	\$ 19,881
Corporate bonds	—	82,008	—	82,008
Commercial paper	—	57,381	—	57,381
U.S. government bonds	98,972	12,373	—	111,345
Agency bonds	—	11,468	—	11,468
Asset-backed securities	—	2,474	—	2,474
Foreign government bonds	—	4,980	—	4,980
Convertible promissory note	—	—	1,000	1,000
Total	\$ 118,853	\$ 170,684	\$ 1,000	\$ 290,537

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. During the three and nine months ended September 30, 2023, a total of \$8.5 million and \$15.4 million, respectively, of U.S. treasury notes and bills were transferred from Level 1 to Level 2 as such instruments were changed to off-the-run when they were issued before the most recent issue and were still outstanding at measurement day.

6. Balance Sheet Components

Cash and Cash Equivalents

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

	September 30, 2023	December 31, 2022
Cash	\$ 70,982	\$ 135,819
Commercial paper	22,942	—
Money market funds	22,016	19,881
U.S. government bonds	4,974	—
Total cash and cash equivalents	<u>\$ 120,914</u>	<u>\$ 155,700</u>

At September 30, 2023 and December 31, 2022, a total of \$60.1 million and \$92.5 million 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, respectively.

Investments

The Company's investments consist primarily of available-for-sale debt 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):

	September 30, 2023			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Corporate bonds	\$ 11,987	\$ —	\$ (77)	\$ 11,910
Commercial paper	55,859	—	(1)	55,858
U.S. government bonds	57,734	3	(46)	57,691
Agency bonds	4,965	2	—	4,967
Total investments	<u>\$ 130,545</u>	<u>\$ 5</u>	<u>\$ (124)</u>	<u>\$ 130,426</u>

	December 31, 2022			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Corporate bonds	\$ 83,080	\$ —	\$ (1,072)	\$ 82,008
Commercial paper	57,381	—	—	57,381
U.S. government bonds	112,547	5	(1,207)	111,345
Agency bonds	11,690	—	(222)	11,468
Asset-backed securities	2,484	—	(10)	2,474
Foreign government bonds	5,007	—	(27)	4,980
Convertible promissory note	1,000	—	—	1,000
Total investments	<u>\$ 273,189</u>	<u>\$ 5</u>	<u>\$ (2,538)</u>	<u>\$ 270,656</u>

The following table summarizes, for all available for sale securities in an unrealized loss position, the fair value and gross unrealized loss by length of time the security has been in a continual unrealized loss position (in thousands):

	September 30, 2023					
	Less than 12 Months		12 Months or More		Total	
	Estimated Fair Value	Gross Unrealized Holding Losses	Estimated Fair Value	Gross Unrealized Holding Losses	Estimated Fair Value	Gross Unrealized Holding Losses
Corporate bonds	\$ 2,483	\$ (8)	\$ 9,427	\$ (69)	\$ 11,910	\$ (77)
U.S. government bonds	17,360	(4)	8,960	(42)	26,320	(46)
Commercial paper	3,481	(1)	—	—	3,481	(1)
Total	<u>\$ 23,324</u>	<u>\$ (13)</u>	<u>\$ 18,387</u>	<u>\$ (111)</u>	<u>\$ 41,711</u>	<u>\$ (124)</u>

	December 31, 2022					
	Less than 12 Months		12 Months or More		Total	
	Estimated Fair Value	Gross Unrealized Holding Losses	Estimated Fair Value	Gross Unrealized Holding Losses	Estimated Fair Value	Gross Unrealized Holding Losses
Corporate bonds	\$ 6,738	\$ (147)	\$ 75,270	\$ (925)	\$ 82,008	\$ (1,072)
U.S. government bonds	22,326	(13)	67,909	(1,194)	90,235	(1,207)
Agency bonds	—	—	11,468	(222)	11,468	(222)
Asset-backed securities	2,474	(10)	—	—	2,474	(10)
Foreign government bonds	—	—	4,980	(27)	4,980	(27)
Total	<u>\$ 31,538</u>	<u>\$ (170)</u>	<u>\$ 159,627</u>	<u>\$ (2,368)</u>	<u>\$ 191,165</u>	<u>\$ (2,538)</u>

At September 30, 2023, the available-for-sale investments had remaining contractual maturities of less than twelve months.

The Company periodically assesses whether the unrealized losses on its available-for-sale investments were temporary. The Company considers factors such as the severity and the reason for the decline in value and the potential recovery period and its intent to sell. For debt securities, the Company also considers whether (i) it is more likely than not that the Company will be required to sell the debt securities before recovery of their amortized cost basis, and (ii) the amortized cost basis cannot be recovered as a result of credit losses. Based on the results of its review, the Company did not recognize any impairment for its available-for-sale investments during the three and nine months ended September 30, 2023 and 2022.

Inventories

Inventories consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Raw materials	\$ 1,179	\$ 1,241
Work-in-progress	34,906	36,003
Finished goods	4,611	3,192
Total inventories	<u>\$ 40,696</u>	<u>\$ 40,436</u>

Accrued and Other Current Liabilities

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

	September 30, 2023	December 31, 2022
Preclinical and clinical trial accruals	\$ 34,670	\$ 57,780
API and bulk drug product price true-up	40,325	75,055
Litigation settlement	28,500	—
Payroll and related accruals	14,054	22,562
Accrued restructuring charge	4,694	—
Accrued co-promotion expenses - current	10,065	36,677
Roxadustat profit share to AstraZeneca	6,884	7,280
Property taxes and other taxes	7,950	7,691
Professional services	11,016	5,480
Current portion of liability related to sale of future revenues	5,860	—
Other	6,968	7,248
Total accrued and other current liabilities	<u>\$ 170,986</u>	<u>\$ 219,773</u>

The accrued liabilities of \$40.3 million for API and bulk drug product price true-up as of September 30, 2023 resulted from changes in estimated variable consideration associated with the API shipments fulfilled under the terms of the Astellas Japan Amendment, the bulk drug product transferred under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement, and the bulk drug product shipments to AstraZeneca under the terms of the AstraZeneca Master Supply Agreement. See the *Drug Product Revenue, Net* section in Note 2, *Collaboration Agreements, License Agreement and Revenues*, for details.

As of September 30, 2023, the accrued litigation settlement of \$28.5 million was related to the Company's agreement in principle with plaintiffs to settle the class action lawsuit. The Company maintains insurance that covers exposure related to the class action lawsuit. As the amount is fully recoverable under the Company's insurance policies, the Company recorded a corresponding receivable in prepaid expenses and other current assets in the condensed consolidated balance sheet. The determination that the recorded receivables are probable of collection is based on the terms of the applicable insurance policies and communications with the insurers. See the *Legal Proceedings and Other Matters* section in Note 12, *Commitments and Contingencies*, for details.

On July 14, 2023, the Company approved a restructuring plan (the "Plan") to lower the Company's operating expenses. The Plan included a reduction to the Company's U.S. workforce of approximately 32%. As a result, the Company recorded a total of \$12.6 million non-recurring restructuring charge during the three months ended September 30, 2023, primarily consisting of notice period and severance payments, accrued vacation, and employee benefits contributions. During the three months ended September 30, 2023, total cash payments under the Plan was \$7.9 million. The remaining accrued restructuring charge was \$4.7 million as of September 30, 2023 and will be substantially paid out by early 2024. The Plan is in connection with the Company's efforts to streamline operations to align with the Company's business goals.

7. Senior Secured Term Loan Facilities

On April 29, 2023, the Company entered into a financing agreement ("Financing Agreement") with investment funds managed by Morgan Stanley Tactical Value, as lenders (the "Lenders"), and Wilmington Trust, National Association, as the administrative agent, providing for senior secured term loan facilities consisting of (i) a \$75.0 million initial term loan (the "Initial Term Loan"), (ii) a \$37.5 million delayed draw term loan that will be funded upon the achievement of certain clinical development milestones ("Delayed Draw Term Loan 1") and, (iii) an uncommitted delayed draw term loan of up to \$37.5 million to be funded at the Lenders sole discretion, ("Delayed Draw Term Loan 2" and, together with the Initial Term Loan and Delayed Draw Term Loan 1, the "Term Loans").

Pursuant to the Financing Agreement, the Lenders have funded the Initial Term Loan. The clinical development milestones which could have triggered Delayed Draw Term Loan 1 were not achieved, and the Lenders have not funded Delayed Draw Term Loan 2. As such, these features have expired as of September 30, 2023.

The Term Loans shall accrue interest at a fixed rate of 14.0% per annum, payable monthly in arrears. The Term Loans shall mature on May 8, 2026. The Term Loans will not be subject to amortization payments. The Company is permitted to prepay the Term Loans from time to time, in whole or in part, subject to payment of a make-whole amount equal to the unpaid principal amount of the portion of the Term Loans being repaid or prepaid, plus accrued and unpaid interest of the portion of the Term Loans being repaid or prepaid, plus an amount equal to the remaining scheduled interest payments due on such portion of the Term Loans being repaid or prepaid as if such Term Loans were to remain outstanding until the scheduled maturity date.

On May 8, 2023, the Company received \$74.1 million, representing the Initial Term Loan of \$75.0 million net of \$0.9 million issuance costs. The issuance costs and the related transaction costs, totaling \$3.7 million is amortized as interest expense using the effective interest method over the term of the Initial Term Loan and are reported on the balance sheet as a direct deduction from the amount of the Initial Term Loan. The effective annual interest rate of the Initial Term Loan was 16.13% for three and nine months ended September 30, 2023. The Company recorded interest expense of \$2.9 million and \$4.5 million for the three and nine months ended September 30, 2023, respectively. As of September 30, 2023, the related accrued interest was \$0.4 million. The Company was in compliance with all debt covenants associated with the senior secured term loan facilities as of September 30, 2023, including maintaining a minimum balance of \$30 million of unrestricted cash and cash equivalents held in accounts in the U.S.

The Company has determined that certain other features embedded within the Loan should be bifurcated and accounted for separately as a derivative. At inception and as of September 30, 2023, the fair values of such derivatives were negligible due to the low probability of the underlying events.

The Company's senior secured term loan facilities as of September 30, 2023 were as follows (in thousands):

	September 30, 2023
Principal of senior secured term loan facilities	\$ 75,000
Less: Unamortized issuance costs and transaction costs	(3,334)
Senior secured term loan facilities, ending balance	71,666
Less: Current Portion classified to accrued and other current liabilities	—
Senior secured term loan facilities, non-current	\$ 71,666

8. Liability Related to Sale of Future Revenues

On November 4, 2022, the Company entered into a Revenue Interest Financing Agreement (the "RIFA") with an affiliate of NovaQuest Capital Management ("NovaQuest"), pursuant to which the Company granted NovaQuest 22.5% of its drug product revenue and 10.0% (20.0% for fiscal year 2028 and thereafter) of its revenue from milestone payments that it is entitled to under the Astellas Agreements, for a consideration of \$50.0 million ("Investment Amount") before advisory fees.

In November 2022, the Company received the Investment Amount, net of initial issuance costs, and accounted for it as long-term debt based on the terms of the RIFA because the risks and rewards to NovaQuest are limited by the terms of the transaction. The related debt discount and transaction costs are amortized as interest expense based on the projected balance of the liability as of the beginning of each period. As payments are made to NovaQuest, the balance of the liability related to sale of future revenues is being effectively repaid over the life of the RIFA. The payments to NovaQuest are accounted for as a reduction of debt.

The Company may prepay its obligations to NovaQuest in full at any time during the term of RIFA. The prepayment amount varies from \$80.0 million to \$125.0 million less any revenue interest payments made up to such prepayment date. Under the RIFA the Company shall pay to NovaQuest up to a specified maximum amount ("Payment Cap") of (a) \$100.0 million, if the payment is made on or before December 31, 2028; (b) \$112.5 million, if the payment is made on or after January 1, 2029, but on or before December 31, 2029; or (c) \$125.0 million, if the payment is made after January 1, 2030.

After January 1, 2028, if the product (as defined) is not commercialized for a consecutive twelve-month period, then, the payments owed under the RIFA by the Company to NovaQuest for each fiscal year shall be the greater of: (i) the amount which would otherwise be due pursuant to revenue interest payments terms; or (ii) \$10.0 million.

Before December 31, 2028, if the sum of all payments under the RIFA paid to NovaQuest, does not equal or exceed \$62.5 million, then the Company shall pay NovaQuest the difference of these two amounts by no later than March 1, 2029. If, by no later than December 31, 2030, the sum of all payments under the RIFA paid to NovaQuest does not equal or exceed \$125.0 million, then the Company shall pay NovaQuest the difference of these two amounts by no later than March 1, 2031.

NovaQuest will retain this entitlement until it has reached the Payment Cap, at which point 100% of such revenue interest on future global net sales of Astellas will revert to the Company.

Over the course of the RIFA, the effective interest rate is affected by the amount and timing of drug product revenue and revenue from milestone payments recognized, the changes in the timing of forecasted drug product revenue and revenue from milestone payments, and the timing of the Company's payments to NovaQuest. On a quarterly basis, the Company reassesses the expected total revenue and the timing of such revenue, recalculates the amortization of debt discount and transactions costs and effective interest rate, and adjusts the accounting prospectively as needed. The Company's estimated effective annual interest rate was 16.07% as of September 30, 2023.

The following table summarizes the activities of the liability related to sale of future revenues for the nine months ended September 30, 2023:

	Nine Months Ended September 30, 2023
Liability related to sale of future revenues - beginning balance	\$ 49,333
Interest expense recognized	5,636
Liability related to sale of future revenues - ending balance	54,969
Less: Current portion classified to accrued and other current liabilities	(5,860)
Liability related to sale of future revenues, non-current	\$ 49,109

During the three and nine months ended September 30, 2023, the Company recognized, under Astellas Agreements, development revenue of \$2.4 million and \$5.8 million, respectively, and drug product revenue of \$1.3 million and \$17.7 million, respectively. See Note 2, *Collaboration Agreements, License Agreement and Revenue*, for details.

During the three and nine months ended September 30, 2023, the Company recognized the related non-cash interest expense of \$2.1 million and \$5.6 million, respectively.

Based on the current estimates of drug product revenue and revenue from milestone payments under the Astellas Agreements, and taking into the consideration of the terms discussed above, the Company anticipates to reach a Payment Cap up to \$125.0 million by 2031.

9. At-the-Market Program

On February 27, 2023, the Company entered into an Amended and Restated Equity Distribution Agreement (the “at-the-market agreement”) with Goldman Sachs & Co., LLC and BofA Securities, Inc. (each a “Sales Agent”), which amended and restated its Equity Distribution Agreement with Goldman Sachs & Co., LLC, dated August 8, 2022, to add BofA Securities, Inc. as an additional Sales Agent under that agreement. Under the at-the-market agreement, the Company may issue and sell, from time to time and through the Sales Agents, shares of its common stock having an aggregate offering price of up to \$200.0 million (the “ATM Program”).

There was no transaction under the ATM Program for the three months ended September 30, 2023. For the nine months ended September 30, 2023, the Company sold 2,472,090 shares under the ATM Program, for proceeds of approximately \$48.4 million, net of commissions to Sales Agents, at a weighted-average offering prices per share of \$19.63.

10. Income Taxes

Provisions for (benefits from) income tax for the three and nine months ended September 30, 2023 and 2022 were primarily due to 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.

11. Related Party Transactions

Astellas is an equity investor in the Company and is considered a related party. The Company recorded license and development revenue related to collaboration agreements with Astellas of \$2.4 million and \$1.4 million for the three months ended September 30, 2023 and 2022, and \$5.8 million and \$31.0 million for the nine months ended September 30, 2023 and 2022, respectively. The Company also recorded drug product revenue from Astellas of \$1.3 million and \$(4.1) million for the three months ended September 30, 2023 and 2022, and \$17.7 million and \$4.6 million for the nine months ended September 30, 2023 and 2022, respectively. See Note 2, *Collaboration Agreements, License Agreement and Revenues*, for details.

The Company’s expense related to collaboration agreements with Astellas was immaterial for each of the three and nine months ended September 30, 2023 and 2022.

As of September 30, 2023 and December 31, 2022, accounts receivable from Astellas were \$8.7 million and \$1.5 million, respectively.

As of September 30, 2023 and December 31, 2022, total deferred revenue from Astellas was \$10.2 million and \$40.3 million, respectively.

As of September 30, 2023, the amounts due to Astellas, included in accrued and other current liabilities, and other long-term liabilities, totaled \$29.8 million. As of December 31, 2022, the amount due to Astellas, included in accrued and other current liabilities, was \$63.9 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 4, *Equity method investment - Variable Interest Entity*, for details.

The net product revenue from Falikang was \$26.5 million and \$14.9 million for the three months ended September 30, 2023 and 2022, and \$68.3 million and \$50.9 million for the nine months ended September 30, 2023 and 2022, respectively. See the *Product Revenue, Net* section in Note 2, *Collaboration Agreements, License Agreement and Revenues*, for details.

The investment income in Falikang was \$0.7 million and \$0.4 million for the three months ended September 30, 2023 and 2022, and \$2.0 million and \$1.3 million for the nine months ended September 30, 2023 and 2022, respectively. During the three months ended September 30, 2023, the Company received \$2.3 million of dividend distribution from Falikang. As of September 30, 2023 and December 31, 2022, the Company's equity method investment in Falikang was \$4.5 million and \$5.1 million, respectively. See Note 4, *Equity method investment - Variable Interest Entity*, for details. The other income from Falikang was immaterial for each of the three and nine months ended September 30, 2023 and 2022.

