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

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2025

OR

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

For the transition period from _____ to

Commission file number: 001-36740

FIBROGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0357827**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
350 Bay Street, Suite 100, #6009 **San Francisco, CA**	**94158**
(Address of Principal Executive Offices)	**(Zip Code)**

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

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

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

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

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

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

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

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

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

The number of shares of common stock outstanding as of July 31, 2025 was 4,043,899.

FIBROGEN, INC.

TABLE OF CONTENTS

FIBROGEN, INC.

PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 23,367	$ 50,482
Accounts receivable, net	136	481
Inventories	3,863	3,155
Prepaid expenses and other current assets	2,306	31,542
Current assets held for sale	132,650	110,849
Total current assets	162,322	196,509
Other assets	839	1,405
Long-term assets held for sale	14,894	16,611
Total assets	$ 178,055	$ 214,525
Liabilities, redeemable non-controlling interests and deficit		
Current liabilities:		
Accounts payable	$ 10,477	$ 5,064
Accrued and other current liabilities	35,916	62,035
Deferred revenue	27,311	27,290
Senior secured term loan facilities, current	73,733	—
Current liabilities held for sale	8,458	38,917
Total current liabilities	155,895	133,306
Product development obligations	19,398	17,012
Deferred revenue, net of current	122,224	114,708
Senior secured term loan facilities, non-current	—	73,092
Liability related to sale of future revenues, non-current	61,306	58,864
Other long-term liabilities	106	822
Long-term liabilities held for sale	156	356
Total liabilities	359,085	398,160
Commitments and Contingencies (Note 10)		
Redeemable non-controlling interests	21,480	21,480
Stockholders' deficit:		
Preferred stock, $0.01 par value; 125,000 shares authorized; no shares issued and outstanding at June 30, 2025 and December 31, 2024	—	—
Common stock, $0.01 par value; 225,000 shares authorized at June 30, 2025 and December 31, 2024; 4,044 and 4,037 shares issued and outstanding at June 30, 2025 and December 31, 2024	1,011	1,009
Additional paid-in capital	1,673,249	1,668,620
Accumulated other comprehensive loss	(4,794)	(5,732)
Accumulated deficit	(1,892,463)	(1,889,499)
Total stockholders' deficit attributable to FibroGen	(222,997)	(225,602)
Nonredeemable non-controlling interests	20,487	20,487
Total deficit	(202,510)	(205,115)
Total liabilities, redeemable non-controlling interests and deficit	$ 178,055	$ 214,525

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

FIBROGEN, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue:				
Development and other revenue	$ 133	$ 269	277	1,147
Drug product revenue, net	1,215	729	3,811	25,216
Total revenue	1,348	998	4,088	26,363
Operating costs and expenses:				
Cost of goods sold	85	140	337	21,483
Research and development	5,865	32,360	15,040	68,848
Selling, general and administrative	7,057	14,906	15,164	31,622
Restructuring charge	393	—	519	—
Total operating costs and expenses	13,400	47,406	31,060	121,953
Loss from operations	(12,052)	(46,408)	(26,972)	(95,590)
Interest and other, net				
Interest expense	(2,009)	(1,868)	(4,265)	(3,960)
Interest income and other income (expenses), net	286	900	698	3,135
Total interest and other, net	(1,723)	(968)	(3,567)	(825)
Loss from continuing operations before income taxes	(13,775)	(47,376)	(30,539)	(96,415)
Benefit from income taxes	(92)	(281)	(90)	(274)
Loss from continuing operations	(13,683)	(47,095)	(30,449)	(96,141)
Income from discontinued operations, net of tax	6,080	31,551	27,485	47,664
Net loss	$ (7,603)	$ (15,544)	$ (2,964)	$ (48,477)
Loss from continuing operations per share - basic and diluted	$ (3.38)	$ (11.79)	$ (7.54)	$ (24.18)
Income from discontinued operations per share - basic and diluted	1.50	7.90	6.81	11.99
Net loss per share - basic and diluted	$ (1.88)	$ (3.89)	$ (0.73)	$ (12.19)
Weighted average number of common shares used to calculate net income (loss) per share - basic and diluted	4,042	3,993	4,040	3,976

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

FIBROGEN, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Net loss	$ (7,603)	$ (15,544)	$ (2,964)	$ (48,477)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(360)	2,700	939	3,092
Available-for-sale investments:				
Unrealized loss on investments, net of tax effect	—	(2)	(1)	(26)
Other comprehensive income (loss), net of taxes	(360)	2,698	938	3,066
Comprehensive loss	(7,963)	(12,846)	(2,026)	(45,411)

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

FIBROGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE NON-CONTROLLING INTERESTS AND STOCKHOLDERS' DEFICIT
(In thousands, except share data)
(Unaudited)

	For The Three Month Period							
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Nonredeemable Non-Controlling Interests	Total Deficit	Redeemable Non-Controlling Interests
	Shares (Note 1)	Amount						
Balance at March 31, 2025	4,041,758	$ 1,010	$ 1,671,388	$ (4,434)	$ (1,884,860)	$ 20,487	$ (196,409)	$ 21,480
Net loss	—	—	—	—	(7,603)	—	(7,603)	—
Foreign currency translation adjustments	—	—	—	(360)	—	—	(360)	—
Shares issued from stock plans, net of payroll taxes paid	2,196	1	(12)	—	—	—	(11)	—
Redemption of fractional shares due to reverse stock split	(55)	—	—	—	—	—	—	—
Stock-based compensation	—	—	1,873	—	—	—	1,873	—
Balance at June 30, 2025	4,043,899	$ 1,011	$ 1,673,249	$ (4,794)	$ (1,892,463)	$ 20,487	$ (202,510)	$ 21,480
Balance at March 31, 2024	3,978,975	$ 995	$ 1,652,243	$ (6,507)	$ (1,874,853)	$ 20,487	$ (207,635)	$ 21,480
Net loss	—	—	—	—	(15,544)	—	(15,544)	—
Change in unrealized gain or loss on investments	—	—	—	(2)	—	—	(2)	—
Foreign currency translation adjustments	—	—	—	2,700	—	—	2,700	—
Shares issued from stock plans, net of payroll taxes paid	37,015	9	31	—	—	—	40	—
Stock-based compensation	—	—	8,588	—	—	—	8,588	—
Balance at June 30, 2024	4,015,990	$ 1,004	$ 1,660,862	$ (3,809)	$ (1,890,397)	$ 20,487	$ (211,853)	$ 21,480

FIBROGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE NON-CONTROLLING INTERESTS AND STOCKHOLDERS' DEFICIT (CONTINUED)
(In thousands, except share data)
(Unaudited)

	For The Six Month Period							
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Nonredeemable Non-Controlling Interests	Total Deficit	Redeemable Non-Controlling Interests
	Shares (Note 1)	Amount						
Balance at December 31, 2024	4,036,678	$ 1,009	$ 1,668,620	$ (5,732)	$ (1,889,499)	$ 20,487	$ (205,115)	$ 21,480
Net loss	—	—	—	—	(2,964)	—	(2,964)	—
Change in unrealized gain or loss on investments	—	—	—	(1)	—	—	(1)	—
Foreign currency translation adjustments	—	—	—	939	—	—	939	—
Shares issued from stock plans, net of payroll taxes paid	7,276	2	(50)	—	—	—	(48)	—
Issuance cost under ATM Program	—	—	(46)	—	—	—	(46)	—
Redemption of fractional shares due to reverse stock split	(55)	—	—	—	—	—	—	—
Stock-based compensation	—	—	4,725	—	—	—	4,725	—
Balance at June 30, 2025	4,043,899	$ 1,011	$ 1,673,249	$ (4,794)	$ (1,892,463)	$ 20,487	$ (202,510)	$ 21,480
Balance at December 31, 2023	3,950,809	$ 988	$ 1,643,641	$ (6,875)	$ (1,841,920)	$ 20,487	$ (183,679)	$ 21,480
Net loss	—	—	—	—	(48,477)	—	(48,477)	—
Change in unrealized gain or loss on investments	—	—	—	(26)	—	—	(26)	—
Foreign currency translation adjustments	—	—	—	3,092	—	—	3,092	—
Shares issued from stock plans, net of payroll taxes paid	65,181	16	(129)	—	—	—	(113)	—
Stock-based compensation	—	—	17,350	—	—	—	17,350	—
Balance at June 30, 2024	4,015,990	$ 1,004	$ 1,660,862	$ (3,809)	$ (1,890,397)	$ 20,487	$ (211,853)	$ 21,480

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

FIBROGEN, INC.

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

	Six Months Ended June 30,	
	2025	**2024**
Operating activities		
Net loss	$ (2,964)	$ (48,477)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	530	1,582
Amortization of finance lease right-of-use assets	18	19
Net accretion of premium and discount on investments	(1)	(1,681)
Investment income in unconsolidated variable interest entity	(1,108)	(1,766)
Impairment of property and equipment	2,062	—
Loss on disposal of property and equipment	—	306
Stock-based compensation	4,725	17,350
Changes in operating assets and liabilities:		
Accounts receivable, net	(3,001)	5,962
Inventories	4,210	15,578
Prepaid expenses and other current assets	51,479	4,527
Operating lease right-of-use assets	620	6,806
Other assets	549	441
Accounts payable	(21,692)	(7,977)
Accrued and other liabilities	(30,700)	(52,663)
Operating lease liabilities, current	(434)	1,489
Deferred revenues	7,537	(29,501)
Accrued interest expense related to sale of future revenues	3,684	(1,904)
Accrued interest for finance lease liabilities	(11)	12
Operating lease liabilities, non-current	(205)	(8,128)
Other long-term liabilities	103	(1,132)
Net cash provided by (used in) operating activities	15,401	(99,157)
Investing activities		
Purchases of property and equipment	(29)	(43)
Proceeds from sale of property and equipment	—	3
Purchases of available-for-sale securities	—	(8,628)
Proceeds from maturities of investments	—	132,183
Net cash provided by (used in) investing activities	(29)	123,515
Financing activities		
Repayments of finance lease liabilities	(2)	(20)
Cash paid for payroll taxes on restricted stock unit releases	(49)	(229)
Payment of issuance cost under ATM Program	(46)	—
Proceeds from issuance of common stock under employee stock plans	—	116
Net cash used in financing activities	(97)	(133)
Effect of exchange rate change on cash and cash equivalents	2,388	2,801
Net increase in cash and cash equivalents	17,663	27,026
Total cash and cash equivalents at beginning of period	102,178	113,688
Total cash and cash equivalents at end of period	$ 119,841	$ 140,714

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 a biopharmaceutical company focused on development of novel therapies at the frontiers of cancer biology and anemia.

The Company is developing FG-3246, a potential first-in-class antibody-drug conjugate ("ADC") targeting CD46, for the treatment of metastatic castration-resistant prostate cancer ("mCRPC") and potentially other cancers. This program also includes the development of FG-3180, an associated CD46-targeted positron emission tomography ("PET") biomarker and imaging agent. The Company anticipates initiation of a Phase 2 monotherapy dose optimization study of FG-3246 for the treatment of mCRPC, along with the exploratory analysis of FG-3180, in the third quarter of 2025, pending close of the sale of FibroGen International to AstraZeneca Treasury Limited.

The Company and its collaboration partners have developed roxadustat (爱瑞卓®, EVRENZO™), which is currently approved in the People's Republic of China ("China"), Europe, Japan, and numerous other countries for the treatment of anemia in chronic kidney disease ("CKD") patients on dialysis and not on dialysis.

On February 20, 2025, the Company entered into a share purchase agreement (the "Share Purchase Agreement") with AstraZeneca Treasury Limited pursuant to which FibroGen and its subsidiary FibroGen China Anemia Holdings, Ltd. agreed to sell all of the issued and outstanding equity interests of FibroGen International (Hong Kong) Ltd. ("FibroGen International") to AstraZeneca Treasury Limited. AstraZeneca AB ("AstraZeneca") is the Company's long-time commercialization partner for roxadustat in greater China and South Korea. This sale includes all of FibroGen's roxadustat assets in China, including FibroGen International's subsidiary FibroGen (China) Medical Technology Development Co., Ltd ("FibroGen Beijing") and its 51.1% interest in Beijing Falikang Pharmaceutical Co., Ltd. ("Falikang"). The transaction is expected to close in the third quarter of 2025, and is subject to customary closing conditions and closing deliverables, including receipt of regulatory approval from the China State Administration for Market Regulation ("SAMR").

FibroGen has retained the rights to roxadustat in the United States of America ("U.S."), Canada, Mexico, and in all markets not held by AstraZeneca or licensed to Astellas Pharma Inc. ("Astellas"). Roxadustat is not approved for commercialization in any indication in the U.S., Canada, or Mexico. Astellas is commercializing roxadustat (EVRENZO™) in Europe and Japan to treat anemia under two development and commercialization license agreements: one for Japan, and one for Europe, the Commonwealth of Independent States, the Middle East and South Africa.

The Company continues to work on its development plan for roxadustat in anemia associated with lower-risk myelodysplastic syndromes ("MDS"), a high-value indication with significant unmet medical need.

Basis of Presentation and Principles of Consolidation

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, 2024, filed on March 17, 2025.

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.

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

Discontinued Operations

On February 20, 2025, the Company entered into the Share Purchase Agreement with AstraZeneca Treasury Limited pursuant to which FibroGen and its subsidiary FibroGen China Anemia Holdings, Ltd. agreed to sell all of the issued and outstanding equity interests of FibroGen International to AstraZeneca Treasury Limited for an aggregate purchase price comprised of $85 million in cash for the enterprise value of FibroGen International, plus an additional cash amount equal to the net cash held in China by FibroGen International and its subsidiaries as of the closing. This sale includes all of FibroGen's roxadustat assets in China, including FibroGen International's subsidiary FibroGen Beijing and its 51.1% interest in Falikang. The transaction is expected to close in the third quarter of 2025, and is subject to customary closing conditions and closing deliverables, including receipt of regulatory approval from the China SAMR. The Company analyzed the quantitative and qualitative factors and concluded that the sale of FibroGen International represents a strategic shift in FibroGen's business and qualified as a discontinued operation. As a result, the Company determined that FibroGen International met the "held for sale" criteria and the "discontinued operations" criteria in accordance with Financial Accounting Standard Board ("FASB") Accounting Standards Codification ("ASC") 205, *Presentation of Financial Statements*, as of June 30, 2025 and December 31, 2024. Accordingly, the condensed consolidated balance sheets and the condensed consolidated statements of operations, and the notes to the condensed consolidated financial statements were recasted for all periods presented to reflect the discontinuation of FibroGen International in accordance with ASC 205. The operating results related to FibroGen International are classified as discontinued operations, and have been reflected as discontinued operations in the condensed consolidated statements of operations, while the related assets and liabilities were classified within the condensed consolidated balance sheets as held for sale for all periods presented. See Note 2, *Discontinued Operations*, for related disclosures. Unless otherwise noted, discussion in the notes to these consolidated financial statements, relates to solely to the Company's continuing operations.