As of September 30, 2023 and December 31, 2022, accounts receivable, net, from Falikang, were \$14.2 million and \$10.5 million, respectively.

12. Commitments and Contingencies

Contract Obligations

As of September 30, 2023, the Company had outstanding total non-cancelable purchase obligations of \$37.8 million, including \$22.8 million for manufacture and supply of pamrevlumab, \$2.2 million for manufacture and supply of roxadustat, and \$12.8 million for other purchases and programs. The Company expects to fulfill its 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 September 30, 2023, future milestone payments for research and preclinical stage development programs consisted of up to approximately \$697.9 million in total potential future milestone payments under the Company's license agreements with HiFiBiO (for Gal-9 and CCR8), 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.

As of September 30, 2023, the Company had \$81.9 million of operating lease liabilities.

In addition, see Note 7, *Senior Secured Term Loan Facilities* and Note 8, *Liability Related to Sale of Future Revenues* for details of the related obligations.

Legal Proceedings and Other Matters

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 any material accruals for any active legal action, except for the class action settlement mentioned below, in its condensed consolidated balance sheet as of September 30, 2023, as the Company could not predict the ultimate outcome of these matters, or reasonably estimate the potential exposure.

Between April 2021 and May 2021, five 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 U.S. Food and Drug Administration approval. On August 30, 2021, the Court consolidated the actions and appointed a group of lead plaintiffs. Plaintiffs filed their consolidated amended complaint on October 29, 2021 and a corrected consolidated amended complaint on November 19, 2021 (the “Complaint”). The Complaint alleges false and misleading statements between December 2018 and June 2021 and seeks to represent a class of persons or entities that purchased FibroGen securities between December 20, 2018 and July 15, 2021. On July 15, 2022, the court issued an order denying Defendants’ motions to dismiss. Defendants answered the Complaint on September 13, 2022. On January 27, 2023, Plaintiffs filed a motion for class certification, which the court granted in part and denied in part on October 3, 2023. On October 17, 2023, the parties reached an agreement in principle to settle the class action at \$28.5 million. Accordingly, as of September 30, 2023, the Company recorded the \$28.5 million in accrued and other current liabilities in the condensed consolidated balance sheet. The Company maintains insurance that covers exposure related to the class action lawsuit. As the amount is fully recoverable under the Company’s insurance policies, the Company recorded a corresponding receivable in prepaid expenses and other current assets in the condensed consolidated balance sheet. The determination that the recorded receivables are probable of collection is based on the terms of the applicable insurance policies and communications with the insurers. Another case, filed on May 25, 2023, against the same defendants, asserting similar claims as the class action and additional common-law and California state fraud claims, remains pending. Defendants filed a motion to dismiss the complaint in that case on September 20, 2023.

On July 30, 2021, a purported shareholder derivative complaint was filed in the U.S. District Court for the Northern District of California (the “California Federal Derivative”). On December 27, 2021, a second purported shareholder derivative complaint was filed in the U.S. District Court for the District of Delaware (the “Delaware Federal Derivative”). On April 14, 2022, a third purported shareholder derivative complaint was filed in the Delaware Court of Chancery (the “First Delaware Chancery Derivative”). On June 1, 2023, a fourth purported shareholder derivative complaint was filed in the Delaware Court of Chancery (the “Second Delaware Chancery Derivative”). All four derivative actions name FibroGen’s current and former officers and directors as defendants, as well as FibroGen as nominal defendant, and assert state and federal claims based on some of the same alleged misstatements as the securities class action complaint. The complaints seek unspecified damages, attorneys’ fees, and other costs. The California Federal Derivative action and the Delaware Federal Derivative action are stayed pending the resolution of any motions for summary judgment in the securities class action. The First and Second Delaware Chancery Derivative actions have been consolidated and the plaintiffs in the consolidated Delaware Chancery Derivative filed their amended complaint on November 3, 2023. On June 30, 2023, a fifth derivative action was filed in the U.S. District Court for the District of Delaware (the “Demand Refused Derivative”). The Demand Refused Derivative action names FibroGen’s current and former officers, as well as FibroGen as nominal defendant, and asserts state and federal claims based on some of the same alleged misstatements as the securities class action complaint. The Demand Refused Derivative has been stayed pending the outcome of any motion to dismiss the amended complaint in the Delaware Chancery Derivative.

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.

In the fourth quarter of 2021, the Company received a subpoena from the SEC requesting documents related to roxadustat’s pooled cardiovascular safety data. The Company is fully cooperating with the SEC. The Company cannot predict with any degree of certainty the outcome of the SEC’s investigation or determine the extent of any potential liabilities. The Company also cannot predict whether there will be any loss as a result of the investigation nor can it provide an estimate of the possible loss or range of loss. Any adverse outcome in this matter or any related proceeding could expose the Company to substantial damages, penalties, or reputational harm that may have a material adverse impact on the Company’s business, results of operations, financial condition, growth prospects, and price of its common stock.

Between August 3, 2022 and August 4, 2022, the Company's Board of Directors received three litigation demands from purported shareholders of the Company, asking the Board of Directors to investigate and take action against certain current and former officers and directors of the Company for alleged wrongdoing based on the same allegations in the pending derivative and securities class action lawsuits. On March 27, 2023, the Company's Board of Directors received another litigation demand from a purported shareholder of the Company, seeking similar action as the other litigation demands. The Company may in the future receive such additional demands.

Starting in October 2021, certain challenges have been filed with the China National Intellectual Property Administration against patents which claim a crystalline form of roxadustat. Final resolution of such proceedings will take time and the Company could not predict the ultimate outcome, or reasonably estimate the potential exposure.

Indemnification Agreements

The Company enters into standard indemnification arrangements in the ordinary course of business, including for example, service, manufacturing and collaboration agreements. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, including in connection with intellectual property infringement claims by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The Company has entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the extent permissible under applicable law. The maximum potential amount of future payments the Company could be required to make under these arrangements is not determinable. The Company believes the estimated fair value of these arrangements is minimal.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the condensed consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q, and in our Securities and Exchange Commission ("SEC") filings, including our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on February 27, 2023 ("2022 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," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Such forward-looking and other 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 and other 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 and other statements. While we may elect to update these forward-looking and other 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 and other 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 discovering, developing and commercializing a pipeline of first-in-class therapeutics. Our lead product candidate and product are pamrevlumab and roxadustat, respectively. We apply our pioneering expertise in hypoxia-inducible factor ("HIF") biology, 2-oxoglutarate enzymology, and connective tissue growth factor ("CTGF") biology to advance innovative medicines for the treatment of anemia and cancer.

Pamrevlumab, a human monoclonal antibody targeting CTGF, is in Phase 3 clinical development for the treatment of locally advanced unresectable pancreatic cancer ("LAPC"). Pamrevlumab is also in Phase 2/3 development for the treatment of metastatic pancreatic cancer. To date, we have retained exclusive worldwide rights for pamrevlumab.

Roxadustat is an oral small molecule inhibitor of HIF prolyl hydroxylase ("HIF-PH") activity. Roxadustat ([®], EVRENZO[™]) is approved in China, Europe, Japan, and numerous other countries for the treatment of anemia in chronic kidney disease ("CKD") for patients who are on dialysis and not on dialysis. Roxadustat is in clinical development for chemotherapy-induced anemia ("CIA") in China.

Our goal is to build a diversified pipeline with novel drugs that will address unmet patient needs with a refined focus in oncology.

Financial Highlights

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(in thousands, except for per share data)			
Result of Operations				
Revenue	\$ 40,134	\$ 15,735	\$ 120,614	\$ 106,367
Operating costs and expenses	103,616	109,392	348,234	341,240
Net loss	(63,615)	(91,650)	(228,000)	(227,479)
Net loss per share - basic and diluted	\$ (0.65)	\$ (0.98)	\$ (2.35)	\$ (2.43)

	September 30, 2023		December 31, 2022	
	(in thousands)			
Balance Sheet				
Cash and cash equivalents	\$	120,914	\$	155,700
Short-term and long-term investments		130,426		270,656
Accounts receivable	\$	31,694	\$	16,299

Our revenue for the three and nine months ended September 30, 2023 included primarily the revenue recognized related to the following:

- \$29.4 million and \$77.4 million of net product revenue from roxadustat commercial sales in China;
- \$6.0 million and \$13.8 million of development revenue recognized under our collaboration agreements with our partners Astellas Pharma Inc. (“Astellas”) and AstraZeneca AB (“AstraZeneca”);
- \$4.0 million regulatory milestone recognized during the three months ended September 30, 2023, under AstraZeneca China Agreement (defined further below) associated with the renewal of our right to continue to market Roxadustat in China. Of this amount, \$2.7 million was recognized as license revenue, \$0.8 million was recognized as development revenue and the remainder was included in deferred revenue;
- \$1.3 million and \$17.7 million of drug product revenue related to active pharmaceutical ingredient (“API”) deliveries to Astellas; and
- \$1.0 million upfront payment for the second quarter of 2023 and a \$3.0 million milestone payment based on Eluminex Biosciences (Suzhou) Limited (“Eluminex”) implanting a biosynthetic cornea in the first patient of its clinical trial in China and a \$3.0 million manufacturing related milestone payment in the first quarter of 2023 for the first quarter of 2023, recognized under our license agreement and amendments with Eluminex.

As a comparison, our revenue for the three and nine months ended September 30, 2022 included primarily the revenue recognized related to the following:

- \$17.4 million and \$59.5 million of net product revenue for the three and nine months ended September 30, 2022, respectively, from roxadustat commercial sales in China;
- \$2.0 million and \$18.2 million of development revenue for the three and nine months ended September 30, 2022, respectively, recognized under our collaboration agreements with our partners Astellas and AstraZeneca;
- \$25.0 million regulatory milestone for the nine months ended September 30, 2022, recognized in the first quarter of 2022, under our collaboration agreements with our partner Astellas associated with the approval of EVRENZO[®] (roxadustat) in Russia. Of this amount, \$22.6 million was recognized as license revenue and the remainder was included as development revenue; and
- \$(4.1) million and \$4.6 million of drug product revenue for the three and nine months ended September 30, 2022, respectively, related to API deliveries to Astellas.

Operating costs and expenses for the three months ended September 30, 2023 decreased compared to the same period a year ago primarily as a result of the net effect of the following:

- \$14.5 million lower drug development expenses associated with drug substance and drug product manufacturing activities related to pamrevlumab which was largely completed in the prior year or terminated in the current year period;
- \$6.1 million lower stock-based compensation primarily resulting from significantly lower stock price and cancellations of stock options and restricted stock units;
- \$4.3 million lower employee-related expenses primarily due to the reduction in force in July 2023, offset by overall merit increase, and the impact from a payroll tax refund received during the third quarter of 2022 that did not recur in the current year period;
- \$12.6 million of restructuring charge recorded in the third quarter of 2023 related to the reduction in force in July 2023;
- \$4.0 million higher outside services expenses due to higher consulting activities in roxadustat post-approval safety studies and general administrative function; and
- \$1.8 million higher clinical trial expenses primarily associated with Phase 2/3 trials for pamrevlumab for the treatment of metastatic pancreatic cancer.

Operating costs and expenses for the nine months ended September 30, 2023 increased compared to the same period a year ago primarily as a result of the net effect of the following:

- \$24.6 million one-time, non-cash charge of acquired in-process research and development (“IPR&D”) expenses associated with the recent exclusive license for FG-3246 from Fortis Therapeutics (“Fortis”) and the acquisition of Fortis;
- \$12.6 million of restructuring charge recorded in the third quarter of 2023 related to the reduction in force in July 2023;
- \$7.6 million higher outside services expenses due to higher consulting activities in roxadustat post-approval safety studies and general administrative function;
- \$3.7 million higher employee-related expenses primarily due to overall merit increase, more business travel activities and higher severance during the current year period, and the impact from a payroll tax refund received during the third quarter of 2022 that did not recur in the current year period, offset by the impact from the reduction in force in July 2023;
- \$36.0 million lower drug development expenses associated with drug substance and drug product manufacturing activities related to roxadustat post-approval safety studies in China and pamrevlumab which were largely completed in the prior periods; and
- \$7.9 million lower stock-based compensation primarily resulting from significantly lower stock price and cancellations of stock options and restricted stock units.

For the three months ended September 30, 2023, we had a net loss of \$63.6 million, or a net loss per basic and diluted share of \$0.65, as compared to a net loss of \$91.7 million, or a net loss per basic and diluted share of \$0.98, for the same period a year ago, due to increases in revenue and decreases in operating costs and expenses as discussed above.

For the nine months ended September 30, 2023, we had a net loss of \$228.0 million, or a net loss per basic and diluted share of \$2.35, as compared to a net loss of \$227.5 million, or a net loss per basic and diluted share of \$2.43, for the same period a year ago, due to increases in revenue, offset by increases in operating costs and expenses, as discussed above.

Cash and cash equivalents, investments, and accounts receivable totaled \$283.0 million at September 30, 2023, a decrease of \$159.6 million from December 31, 2022, primarily due to the cash used in operations, partially offset by the net proceeds received under our senior secured term loan facilities and at-the-market program, discussed under the *Liquidity and Capital Resources* section below.

Commercial, Development and Research Programs

Our goals are to continue our commercialization of roxadustat in China and other approved countries, continue our development of pamrevlumab in pancreatic cancer, and build a diversified pipeline with novel drugs that will address unmet patient needs with a refined focus in oncology.

The following is an overview of our clinical, commercial, and research programs.

Pamrevlumab: Monoclonal Antibody Targeting Connective Tissue Growth Factor

Pamrevlumab is our first-in-class antibody developed to inhibit the activity of CTGF. In addition to enabling progression of fibrosis, CTGF has been shown preclinically to have pro-tumorigenic effects in pancreatic cancer through increasing tumor cell proliferation and survival and promoting tumor angiogenesis and metastasis.

The United States (“U.S.”) Food and Drug Administration has granted Fast Track and Orphan Drug designations to pamrevlumab for the treatment of LAPC.

Pamrevlumab for the Treatment of Locally Advanced Unresectable Pancreatic Cancer

LAPIS is our double-blind placebo-controlled Phase 3 clinical program for pamrevlumab as a therapy for LAPC. We completed enrollment of 284 patients that are randomized at a 1:1 ratio to receive either pamrevlumab or placebo, in each case in combination with chemotherapy (either FOLFIRINOX or gemcitabine plus nab-paclitaxel). We expect topline data for the primary endpoint of overall survival in the first quarter of 2024.

Pamrevlumab for the Treatment of Metastatic Pancreatic Cancer

In June 2021, the Pancreatic Cancer Action Network’s (PanCAN) Precision PromiseSM Phase 2/3 registration study, an adaptive trial platform, included pamrevlumab in combination with standard of care chemotherapy treatments for pancreatic cancer (gemcitabine and Abraxane[®]), for patients with metastatic pancreatic cancer. Drug candidates in the Precision Promise study will continue to progress (including from Phase 2 to Phase 3) unless stopped sooner for safety or futility. The pamrevlumab combination therapy is offered to patients as either a first- or second-line treatment option. Pamrevlumab was 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. The pamrevlumab portion of the trial is still ongoing, fully enrolled, and we expect topline results in the first half of 2024.

Pamrevlumab for the Treatment of Duchenne Muscular Dystrophy

Ambulatory DMD Patients

In August 2023, we announced topline results from LELANTOS-2, our double-blind, placebo-controlled Phase 3 trial evaluating pamrevlumab in ambulatory DMD, in combination with systemic corticosteroids. The study did not meet the primary endpoint of change in the North Star Ambulatory Assessment (NSAA) total score from baseline to week 52 (placebo-corrected mean difference -0.528 points; 95% CI -2.308 to 1.251; p=0.5553). Secondary endpoints measured by change from baseline at week 52 in 4-stair climb velocity, 10-meter walk/run test, time to stand, time to loss of ambulation, and proportion of patients with greater than 10 seconds in the 10-meter walk/run test were also not met.

Preliminary safety data showed that pamrevlumab was generally safe and well tolerated. The majority of treatment emergent adverse events were mild or moderate.

The Company plans to communicate the full results of the LELANTOS-2 study at an upcoming medical forum.

Roxadustat for the Treatment of Anemia in Chronic Kidney Disease

Roxadustat is our commercial-stage 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.

Roxadustat ([®], EVRENZO[™]) is approved in China, Europe, Japan, and numerous other countries for the treatment of anemia in CKD for patients who are on dialysis and not on dialysis.

In China, roxadustat (tradename: [®]) continues to see significant volume growth in the treatment of anemia caused by CKD in non-dialysis and dialysis patients. In the third quarter of 2023, roxadustat achieved an over 37% increase in sales volume relative to the third quarter of 2022. As of August 2023, roxadustat was the top CKD anemia brand in China with approximately 42% value share within the segment of erythropoiesis stimulating agents and HIF-PH inhibitors (roxadustat is currently the only HIF-PH inhibitor on the market in China).