Reverse Stock Split

On June 16, 2025, the Company effected a 1-for-25 reverse stock split (the "Reverse Stock Split"). The Reverse Stock Split reduced the number of issued and outstanding shares of common stock from approximately 101.1 million shares to approximately 4.0 million shares. Proportionate adjustments have been made to the number of shares available for issuance under the Company's equity incentive plans as well as outstanding equity awards, in accordance with their respective terms. All share amounts have been retroactively adjusted in the condensed consolidated financial statements and the notes to the condensed consolidated financial statements, where applicable, to reflect the Reverse Stock Split.

Liquidity and Going Concern

The unaudited condensed consolidated financial statements are prepared in accordance with the U.S. GAAP applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business and does not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described below.

If the Company is unable to complete the above mentioned sale of FibroGen International, access additional cash from its China operations, or raise additional capital in the U.S., the Company would not have sufficient liquidity to continue operations in the U.S. for the 12 months from the date that the financial statements are issued and would not be able to comply with its financial covenant that requires a minimum balance of $18.75 million of unrestricted cash and cash equivalents to be held in accounts in the United States. Upon an event of default, the Company's senior secured term loan facilities could become immediately due and payable. The Company has evaluated measures to access additional cash from its China operations and believes the sale of FibroGen International represents the most efficient way to access the entirety of its cash from China upon closing of the transaction. There is also the potential that the Company raises additional funds in the U.S. at any time through equity, equity-linked, or debt financing arrangements or from other sources. There can be no assurances that these plans will be successful. As a result of these factors, the Company has determined that there is substantial doubt about its ability to continue as a going concern within 12 months after the date that the financial statements are issued.

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 Company's Annual Report on Form 10-K for the year ended December 31, 2024, filed on March 17, 2025.

Net Income (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 loss from continuing operations for each of the three and six months ended June 30, 2025 and 2024. 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Employee stock options	490	603	500	551
RSUs, PRSUs and TSR awards	36	156	42	157
ESPP	—	18	—	20
	526	777	542	728

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.

Recently Issued Accounting Guidance Not Yet Adopted

In November 2024, the FASB issued Accounting Standards Update ("ASU") 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40),* and relevantly in January 2025, the FASB issued ASU 2025-01, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date.* The guidance requires entities to disaggregate operating expenses into specific categories to provide enhanced transparency into the nature and function of expenses. This guidance is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. This guidance should be applied either prospectively to financial statements issued for reporting periods after the effective date or retrospectively to any or all prior periods presented in the financial statements. The Company is currently in the process of evaluating the effects of this guidance on its related disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires enhanced income tax disclosures, including specific categories and disaggregation of information in the effective tax rate reconciliation, disaggregated information related to income taxes paid, income or loss from continuing operations before income tax expense or benefit, and income tax expense or benefit from continuing operations. This guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently in the process of evaluating the impact of this pronouncement on its related disclosures.

2. Discontinued Operations

On February 20, 2025, the Company entered into the Share Purchase Agreement with AstraZeneca Treasury Limited, pursuant to which FibroGen and its subsidiary FibroGen China Anemia Holdings, Ltd. agreed to sell all of the issued and outstanding equity interests of FibroGen International to AstraZeneca Treasury Limited for an aggregate purchase price comprised of $85 million in cash for the enterprise value of FibroGen International, plus an additional cash amount equal to the net cash held in China by FibroGen International and its subsidiaries as of the closing. This sale includes all of our roxadustat assets in China, including FibroGen International's subsidiary FibroGen Beijing and its 51.1% interest in Falikang. The transaction is expected to close in the third quarter of 2025, and is subject to customary closing conditions and closing deliverables, including receipt of regulatory approval from the China SAMR. The Company analyzed the quantitative and qualitative factors and concluded that the sale of FibroGen International represents a strategic shift in FibroGen's business and qualified as a discontinued operation. As a result, Company determined that FibroGen International met the "held for sale" criteria and the "discontinued operations" criteria in accordance with FASB ASC 205, *Presentation of Financial Statements*, as of June 30, 2025 and December 31, 2024. Accordingly, the operating results related to the FibroGen International are classified as discontinued operations, and have been reflected as discontinued operations in the condensed consolidated statements of operations, while the related assets and liabilities were classified within the condensed consolidated balance sheets as held for sale for all periods presented.

The financial results of the discontinued operations with respect to FibroGen International reflected in the condensed consolidated statements of operations for the three and six months ended June 30, 2025 and 2024 were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue:				
Product revenue, net	$ 19,655	49,643	$ 59,472	$ 80,181
Operating costs and expenses:				
Cost of goods sold	4,290	5,038	9,692	9,448
Research and development	542	1,746	1,301	3,650
Selling, general and administrative	6,074	7,370	13,538	13,475
Total operating costs and expenses	10,906	14,154	24,531	26,573
Income from operations	8,749	35,489	34,941	53,608
Interest and other, net				
Interest expense	(2,964)	(2,915)	(5,915)	(5,819)
Interest income and other income (expenses), net	(1,367)	(2,181)	(2,649)	(1,846)
Total interest and other, net	(4,331)	(5,096)	(8,564)	(7,665)
Income before income taxes	4,418	30,393	26,377	45,943
Provision for income taxes	—	19	—	45
Investment income in unconsolidated variable interest entity	1,662	1,177	1,108	1,766
Income from discontinued operations, net of tax	$ 6,080	$ 31,551	$ 27,485	$ 47,664

The product revenue, net, consists primarily of revenues from sales of roxadustat commercial product to Falikang, a distribution entity jointly owned by AstraZeneca and FibroGen Beijing, and is discussed in the *China Performance Obligation* section in Note 3, *Collaboration Agreements, License Agreement and Revenues*.

The carrying value of the assets and liabilities of the discontinued operations with respect to FibroGen International on the condensed consolidated balance sheets as of June 30, 2025 and December 31, 2024 were as follows (in thousands):

	June 30, 2025	December 31, 2024
Assets		
Cash and cash equivalents	$ 96,474	$ 51,696
Accounts receivable, net	22,143	18,443
Inventories	10,871	15,547
Prepaid expenses and other current assets	3,162	25,163
Total current assets held for sale	132,650	110,849
Property and equipment, net	4,670	7,041
Equity method investment in unconsolidated variable interest entity	8,115	6,864
Operating lease right-of-use assets	1,122	1,716
Other assets	987	990
Total long-term assets held for sale	14,894	16,611
Liabilities		
Accounts payable	$ 123	$ 26,974
Accrued and other current liabilities	7,486	10,679
Operating lease liabilities, current	849	1,264
Total current liabilities held for sale	8,458	38,917
Operating lease liabilities, non-current	156	356
Total long-term liabilities held for sale	156	356

The significant non-cash items and capital expenditures for the discontinued operations with respect to FibroGen International included in the condensed consolidated statements of cash flows for the six months ended June 30, 2025 and 2024 were as follows (in thousands):

	Six Months Ended June 30,	
	2025	2024
Depreciation	$ 530	$ 753
Investment loss (income) in unconsolidated variable interest entity	(1,108)	(1,766)
Impairment of property and equipment	2,062	—
Stock-based compensation	$ 943	$ 884

Included in the discontinued operations, 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.

The net product revenue from sales to Falikang were $16.4 million and $46.0 million for the three months ended June 30, 2025 and 2024, and $53.3 million and $73.1 million for the six months ended June 30, 2025 and 2024, respectively. The product revenue recognized for the three months ended June 30, 2025 included a decrease in revenue of $12.1 million resulting from changes to estimated variable consideration in the current period relating to performance obligation satisfied in previous periods. The other income from Falikang were immaterial for the three and six months ended June 30, 2025 and 2024.

The investment income in Falikang was $1.7 million and $1.2 million for the three months ended June 30, 2025 and 2024, and $1.1 million and $1.8 million for the six months ended June 30, 2025 and 2024, respectively. As of June 30, 2025 and December 31, 2024, the Company's equity method investment in Falikang were $8.1 million and $6.9 million, respectively, which were included in the long-term assets held for sale on the condensed consolidated balance sheets.

As of June 30, 2025 and December 31, 2024, accounts receivable, net, from Falikang were $19.1 million and $13.9 million, respectively, which were included in the current assets held for sale on the condensed consolidated balance sheets.

3. Collaboration Agreements, License Agreement and Revenues

Astellas Agreements

Astellas Japan Agreement

In June 2005, the Company entered into a collaboration agreement with Astellas for the development and commercialization (but not manufacture) of roxadustat for the treatment of anemia in Japan ("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 under the Astellas Japan Agreement through June 30, 2025 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 not material for the three and six months ended June 30, 2025 and 2024.

The transaction price related to consideration received through June 30, 2025 and accounts receivable has been allocated to each of the performance obligations under the Astellas Japan Agreement, including $100.3 million for license and $17.1 million for co-development.

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 June 30, 2025 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.

The aggregate amount of consideration received under the Astellas Europe Agreement through June 30, 2025 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 not material for the three and six months ended June 30, 2025 and 2024.

The transaction price related to consideration received through June 30, 2025 and accounts receivable has been allocated to each of the performance obligations under the Astellas Europe Agreement, including $619.0 million for license and $288.4 million for co-development.

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 June 30, 2025 under the Astellas Europe 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 Europe Agreement.

In 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 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").

On February 23, 2024, the Company and AstraZeneca entered into an agreement to terminate the AstraZeneca U.S./RoW Agreement, effective as of February 25, 2024 ("AstraZeneca Termination and Transition Agreement"). Pursuant to the AstraZeneca Termination and Transition Agreement, AstraZeneca returns all of their non-China roxadustat rights to the Company, with the exception of South Korea, and provides certain assistance during a transition period. In addition, as a part of this AstraZeneca Termination and Transition Agreement, AstraZeneca will receive tiered mid-single digit royalties on FibroGen's sales of roxadustat in the terminated territories, or thirty-five percent of all revenue FibroGen receives if it licenses or sells such rights to a third-party. Neither party incurred any early termination penalties.

The aggregate amount of consideration for milestone and upfront payments received under the AstraZeneca U.S./RoW Agreement through the termination totaled $439.0 million, excluding drug product revenue under the Master Supply Agreement with AstraZeneca under the AstraZeneca U.S./RoW Agreement ("AstraZeneca Master Supply Agreement"), entered in 2020, which is described under the *Drug Product Revenue, Net* section below. In addition, resulting from the AstraZeneca Termination and Transition Agreement, the Company and AstraZeneca settled the outstanding balances relating to past transactions under the AstraZeneca Master Supply Agreement. Accordingly, during the first quarter of 2024, the Company accounted for the termination of the AstraZeneca U.S./RoW agreement as a contract modification under the ASC 606, *Revenue from Contracts with Customers* ("ASC 606") and recorded a cumulative catch-up adjustment as described under the *Drug Product Revenue, Net* section below.

The Company's collaboration agreement with AstraZeneca for roxadustat in China, as described below, remains in place.

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 as defined and 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 June 30, 2025 totaled $81.2 million.

AstraZeneca China Amendment

In July 2020, FibroGen China Anemia Holdings, Ltd., FibroGen Beijing, FibroGen International, 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, 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 limited areas 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. Further discussion related to the sales to Falikang is discussed under the *China Performance Obligation* section below.

The related net product revenue recognized from the sales to Falikang was $16.4 million and $46.0 million for the three months ended June 30, 2025 and 2024, and $53.3 million and $73.1 million for the six months ended June 30, 2025 and 2024, respectively, which were included in the discontinued operations in the condensed consolidated statements of operations together with the sales directly to distributors, resulting from the Share Purchase Agreement with AstraZeneca Treasury Limited as discussed in Note 2, *Discontinued Operations*.

Prior to the above-mentioned termination of the AstraZeneca U.S./RoW Agreement, the Company evaluated under the ASC 606 and accounted for the AstraZeneca U.S./RoW Agreement and the AstraZeneca China Agreement as a single arrangement with the presumption that two or more agreements executed with a single customer at or around the same time should be presumed to be a single arrangement. As a result of the termination of the AstraZeneca U.S./RoW Agreement, during the first quarter of 2024, the Company recorded the final development revenue under the AstraZeneca U.S./RoW Agreement and AstraZeneca China Agreement, which was immaterial.

The transaction price related to consideration received and accounts receivable through the termination of the AstraZeneca U.S./RoW Agreement has been allocated to each of the performance obligations under the AstraZeneca U.S./RoW Agreement and AstraZeneca China Agreement, including $344.5 million for license, $625.5 million for co-development, information sharing and committee services, and $551.1 million for China performance obligation (with cumulative revenue of $408.1 million through June 30, 2025) that is recognized as product revenue, net included in discontinued operations as described under *China Performance Obligation* section below.

China Performance Obligation

Product revenue, net, which is included in the discontinued operations, consists primarily of revenues from sales of roxadustat commercial product to Falikang. 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 transaction price for FibroGen Beijing's product sales to Falikang is based on a gross transaction price, adjusted for the estimated profit share.

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. Periodically, the Company updates its assumptions such as total sales quantity, timing of China's volume-based purchasing program, performance period, gross transaction price, profit share and other inputs including foreign currency translation impact, among others. The China Health Authority has accepted abbreviated new drug applications for over 20 generics roxadustat applicants and approved multiple for marketing in China, since roxadustat's inclusion in the 2023 National Reimbursement Drug List. In July 2025, roxadustat was announced as being included in the 11th round of the China's volume-based purchasing program whereby a national tender has been called. 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. While the related product revenue recognized is included in discontinued operations, as of June 30, 2025 and December 31, 2024, the related deferred revenues were not included in the disposal group held for sale as the related obligation to AstraZeneca will be satisfied upon the closing of the divestiture of FibroGen International.

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

	Balance at December 31, 2024	Additions	Recognized as Revenue (Discontinued Operations)	Currency Translation and Other	Balance at June 30, 2025
AstraZeneca China performance obligation - deferred revenue	$ (132,097)	$ (63,509)	$ 53,308	$ (649)	$ (142,947)

Deferred revenue includes amounts allocated to the China performance obligation under the AstraZeneca arrangement as revenue recognition associated with this unit of accounting is tied to the commercial launch of the products within China and to when the control of the manufactured commercial products is transferred to AstraZeneca. As of June 30, 2025, approximately $20.7 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.

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 six months ended June 30, 2025 and 2024 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Astellas Japan Agreement	$ 44	$ (366)	$ 1,825	$ (2,571)
Astellas Europe Agreement	1,171	1,095	1,986	2,116
AstraZeneca U.S./RoW Agreement	—	—	—	25,671
Drug product revenue, net	$ 1,215	$ 729	$ 3,811	$ 25,216

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. The adjustment to the drug product revenue for the three months ended June 30, 2025 was immaterial.

For the three months ended March 31, 2025, 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 $1.8 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 yield from the manufacture of bulk product tablets, among others.

For the three months ended June 30, 2024, 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 $0.4 million Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect foreign exchange impacts and the changes in the estimated bulk product strength mix intended to be manufactured by Astellas, among others.

For the three months ended March 31, 2024, 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 $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, and foreign exchange impacts, among others.