Roxadustat for the Treatment of Chemotherapy-Induced Anemia

In May 2023, we announced positive topline data from our Phase 3 clinical study of roxadustat for treatment of anemia in patients receiving concurrent chemotherapy treatment for non-myeloid malignancies in China. Roxadustat ([®]) demonstrated non-inferiority compared to recombinant erythropoietin alfa (SEPO[®]) on the primary endpoint of change in hemoglobin (Hb) level from baseline to the average level during Weeks 9-13.

In the preliminary safety analysis, the adverse event profile of roxadustat was generally consistent with previous findings and supportive of a positive benefit risk in this patient population.

A total of 159 patients with non-myeloid malignancy (solid tumor) with a baseline hemoglobin level at or below 10 g/dL were enrolled into this Phase 3, randomized, open-label, active-controlled study investigating the efficacy and safety of roxadustat for treatment of CIA. Patients were randomly assigned roxadustat or erythropoietin alfa three times per week (TIW), during a treatment period of 12 weeks, with an additional 4-week follow-up period. We recently presented results from this study in an oral presentation at the European Society for Medical Oncology Congress 2023.

Our supplemental New Drug Application for roxadustat in CIA was accepted by the China Health Authority in August 2023.

Although CIA is one of the most common side effects of chemotherapy, it is frequently undertreated. CIA can adversely affect long-term patient outcomes, as anemia limits both quality of life and the ability of patients to continue chemotherapy treatment. The incidence and severity of CIA depends on a variety of factors. This includes the type of cancer and the treatment, including the type of chemotherapy, schedule, and intensity of therapy. It also depends on whether the patient has received prior myelosuppressive chemotherapy, radiation therapy, or both. Almost 80% of cancer patients in China receiving chemotherapy develop anemia. Approximately 50% of cancer patients in China receiving chemotherapy develop severe anemia that merits treatment (hemoglobin under 10g/dL). In China, over 3 million cancer patients undergo chemotherapy.

FG-3246: Prostate Cancer; Potential Additional Cancer Indications

In May 2023 we obtained an exclusive license to develop FG-3246 (previously FOR46) in metastatic castration-resistant prostate cancer (“mCRPC”) and other cancer indications. FG-3246 is a first-in-class antibody-drug conjugate targeting a novel epitope on CD46 that is expressed at high levels in certain tumor types with limited expression in most normal tissues. The cytotoxic payload of FG-3246 is monomethyl auristatin E, an anti-mitotic agent that has been utilized in four commercially approved antibody-drug conjugate drugs.

FG-3246 showed monotherapy efficacy in a Phase 1 clinical study in patients with mCRPC, with a PSA50 interim response rate of 45% and an objective partial response rate of 19%. We expect final topline results of this study by the first quarter of 2024.

An investigator sponsored trial of FG-3246 plus enzalutimide is ongoing. Side effects have been manageable and are consistent with other monomethyl auristatin E-based antibody-drug conjugate drugs.

We anticipate the initiation of a PET biomarker driven Phase 2 trial of FG-3246 for mCRPC in the second half of 2024. Development of the CD46-targeted PET biomarker is currently underway with UCSF, a collaborator of Fortis. We are also exploring additional potential tumor indications in which CD46 is commonly expressed.

Preclinical Pipeline

Our preclinical pipeline consists of two antibodies for immuno-oncology that are in investigational new drug application-enabling studies, and an additional small molecule drug discovery pipeline that leverages the expertise we developed through our HIF-PH inhibitor programs in 2 oxoglutarate dependent dioxygenase biology.

FG-3165 is a galectin-9 (“Gal9”) targeted antibody under development for treatment of solid tumors characterized by high Gal9 levels of expression. Gal9 has been reported to bind to multiple immune checkpoints on lymphocytes that suppress T and natural killer cell activation. In preclinical studies FG-3165 and its variants inhibit Gal9 mediated T cell death, and also promotes anti-tumor immune responses in combination with other immune checkpoint targeted drugs. We plan to submit an investigational new drug application in the first quarter of 2024.

FG-3175 is a c-c motif chemokine receptor 8 (“CCR8”) targeted antibody under development for treatment of solid tumors that are highly infiltrated by CCR8-positive T regulatory cells. T regulatory cells contribute to an immune suppressed tumor microenvironment, and multiple preclinical studies have demonstrated immune activation and tumor regression following depletion of this cell type from the tumor microenvironment. FG-3175 is a variant of our previous lead anti-CCR8 antibody, FG-3163, and was deemed to be a superior clinical candidate following extended characterization of both antibodies. FG-3175 has enhanced antibody dependent cellular cytotoxicity activity and induces potent killing of CCR8 expressing cells by natural killer cells in in vitro assay systems. An investigational new drug application is planned for the second half of 2024.

The 2 oxoglutarate dependent dioxygenase targeted small molecule pipeline is being developed to target cancer epigenetic pathways that contribute to tumor proliferation.

Debt Financing Agreement

On April 29, 2023, we entered into a financing agreement (the “Financing Agreement”) with a \$75.0 million senior secured term loan with investment funds managed by Morgan Stanley Tactical Value, as lenders, and Wilmington Trust, National Association, as the administrative agent.

For additional details about this financing transaction, see Note 7, *Senior Secured Term Loan Facilities*, to the condensed consolidated financial statements.

Exclusive License and Option to Acquire Fortis Therapeutics

On May 5, 2023, we entered into an exclusive option agreement to acquire Fortis with its novel Phase 1 antibody-drug conjugate, FG-3246 (previously FOR46), that targets a novel epitope on CD46 preferentially expressed on certain cancer cells. FG-3246 is in development for the treatment of metastatic castration-resistant prostate cancer with potential applicability in other solid tumors and hematologic malignancies.

Pursuant to an evaluation agreement entered into with Fortis concurrent with the option agreement, FibroGen has exclusively licensed FG-3246 and will control and fund future research, development, including a Phase 2 clinical study sponsored by FibroGen, and manufacturing of FG-3246 during the option period. As part of the clinical development strategy, we will continue the work to develop a PET-based biomarker utilizing a radiolabeled version of the targeting antibody for patient selection.

FibroGen will pay Fortis \$5.0 million during the up to four-year option period in support of their continued development obligations.

If we exercise the option to acquire Fortis, we will pay Fortis \$80.0 million, and thereafter, Fortis would be eligible to receive from FibroGen up to \$200.0 million in contingent payments associated with the achievement of various regulatory approvals. If we acquire Fortis, we would also be responsible to pay UCSF, an upstream licensor to Fortis, development milestone fees and a single digit royalty on net sales of therapeutic or diagnostic products arising from the collaboration. If FibroGen chooses not to acquire Fortis, its exclusive license to FG-3246 would expire.

For additional details about this transaction, see Note 3, *Exclusive License and Option to Acquire Fortis Therapeutics*, to the condensed consolidated financial statements.

Eluminex Agreement

In April 2023, FibroGen and Eluminex entered into an Amended and Restated Exclusive License Agreement (“A&R Eluminex Agreement”) in order to add to the license rights to recombinant human collagen Type I (in addition to the rights to collagen Type III that were already licensed). The A&R Eluminex Agreement included additional total upfront payments of \$1.5 million.

During the three months ended September 30, 2023, we recognized a \$0.5 million upfront payment under the A&R Eluminex Agreement. During the three months ended June 30, 2023, we recognized a \$1.0 million upfront payment under the above amendment. During the three months ended March 31, 2023, we recognized a \$3.0 million milestone payment based on Eluminex implanting a biosynthetic cornea in the first patient of its clinical trial in China, and a \$3.0 million manufacturing related milestone payment.

See the *Eluminex Agreement* section in Note 2, *Collaboration Agreements, License Agreement and Revenues*, to the condensed consolidated financial statements for details.

Collaboration Partnerships for Roxadustat

Our current and future research, development, manufacturing and commercialization efforts with respect to roxadustat depend on funds from our collaboration agreements with Astellas and AstraZeneca. See Note 2, *Collaboration Agreements, License Agreement 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 (“Astellas Japan Agreement”). In April 2006, we entered into a separate collaboration agreement with Astellas for roxadustat for the treatment of anemia in Europe, the Commonwealth of Independent States, the Middle East, and South Africa (“Astellas Europe Agreement”). Under these agreements, the aggregate amount of consideration received through September 30, 2023 totaled \$790.1 million.

On March 21, 2022, EVRENZO[®] (roxadustat) was registered with the Russian Ministry of Health. We evaluated the regulatory milestone payment associated with the approval in Russia under the Astellas Europe Agreement and concluded that this milestone was achieved in the first quarter of 2022. Accordingly, the consideration of \$25.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the Astellas Europe Agreement, all of which was recognized as revenue during the first quarter of 2022 from performance obligations satisfied.

In 2018, we and Astellas entered into an amendment to the Astellas Japan Agreement that allows Astellas to manufacture roxadustat drug product for commercialization in Japan (the “Astellas Japan Amendment”). The related drug product revenue was \$0.7 million and \$(4.3) million for the three months ended September 30, 2023 and 2022, and \$16.2 million and \$3.3 million for the nine months ended September 30, 2023 and 2022, respectively.

During the first quarter of 2021, we entered into an EU Supply Agreement with Astellas under the Astellas Europe Agreement 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 “Astellas EU Supply Agreement”). The related drug product revenue was \$0.6 million and \$0.2 million for the three months ended September 30, 2023 and 2022, and \$1.5 million and \$1.3 million for the nine months ended September 30, 2023 and 2022, respectively.

AstraZeneca

In July 2013, we entered into a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in the U.S. and all territories not previously licensed to Astellas, except China (the “AstraZeneca U.S./RoW Agreement”). In July 2013, through our China subsidiary and related affiliates, we entered into a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in China (the “AstraZeneca China Agreement”). Under the AstraZeneca agreements, the aggregate amount of consideration received through September 30, 2023 totaled \$516.2 million.

Under the AstraZeneca 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 AstraZeneca China Amendment in the third quarter of 2020, as discussed and defined below in *AstraZeneca China Amendment*.

On September 18, 2023, we received the formal notice, from Beijing Medical Products Administration, of renewal of its right to continue to market Roxadustat in China through 2028. The Company evaluated the regulatory milestone payment associated with this renewal under the AstraZeneca China Agreement and concluded that this milestone was achieved in the third quarter of 2023. Accordingly, the consideration of \$4.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the AstraZeneca U.S./RoW Agreement and the AstraZeneca China Agreement, \$3.5 million of which was recognized as revenue during the third quarter of 2023 from performance obligations satisfied or partially satisfied.

In 2020, we entered into a Master Supply Agreement with AstraZeneca under the AstraZeneca U.S./RoW Agreement (the “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. There was no related drug product revenue for the three and nine months ended September 30, 2023 and 2022.

AstraZeneca China Amendment

In July 2020, FibroGen China and AstraZeneca entered into an amendment, effective July 1, 2020, to the AstraZeneca China Agreement, relating to the development and commercialization of roxadustat in China (the “AstraZeneca China Amendment”). Under the AstraZeneca 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 conducts 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. We recognized related net product revenue of \$29.4 million and \$17.4 million for the three months ended September 30, 2023 and 2022, and \$77.4 million and \$59.5 million for the nine months ended September 30, 2023 and 2022, respectively.

Additional Information Related to Collaboration Agreements

Total cash consideration received through September 30, 2023 and potential cash consideration, for upfront payments and milestone payments under our collaboration agreements are as follows:

	<u>Cash Received for Upfront Payments and Milestone Payments Through September 30, 2023</u>	<u>Additional Potential Cash Payment for Milestones (in thousands)</u>	<u>Total Potential Cash Payments for Upfront Payments and Milestones</u>
Astellas--related-party:			
Astellas Japan Agreement	\$ 105,093	\$ 67,500	\$ 172,593
Astellas Europe Agreement	685,000	60,000	745,000
Total Astellas	790,093	127,500	917,593
AstraZeneca:			
AstraZeneca U.S./RoW Agreement	439,000	810,000	1,249,000
AstraZeneca China Agreement	77,200	299,500	376,700
Total AstraZeneca	516,200	1,109,500	1,625,700
Total	<u>\$ 1,306,293</u>	<u>\$ 1,237,000</u>	<u>\$ 2,543,293</u>

The above table does not include development cost reimbursement, transfer price payments, and royalties and profit share under our existing collaboration agreements. Based on our current development plans for roxadustat in Japan, Europe and U.S., we do not expect to receive most or all of these additional potential milestones under the Astellas Japan Agreement, the Astellas Europe Agreement and the AstraZeneca U.S./RoW Agreement.

RESULTS OF OPERATIONS

Revenue

	<u>Three Months Ended September 30,</u>		<u>Change</u>		<u>Nine Months Ended September 30,</u>		<u>Change</u>	
	<u>2023</u>	<u>2022</u>	<u>\$</u>	<u>%</u>	<u>2023</u>	<u>2022</u>	<u>\$</u>	<u>%</u>
(dollars in thousands)								
Revenue:								
License revenue	\$ 2,649	\$ —	\$ 2,649	NM	\$ 9,649	\$ 22,590	\$ (12,941)	(57) %
Development and other revenue	6,775	2,453	4,322	176 %	15,825	19,672	(3,847)	(20) %
Product revenue, net	29,390	17,359	12,031	69 %	77,439	59,495	17,944	30 %
Drug product revenue, net	1,320	(4,077)	5,397	132 %	17,701	4,610	13,091	284 %
Total revenue	<u>\$ 40,134</u>	<u>\$ 15,735</u>	<u>\$ 24,399</u>	155 %	<u>\$ 120,614</u>	<u>\$ 106,367</u>	<u>\$ 14,247</u>	13 %

NM = Not meaningful

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 respective periods. This revenue is generally recognized as deliverables are met and services are performed.

Development revenue includes co-development and other development related services. We recognize development services as revenue in the period in which they are billed to our partners, excluding China. As of September 30, 2023, we expect the future development services to continue through the end of 2023. For China co-development services, we defer revenue until we begin to transfer control of the manufactured commercial product to AstraZeneca, which commenced in the first quarter of 2021 and we expect to continue through 2028, which reflects our best estimates. Other revenues consist of contract manufacturing revenue, patent transfer and sales of research and development material, which have not been material for any of the periods presented.

We recognize product revenue 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, under the AstraZeneca U.S./RoW Agreement, and Astellas in support of pre-commercial preparation prior to the New Drug Application or marketing authorization application approval, and to Astellas for ongoing commercial launch in Japan and Europe. We recognize drug product revenue when we fulfill the inventory transfer obligations. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the drug product revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period when the uncertainty associated with the variable consideration is subsequently resolved. Actual amounts of consideration ultimately received in the future may differ from our estimates, for which we will adjust these estimates and affect the drug product revenue in the period such variances become known.

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

Total revenue increased \$24.4 million, or 155% for the three months ended September 30, 2023, and increased \$14.2 million, or 13% for the nine months ended September 30, 2023, respectively, compared to the same periods a year ago for the reasons discussed in the sections below.

License Revenue

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%
(dollars in thousands)								
License revenue:								
Astellas	\$ —	\$ —	\$ —	NM	\$ —	\$ 22,590	\$ (22,590)	NM
AstraZeneca	2,649	—	2,649	NM	2,649	—	2,649	NM
Eluminex	—	—	—	NM	7,000	—	7,000	NM
Total license revenue	\$ 2,649	\$ —	\$ 2,649	NM	\$ 9,649	\$ 22,590	\$ (12,941)	(57) %

NM = Not meaningful

License revenue recognized under our collaboration agreements with AstraZeneca for three and nine months ended September 30, 2023 represented the allocated revenue related to \$4.0 million regulatory milestone associated with the renewal of our right to continue to market roxadustat in China that was included in the transaction price during the third quarter of 2023 when such milestone was achieved. License revenue recognized for the nine months ended September 30, 2023 also included a \$1.0 million upfront payment under the A&R Eluminex Agreement, a \$3.0 million milestone payment based on Eluminex implanting a biosynthetic cornea in the first patient of its clinical trial in China, and a \$3.0 million manufacturing related milestone payment when such milestones were achieved.

License revenue recognized under our collaboration agreements with Astellas for the nine months ended September 30, 2022 represented the allocated revenue related to a \$25.0 million regulatory milestone payment associated with the approval of EVRENZO® (roxadustat) in Russia that was included in the transaction price during the first quarter of 2022 when such milestone was achieved.

Development and Other Revenue

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change		
	2023	2022	\$	%	2023	2022	\$	%	
(dollars in thousands)									
Development revenue:									
Astellas	\$ 2,358	\$ 1,414	\$ 944	67 %	\$ 5,821	\$ 8,419	\$ (2,598)	(31) %	
AstraZeneca	3,676	579	3,097	535 %	7,981	9,750	(1,769)	(18) %	
Total development revenue	6,034	1,993	4,041	203 %	13,802	18,169	(4,367)	(24) %	
Other revenue	741	460	281	61 %	2,023	1,503	520	35 %	
Total development and other revenue	\$ 6,775	\$ 2,453	\$ 4,322	176 %	\$ 15,825	\$ 19,672	\$ (3,847)	(20) %	

Development and other revenue increased \$4.3 million, or 176% for the three months ended September 30, 2023, and decreased \$3.8 million, or 20% for the nine months ended September 30, 2023, respectively, compared to the same periods a year ago.