As of June 30, 2025, the balances related to the API price true-up under the Astellas Japan Agreement were $0.6 million in accrued liabilities, representing the Company's best estimate of the timing for these amounts to be paid. As of December 31, 2024, the balances related to the API price true-up under the Astellas Japan Agreement were $2.5 million in accrued liabilities and $0.6 million in other long-term liabilities.

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 the fourth quarter of 2024, the Company transferred bulk drug product for commercial purposes under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement, and recognized the related fully-burdened manufacturing costs of $0.6 million as drug product revenue, and recorded $4.4 million as deferred revenue due to a high degree of uncertainty associated with the variable consideration for revenue recognition purposes. In addition, 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, for the year ended December 31, 2024, the Company reclassified $7.2 million from the related deferred revenue to accrued liabilities. As of December 31, 2024, the related balance in accrued liabilities was $10.5 million. Further for the six months ended June 30, 2025, the Company reclassified $1.3 million from the related deferred revenue to accrued liabilities. As of June 30, 2025, the balances related to the bulk drug product price true-up under the Astellas Europe Agreement and the Astellas EU Supply Agreement were $11.9 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 $1.2 million and $1.1 million as drug product revenue from the deferred revenue under the Astellas Europe Agreement for the three months ended June 30, 2025 and 2024, and $2.0 million and $2.1 million for the six months ended June 30, 2025 and 2024, 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, 2024	Recognized as Revenue	Reclassified to Accrued Liability / Accounts Payable	Balance at June 30, 2025
Drug product revenue - deferred revenue:				
Astellas Europe Agreement	$ (9,901)	$ 1,986	$ 1,327	$ (6,588)

AstraZeneca U.S./RoW Agreement

As described under *AstraZeneca Agreements* section above, pursuant to the AstraZeneca Termination and Transition Agreement related to the AstraZeneca U.S./RoW Agreement, the Company and AstraZeneca settled the outstanding balances relating to past transactions under the AstraZeneca Master Supply Agreement. Accordingly, during the first quarter of 2024, the Company accounted for the termination of the AstraZeneca U.S./RoW agreement as a contract modification under the ASC 606 and recorded a cumulative catch-up net adjustment of $25.7 million to the drug product revenue and received the cash during the second quarter of 2024. Corresponding to the drug product revenue, during the first quarter of 2024, the Company recorded the related cost of goods sold of $21.1 million.

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. 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 be eligible to receive mid-single-digit to low double-digit royalties based upon worldwide net sales of cornea products, and low single-digit to mid-single-digit royalties based on worldwide net 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.

The Company received an $8.0 million upfront payment from Eluminex in 2022 and thereafter recognized a total of $6.0 million milestone payments and a total of $1.5 million upfront payment in 2023.

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, which occurred by the end of 2023. Such contract manufacturing activity was generally ceased during the first quarter of 2024.

There was no material revenue recognized under the agreements with Eluminex for the three and six months ended June 30, 2025 and 2024.

4. Consolidated Variable Interest Entity - Fortis

In May 2023 (the "Option Acquisition Date"), the Company entered into an exclusive option agreement to acquire Fortis Therapeutics, Inc. ("Fortis") with its novel Phase 1 ADC, 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 mCRPC with potential applicability in other solid tumors and hematologic malignancies. 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 University of California, San Francisco ("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.

On March 28, 2025, the Company and Fortis entered into amendments and modified the option exercise deadline to December 31, 2027.

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 (which ends on the earlier of 120 days after Fortis or FibroGen submits data from any Phase 2 clinical trial of a product to the U.S. Food and Drug Administration for the purpose of progressing to a Phase 3 clinical trial or December 31, 2027 absent extension). 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. Additionally, the Company is obligated to make four quarterly payments totaling $5.4 million to Fortis in support of its continued development obligations, of which the last payment was $1.7 million and made during the three months ended March 31, 2024.

Pursuant to the guidance under 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 June 30, 2025.

Fortis has authorized and issued common shares and Series A preferred shares. As of the Option Acquisition Date and June 30, 2025, the Company owned approximately 2% of Fortis' Series A preferred shares, which was acquired previously and carried at zero cost. The non-controlling interests ("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 shareholders 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.

As of June 30, 2025, total assets and liabilities of Fortis were immaterial. For the three and six months ended June 30, 2025 and 2024, Fortis' net income (losses) was immaterial.

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):

	June 30, 2025			
	Level 1	Level 2	Level 3	Total
Money market funds	$ 5,296	$ —	$ —	$ 5,296
Commercial paper	—	12,082	—	12,082
U.S. government bonds	3,190	1,295	—	4,485
Total	$ 8,486	$ 13,377	$ —	$ 21,863

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Money market funds	$ 28,241	$ —	$ —	$ 28,241
Commercial paper	—	14,269	—	14,269
U.S. government bonds	2,987	2,981	—	5,968
Total	$ 31,228	$ 17,250	$ —	$ 48,478

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 six months ended June 30, 2025, a total of $1.3 million and $7.8 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):

	June 30, 2025	December 31, 2024
Cash	$ 1,504	$ 2,004
Commercial paper	12,082	14,269
Money market funds	5,296	28,241
U.S. government bonds	4,485	5,968
Total cash and cash equivalents	$ 23,367	$ 50,482

Prepaid Expenses and Other Current Assets

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

	June 30, 2025	December 31, 2024
Insurance proceeds receivable for litigation settlement	$ —	$ 28,500
Prepaid assets	1,031	1,903
Other current assets	1,275	1,139
Total prepaid expenses and other current assets	$ 2,306	$ 31,542

As of December 31, 2024, the Company recorded a $28.5 million receivable in prepaid expenses and other current assets, corresponding to the accrued litigation settlement of the same amount related to the Company's agreement in principle with plaintiffs to settle the class action lawsuit. As the Company maintains insurance that covers exposure related to the class action lawsuit, this amount is fully recoverable under the Company's insurance policies. 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. Such amount was fully distributed during the first quarter of 2025. As a result, the related accrued liability and the corresponding receivable were fully settled in the same period. See the *Accrued and Other Current Liabilities* section below, and the *Legal Proceedings and Other Matters* section in Note 10, *Commitments and Contingencies*, for details.

Accrued and Other Current Liabilities

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

	June 30, 2025	December 31, 2024
Preclinical and clinical trial accruals	$ 5,991	$ 6,327
API and bulk drug product price true-up	12,444	13,071
Litigation settlement	—	28,500
Payroll and related accruals	4,998	4,640
Accrued restructuring charge	1,715	4,572
Professional services	6,204	2,049
Current portion of liability related to sale of future revenues	1,702	460
Other	2,862	2,416
Total accrued and other current liabilities	$ 35,916	$ 62,035

The accrued liabilities of $12.4 million and $13.1 million for API and bulk drug product price true-up as of June 30, 2025 and December 31, 2024, respectively, resulted 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. See the *Drug Product Revenue, Net* section in Note 3, *Collaboration Agreements, License Agreement and Revenues,* for details.

As of December 31, 2024, 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, which was fully distributed during the first quarter of 2025 as mentioned above. See the *Legal Proceedings and Other Matters* section in Note 10, *Commitments and Contingencies*, for details.

Responding to the reported results for pamrevlumab in July 2024, the Company implemented an immediate and significant cost reduction plan in the U.S., including terminating pamrevlumab research and development investment and expeditiously wind down remaining obligations, and reducing U.S. workforce by approximately 75%. The total cash payments under the reduction in force was $0.8 million and $2.4 million during the three and six months ended June 30, 2025, respectively. The remaining accrued restructuring charge of $1.7 million as of June 30, 2025 will be substantially paid out in the second half of 2025.

7. Senior Secured Term Loan Facilities

In April 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 expired during 2023. 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 June 30, 2025, the fair values of such derivatives were negligible due to the low probability of the underlying events.