Development revenue recognized under our collaboration agreements with Astellas for the three and nine months ended September 30, 2023 was impacted by the increase in co-development billings due to the closeout activities under our collaboration agreements with Astellas for roxadustat.

Development revenue recognized under our collaboration agreements with Astellas for the nine months ended September 30, 2022 included the allocated revenue of \$2.4 million related to the above-mentioned \$25.0 million regulatory milestone payment associated with the approval in Russia during the first quarter of 2022.

Development revenue recognized under our collaboration agreements with AstraZeneca for the three months ended September 30, 2023 was impacted by the increase in co-development billings due to the closeout activities under our collaboration agreements with AstraZeneca for roxadustat, and included the allocated revenue of \$0.8 million related to the above-mentioned \$4.0 million regulatory milestone associated with the renewal of our right to continue to market Roxadustat in China.

Development revenue recognized under our collaboration agreements with AstraZeneca for the nine months ended September 30, 2023 was impacted by the decrease in CKD-related co-development billings in the U.S.

Other revenue recognized for the three months ended September 30, 2023 included a \$0.5 million upfront payment related to patent transfer under from Eluminex. Other revenue recognized for the three and nine months ended September 30, 2023 and 2022 also included our contract manufacturing agreement with Eluminex, under which we are responsible for supplying the cornea product at 110% of our product manufacturing costs until our manufacturing technology is fully transferred to Eluminex, as well as revenue from sales of certain research and development material.

Product Revenue, Net

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%
(dollars in thousands)								
Direct Sales:								
Gross revenue	\$ 3,186	\$ 2,610	\$ 576	22 %	\$ 9,853	\$ 8,972	\$ 881	10 %
Discounts and rebates	(261)	(166)	(95)	57 %	(763)	(353)	(410)	116 %
Sales returns	2	1	1	100 %	2	3	(1)	(33) %
Direct sales revenue, net	2,927	2,445	482	20 %	9,092	8,622	470	5 %
Sales to Falikang:								
Gross transaction price	42,294	32,510	9,784	30 %	118,696	83,517	35,179	42 %
Profit share	(18,130)	(12,980)	(5,150)	40 %	(51,430)	(31,894)	(19,536)	61 %
Net transaction price	24,164	19,530	4,634	24 %	67,266	51,623	15,643	30 %
Decrease (increase) in deferred revenue	2,299	(4,616)	6,915	(150) %	1,081	(750)	1,831	(244) %
Sales to Falikang revenue, net	26,463	14,914	11,549	77 %	68,347	50,873	17,474	34 %
Total product revenue, net	\$ 29,390	\$ 17,359	\$ 12,031	69 %	\$ 77,439	\$ 59,495	\$ 17,944	30 %

Substantially all direct product sales to distributors in China have been made by Falikang, while FibroGen Beijing continues to sell product directly in one province in China. Total product revenue, net increased \$12.0 million, or 69% for the three months ended September 30, 2023, and increased \$17.9 million, or 30%, respectively, compared to the same periods a year ago.

We recognize product revenue from direct sales to distributors in an amount that reflects the consideration that we expect to be entitled to in exchange for those products, net of various sales rebates and discounts. 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.

Product revenue from direct sales, increased \$0.5 million, or 20% for the three months ended September 30, 2023, and increased \$0.5 million, or 5% for the nine months ended September 30, 2023, respectively, compared to the same periods a year ago, due to the increase in sales volume during the current year period. The total discounts and rebates were immaterial for each of the three and nine months ended September 30, 2023 and 2022.

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. We recognize revenue 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.

Sales to Falikang revenue, net increased \$11.5 million, or 77% for the three months ended September 30, 2023, and increased \$17.5 million, or 34% for the nine months ended September 30, 2023, respectively, compared to the same periods a year ago. The gross transfer price increased \$9.8 million and \$35.2 million, and the calculated profit share increased \$5.2 million and \$19.5 million for the three and nine months ended September 30, 2023, respectively, compared to the same periods a year ago, primarily due to the increase in sales volume during the current year period.

Periodically, we update our assumptions such as total sales quantity, performance period and other inputs including foreign currency translation impact, among others. Following updates to our estimates, for the three and nine months ended September 30, 2023, we recognized \$2.3 million and \$1.1 million, respectively, from the net transfer price to Falikang, which was included in the related deferred revenue of the China performance obligation. Comparatively, for the three and nine months ended September 30, 2022, we deferred \$4.6 million and \$0.8 million, respectively, from the net transfer price to Falikang, which was included in the related deferred revenue of the China performance obligation.

Drug Product Revenue, Net

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%
(dollars in thousands)								
Drug product revenue, net:								
Astellas Japan Agreement	\$ 695	\$ (4,313)	\$ 5,008	116	\$ 16,236	\$ 3,297	\$ 12,939	392 %
Astellas Europe Agreement	625	236	389	165 %	1,465	1,313	152	12 %
Total drug product revenue, net:	\$ 1,320	\$ (4,077)	\$ 5,397	132 %	\$ 17,701	\$ 4,610	\$ 13,091	284 %

Drug product revenue, net increased \$5.4 million, or 132% for the three months ended September 30, 2023, and increased \$13.1 million, or 284% for the nine months ended September 30, 2023, respectively, compared to the same periods a year ago.

Astellas Japan Agreement

During the third quarter of 2023, we updated our estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment, and accordingly recorded an adjustment to the drug product revenue of \$0.7 million for the three months ended September 30, 2023. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect the changes in the estimated bulk product strength mix intended to be manufactured by Astellas, and foreign exchange impacts, among others.

During the second quarter of 2023, we fulfilled two shipment obligations under the terms of Astellas Japan Amendment, and recognized related drug product revenue of \$14.4 million in the same period. In addition, we updated our estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment, and accordingly recorded a reduction to the drug product revenue of \$0.6 million. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect the changes in the estimated bulk product strength mix intended to be manufactured by Astellas, and foreign exchange impacts, among others.

During the first quarter of 2023, we updated our estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment, and accordingly recorded adjustments to the drug product revenue of \$1.7 million. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect the changes in the estimated bulk product strength mix intended to be manufactured by Astellas, and estimated yield from the manufacture of bulk product tablets, among others.

During the third quarter of 2022, we updated our estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment, and accordingly recorded a reduction to the drug product revenue of \$4.3 million. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect the changes in the estimated bulk product strength mix intended to be manufactured by Astellas and foreign currency translation impact, among others.

During the first quarter of 2022, we fulfilled a shipment obligation under the terms of Astellas Japan Amendment and recognized related drug product revenue of \$9.8 million in the same period. In addition, during the first quarter of 2022, we updated our estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment, and recorded a reduction to the drug product revenue of \$2.2 million. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, 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.

As of September 30, 2023, the balances related to the API price true-up under the Astellas Japan Agreement were \$0.6 million in accrued liabilities and \$0.7 million in other long-term liabilities, representing the Company's best estimate of the timing for these amounts to be paid. As of December 31, 2022, the related balance in accrued liabilities was \$6.5 million.

Astellas Europe Agreement

During the first quarter of 2022, we updated our estimate of variable consideration related to the bulk drug product transferred in prior years. Specifically, the change in estimated variable consideration was based on the bulk drug product held by Astellas at the period end, adjusted to reflect the changes in the estimated transfer price, forecast information, shelf-life estimates and other items. As a result, we reclassified the related deferred revenue to accrued liabilities during the year ended December 31, 2022. As of December 31, 2022, the related balance was \$57.4 million in accrued liabilities. Further during the first three quarters of 2023, we reclassified \$28.7 million from the related deferred revenue to accrued liabilities. As of September 30, 2023, the balances related to the bulk drug product price true-up under the Astellas Europe Agreement and the Astellas EU Supply Agreement were \$28.6 million in accrued liabilities, representing our best estimate that these amounts will be paid within the next 12 months.

We recognized royalty revenue as drug product revenue, from the deferred revenue under the Astellas Europe Agreement, of \$0.6 million and \$1.5 million for the three and nine months ended September 30, 2023, and \$0.2 million and \$1.3 million for the three and nine months ended September 30, 2022, respectively. It is our best estimate that the remainder of the deferred revenue will be recognized as revenue and when uncertainty is resolved, based on the performance of roxadustat product sales in the Astellas territory.

AstraZeneca U.S./RoW Agreement

There was no shipment of bulk drug product to AstraZeneca as commercial supply under the terms of the AstraZeneca Master Supply Agreement during the three and nine months ended September 30, 2023 and 2022.

During the first quarter of 2022, we evaluated the current developments in the U.S. market, and updated our estimates of variable consideration associated with bulk drug product shipments to AstraZeneca in prior years as commercial supply under the terms of the AstraZeneca Master Supply Agreement. As a result, we reclassified \$11.2 million from the related deferred revenue to accrued liabilities during the year ended December 31, 2022, which remained unchanged as of September 30, 2023 and December 31, 2022, representing our best estimate that this amount will be paid within the next 12 months.

Operating Costs and Expenses

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%
(dollars in thousands)								
Operating costs and expenses								
Cost of goods sold	\$ 4,243	\$ 4,308	\$ (65)	(2) %	\$ 13,441	\$ 15,355	\$ (1,914)	(12) %
Research and development	61,194	75,182	(13,988)	(19) %	231,158	235,163	(4,005)	(2) %
Selling, general and administrative	25,573	29,902	(4,329)	(14) %	91,029	90,722	307	— %
Restructuring charge	12,606	—	12,606	NM	12,606	—	12,606	NM
Total operating costs and expenses	<u>\$ 103,616</u>	<u>\$ 109,392</u>	<u>\$ (5,776)</u>	(5) %	<u>\$ 348,234</u>	<u>\$ 341,240</u>	<u>\$ 6,994</u>	2 %

NM = Not meaningful

Total operating costs and expenses decreased \$5.8 million, or 5% for the three months ended September 30, 2023, and increased \$7.0 million, or 2% for the nine months ended September 30, 2023, respectively, compared to the same periods a year ago for the reasons discussed in the sections below.

Cost of Goods Sold

Cost of goods sold decreased \$0.1 million, or 2% for the three months ended September 30, 2023, and decreased \$1.9 million, or 12% for the nine months ended September 30, 2023, respectively, compared to the same periods a year ago.

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 \$3.9 million and \$4.0 million for the three months ended September 30, 2023 and 2022, and \$10.7 million and 11.5 million for the nine months ended September 30, 2023 and 2022, respectively. Cost of goods sold in China decreased as compared to the prior year periods resulting from the improved unit cost efficiency due to higher production volume, offset by the increases in the sales volume.

Cost of goods sold in the U.S. was immaterial for the three months ended September 30, 2023 and 2022, and \$2.1 million and \$2.7 million for the nine months ended September 30, 2023 and 2022, respectively, associated with the costs of the roxadustat API or bulk drug product delivered to Astellas in the respective periods. 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.

Cost of goods sold also included manufacturing costs related to our contract manufacturing revenue from Eluminex, which was immaterial for the periods presented.

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 expenses include employee-related expenses for research and development functions, expenses incurred under agreements with clinical research organizations, other clinical and preclinical costs and allocated direct and indirect overhead costs, such as facilities costs, information technology costs and other overhead. We expense research and development costs as incurred. We recognize costs for certain development activities 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 IPR&D assets that have 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 nine months ended September 30, 2023 and 2022:

Product Candidate	Phase of Development	Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
(in thousands)					
Pamrevlumab	Phase 2/3	\$ 27,466	\$ 53,582	\$ 115,237	\$ 149,590
Roxadustat	Approved / Phase 3	9,120	9,147	26,570	31,873
FG-3246	Preclinical	1,759	—	27,654 *	—
Other research and development expenses		22,849	12,453	61,697	53,700
Total research and development expenses		<u>\$ 61,194</u>	<u>\$ 75,182</u>	<u>\$ 231,158</u>	<u>\$ 235,163</u>

* Included \$24.6 million one-time, non-cash acquired IPR&D expenses associated with the recent exclusive license for FG-3246 from Fortis and the acquisition of Fortis. See Note 3, *Exclusive License and Option to Acquire Fortis Therapeutics*, to the condensed consolidated financial statements.

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.

Research and development expenses decreased \$14.0 million, or 19% for the three months ended September 30, 2023, compared to the same period a year ago, primarily as a result of the net effect of the following:

- Decrease of \$14.5 million in drug development expenses associated with drug substance, drug product manufacturing and logistic activities related to pamrevlumab which was largely completed in the prior year;
- Decrease of \$3.1 million in employee-related costs primarily due to the reduction in force in July 2023, offset by overall merit increase and the impact from a payroll tax refund received during the third quarter of 2022 that did not recur in the current year period;
- Decrease of \$2.3 million in stock-based compensation primarily resulting from significantly lower stock price and cancellations of stock options and restricted stock units;
- Increase of \$2.5 million in outside services expenses primarily related to roxadustat post-approval safety studies activities in China; and
- Increase of \$1.8 million in clinical trials costs primarily due to Phase 3 trials for pamrevlumab for the treatment of metastatic pancreatic cancer.

Research and development expenses decreased \$4.0 million, or 2% for the nine months ended September 30, 2023, compared to the same period a year ago, primarily as a result of the net effect of the following:

- Decrease of \$36.0 million in drug development expenses associated with drug substance, drug product manufacturing activities and logistic activities related to roxadustat post-approval safety studies in China and pamrevlumab which were largely completed in the prior periods;
- Decrease of \$5.2 million in stock-based compensation primarily resulting from significantly lower stock price and cancellations of stock options and restricted stock units;
- Increase of \$2.2 million in employee-related costs primarily due to overall merit increase and higher business travel activities during the current year period, as well as the impact from a payroll tax refund received during the third quarter of 2022 that did not recur in the current year period, offset by the impact from the reduction in force in July 2023;
- Increase of \$4.1 million information technology, facilities and allocated costs primarily associated with software costs and maintenance services;
- Increase of \$3.7 million in outside services expenses primarily related to roxadustat post-approval safety studies activities in China; and
- \$24.6 million one-time, non-cash acquired IPR&D expenses associated with the recent exclusive license for FG-3246 from Fortis and the acquisition of Fortis.

Selling, General and Administrative Expenses

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 associated with our commercialization efforts in China, recruiting fees and expenses associated with obtaining and maintaining patents.

SG&A expenses decreased \$4.3 million, or 14% for the three months ended September 30, 2023, compared to the same period a year ago, primarily as a result of the net effect of the following:

- Decrease of \$3.8 million in stock-based compensation primarily resulting from significantly lower stock price and cancellations of stock options and restricted stock units;
- Decrease of \$1.2 million in employee-related costs primarily due to the reduction in force in July 2023, offset by overall merit increase and the impact from a payroll tax refund received during the third quarter of 2022 that did not recur in the current year period; and
- Increase of \$1.6 million in outside services expenses primarily due to higher consulting activities in general administrative function.

SG&A expenses remained relatively flat for the nine months ended September 30, 2023, compared to the same period a year ago, primarily as a result of the net effect of the following:

- Increase of \$3.9 million in outside services expenses due to higher consulting activities in general administrative function and efforts to prepare for commercialization in the first half of the year;
- Increase of \$1.5 million in employee-related costs primarily due to overall merit increase and the impact from a payroll tax refund received during the third quarter of 2022 that did not recur in the current year period, offset by the impact from the reduction in force in July 2023;
- Decrease of \$2.7 million in stock-based compensation primarily resulting from significantly lower stock price and cancellations of stock options and restricted stock units; and
- Decrease of \$3.8 million due to higher allocated-out information technology, facilities and costs primarily associated with software costs and maintenance services.

Restructuring Charge

On July 14, 2023, we approved a restructuring plan (the “Plan”) to lower our operating expenses. The Plan included a reduction to our U.S. workforce of approximately 32%. As a result, we recorded a total of \$12.6 million non-recurring restructuring charge during the three months ended September 30, 2023, primarily consisting of notice period and severance payments, accrued vacation and employee benefits contributions. The Plan is in connection with the Company’s efforts to streamline operations to align with the Company’s business goals.

Interest and Other, Net

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%
(dollars in thousands)								
Interest and other, net:								
Interest expense	\$ (5,022)	\$ (84)	\$ (4,938)	5,879 %	\$ (10,464)	\$ (321)	\$ (10,143)	3,160 %
Interest income and other income (expenses), net	4,296	1,798	2,498	139 %	7,984	6,672	1,312	20 %
			(2,44)				(8,83)	
Total interest and other, net	\$ (726)	\$ 1,714	\$ (2,440)	(142) %	\$ (2,480)	\$ 6,351	\$ (8,831)	(139) %

Interest Expense

Interest expense represents the interest related to the senior secured term loan facilities, interest related to sale of future revenues and interest related to the Technology Development Center of the Republic of Finland product development obligations.

Interest expense for the three and nine months ended September 30, 2023 included \$2.1 million and \$5.6 million, respectively, related to sale of future revenues under the Revenue Interest Financing Agreement (“RIFA”) with an affiliate of NovaQuest Capital Management (“NovaQuest”). See Note 8, *Liability Related to Sale of Future Revenues*, to the condensed consolidated financial statements for details.

Interest expense for each of the three and nine months ended September 30, 2023 also included \$2.9 million and \$4.5 million, respectively, related to the senior secured term loan facilities. See Note 7, *Senior Secured Term Loan Facilities*, to the condensed consolidated financial statements for details.

Interest Income and Other Income (Expenses), Net

Interest income and other income (expenses), 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 income (expenses), net increased \$2.5 million, or 139% for the three months ended September 30, 2023, and \$1.3 million, or 20% for the nine months ended September 30, 2023, compared to the same periods a year ago, primarily due to higher interest income from our investments with higher interest rate during the current year period, and favorable foreign exchange impact. The increases in the nine-month period was partially offset by an impact of \$5.0 million recorded during the second quarter of 2022, which did not recur in the current year period, resulting from a reduction to other expenses to release the previously estimated late payment fees related to value added tax in China.

Income Taxes

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(dollars in thousands)			
Loss before income taxes	\$ (64,208)	\$ (91,943)	\$ (230,100)	\$ (228,522)
Provision for (benefit from) income taxes	84	114	(77)	250
Effective tax rate	(0.1) %	(0.1) %	— %	(0.1) %

Provisions for (benefit from) income taxes for the three and nine months ended September 30, 2023 and 2022 were primarily due to foreign taxes.

Based upon the weight of available evidence, which includes our historical operating performance, reported cumulative net losses since inception and expected continuing net loss, we have established 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. We intend to continue maintaining a full valuation allowance on our deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of this allowance.

Investment Income in Unconsolidated Variable Interest Entity

Investment income in unconsolidated variable interest entity represented our proportionate share of the reported profits of Falikang, an unconsolidated variable interest entity accounted for under the equity method, which was immaterial for the three and nine months ended September 30, 2023 and 2022. See Note 4, *Equity method investment - Variable Interest Entity*, to the condensed consolidated financial statements for details.

LIQUIDITY AND CAPITAL RESOURCES

Financial Condition

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

On November 4, 2022, we entered into a RIFA with NovaQuest with respect to our revenues from Astellas' sales of roxadustat in Europe, Japan and the other Astellas territories. Pursuant to the RIFA, in the fourth quarter of 2022, we received \$49.8 million from NovaQuest, representing the gross proceeds of \$50.0 million net of initial issuance costs, in consideration for a portion of future revenues we will receive from Astellas. For additional details about this financing transaction, see Note 8, *Liability Related to Sale of Future Revenues*, to the condensed consolidated financial statements.

On February 27, 2023, we entered into an Amended and Restated Equity Distribution Agreement (the “at-the-market agreement”) with Goldman Sachs & Co., LLC and BofA Securities, Inc. (each a “Sales Agent”), which amended and restated its Equity Distribution Agreement with Goldman Sachs & Co., LLC, dated August 8, 2022, to add BofA Securities, Inc. as an additional Sales Agent under that agreement. Under the at-the-market agreement, we may issue and sell, from time to time and through the Sales Agents, shares of our common stock having an aggregate offering price of up to \$200.0 million (the “ATM Program”). Under the ATM Program, we sold 2,472,090 shares of our common stock and received net proceeds of approximately \$48.4 million during the nine months ended September 30, 2023. See Note 9, *At-the-Market Program*, to the condensed consolidated financial statements for details.

On April 29, 2023, we entered into the Financing Agreement with investment funds managed by Morgan Stanley Tactical Value, (“Lenders”), and Wilmington Trust, National Association, as the administrative agent, providing for senior secured term loan facilities consisting of (i) a \$75.0 million initial term loan, (ii) a \$37.5 million delayed draw term loan that will be funded upon the achievement of certain clinical development milestones and, (iii) an uncommitted delayed draw term loan of up to \$37.5 million, to be funded at the Lenders sole discretion. The clinical development milestones which could have triggered Delayed Draw Term Loan 1 were not achieved, and the Lenders have not funded Delayed Draw Term Loan 2. For additional details about this financing transaction, see Note 7, *Senior Secured Revolving Line of Credit*, to the condensed consolidated financial statements.

As of September 30, 2023, we had cash and cash equivalents of \$120.9 million, compared to \$155.7 million as of December 31, 2022. Cash is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting of available-for-sale securities, and stated at fair value, are also available as a source of liquidity. As of September 30, 2023, we had short-term investments of \$130.4 million, compared to short-term investments of \$266.3 million and long-term investments of \$4.3 million as of December 31, 2022. As of September 30, 2023, a total of \$60.1 million of our cash and cash equivalents was held outside of the U.S. in our foreign subsidiaries, substantially all held in China, to be used primarily for our China operations.

Our long-term plans for distributing cash flows from FibroGen Beijing may involve any number of scenarios including keeping the money onshore to fund future expansion of our China operations or paying down certain debt obligations. During the three months ended September 30, 2023, FibroGen Beijing made a repayment of \$11.8 million of intercompany loans. In addition, in October 2023, FibroGen Beijing made another repayment of \$21.2 million of intercompany loans. Our capital contributions to FibroGen Beijing and the liquidity position of FibroGen Beijing depend on many factors, including those set forth under Part II, Item 1A “*Risk Factors*” in this Quarterly Report.

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):

	Nine Months Ended September 30,	
	2023	2022
Net cash provided by (used in):		
Operating activities	\$ (296,700)	\$ (93,420)
Investing activities	143,415	88,023
Financing activities	122,995	(1,898)
Effect of exchange rate changes on cash and cash equivalents	(4,496)	(7,968)
Net decrease in cash and cash equivalents	\$ (34,786)	\$ (15,263)

Operating Activities

Net cash used in operating activities was \$296.7 million for the nine months ended September 30, 2023 and consisted primarily of net loss of \$228.0 million adjusted for non-operating cash items of \$77.6 million, and a net decrease in operating assets and liabilities of \$146.3 million. The significant non-operating cash items included stock-based compensation expense of \$41.5 million, acquired IPR&D expenses associated with the acquisition of Fortis of \$24.6 million, depreciation expense of \$7.7 million and non-cash interest expense related to sale of future revenues of \$5.6 million. The significant items in the changes in operating assets and liabilities included the following:

- Accrued and other liabilities decreased \$50.2 million, primarily related to the movements related to API and bulk drug product price true-up, resulting from changes in estimated variable consideration associated with the API shipments fulfilled under the terms of the Astellas Japan Amendment, and the bulk drug product transferred under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement, including the payment of \$57.4 million previously accrued balance made during the current year period. See the *Drug Product Revenue, Net* section in Note 2, *Collaboration Agreements, License Agreement and Revenues*, to the condensed consolidated financial statements for details. The decrease was partially offset by the accrued liabilities of \$28.5 million for the litigation settlement as of September 30, 2023, which is fully recoverable under our insurance policies. See Note 12, *Commitments and Contingencies*, to the condensed consolidated financial statements for details. The accrued and other liabilities were also impacted by the timing of invoicing and payment;
- Deferred revenue decreased \$36.9 million, primarily related to the reclassification of \$28.7 million to accrued liabilities, resulting from changes in estimated variable consideration associated with the bulk drug product transferred to Astellas under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement during the current year period. See the *Drug Product Revenue, Net* section in Note 2, *Collaboration Agreements, License Agreement and Revenues*, to the condensed consolidated financial statements for details.
- Accounts receivable increased \$16.3 million, primarily driven by the receivable related to the API shipments to Astellas during the second quarter of 2023, as well as the timing of the receipt of payments and the billings under our collaboration and license agreements;
- Accounts payable decreased \$14.1 million, primarily driven by the payments made for the historical co-promotion expenses to AstraZeneca during the current year period, as well as the timing of invoicing and payments; and
- Prepaid expenses and other current assets increased \$27.4 million, primarily due to the \$28.5 million receivable as of September 30, 2023 for the insurance recovery for the above-mentioned litigation settlement.

Net cash used in operating activities was \$93.4 million for the nine months ended September 30, 2022 and consisted primarily of net loss of \$227.5 million adjusted for non-operating cash items of \$57.8 million, partially offset by a net increase in operating assets and liabilities of \$76.2 million. The significant non-operating cash items included stock-based compensation expense of \$49.4 million, and depreciation expense of \$7.5 million. The significant items in the changes in operating assets and liabilities included the following:

- Accrued and other liabilities increased \$87.2 million, primarily related to the total of \$66.5 million for API and bulk drug product price true-up as of September 30, 2022, resulting from changes in estimated variable consideration associated with the API shipments fulfilled under the terms of the Astellas Japan Amendment, the bulk drug product transferred under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement, and the bulk drug product shipments to AstraZeneca under the terms of the AstraZeneca Master Supply Agreement. The accrued and other liabilities were also impacted by the classification of a portion of accrued co-promotion expenses from other long-term liabilities to current liabilities based on the updated estimate of timing for payment, and by the timing of invoicing and payment;
- Prepaid expenses and other current assets decreased \$8.3 million, primarily due to the collection of \$8.0 million from Eluminex for upfront license payment during the first quarter of 2022, and less prepayments made for roxadustat API manufacturing activities;
- Deferred revenue increased \$4.5 million, primarily related to the deferred considerations of the bulk drug product transferred to Astellas under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement during the current year period, offset by the above-mentioned reclassification to accrued liabilities, resulting from changes in estimated variable consideration associated with the API or bulk drug product deliveries fulfilled with Astellas and AstraZeneca;
- Inventories increased \$11.1 million, driven by the increased inventory level primarily related to inventory cost capitalized related to Europe and other territories, and FibroGen Beijing's productions of roxadustat for commercial sales purposes;

- Other long-term liabilities decreased \$10.3 million driven by the above-mentioned classification of a portion of accrued co-promotion expenses from other long-term liabilities to current liabilities based on the updated estimate of timing for payment; and
- Accounts payable decreased \$5.1 million, primarily driven by the timing of invoicing and payments.

Investing Activities

Investing activities primarily consist of purchases of property and equipment, purchases of investments, purchase of acquired IPR&D assets and proceeds from the maturity and sale of investments.

Net cash provided by investing activities was \$143.4 million for the nine months ended September 30, 2023 and consisted primarily of \$300.5 million of proceeds from maturities of investments, partially offset by \$157.2 million of cash used in purchases of available-for-sale securities.

Net cash provided by investing activities was \$88.0 million for the nine months ended September 30, 2022 and consisted primarily of \$216.3 million of proceeds from maturities of investments and \$7.4 million of proceeds from sales of available-for-sale securities, partially offset by \$97.3 million of cash used in purchases of available-for-sale securities, \$35.0 million of cash paid for the acquired IPR&D asset, and \$3.4 million of cash used in purchases of property and equipment.

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 \$123.0 million for the nine months ended September 30, 2023 and consisted primarily of \$71.3 million net proceeds from senior secured term loan facilities, \$48.4 million net proceeds received under the ATM Program, \$3.7 million of proceeds from the issuance of common stock upon exercise of stock options and purchases under our Employee Stock Purchase Plan.

Net cash used in financing activities was \$1.9 million for the nine months ended September 30, 2022 and consisted primarily of \$4.6 million of cash paid for payroll taxes on restricted stock unit releases, partially offset by \$3.0 million of proceeds from the issuance of common stock upon exercise of stock options and purchases under our Employee Stock Purchase Plan.

Material Cash Requirements

We generate revenue from commercial sales of roxadustat product in China, Japan and Europe. Even with the expectation of increases in these revenues, we anticipate that we will continue to generate losses for the foreseeable future. To date, we have funded certain portions of our research and development and manufacturing efforts globally through collaboration partners, debt financings, and equity financing. We expect to continue to incur significant research and development expenses to invest in our other programs and there is no guarantee that sufficient funds will be available to continue to fund these development efforts through commercialization or otherwise. We are also 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 factors outlined under Part II, Item 1A “*Risk Factors*” in this Quarterly Report on Form 10-Q, as well as unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We believe that our existing cash and cash equivalents, short-term and long-term investments and accounts receivable, together with the proceeds from senior secured term loan facilities in the second quarter of 2023, the financing amount under the RIFA received in the fourth quarter of 2022, and the net proceeds received under our ATM program in the first half of 2023, as well as the cost savings we have recently implemented (including from the reduction in workforce that we announced on July 19, 2023), will be sufficient to meet our anticipated cash requirements for at least the next 12 months from the date of issuance of the financial statements included in this Quarterly Report on Form 10-Q. However, we may need additional capital thereafter and our liquidity assumptions could turn out to be wrong, or may change over time, and we could utilize our available financial resources sooner than we currently expect. We may incur additional expenses not currently contemplated due to events associated with the recently announced reduction in workforce. In addition, we may elect to raise additional funds at any time through equity, equity-linked, debt financing arrangements or from other sources. 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. 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.

Commitments and Contingencies

Contractual Obligations

As of September 30, 2023, we had \$81.9 million of operating lease liabilities. The material cash requirements related to our lease liabilities included \$15.2 million expected to be paid within the next 12 months.

As of September 30, 2023, we had outstanding total non-cancelable purchase obligations of \$37.8 million, including \$22.8 million for manufacture and supply of pamrevlumab, \$2.2 million for manufacture and supply of roxadustat, and \$12.8 million for other purchases and programs. We expect to fulfill our commitments under these agreements in the normal course of business, and as such, no liability has been recorded. The material cash requirements related to our non-cancelable purchase obligations included \$31.8 million expected to be paid within the next 12 months.

Under the Financing Agreement with Morgan Stanley Tactical Value, as of September 30, 2023, we had \$71.7 million of senior secured term loan facilities balance on the condensed consolidated balance sheets, which are not subject for repayment until May 2026. Meanwhile, we are obliged to pay interest on a monthly basis, for which we expect to pay a total of \$10.5 million within the next 12 months. See Note 7, *Senior Secured Term Loan Facilities*, to the condensed consolidated financial statements for details.

Under the RIFA with NovaQuest, as of September 30, 2023, we had \$55.0 million of liability related to sale of future revenues on the condensed consolidated balance sheets, \$5.9 million of which we anticipate to pay within the next 12 month. Based on our current estimates of drug product revenue and revenue from milestone payments under the Astellas Agreements, and taking into the consideration of the terms under the RIFA, we anticipate to reach a Payment Cap up to \$125.0 million by 2031. See Note 8, *Liability Related to Sale of Future Revenues*, to the condensed consolidated financial statements for details.

Some of our 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 September 30, 2023, future milestone payments for research and preclinical stage development programs consisted of up to approximately \$697.9 million in total potential future milestone payments under our license agreements with HiFiBiO (for Gal-9 and CCR8), 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.

Off-Balance Sheet Arrangements

During the three and nine months ended September 30, 2023, 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.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

There have been no material changes in our critical accounting policies, estimates and judgments during the three and nine months ended September 30, 2023 compared with the disclosures in Part II, Item 7 of our 2022 Form 10-K.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

During the three and nine months ended September 30, 2023, 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 2022 Form 10-K.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive Officer and our Principal Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2023, 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 Principal Executive Officer and Principal Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our evaluation, the Principal Executive Officer and Principal Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2023.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended September 30, 2023 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 because of the inherent limitations in all control systems, any controls and procedures, no matter how well designed and operated, can provide only reasonable not absolute, 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 the benefits of controls and procedures must be considered relative to their costs.

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 active legal action in our condensed consolidated balance sheet as of September 30, 2023, as we could not predict the ultimate outcome of these matters, or reasonably estimate the potential exposure. See Note 12, *Commitments and Contingencies*, to the condensed consolidated financial statements for details.

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 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, 2022, filed on February 27, 2023 (“2022 Form 10-K”).

SUMMARY RISK FACTORS

The success of FibroGen 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 products pamrevlumab and roxadustat.
- As a company, we have limited late-stage development and commercialization experience, and the time and resources required to develop such experience are significant.
- Drug development and obtaining marketing authorization is a very difficult endeavor and we may ultimately be unable to obtain regulatory approval for our various product candidates in one or more jurisdictions and in one or more indications.
- 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.
- If our manufacturers or we cannot properly manufacture the appropriate volume of product, we may experience delays in development, regulatory approval, launch, or successful commercialization.
- 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.

Risks Related to Our Reliance on Third Parties

- If our collaborations were terminated or if our partners were unwilling or unable to contribute or participate in these collaborations, our ability to successfully develop and commercialize the relevant product candidate 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.
- We may have shortfalls, delays, or excesses in manufacturing.
- 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.
- 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.

Risks Related to Government Regulation

- The regulatory approval process is highly uncertain and we may not obtain regulatory approval for our product candidates.
- 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, and other regulations. If we are unable to comply with such laws, we could face substantial penalties.
- We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

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 use our own manufacturing facilities in China to produce roxadustat API and drug product for the market in China. 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 may experience difficulties in successfully growing and sustaining sales of roxadustat in China.
- The retail prices of any product candidates that we develop will be subject to pricing control in China and elsewhere.
- 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.
- 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 and regulations 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.

RISK FACTORS

Risks Related to the Development and Commercialization of Our Product Candidates

*We are substantially dependent on the success of our lead products pamrevlumab and roxadustat.**

To date, we have invested substantially in the research and development of pamrevlumab and roxadustat.

The near-term value drivers for the Company depend in large part on pamrevlumab, which is in clinical development for locally advanced unresectable pancreatic cancer and metastatic pancreatic cancer. If the Phase 3 clinical trials are successful, pamrevlumab will require substantial further investment. At this time, we do not have a collaboration partner to support the development and commercialization of pamrevlumab. Additionally, as a monoclonal antibody, pamrevlumab may require greater financial resources to commercialize (particularly in manufacturing).