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. Therefore, the balance of the Term Loans was included in senior secured term loan facilities, current, under the current liabilities on the condensed consolidated balance sheet as of June 30, 2025. 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.

The initial 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 the three and six months ended June 30, 2025 and 2024. The Company recorded interest expense of $3.0 million and $5.9 million for the three and six months ended June 30, 2025, and $2.9 million and $5.8 million for the three and six months ended June 30, 2024, respectively, which were included in discontinued operations as the Company is required to repay the loan upon the closing of the divestiture of FibroGen International.

As of June 30, 2025, 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 June 30, 2025, including maintaining a minimum balance of $22.5 million of unrestricted cash and cash equivalents held in accounts in the U.S.; such minimum balance covenant was subsequently amended to be $18.75 million on July 14, 2025 by the Company and the Lenders.

The balances of the Company's senior secured term loan facilities as of June 30, 2025 and December 31, 2024 were as follows (in thousands):

	June 30, 2025	December 31, 2024
Principal of senior secured term loan facilities	$ 75,000	$ 75,000
Less: Unamortized issuance costs and transaction costs	(1,267)	(1,908)
Senior secured term loan facilities, ending balance	$ 73,733	$ 73,092
Representing:		
Senior secured term loan facilities, current	$ (73,733)	$ —
Senior secured term loan facilities, non-current	$ —	$ 73,092

8. Liability Related to Sale of Future Revenues

In November 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 15.43% as of June 30, 2025.

The following table summarizes the activities of the liability related to sale of future revenues for the six months ended June 30, 2025:

	Six Months Ended June 30, 2025
Liability related to sale of future revenues - beginning balance	$ 59,324
Interest paid	(450)
Interest expense recognized	4,134
Liability related to sale of future revenues - ending balance	63,008
Less: Current portion classified to accrued and other current liabilities	(1,702)
Liability related to sale of future revenues, non-current	$ 61,306

During the three and six months ended June 30, 2025, the Company recognized, under Astellas Agreements, development revenue of $0.1 million and $0.3 million, respectively, and drug product revenue of $1.2 million and $3.8 million, respectively. During the three and six months ended June 30, 2024, the Company recognized, under Astellas Agreements, development revenue of $0.3 million and $0.6 million, respectively, and drug product revenue of $0.7 million and $(0.5) million, respectively. See Note 3, *Collaboration Agreements, License Agreement and Revenue*, for details.

During the three and six months ended June 30, 2025, the Company recognized the related interest expense of $2.0 million and $4.1 million, respectively. During the three and six months ended June 30, 2024, the Company recognized the related interest expense of $1.7 million and $3.7 million, respectively. During six months ended June 30, 2025 and 2024, the Company paid $0.5 million and $5.7 million accrued interest, 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 reaching a Payment Cap up to $125.0 million by 2031.

9. Income Taxes

Provisions for income tax for the three and six months ended June 30, 2025 and 2024 were immaterial and 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.

On July 4, 2025, the One Big Beautiful Bill Act was signed into law in the U.S. which contains a broad range of tax reform provisions affecting businesses. The Company is still in the process of evaluating the legislation and an estimate of the financial impact cannot be made at this time.

10. Commitments and Contingencies

Contract Obligations

As of June 30, 2025, the Company had outstanding total non-cancelable purchase obligations of $3.1 million for general purchases and other programs and $0.5 million for manufacture and supply of roxadustat. The Company expects to fulfill its commitments under these agreements in the normal course of business, and as such, no liability has been recorded.

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 June 30, 2025, 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 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. On October 17, 2023, the parties reached an agreement in principle to settle the class action at $28.5 million. Accordingly, as of December 31, 2024, the Company recorded the $28.5 million in accrued and other current liabilities on 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 on the condensed consolidated balance sheet as of December 31, 2024. 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. The Court preliminarily approved the settlement on February 13, 2024 and approved the settlement Plan of Allocation on May 28, 2024 and Plaintiffs' motion for attorney's fees on August 1, 2024, reserving further orders on the final judgment until after the claims and distribution process was completed. The court entered a class distribution order on January 1, 2025 and the amount was fully distributed during the first quarter of 2025. As a result, the related accrued liability and the corresponding receivable were fully settled in the same period. 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 was voluntarily dismissed on December 20, 2023.

Between July 30, 2021 and April 3, 2024, seven shareholder derivative complaints were filed, naming as defendants certain of the Company's current and former officers and certain current and former members of the Company's board, as well as FibroGen as nominal defendants (the "Derivative Lawsuits"). Of these Derivative Lawsuits, four were filed in the Delaware Court of Chancery, two were filed in the U.S. District Court for the District of Delaware (the "Delaware Federal Derivative Actions"), and one was filed in the U.S. District Court for the Northern District of California (the "California Federal Derivative Action"). The plaintiffs 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. All seven Derivative Lawsuits have been dismissed.

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 SEC followed up with a subpoena for additional documents in the second quarter of 2024. In May 2025, the Company entered into a settlement with the SEC, subject to Commission approval. As part of the settlement, and without admitting or denying the findings in the settlement offer or administrative order to be issued by the SEC, the Company agreed to pay a $1.25 million civil penalty.

Between 2022 and 2024, the Company's Board of Directors received seven 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. The Company may in the future receive additional similar 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.

11. Segment Information

The Company has one operating and reporting segment which primarily focuses on the development and commercialization of novel therapeutics to treat serious unmet medical needs. The Company has determined that the chief executive officer is the chief operating decision maker ("CODM"). The CODM assesses performance of the business, monitors budget versus actual results and manages and allocates resources to the Company's operations using consolidated net income (loss) as the primary measurement. The CODM is regularly provided with entity-wide expense categories that are consistent with those found on the Company's condensed consolidated statements of operations. These significant segment expense include cost of goods sold, research and development expenses, selling, general and administrative expenses, and restructuring charge. Other segment items that are presented on the condensed consolidated statements of operations include interest and other income (expense), net, and provision for (benefit from) income taxes. The measure of segment assets is reported on the balance sheet as total consolidated assets.

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, 2024 filed with the SEC on March 17, 2025 ("2024 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

FibroGen, Inc. ("FibroGen" or the "Company") is a biopharmaceutical company focused on development of novel therapies at the frontiers of cancer biology and anemia.

We are developing FG-3246, a potential first-in-class antibody-drug conjugate ("ADC") targeting CD46, for the treatment of metastatic castration-resistant prostate cancer ("mCRPC") and potentially other cancers. This program also includes the development of FG-3180, an associated CD46-targeted positron emission tomography ("PET") biomarker and imaging agent. We anticipate initiation of a Phase 2 monotherapy dose optimization study of FG-3246 for the treatment of mCRPC, along with the exploratory analysis of FG-3180, in the third quarter of 2025.

We and our collaboration partners have developed roxadustat (爱瑞卓®, EVRENZO™), which is currently approved in the People's Republic of China ("China"), Europe, Japan, and numerous other countries for the treatment of anemia in chronic kidney disease ("CKD") patients on dialysis and not on dialysis.

On February 20, 2025, we entered into a share purchase agreement (the "Share Purchase Agreement") with AstraZeneca Treasury Limited pursuant to which we and our subsidiary FibroGen China Anemia Holdings, Ltd. agreed to sell all of the issued and outstanding equity interests of FibroGen International (Hong Kong) Ltd. ("FibroGen International") to AstraZeneca Treasury Limited. AstraZeneca AB ("AstraZeneca") is our long-time commercialization partner for roxadustat in greater China and South Korea. This sale includes all of our roxadustat assets in China, including FibroGen International's subsidiary FibroGen (China) Medical Technology Development Co., Ltd. ("FibroGen Beijing") and its 51.1% interest in Beijing Falikang Pharmaceutical Co., Ltd. ("Falikang"). The transaction is expected to close in the third quarter of 2025, and is subject to customary closing conditions and closing deliverables, including receipt of regulatory approval from the China State Administration for Market Regulation ("SAMR").