Our near-term value drivers also include continued development and commercialization of roxadustat in the People's Republic of China ("China"), Japan, Europe, and elsewhere. While we continue to co-commercialize roxadustat in China with AstraZeneca AB ("AstraZeneca") and develop roxadustat in China in chemotherapy-induced anemia ("CIA"), we have no plans to develop roxadustat in the United States ("U.S.") for anemia associated with chronic kidney disease ("CKD") (and have withdrawn our New Drug Application for CKD anemia), myelodysplastic syndromes, or CIA.

With an eye toward our longer-term success, we are investing in new drug programs to expand our early-stage clinical pipeline. While we see great potential value in our early-stage pipeline, these programs are years away from commercialization, and the success of any development program is not guaranteed. Our biggest value drivers in the near-term rely on the success of pamrevlumab Phase 3 trials and roxadustat commercialization.

As a company, we have limited late-stage and commercialization experience, and the time and resources required to develop such experience are significant.

If any of our late stage programs are successful, and we choose to undertake sales, distribution, and marketing of any of our products directly, there are risks involved with establishing these 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.

Successful development and commercialization of any of our products requires us to establish and further develop our clinical, regulatory, and commercialization capabilities, including but not limited to, medical affairs, marketing, product reimbursement, sales, price reporting, pharmacovigilance, supply-chain, and distribution. These efforts require resources and time to either develop or acquire expertise in these areas and there is a risk that we are unsuccessful or we fail to comply with rules or regulations applicable to development or commercialization of our products. There is also a risk that we are delayed due to the need to develop these capabilities or due to a lack of resources. All of which would adversely affect our business and financial condition.

Drug development and obtaining marketing authorization is a very difficult endeavor and we may ultimately be unable to obtain regulatory approval for our various product candidates in one or more jurisdictions and in one or more indications.*

The development, manufacturing, marketing, and selling of our products and product candidates are and will continue to 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 drug development and approval processes are expensive and require 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 any of our other product candidates in one or more indications and jurisdictions.

Moreover, for any clinical trial to support a New Drug Application/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 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 our product candidate is safe and effective in a particular indication, or that such 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 information (including additional preclinical or clinical data or trials) are necessary to demonstrate the safety and efficacy of a product candidate,
- disagreement over the design or implementation of our clinical trials;
- our product candidates may exhibit an unacceptable safety signal at any stage of development;
- we, or the clinical research organizations (“CROs”) or investigators that conduct clinical trials on our behalf, may fail to comply with regulations or GCPs, clinical trial protocols, or contractual agreements, which may adversely impact our clinical trials;
- disagreement over whether to accept results from clinical trial sites in a country where the standard of care is potentially different from that in the U.S.;
- 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 require us to exclude the use of patient data from unreliable clinical trials, or 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 delay or jeopardize our or our collaboration partners’ abilities to obtain regulatory approval for our product candidates in one or more indications.

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. For example, while we have received approval of our marketing authorization applications for roxadustat in the European Union, Great Britain, China, Japan, and other countries for the treatment of anemia in CKD for patients who are on dialysis and not on dialysis, we received a complete response letter in CKD anemia in the U.S. from the FDA regarding roxadustat's New Drug Application for the treatment of anemia due to CKD, stating that it could not be approved in its present form. In addition, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process or commercial uptake in other countries.

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.

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. For example, our Phase 3 clinical trials of pamrevlumab in idiopathic pulmonary fibrosis ("IPF") and Duchenne muscular dystrophy ("DMD") were unable to replicate the efficacy results we saw in smaller Phase 2 studies.

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, 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, for a variety of reasons or factors, including:

- delay or failure to address any physician or patient safety concerns that arise during the course of the trial, including unforeseen safety issues or adverse side effects, or a principal investigator's determination that a serious adverse event could be related to our product candidates;
- delay or failure to obtain required regulatory or institutional review board approval or guidance;
- delay or failure to reach timely agreement on acceptable terms with prospective CROs and clinical trial sites;
- delay or failure to recruit, enroll and retain patients through the completion of the trial;
- patient recruitment, enrollment, or retention, or clinical site initiation or retention problems associated with the Severe Acute Respiratory Syndrome Coronavirus 2 and the resulting Coronavirus Disease ("COVID-19") pandemic;
- patient recruitment, enrollment, or retention, clinical site initiation, or retention problems associated with civil unrest or military conflicts around the world;
- delay or failure to maintain clinical sites in compliance with clinical trial protocols or to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- delay or failure to initiate or add a sufficient number of clinical trial sites;
- delay or failure to manufacture sufficient quantities of product candidate for use in clinical trials;
- difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned;

- inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, warning letter, or other regulatory action; and
- changes in laws or regulations.

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;
- 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.

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 expensive;
- terminating some of our clinical trials for the product candidates or specific indications affected;
- 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.

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. Pamrevlumab is being studied in patient populations that are at high risk of death and adverse events, and even if unrelated to pamrevlumab, adverse safety findings in these trials may limit its further development or commercial potential. 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, for which safety concerns have been uncovered following approval by regulatory authorities. Such safety concerns have led to labeling changes or withdrawal of erythropoiesis stimulating agent products from the market. While roxadustat is chemically unique from erythropoiesis stimulating agents, 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 volume 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 relatively 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 and customs management) for launch or commercialization, which is a complex process involving our third-party manufacturers and logistics providers, and for roxadustat, our collaboration partners. We may not be able to accurately forecast supplies for commercial launch or do so in a timely manner and our efforts to establish these manufacturing and supply chain management capabilities may not meet our requirements as to quantities, scale-up, yield, cost, potency or quality in compliance with cGMP, particularly if the marketing authorization or market uptake is more rapid than anticipated or we have an unanticipated surge in demand.

We have a limited amount of roxadustat and pamrevlumab in storage, limited capacity reserved at our third-party manufacturers, and, even if we have or are able to put 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 well as for raw materials and components for manufacture of our products, as required for both late-stage clinical trials, post-approval trials, and commercial supply. There is a general risk of delayed drug supply due to delays experienced by any third-party provider in the supply chain, including raw material and components suppliers, export and customs locations, and shipping companies. In addition, due to our withdrawal of our New Drug Application in the U.S. in CKD anemia, we may have excess supply manufactured in anticipation of commercialization. Such roxadustat excess supply 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 roxadustat formulation is approved. 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 and/or delay the regulatory approval process.

We or our partners may add or change manufacturers, change our manufacturing processes, or change packaging specifications to accommodate changes in regulations, manufacturing equipment or to account for different processes at new or second source suppliers. Changes made to roxadustat or pamrevlumab including, but not limited to, demonstration of comparability to regulatory approved/ in approval products and processes, additional clinical trials, delays in development or commercialization, earlier expiration dates, shorter shelf life, or specification failures, 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;
- natural disasters, such as pandemics, floods, storms, earthquakes, tsunamis, and droughts, or accidents such as fire, that affect facilities, possibly limit or postpone production, and increase costs;
- delays in transporting intermediates, active pharmaceutical ingredients (“API”) or finished products from one geography to another; and
- failure to obtain license to proprietary starting materials.

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, regulatory authorities 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. Furthermore, while we may seek regulatory advice or agreement in key commercial markets prior to and after application for marketing authorization, regulatory authorities may change their approvability criteria based on the data, their internal analyses and external factors, including discussions with expert advisors. Regulatory authorities may approve one of our product candidates 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 have and will present to regulatory authorities certain pre-specified and post hoc (not pre-specified) sub-populations, sub-group, and sensitivity 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, regulatory authorities may not include such claims on any approved labeling. 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.

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 marketed products of companies that have large, established commercial organizations. We face competition from generics that could enter the market after expiry of our composition of matter patent. As of the end of the third quarter of 2023, the Chinese health authority has accepted abbreviated New Drug Applications for 12 generic roxadustat applicants.

In addition, we will likely face competition from other companies developing products in the same diseases or indications in which we are developing or commercializing products. We will also face competition for patient recruitment, enrollment for clinical trials.

Refer to Item 1. “*Business - Competition*” in our 2022 Form 10-K for a discussion of the specific companies that are on the market or in late-stage development with which we may compete.

The success of any or all of these potential competitive products may negatively impact the development and potential for success of our products.

Moreover, many of our competitors have significantly greater resources than we do. Large pharmaceutical companies have extensive experience, greater scale, and efficiency, in clinical testing, obtaining regulatory approvals, recruiting patients, manufacturing pharmaceutical products, and commercialization. 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, 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, 2022 to December 31, 2023), after which time we will have to renegotiate a new price for roxadustat.

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 Our Reliance on Third Parties

If our collaborations were terminated or if our partners were unwilling or unable to contribute or participate in the collaborations, our ability to successfully develop and commercialize the relevant product candidate would suffer.*

We have entered into an Evaluation Agreement with Fortis Therapeutics, Inc. (“Fortis”) under which we rely, in part, on Fortis and its development partners, including UCSF, for the continued development of FOR46 (now referred to as “FG-3246”). While we control development of FG-3246 during the up to 4-year evaluation period, we will be doing so under Fortis’s investigational new drug application. If Fortis was unable or unwilling to continue their development efforts, our ability to develop FG-3246 would be delayed.

We rely on the Pancreatic Cancer Action Network (“PanCAN”) to run its Precision PromisesSM Phase 2/3 registration study in metastatic pancreatic cancer. While this study includes pamrevlumab in combination with standard of care chemotherapy, we do not run this study and have very little control over the way it is conducted. Therefore pamrevlumab’s success in this indication is highly dependent on PanCAN’s ability and willingness to run the Precision Promise study. We are also dependent on PanCAN providing sufficient data for us to analyze and, if successful, submit for marketing authorization to the appropriate regulatory authorities.

We have also entered into collaboration agreements with respect to the development and commercialization of roxadustat with Astellas Pharma Inc. (“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 commercialize roxadustat could suffer.

While we continue to co-commercialize roxadustat in China with AstraZeneca and develop roxadustat in China in CIA, it is probable that our U.S./Rest of World Collaboration Agreement with AstraZeneca will be terminated now that we have withdrawn our NDA in the U.S. for CKD anemia. In addition, if our collaboration partners are unsuccessful in their commercialization efforts (particularly in Europe and China), our results will be negatively affected.

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.

We may 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, 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. 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. We compete with many other companies for the resources of these third parties, and other companies may have significantly more extensive agreements and relationships with such third-party providers, and such third-party providers may prioritize these relationships 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.

Despite our reliance on third parties for certain development and management activities, such as clinical trials, we, as the sponsor, remain responsible for ensuring that these activities are conducted in accordance with the FDA and foreign regulatory authorities' investigational plans and protocols, including GCP requirements. Regulatory enforcement of GCP requirements can occur through periodic inspections of trial sponsors, principal investigators, and trial sites.

To ensure the quality and accuracy of our data remains uncompromised and reliable, our third-party service providers must comply with applicable GCP requirements, regulations, protocols, and agreements. Failures to do so by such third-party partners, or needing to replace such third-party service providers, may delay, suspend or terminate development of our product candidates, result in exclusion of patient data from approval applications, or require additional clinical trials before approval of marketing applications. Such events may ultimately prevent 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. We currently rely, and expect to continue to rely, on third parties to scale-up, manufacture and supply roxadustat and our other product candidates for drug product in Europe and other countries, and on our partner Astellas for drug product in Japan. 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;
- significant financial commitments we may be required to make with third-party manufacturers for early-stage clinical or pre-clinical programs that may fail to produce scientific results that would justify further development (without the ability to mitigate the manufacturing investments);
- 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, 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.

Considering we do not control our contract manufacturers' facilities and operations used to manufacture our product candidates, but are still responsible for cGMP adherence, if our contract manufacturers cannot successfully manufacture material that conforms to our or our collaboration partners' specifications, or the regulatory requirements, our development and commercialization plans and activities may be adversely affected. Although our longer-term agreements are expected to provide for requirements to meet our quantity and quality requirements (e.g., through audit rights) to manufacture our products candidates for clinical studies and commercial sale, we have limited or minimal direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If our contract manufacturers' facilities do not pass inspection, are not approved or have their approvals withdrawn by regulatory authorities, 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 legal sanctions/penalties being imposed on us or adverse regulatory consequences, which would be expected to significantly and adversely affect our product supplies.

If any third-party manufacturers terminate their engagements with us or fail to perform as agreed, we may be required to identify, qualify, and contract with replacement manufacturers (including entering into technical transfer agreements to share know-how), which process may result in significant costs and delays to our development and commercialization programs.

We may have shortfalls, delays, or excesses in manufacturing.*

We have entered into an initial commercial supply agreement for the manufacture of pamrevlumab with Samsung Biologics Co., Ltd. (“Samsung”).

We have made certain manufacturing commitments to Samsung, and there is a contractual risk we will not require the quantities of pamrevlumab we have committed to, particularly if we cease our final pamrevlumab clinical trials in pancreatic cancer, such as we did for our ZEPHYRUS-2 study and LELANTOS studies, as well as open label extensions for IPF and DMD indications. We may also not require quantities of pamrevlumab we have prepared for launch supply (for example for the above studies). 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 also carry the risk that we may need to pay termination fees to Samsung or other manufacturers in the event that we have to manufacture lower volumes or not at all depending on the results of our clinical trials. We may be subject to payments to Samsung to cover for committed manufacturing campaigns even if we do not need the material for clinical or commercial usage. In addition, third party manufacturers tend to change their upfront fees or postponement/cancelation fees over time or upon initiation of additional contracts, and this may lead to unanticipated financial loss for FibroGen.

There may also be additional delays in importing or exporting products, intermediates, or raw materials between countries.

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 commercial products and product candidates. While we have obligations for second-source suppliers in our roxadustat collaboration agreements, we may be unable to enter into long-term commercial supply arrangements for some of our other products, or do so on commercially reasonable terms, which could have a material adverse impact upon our business. Although we have entered into long-term clinical and commercial supply arrangements for pamrevlumab, we currently rely on our contract manufacturers to purchase from third-party suppliers some of the materials necessary to produce our product candidates. We do not have direct control over the acquisition of those materials by our contract manufacturers.

The logistics of our supply chain, which include shipment of materials and intermediates from countries such as China and India add additional time and risk (including risk of loss) to the manufacture of our product candidates. While we have in the past maintained sufficient inventory of materials, API, and drug product to meet our and our collaboration partners’ needs 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 to the extent that our patents, trade secrets, contractual position, and governmental regulations and laws allow us to do so. Any unauthorized use or disclosure of proprietary information or technology could compromise our competitive position. Moreover, we are, have been, and may in the future be involved in legal proceedings involving our intellectual property and initiated by third parties, which proceedings can be associated with significant costs and commitment of management time and attention.

We have in the past been involved, 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 we own or license may fail to result in granted or 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 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 employees, consultants, advisors and 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, use, or misappropriation 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 cannot prevent unauthorized disclosure of our intellectual property related to our product candidates and technology to third parties, we may not establish or maintain a competitive advantage in our market, which could materially and 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.

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.

Third parties have challenged and may again challenge our patents and patent applications. For example, various challenges against our hypoxia-inducible factor anemia-related technologies patent portfolio are ongoing in several territories, including Europe, the United Kingdom, and Japan. Regardless of final outcome, the potential narrowing or revocation of any of the hypoxia-inducible factor 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 European Patent Nos. 2872488 (the “488 Patent”) and 3470397 (the “397 Patent”), which claims relate to a crystalline form of roxadustat, and against European Patent No. 3003284 (the “284 Patent”), which claims photostable formulations of roxadustat. Similar challenges have been filed in China against patents which claim a crystalline form of roxadustat. Final resolution of such proceedings will take time, and we cannot be assured that these patents will ultimately survive as originally granted or at all.

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 or independently develop similar or alternative technologies 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.
- 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. 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. For example, while we have received approval of our marketing authorization applications for roxadustat in the European Union, Great Britain, China, Japan, and other countries for the treatment of anemia in CKD for patients who are on dialysis and not on dialysis, we received a complete response letter for roxadustat in CKD anemia in the U.S. from the FDA. It is possible that roxadustat will not obtain regulatory approval in additional countries or indications. It is possible that our other product candidates we may discover, in-license or acquire and seek to develop in the future, will not obtain regulatory approval in any particular jurisdiction.

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, 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; federal civil and criminal false claims laws and civil monetary penalty laws; the Health Insurance Portability and Accountability Act, including as amended by Health Information Technology for Economic and Clinical Health Act, and its implementing regulations; the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act; and the Trade Agreement Act. In addition, foreign and state law equivalents of each of the above federal 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.

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. Such actions could have a substantial adverse effect on the price of our common shares and could have a material adverse effect on our operations.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.*

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share confidential, proprietary, and sensitive information, including personal information, business data, trade secrets, intellectual property, information we collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, and financial information.

Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the U.S., there are State data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and the Federal Health Insurance Portability and Accountability Act, and other similar laws (e.g., wiretapping laws). For example, the California Consumer Privacy Act of 2018 (“CCPA”) applies to personal data of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to \$7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. In addition, the California Privacy Rights Act of 2020 expands the CCPA’s requirements, including by adding a new right for individuals to correct their personal data and establishing a new regulatory agency to implement and enforce the law.