FibroGen has retained the rights to roxadustat in the United States of America ("U.S."), Canada, Mexico, and in all markets not held by AstraZeneca or licensed to Astellas Pharma Inc. ("Astellas"). Roxadustat is not approved for commercialization in any indication in the U.S., Canada, or Mexico. Astellas is commercializing roxadustat (EVRENZO™) in Europe and Japan to treat anemia under two development and commercialization license agreements: one for Japan, and one for Europe, the Commonwealth of Independent States, the Middle East and South Africa.

We continue to work on our development plan for roxadustat in anemia associated with lower-risk myelodysplastic syndromes ("MDS"), a high-value indication with significant unmet medical need. We had a positive Type-C meeting with the U.S. Food and Drug Administration ("FDA") in July 2025 and reached alignment on several elements of our proposed Phase 3 study design for roxadustat in anemia associated with lower-risk MDS.

Financial Highlights

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	(in thousands, except for per share data)			
Result of Operations				
Revenue	$ 1,348	$ 998	$ 4,088	$ 26,363
Operating costs and expenses	13,400	47,406	31,060	121,953
Loss from continuing operations	(13,683)	(47,095)	(30,449)	(96,141)
Loss from continuing operations per share - basic and diluted	$ (3.38)	$ (11.79)	$ (7.54)	$ (24.18)

	June 30, 2025	December 31, 2024
	(in thousands)	
Balance Sheet		
Cash and cash equivalents	$ 23,367	$ 50,482
Accounts receivable	$ 136	$ 481

Our revenue for the three and six months ended June 30, 2025 included primarily the drug product revenue of $1.2 million and $3.8 million, respectively, related to active pharmaceutical ingredient ("API") deliveries to Astellas.

As a comparison, our revenue for the three and six months ended June 30, 2024 included primarily the revenue recognized related to the following, respectively:

- $0.7 million and a net reduction of $0.5 million to drug product revenue related to API deliveries to Astellas; in addition, $25.7 million cumulative catch-up net adjustment in the drug product revenue, for the six months ended June 30, 2024, as a result of terminating the AstraZeneca U.S./RoW Agreement, effective in February 2024 ("AstraZeneca Termination and Transition Agreement"), with the exception of South Korea; and
- $0.3 million and $1.1 million of development and other revenue recognized mainly under our collaboration agreements with our partners Astellas and AstraZeneca.

Operating costs and expenses for the three and six months ended June 30, 2025 decreased compared to the same periods a year ago primarily as a result of the net effect of the following, respectively:

- $12.8 million and $24.3 million lower employee-related expenses primarily due to the impact from reduction in force action in August 2024 and cost control efforts;
- $7.2 million and $14.6 million lower facilities-related expenses due to cost control efforts including the lease termination in the third quarter of 2024;
- $6.9 million and $12.7 million lower stock-based compensation primarily resulting from significant lower stock price and cancellations of stock options and restricted stock units due to reduced headcount;
- $3.6 million and $10.5 million lower clinical trial expenses primarily associated with the termination of pamrevlumab programs during the second half of 2024 responding to the topline clinical data results we reported in July 2024;

- $2.6 million and $5.0 million lower drug development expenses associated with drug substance activities and logistic expenses related to pamrevlumab programs which were completed and terminated; and
- $21.1 million one-time cost of goods sold recorded for the six months ended June 30, 2024 correspondingly to the above-mentioned drug product revenue resulting from the AstraZeneca Termination and Transition Agreement related to the AstraZeneca U.S./RoW Agreement, as defined further below.

For the three months ended June 30, 2025, we had a loss from continuing operations of $13.7 million, or a loss per basic and diluted share of $3.38, as compared to a loss of $47.1 million, or a loss per basic and diluted share of $11.79, for the same period a year ago, due to decreases in operating costs and expenses as discussed above. For the six months ended June 30, 2025, we had a loss from continuing operations of $30.4 million, or a loss per basic and diluted share of $7.54, as compared to a loss of $96.1 million, or a loss per basic and diluted share of $24.18, for the same period a year ago, due to decreases in operating costs and expenses offset by decreases in revenue as discussed above.

Cash and cash equivalents and accounts receivable for continuing operations totaled $23.5 million at June 30, 2025, a decrease of $27.5 million from December 31, 2024. Consolidated cash and cash equivalents and accounts receivable for both continuing operations and discontinued operations totaled $142.1 million at June 30, 2025, an increase of $21.0 million from December 31, 2024, primarily due to the cash provided by operations as discussed under the *Liquidity and Capital Resources* section below.

Commercial, Development and Research Programs

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

FG-3246 and FG-3180 in Metastatic Castration Resistant Prostate Cancer

Disease Overview

Prostate cancer is the second most common malignancy in men, contributing significantly to male mortality rates. Approximately 13% of men will be diagnosed with prostate cancer at some point during their lifetime. There are about 65,000 drug treatable mCRPC cases in the U.S. annually and 5-year survival in mCRPC is approximately 30%.

Current Standard of Care

Treatment choice in first and second line mCRPC significantly depends on patients' prior treatments. Androgen receptor signaling inhibitors ("ARSIs") and chemotherapy are the preferred treatments in patients who have not been exposed to either in earlier lines of therapy. Most patients previously treated with an ARSI for metastatic hormone-sensitive prostate cancer receive chemotherapy in first-line mCRPC. Rechallenge with an alternative ARSI is associated with limited benefit in this setting.

For the 25-30% of patients with homologous recombination repair mutation, poly (ADP-ribose) polymerase inhibitors are the standard of care for mCRPC patients.

Recent approvals of prostate-specific membrane antigen ("PSMA")-targeted radiopharmaceuticals in the post-ARSI and post-chemotherapy setting have diversified treatment options in advanced mCRPC. Furthermore, PSMA-PET has been validated as standard of care diagnostic in prostate cancer, while LOCAMETZ or an approved PSMA-11 imaging agent are approved to select patients for treatment with Pluvicto (lutetium Lu 177 vipivotide tetraxetan).

FibroGen is developing FG-3246 in the post-ARSI, pre-chemotherapy mCRPC setting. This is an area of high unmet need, where radiographic progression free survival is approximately 5.6-6 months after switching to a different ARSI, and approximately 8 months with chemotherapy. Novel mechanisms of action that extend survival are critical in this setting as well as biomarker driven treatment approaches. FG-3246 and the potential patient selection biomarker FG-3180 are being developed to address these unmet medical needs.

FG-3246 and FG-3180 for the Treatment of mCRPC

We are developing FG-3246 in mCRPC and exploring other potential cancer indications. FG-3246 is a potential first-in-class ADC targeting a novel epitope on CD46. In addition to CD46 being expressed at high levels in certain tumor types with limited expression in most normal tissues, CD46 is a cell receptor that induces internalization upon antibody binding, which makes it an ideal target for an ADC. The cytotoxic payload of FG-3246 is monomethyl auristatin E ("MMAE"), an anti-mitotic agent that has been utilized in four commercially approved ADC drugs.

We have met with the FDA to discuss the development pathway of FG-3246, and we anticipate initiation of a Phase 2 monotherapy dose optimization study of FG-3246 for the treatment of mCRPC in the third quarter of 2025, pending close of the sale of FibroGen International to AstraZeneca Treasury Limited.