Outside the U.S., laws, regulations, and industry standards govern data privacy and security. For example, the European Union’s General Data Protection Regulation (“GDPR”), the United Kingdom (“UK’s) GDPR, Brazil’s General Data Protection Law (Lei Geral de Proteção de Dados Pessoais) (Law No. 13,709/2018), and China’s Personal Information Protection Law impose strict requirements for processing personal data, including health-related information. For example, under the European Union GDPR, companies may face fines of up to 20 million Euros or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data. We also target customers in Asia and have operations in China and are subject to the data privacy laws in Asia, including China’s Personal Information Protection Law, Japan’s Act on the Protection of Personal Information, and Singapore’s Personal Data Protection Act.

Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the U.S. in compliance with law, such as the EEA and UK’s standard contractual clauses, these mechanisms are subject to legal challenges. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions are subject to scrutiny from regulators, individual litigants, and activities groups.

Preparing for and complying with these obligations requires us to devote resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims); additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

We are subject to laws and regulations governing corruption, which 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 U.S. Foreign Corrupt Practices Act (“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.

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.

Considering our current presence and potential expansion in international jurisdictions, the creation, implementation, and maintenance 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 U.S. Securities and Exchange Commission (“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.

If we 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.

Efforts required to remediate an ineffective system of control over financial reporting may place a significant burden on management and add increased pressure on our financial resources and processes. Moreover, we implemented an enterprise resource planning (“ERP”) system in the first quarter of 2023, which replaced our existing operating and financial systems, to improve the efficiency of certain financial and transactional processes. However, there is an increased risk that changing controls may be ineffective during the implementation and this ERP system may place additional burden on employees to learn and adapt our processes to effectively operate under the ERP system. If the ERP system does not operate as intended, the effectiveness of our internal control over financial reporting could be negatively impacted. If we experience material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting, the accuracy and timing of our financial reporting and subsequently our liquidity and 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 U.S. healthcare reform may adversely affect our business model.

In the U.S. and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could affect our operations. In particular, 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.

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 presidential executive orders, 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. For example, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions the HHS can take to advance these principles. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. Further, the IRA (1) directs the HHS to negotiate the price of certain single-source drugs or biologics covered under Medicare, and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. The HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA of 2022 will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing the HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. At the state level, individual states are increasingly aggressive in passing legislation and implementing 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 state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products if approved 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 data privacy and security laws protecting personal data;
- 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 protecting us from the negative impacts of governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. An unfavorable outcome or settlement in connection with a governmental investigation or other action or lawsuit may result in a material adverse impact on our business, results of operations, financial condition, prospects, and stock price. Regardless of the outcome, litigation and governmental investigations can be costly, time-consuming, and disruptive to our business, results of operations, financial condition, reputation, and prospects.

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.

A number of risks related to our international operations, many of which may be beyond our control, include: different regulatory requirements in different countries, including for drug approvals, manufacturing, and distribution; potential liability resulting from development work conducted by foreign distributors; economic weakness, including inflation, or 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.; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; political instability in particular foreign economies and markets; and business interruptions resulting from geopolitical actions specific to an international region, including war and terrorism, natural disasters, or pandemics.

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.

The China-operations portion of our audit is conducted by PricewaterhouseCoopers Zhong Tian LLP, an independent registered public accounting firm headquartered in China.*

The majority of audit work incurred for the audit report included in the 2022 Form 10-K was performed by the U.S.-based independent registered public accounting firm we have retained, PricewaterhouseCoopers LLP, which is headquartered in the U.S. and was not identified in the report issued by the PCAOB on December 16, 2021.

However, we estimate that between 30% and 40% of the total audit hours for our December 31, 2022 audit were provided by PricewaterhouseCoopers Zhong Tian LLP.

On December 18, 2020, the Holding Foreign Companies Accountable Act (the “HFCAA”) was signed into law. The HFCAA requires that the SEC identify issuers that retain an auditor that has a branch or office that is located in a foreign jurisdiction and that the PCAOB determines it is unable to inspect or investigate completely because of a position taken by an authority in that foreign jurisdiction. Among other things, the HFCAA requires the SEC to prohibit the securities of any issuer from being traded on any of the U.S. national securities exchanges, such as The Nasdaq Global Select Market, or on the U.S. “over-the-counter” markets, if the auditor of the issuer’s financial statements is not subject to PCAOB inspections for three consecutive “non-inspection” years after the law became effective. On December 29, 2022, the Accelerating Holding Foreign Companies Accountable Act (the “AHFCAA”) signed into law as part of a package of bills reduced the number of consecutive non-inspection years required for triggering the listing and trading prohibitions under the HFCA Act from three years to two years.

On December 2, 2021, the SEC adopted final amendments to its rules implementing the HFCAA and established procedures to identify issuers and prohibit the trading of the securities of certain registrants as required by the HFCAA. This rule stated that only the principal accountant, as defined by Rule 2-05 of Regulation S-X and PCAOB AS 1205, is “deemed ‘retained’ for purposes of Section 104(i) of the Sarbanes-Oxley Act and the Commission’s determination of whether the registrant should be a Commission Identified Issuer.” The principal accountant, as defined, that we have retained is PricewaterhouseCoopers LLP. The HFCAA does not apply to registrants that retain a principal accountant that is headquartered in the U.S. and subject to PCAOB inspection. Accordingly, the HFCAA does not currently apply to us.

Although the PCAOB issued a report on December 16, 2021 on its determination that it was unable to inspect or investigate completely PCAOB-registered accounting firms headquartered in China and in Hong Kong, on December 15, 2022, it announced that it was able to conduct inspections and investigations of such accounting firms in 2022 and vacated its previous 2021 determinations accordingly. While vacating those determinations, however, the PCAOB noted that, should it encounter any impediment to conducting an inspection or investigation of auditors in mainland China or Hong Kong as a result of a position taken by any authority there, the PCAOB would act to immediately reconsider the need to issue new determinations consistent with the HFCAA and PCAOB’s Rule 6100.

If our operations fundamentally change in a way that requires our independent registered public accounting firm be located in China or Hong Kong in order to comply with the standards of the PCAOB regarding principal auditor then the HFCAA would apply to us, including the potential delisting from The Nasdaq Global Select Market and prohibition from trading in the over-the counter market in the U.S. Such a restriction would negatively impact our ability to raise capital. We view the likelihood to be remote that our operations will fundamentally change so as to require our principal auditor to be located in China or Hong Kong. Additionally, it is possible that in the future Congress could amend the HFCAA or the SEC could modify its regulations to apply the restrictions, including trading prohibitions and delisting, under the HFCAA in situations in which an independent registered public accounting firm in China or Hong Kong performs part of the audit such as in our current situation. There are currently no such proposals.

Inspections of auditors conducted by the PCAOB in territories outside of China have at times identified deficiencies in those auditors’ audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. In the future, should PCAOB encounter any impediment to continue conducting an inspection of audit work undertaken in China, including by PricewaterhouseCoopers Zhong Tian LLP, it could prevent the PCAOB from evaluating the effectiveness of such audits and such auditors’ quality control procedures. As a result, investors could be deprived of the potential benefits of such PCAOB inspections for this portion of our audit, which could cause investors and potential investors in our common stock to lose confidence in the audit procedures conducted by our U.S. auditor’s China-based subsidiary, which may negatively impact investor sentiment towards us or our China operations, which in turn could adversely affect the market price of our common stock.

Changes in U.S. and China relations, as well as relations with other countries, and/or regulations may adversely impact our business.

The U.S. government, including the SEC, has made statements and taken certain actions that have led to changes to U.S. and international relations, and will impact companies with connections to the U.S. or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China, and issuing statements indicating enhanced review of companies with significant China-based operations. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the U.S. or to China, our industry or on us. We conduct contract manufacturing and development activities and have business operations both in the U.S. and China. Any unfavorable government policies on cross-border relations and/or international trade, including increased scrutiny on companies with significant China-based operations, capital controls or tariffs, may affect the competitive position of our drug products, the hiring of scientists and other research and development personnel, the demand for our drug products, the import or export of products and product components, our ability to raise capital, the market price of our common stock, or prevent us from commercializing and selling our drug products in certain countries.

While we do not operate in an industry that is currently subject to foreign ownership limitations in China, China could decide to limit foreign ownership in our industry, in which case there could be a risk that we would be unable to do business in China as we are currently structured. In addition, our periodic reports and other filings with the SEC may be subject to enhanced review by the SEC and this additional scrutiny could affect our ability to effectively raise capital in the U.S.

If any new legislation, executive orders, tariffs, laws and/or regulations are implemented, if existing trade agreements are renegotiated or if the U.S. or Chinese governments take retaliatory actions due to the recent U.S.-China tension, such changes could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our common stock.

We use our own manufacturing facilities in China to produce roxadustat API and drug product for the market in China. 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 National Medical Products Administration 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. Consequently, we also carry single source supplier risk for all countries we or our partners are selling in, other than China. Natural disasters or other unanticipated catastrophic events, including power interruptions, water shortages, storms, fires, pandemics, earthquakes, terrorist attacks, government appropriation of our facilities, and wars, could significantly impair our ability to operate our manufacturing facilities. Further, the climate of geopolitical tensions in China affecting global supply chains may impact our ability to continually meet market demand. 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.

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 competition and our ability to maintain reasonable pricing and reimbursement, obtain and maintain hospital listing, or other difficulties related to distribution, marketing, and sales efforts in China. Our current National Reimbursement Drug List reimbursement pricing is effective for a standard two-year period (between January 1, 2022 to December 31, 2023), after which time we will have to negotiate a new price for roxadustat. 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 will 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., FibroGen Beijing and its branch offices, and our joint venture distribution entity, Beijing Falikang Pharmaceutical Co., Ltd. (“Falikang”). We may in the future 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 applicable accounting standards and regulations in China. FibroGen Beijing is not permitted to distribute any profits until losses from prior fiscal years have been recouped and in any event must maintain certain minimum capital requirements. FibroGen Beijing is also required to set aside at least 10.0% of its after-tax profit based on Chinese accounting standards each year to its statutory reserve fund until the cumulative amount of such reserves reaches 50.0% of its registered capital. Statutory reserves are not distributable as cash dividends. In addition, if FibroGen Beijing incurs debt on its own behalf in the future, the agreements governing such debt may restrict its ability to pay dividends or make other distributions to us. As of September 30, 2023, approximately \$60.1 million of our cash and cash equivalents is held in China.

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

The Ministry of Commerce in China or its local counterpart must approve the amount and use of any capital contributions from us to FibroGen Beijing, and there can be no assurance that we will be able to complete the necessary government registrations and obtain the necessary government approvals on a timely basis, or at all. If we fail to do so, we may not be able to contribute additional capital or find suitable financing alternatives within China 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 as well as our partner’s operations in Japan and Europe, which could adversely affect our financial performance.

Most of our and our partner’s product sales will occur in local 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 the value of the Renminbi, Euro or Yen against the U.S. dollar and other currencies are affected by, among other things, changes in political and economic conditions. 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 the 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. For example, the Biden administration has proposed to increase the U.S. corporate income tax rate from 21%, increase the U.S. taxation of our international business operations and impose a global minimum tax, although the recently enacted Inflation Reduction Act of 2022 omitted to include any of these proposals but included only a minimum tax on certain large corporations and a tax on certain repurchases of stock on the corporations doing those repurchases. Such proposed changes, as well as regulations and legal decisions interpreting and applying these changes, may adversely impact our effective tax rate.

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 and regulations could have a material adverse effect on us.

The legal system of China is a civil law system primarily based on written statutes. Our financial condition and results of operations may be adversely affected by government control, perceived government interference and/or changes in tax, cyber and data security, capital investments, cross-border transactions and other regulations that are currently or may in the future be applicable to us. In 2022, Chinese regulators announced regulatory actions aimed at providing China's government with greater oversight over certain sectors of China's economy, including the for-profit education sector and technology platforms that have a quantitatively significant number of users located in China. Although the biotech industry is already highly regulated in China and while there has been no indication to date that such actions or oversight would apply to companies that are similarly situated as us and that are pursuing similar portfolios of drug products and therapies as us, China's government may in the future take regulatory actions that may materially adversely affect the business environment and financial markets in China as they relate to us, our ability to operate our business, our liquidity and our access to capital.

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. Furthermore, new laws or regulations may be passed, in some cases with little advance notice, that affect the way we or our collaboration partner do business in China (including the manufacture, sale, or distribution of roxadustat in China). Our business may be affected if we rely on laws and regulations that are subsequently adopted or interpreted in a manner different from our understanding of these laws and regulations. Navigating the uncertainty and change in the China legal and regulatory systems will require the devotion of significant resources and time, and there can be no assurance that our contractual and other rights will ultimately be maintained or 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. Recently, Chinese regulators announced regulatory actions aimed at providing China's government with greater oversight over certain sectors of China's economy, including the for-profit education sector and technology platforms that have a quantitatively significant number of users located in China. Although the biotech industry is already highly regulated in China and while there has been no indication to date that such actions or oversight would apply to companies that are similarly situated as us and that are pursuing similar portfolios of drug products and therapies as us, China's government may in the future take regulatory actions that may materially adversely affect the business environment and financial markets in China as they relate to us. 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.

We may be subject to additional Chinese requirements, approvals or permissions in the future.

We are incorporated in the state of Delaware. To operate our general business activities currently conducted in China, each of our Chinese subsidiaries (and our joint venture with AstraZeneca, Falikang) is required to and does obtain a business license from the local counterpart of the State Administration for Market Regulation. Such business licenses list the business activities we are authorized to carry out and we would be noncompliant if we act outside of the scope of business activities set forth under the relevant business license.

Due to China's regulatory framework in general and for the pharmaceutical industry specifically, we are required to apply for and maintain many approvals or permits specific to many of our business activities, including but not limited to manufacturing, distribution, environment protection, workplace safety, cybersecurity, from both national and local government agencies. For example, FibroGen Beijing is required to maintain a Drug Product Production Permit that allows it to manufacture API and roxadustat capsules. Falikang, our joint venture with AstraZeneca, is required to maintain a Drug Product Distribution Permit in order to be able to distribute our drug product roxadustat in China. For certain of our clinical trials conducted in China, we need to obtain, through the clinical sites, permits from the Human Genetic Resources Administration of China to collect samples that include human genetic resources, such as blood samples.

We may also be required to obtain certain approvals from Chinese authorities before transferring certain scientific data abroad or to foreign parties or entities established or actually controlled by them.

None of our subsidiaries or our joint venture in China are required to obtain approval or prior permission from the China Securities Regulatory Commission, Cyberspace Administration of China, or any other Chinese regulatory authority under the Chinese laws and regulations currently in effect to issue securities to our investors. However, the approvals and permits we do have to comply with are numerous and there are uncertainties with respect to the Chinese legal system and changes in laws, regulations and policies, including how those laws and regulations will be interpreted or implemented. For further information, see the risk factor titled "*Uncertainties with respect to the China legal system and regulations could have a material adverse effect on us.*" There can be no assurance that we will not be subject to new or changing requirements, approvals or permissions in the future in order to operate in China.

If we are unable to obtain the necessary approvals or permissions in order to operate our business in China, if we inadvertently conclude that such approvals or permissions are not required, or if we are subject to additional requirements, approvals, or permissions, it could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our common stock.

If the Chinese government determines that our corporate structure does not comply with Chinese regulations, or if Chinese regulations change or are interpreted differently in the future, the value of our common stock may decline.

In July 2021, the Chinese government provided new guidance on China-based companies raising capital outside of China, including through arrangements called variable interest entities. We do not employ a variable interest entity structure for purposes of replicating foreign investment in Chinese-based companies where Chinese law prohibits direct foreign investment. We do not operate in an industry that is currently subject to foreign ownership limitations in China. However, there are uncertainties with respect to the Chinese legal system and there may be changes in laws, regulations and policies, including how those laws and regulations will be interpreted or implemented. For further information, see the risk factor titled "*Uncertainties with respect to the China legal system and regulations could have a material adverse effect on us.*" If in the future the Chinese government determines that our corporate structure does not comply with Chinese regulations, or if Chinese laws or regulations change or are interpreted differently from our understanding of these laws and regulations, the value of our common stock may decline.

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 financing in order to fund our operations, which may be dilutive to our shareholders, restrict our operations or require us to relinquish rights to our intellectual property or product candidates. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce or eliminate our research and development programs and/or our commercialization efforts.*

We are a biopharmaceutical company with two lead product candidates in clinical development, roxadustat for CIA in China, and pamrevlumab for pancreatic cancer. 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 years ended December 31, 2022, 2021 and 2020 were \$293.7 million, \$290.0 million and \$189.3 million, respectively. As of September 30, 2023, we had an accumulated deficit of \$1.8 billion. As of September 30, 2023, we had capital resources consisting of cash, cash equivalents and short-term investments of \$251.3 million. In addition, as of September 30, 2023, we had \$31.7 million of accounts receivable in our current assets. 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 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 (deficit) 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, continue 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 our existing cash and cash equivalents, short-term and long-term investments and accounts receivable, cash flows from commercial sales and sales of drug product, and expected third-party collaboration revenues will allow us to fund our operating plans through at least 12 months from the date of issuance of these consolidated financial statements. 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 financing or other sources, such as revenue interest monetization or other structured financing. Future sales of equity or debt securities 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.

Accordingly, we may seek additional funds sooner than planned. 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.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize any of our product candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all or that we will be able to satisfy the performance, financial and other obligations in connection with any such financing. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. We could also be required to seek funds through additional collaborations, partnerships, licensing arrangements with third parties or otherwise at an earlier stage than would be desirable and we may be required to relinquish rights to intellectual property, future revenue streams, research programs, product candidates or to grant licenses on terms that may not be favorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. If we raise additional funds by issuing equity securities, dilution to our existing stockholders will result. In addition, as a condition to providing additional funding to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Moreover, any debt financing, if available, may involve restrictive covenants that could limit our flexibility in conducting future business activities and, in the event of insolvency, would be paid before holders of equity securities received any distribution of corporate assets. For example, in 2022 we entered into a Revenue Interest Financing Agreement (“RIFA”) with an affiliate of NovaQuest Capital Management (“NovaQuest”) and in 2023 we entered into a debt financing agreement with investment funds managed by Morgan Stanley Tactical Value, each of which impose certain performance and financial obligations on our business. Our ability to satisfy and meet any future debt service obligations will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control.

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.

We may be required to recognize an impairment of our long-lived assets, which could adversely affect our financial performance.*

Our long-lived assets group is subject to an impairment assessment at least annually, or when certain triggering events or circumstances indicate that its carrying value may be impaired. Prolonged market declines or other factors negatively impacting the performance of our businesses could adversely affect our evaluation of the recoverability of our long-lived assets. If, as a result of the impairment test, we determine that the fair value of our long-lived asset group is less than its carrying amount, we may incur an impairment charge, which could materially and adversely affect our results of operations or financial position.

Our non-dilutive transactions with Morgan Stanley Tactical Value and NovaQuest could limit cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations, and contain various covenants and other provisions, which, if violated, could result in the acceleration of payments due in connection with such transaction or the foreclosure on security interest.*

On November 4, 2022, we entered into a \$50 million RIFA financing with NovaQuest with respect to our revenues from Astellas’ sales of roxadustat in Europe, Japan and the other Astellas territories.

As material inducement for NovaQuest to enter into the RIFA, we granted NovaQuest a security interest over our rights, title and interest in and to the revenue interest payments and intellectual property related to roxadustat and the Astellas territories.

In addition, the RIFA includes customary reporting obligations and events of default by us. Upon the occurrence of an event of default, NovaQuest may exercise all remedies available to it at law or in equity in respect of the security interest.

On April 29, 2023, we entered into a financing agreement (“Financing Agreement”) for up to \$150 million with investment funds managed by Morgan Stanley Tactical Value, as lenders, and Wilmington Trust, National Association, as the administrative agent.

Our Financing Agreement with Morgan Stanley Tactical Value requires us to maintain a minimum balance of \$30 million of unrestricted cash and cash equivalents held in accounts in the U.S. and, while any portion of the term loans or any other obligations under the Financing Agreement remain outstanding, we must comply with certain customary affirmative and negative covenants set forth in the Financing Agreement and related loan documents. The Financing Agreement also provides for customary events of default triggers. Upon an event of default, the administrative agent under the Financing Agreement may, and at the direction of the majority lenders shall, accelerate all of our outstanding obligations under the Financing Agreement and related loan documents, terminate all outstanding funding commitments and/or exercise remedies available at law or equity or under contract for secured creditors. The term loans are secured by substantially all of our and our non-Chinese subsidiaries’ assets, subject to customary exceptions.

For additional details about these financing transactions, see Note 7, *Senior Secured Term Loan Facilities* and Note 8, *Liability Related to Sale of Future Revenues*, to the condensed consolidated financial statements.

Our obligations under these financing transactions could have significant negative consequences for our shareholders, and our business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional non-dilutive financing or enter into collaboration or partnership agreements of a certain size;

- requiring the dedication of a portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business; and
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our ability to comply with the above covenants may be affected by events beyond our control, and future breaches of any of the covenants could result in a default under the RIFA, the Financing Agreement, or any future financing agreements. If not waived, future defaults could cause all of the outstanding indebtedness under either financing transaction to become immediately due and payable and NovaQuest or Morgan Stanley Tactical Value could seek to enforce their security interest in assets that secure such indebtedness.

To the extent we incur additional debt, the risks described above could increase. A default in one of such agreements could trigger a default in the other. Any of the above risks would negatively impact our ability to operate our business and obtain additional debt or equity financing on favorable terms.

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

If either our Astellas collaboration or our AstraZeneca China collaboration were to be terminated, we could have a sudden decrease of revenue and require significant additional capital in order to proceed with development and commercialization of roxadustat or we may require additional partnering in order to help fund our operations. While we continue to co-commercialize roxadustat in China with AstraZeneca, and develop roxadustat in China for CIA, it is probable that our U.S./Rest of World Collaboration Agreement with AstraZeneca will be terminated and we would not be eligible for any remaining development cost sharing or development or commercialization milestones from AstraZeneca (outside of China). In addition, if our collaboration partners are unsuccessful in their commercialization efforts (particularly in Europe and China), our revenue will be negatively affected. 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 development or commercialization efforts.

We may encounter difficulties in expanding our operations, particularly commercialization, successfully.*

For any product candidates that we seek to advance into commercialization, we will need to expand our regulatory, manufacturing, commercialization and administration capabilities or contract with third parties to provide these capabilities for us. This could be a particular challenge as a result of the 2023 restructuring. Our failure or delay in accomplishing any of these steps could prevent us from fully realizing the commercial success of any such product candidate.

Loss of senior management and key personnel could adversely affect our business.*

We are highly dependent on members of our senior management team. The loss of the services of 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. Mark Eisner, our Chief Medical Officer, resigned in September 2023 (not the result of any disagreement with the Company) and we have commenced a search for a new Chief Medical Officer.

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

There is also significant competition, in particular in the San Francisco Bay Area, for the hiring of experienced and qualified personnel, which increases the importance of retention of our existing personnel.

On July 14, 2023, FibroGen approved a reduction to its U.S. workforce of approximately 32% to lower its operating expenses. There is a risk that we will lose valuable skills, experience, and productivity. Furthermore, employee turnover and other risks described above may be exacerbated by the restructuring as well as recent stock performance.

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.

We are exposed to the risks associated with litigation, investigations, regulatory proceedings, and other legal matters, any of which could have a material adverse effect on us.

We are currently and may in the future face legal, administrative and regulatory proceedings, claims, demands, investigations and/or other dispute-related matters involving, among other things, our products, product candidates, or other issues relating to our business as well as allegations of violation of U.S. and foreign laws and regulations relating to intellectual property, competition, securities, consumer protection, and the environment.

For example, we and certain of our current and former executive officers have been named as defendants in a consolidated putative class action lawsuit (“Securities Class Action Litigation”) and certain of our current and former executive officers and directors have been named as defendants in several derivative lawsuits (“Derivative Litigation”). The complaint filed in the Securities Class Action Litigation alleges violations of the securities laws, including, among other things, that the defendants made certain materially false and misleading statements about our Phase 3 clinical studies data and prospects for FDA approval. The complaints filed in the Derivative Litigation asserts claims based on some of the same alleged misstatements and omissions as the Securities Class Action Litigation and seeks, among other things, unspecified damages. We intend to vigorously defend the claims made in the Securities Class Action Litigation and Derivative Litigation; however, the outcome of these matters cannot be predicted, and the claims raised in these lawsuits may result in further legal matters or actions against us, including, but not limited to, government enforcement actions or additional private litigation. In the fourth quarter of 2021, FibroGen received a subpoena from the SEC requesting documents related to roxadustat’s pooled cardiovascular safety data. We have been fully cooperating with the SEC’s investigation.

Our Board of Directors also received litigation demands from our purported shareholders, asking the Board of Directors to investigate and take action against certain current and former officers and directors of ours for alleged wrongdoing based on the same allegations in the pending derivative and securities class action lawsuits. We may in the future receive such additional demands.

We cannot predict whether any particular legal matter will be resolved favorably or ultimately result in charges or material damages, fines or other penalties, government enforcement actions, bars against serving as an officer or director, or civil or criminal proceedings against us or certain members of our senior management. For additional information regarding our pending litigation and SEC investigation, see Note 12, *Commitments and Contingencies*, to the condensed consolidated financial statements.

Legal proceedings in general, and securities and class action litigation and regulatory investigations in particular, regardless of their merits or their ultimate outcomes, are costly, divert management’s attention and may materially adversely affect our business, results of operations, financial condition, prospects, and stock price. In addition, such legal matters could negatively impact our reputation among our customers, collaboration partners or our shareholders. Furthermore, publicity surrounding legal proceedings, including regulatory investigations, even if resolved favorably for us, could result in additional legal proceedings or regulatory investigations, as well as damage to our reputation.

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, product 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 implementing 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 2022, and continue to maintain and 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.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.*

In the ordinary course of our business, we and the third parties upon which we rely process confidential, proprietary, and sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our confidential, proprietary, and sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of confidential, proprietary, and sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process confidential, proprietary, and sensitive data in a variety of contexts, including, without limitation, CROs, CMOs, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on third-party service providers to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our confidential, proprietary, and sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services.

In the third quarter of 2023, we were notified that a service provider of our third-party service provider had a security breach and certain of our pseudo-anonymized clinical data was exfiltrated. Our incident response assessment was unable to determine a material impact to our Company (including the fact that we have found no personally identifiable information involved, and there is no business continuity risk). However, there is a risk that we discover a material impact in the future.

We may expend significant resources or modify our business activities to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and confidential, proprietary, and sensitive data.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, such as governmental authorities, partners, and affected individuals, of security incidents. Such disclosures may involve inconsistent requirements and are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing confidential, proprietary, and sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); delays in our development or other business plans; financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

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 deductibles 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, all critical systems and services can be accessible from the disaster recovery site, but 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 are in draft and 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.*

The market price of our common stock has at times experienced price volatility and may continue to be volatile. For example, during 2023, the closing price of our common stock on The Nasdaq Global Select Market has ranged from \$0.48 per share to \$25.18 per share. 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. We are currently subject to such litigation and it has diverted, and could continue to result in diversions of, our management’s attention and resources and it could result in significant expense, monetary damages, penalties or injunctive relief against us. For a description of our pending litigation and SEC investigation, see Note 12, *Commitments and Contingencies*, to the condensed consolidated financial statements.

There is a risk that our common stock would be delisted due to not meeting the Nasdaq price requirement.*

On October 24, 2023, FibroGen received a letter from the Nasdaq Listing Qualifications Staff of The Nasdaq Stock Market notifying us that for the last 30 consecutive business days the bid price of FibroGen’s common stock had closed below \$1.00 per share, the minimum closing bid price required by the continued listing requirements of Nasdaq listing rule 5450(a)(1).

The notification received has no immediate effect on the listing of FibroGen’s common stock on Nasdaq. In accordance with listing rule 5810(c)(3)(A), we have 180 calendar days, or until April 22, 2024, to regain compliance with the minimum bid price rule. To regain compliance, the closing bid price of our common stock must be at least \$1.00 per share for a minimum of ten consecutive business days (or such longer period of time as the Nasdaq staff may require in some circumstances, but generally not more than 20 consecutive business days) before April 22, 2024.

If our common stock does not achieve compliance by April 22, 2024, we may be eligible for an additional 180-day period to regain compliance if we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards, with the exception of the bid price requirement, and provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period, including by effecting a reverse stock split, if necessary. However, if it appears to the Nasdaq staff that we will not be able to cure the deficiency, or if we do not meet the other listing standards, Nasdaq could provide notice that our common stock will become subject to delisting. In the event we receive notice that our common stock is being delisted, Nasdaq rules permit us to appeal any delisting determination by the Nasdaq staff to a Hearings Panel. We expect that our common stock would remain listed pending the Hearing Panel’s decision.

There can be no assurance that we will regain compliance with the minimum bid price rule or maintain compliance with the other listing requirements within the above timelines, or if it is necessary for us to effect a reverse stock split in order for us to regain compliance with the minimum bid price rule we may fail to do so, in which case our common stock may be delisted. If we appeal a delisting determination by Nasdaq to the Hearing Panel, there can be no assurance that such appeal would be successful.

Delisting from the Nasdaq Global Select Market or any Nasdaq market could make trading our common stock more difficult for investors, potentially leading to declines in our share price and liquidity. In addition, without a Nasdaq market listing, stockholders may have a difficult time getting a quote for the sale or purchase of our common stock, the sale or purchase of our common stock would likely be made more difficult and the trading volume and liquidity of our common stock could decline. Delisting from Nasdaq could also result in negative publicity and could also make it more difficult for us to raise additional capital. The absence of such a listing may adversely affect the value accorded by other parties. Further, if we are delisted, we would also incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our stockholders to sell our common stock in the secondary market. If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on an over-the-counter quotation system, such as the OTCQB market, where an investor may find it more difficult to sell our common stock or obtain accurate quotations as to the market value of our common stock. We cannot assure you that our common stock, if delisted from Nasdaq, will be listed on another national securities exchange or quoted on an over-the counter quotation system. If our common stock is delisted, it may come within the definition of “penny stock” as defined in the Exchange Act, and would be covered by Rule 15g-9 of the Exchange Act. That rule imposes additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors. For transactions covered by Rule 15g-9, the broker-dealer must make a special suitability determination for the purchaser and receive the purchaser’s written agreement to the transaction prior to the sale. Consequently, Rule 15g-9, if it were to become applicable, would affect the ability or willingness of broker-dealers to sell our securities, and accordingly would affect the ability of stockholders to sell their securities in the public market. These additional procedures could also limit our ability to raise additional capital in the future.

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, withholding, 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.

The tax regulations in the U.S. and other jurisdictions in which we operate are extremely complex and subject to change. Changes in tax regulations could have an adverse effect on our results of operations and 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 Court of Chancery of the State of Delaware is 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. While the Delaware courts determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than that designated in the exclusive forum provisions. For example, one of the Derivative Litigation was brought in federal court in California, despite the exclusive forum provision. We are currently moving to dismiss that lawsuit on the basis of improper forum and we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation in any additional litigations that are brought in a venue other than that designated in the exclusive forum provision. 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.

Our business or our share price could be negatively affected as a result of shareholder proposals or actions.

Public companies are facing increasing attention from stakeholders relating to environmental, social and governance matters, including corporate governance, executive compensation, environmental stewardship, social responsibility, and diversity and inclusion. Key stakeholders may advocate for enhanced environmental, social and governance disclosures or policies or may request that we make corporate governance changes or engage in certain corporate actions that we believe are not currently in the best interest of FibroGen or our stockholders. Responding to challenges from stockholders, such as proxy contests or media campaigns, could be costly and time consuming and could have an adverse effect on our reputation, which could have an adverse effect on our business and operational results, and could cause the market price of our common stock to decline or experience volatility.

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.

Rule 10b5-1 Trading Plans

On August 31, 2023, Christine Chung, Senior Vice President, China Operations of the Company, terminated a Rule 10b5-1 trading plan, which was previously adopted on March 7, 2023 and intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. The plan provided for the potential sale of up to 125,000 shares of common stock held by Ms. Chung. Prior to its termination, Ms. Chung sold 12,500 shares under the plan.

On July 12, 2023, Mark Eisner, then Chief Medical Officer of the Company, terminated a Rule 10b5-1 trading plan, which was previously adopted on March 2, 2023 and intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. The plan provided for the potential sale of up to 107,260 shares of common stock held by Mr. Eisner. Prior to its termination, Mr. Eisner sold 0 shares under the plan.

On August 31, 2023, Juan Graham, Chief Financial Officer of the Company, terminated a Rule 10b5-1 trading plan, which was previously adopted on August 26, 2022 and intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. The plan provided for the potential sale of up to 29,911 shares of common stock held by Mr. Graham. Prior to its termination, Mr. Graham sold 7,929 shares under the plan.

On September 22, 2023, Jeffrey Henderson, a member of the Company's Board of Directors, terminated a Rule 10b5-1 trading plan, which was previously adopted on March 3, 2023 and intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. The plan provided for the potential sale of up to 20,000 shares of common stock held by Mr. Henderson. Prior to its termination, Mr. Henderson sold 6,000 shares under the plan.

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	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+	Offer Letter, dated July 23, 2023, between FibroGen, Inc. and Thane Wettig.	8-K	001-36740	10.1	07/25/2023
10.2+	Consulting Agreement, dated July 23, 2023, between FibroGen, Inc. and Enrique Conterno.	8-K	001-36740	10.2	07/25/2023
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.)	—	—	—	—

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

+ Indicates a management contract or compensatory plan.

SIGNATURES

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

FibroGen, Inc.

Date: November 6, 2023

By: /s/ Thane Wettig

Thane Wettig
Chief Executive Officer
(Principal Executive Officer)

Date: November 6, 2023

By: /s/ Juan Graham

Juan Graham
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTIFICATION

I, Thane Wettig, 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2023

/s/ Thane Wettig

Thane Wettig
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

I, Juan Graham, 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2023

/s/ Juan Graham

Juan Graham

Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

CERTIFICATION

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

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 6, 2023

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 6th day of November, 2023.

/s/ Thane Wettig

Thane Wettig
Chief Executive Officer

/s/ Juan Graham

Juan Graham
Senior Vice President 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.