As part of this Phase 2 study, patients will also receive FG-3180, our PET imaging agent. FG-3180 is a diagnostic radiopharmaceutical utilizing a radiolabeled version of our CD46 targeting antibody in FG-3246 to assess the correlation between CD46 expression and the response to FG-3246.

In March 2025, FibroGen announced the peer-reviewed publication titled "A Phase 1, First-in-Human Study of FOR46 (FG-3246), an Immune-Modulating Antibody-Drug Conjugate Targeting CD46, in Patients with Metastatic Castration Resistant Prostate Cancer" in the Journal of Oncology. The manuscript included the complete results from the Fortis Therapeutics, Inc. ("Fortis")-sponsored Phase 1 study of FG-3246 in heavily-pretreated, biomarker un-selected patients with mCRP. Key efficacy highlights observed in the RECIST-evaluable set of 25 patients include: (1) confirmed objective response rate was 20% with median duration of response of 7.5 months, (2) all objective responses observed at a starting dose of 2.7 mg/kg or higher, and (3) disease control rate was 80% with duration of treatment exceeding 24 weeks in 12 patients (48%); (4) PSA50 response rate of 36% in 39 evaluable patients (of eight evaluable patients who received docetaxel in the castration-sensitive setting, four (50%) achieved a confirmed PSA50 response); (5) median radiographic progression-free survival of 8.7 months in all 40 subjects in the efficacy analysis set; (6) of 15 evaluable baseline tumors, 12 (80%) were positive for CD46 expression by immunohistochemistry; and (7) FG-3246 responders were found to have a significantly higher frequency of effector T cells and lower frequency of immunosuppressive myeloid cells.

In May 2024, the University of California, San Francisco ("UCSF") presented positive interim results from the dose escalation portion of the investigator-sponsored Phase 1b/2 study of FG-3246 in combination with enzalutamide in patients with mCRPC at the 2024 American Society of Clinical Oncology Annual Meeting. The presentation includes data from 17 biomarker unselected patients in the dose escalation portion of the trial. Over 70% of the patients in the study received at least two prior ARSIs, which included prior enzalutamide treatment. Dose escalation was explored with and without prophylactic granulocyte colony-stimulating factor ("G-CSF") support. The primary endpoint was determination of the maximally tolerated dose of FG-3246 in combination with enzalutamide. The combination treatment demonstrated an encouraging preliminary estimate of median radiographic progression-free survival ("rPFS") of 10.2 months. The maximally tolerated dose was established at 2.1 mg/kg adjusted body weight, with primary G-CSF prophylaxis, in combination with enzalutamide 160 mg/day. The most frequent adverse events were consistent with other MMAE-based ADCs and included fatigue, weight loss, elevated transaminases, neutropenia, and peripheral neuropathy. We expect topline results from the Phase 2 portion of this study, including data on the CD46 targeted PET imaging agent FG-3180, in the fourth quarter of 2025.

ROXADUSTAT IN ANEMIA ASSOCIATED WITH MYELODYSPLASTIC SYNDROMES

FibroGen maintains its rights to roxadustat in the United States and in all markets not licensed to Astellas.

We had a positive Type-C meeting with the FDA in July 2025, and reached alignment on several elements of our proposed Phase 3 study design for roxadustat in anemia associated with lower-risk MDS, a high-value indication with significant unmet medical needs.

Our planned Phase 3 trial will assess the safety and efficacy of roxadustat in a randomized, double-blind, placebo-controlled design in approximately 200 patients with lower-risk MDS. At our Type-C meeting, we aligned with the FDA on the patient population (patients requiring ≥ 4 packed Red Blood Cell ("RBC") units in two consecutive 8-week periods prior to randomization, who are refractory to, intolerant to, or ineligible for prior erythropoiesis-stimulating agents ("ESA") therapy), dose regimen, as well as management of potential thrombotic risk through eligibility, dose modification, and discontinuation criteria. As the primary endpoint for the study, the Company is considering either 8-week or 16-week RBC transfusion independence.

MDS are a diverse group of bone marrow disorders characterized by ineffective production of healthy blood cells and premature destruction of blood cells in the bone marrow, leading to anemia. In most MDS patients, the cause of the disease is unknown.

The diagnosed prevalence of MDS in the U.S. is estimated to be between 60,000 and 170,000, and continues to rise as more therapies become available and patients are living longer with MDS. Annual incidence rates are estimated to be 4.9/100,000 adults in the U.S.

Anemia is the most common clinical presentation in MDS, seen in approximately 80% of MDS patients, and produces symptoms of fatigue, weakness, exercise intolerance, shortness of breath, dizziness, and cognitive impairment.

Limitations of the Current Standard of Care for Anemia in Myelodysplastic Syndromes

Stem cell transplant is the only potentially curative therapy for MDS, but it is not feasible in most patients due to their advanced age and frailty. The high rate of severe anemia leaves recurring red blood cell transfusions as the mainstay of care in MDS patients. Transfusion can result in direct organ damage through transfusional iron overload. Transfusion-dependent MDS patients suffer higher rates of cardiac events, infections, and transformation to acute leukemia, a decreased overall survival rate when compared with non-transfused patients with MDS, and decreased survival compared to an age-matched elderly population. Patients receiving red blood cell transfusions may require an iron chelator in order to address toxic elements of iron overload such as lipid peroxidation and cell membrane, protein, DNA, and organ damage.

Lower-risk MDS patients represent approximately 77% of the total diagnosed MDS population. National Comprehensive Cancer Network guidelines recommend the use of ESAs, luspatercept and imetelstat in lower risk MDS patients, depending on patients' treatment history, serum erythropoietin ("EPO") levels and *ring sideroblast status*.

Currently available treatment options are effective in only ~50% patients and they are challenging to dose-calibrate and can only be administered via subcutaneous injection or through IV infusion. New strategies that provide durable response and the convenience of oral administration are highly desired in managing patients with MDS.

Market Opportunity for Roxadustat in Myelodysplastic Syndromes

We believe there is a significant need for a safe, effective, and convenient option to address anemia in patients with lower-risk MDS. Roxadustat, our orally administered small molecule hypoxia-inducible prolyl hydroxylase ("HIF-PH") inhibitor, stimulates the body's natural mechanism of red blood cell production and iron hemostasis based on cellular-level oxygen-sensing and iron-regulation mechanisms. Unlike ESAs which are limited to providing exogenous EPO, roxadustat activates a coordinated erythropoietic response in the body that includes the stimulation of red blood cell progenitors, an increase in the body's production of endogenous EPO, and an increase in iron availability for hemoglobin synthesis, which we believe is important in a broad range of MDS patients. Moreover, in anemia of CKD, roxadustat has demonstrated the ability in clinical trials to increase and maintain hemoglobin levels in the presence of inflammation as measured by C-reactive protein ("CRP"), where ESAs have shown limited effect. We believe that roxadustat has the potential to replicate this result in MDS anemia patients, where it is not uncommon for patients to present with autoimmune and inflammatory conditions.

Phase 2/3 Clinical Trial in Myelodysplastic Syndromes

Topline 28-week data from MATTERHORN, our Phase 2/3 placebo-controlled, double-blind clinical trial of roxadustat for the treatment of anemia in MDS, was presented in the fourth quarter of 2023 at the American Society of Hematology annual conference.

More patients in the roxadustat arm (47.5% of 80 patients) achieved transfusion independence for 56 consecutive days (within the first 28 weeks) than the placebo arm (33.3% of 57 patients); however, the p-value was not significant.

However, in a post-hoc analysis of patients with high transfusion burden (4 or more packed RBC units over two consecutive 8-week periods), 36% of the 22 roxadustat patients achieved transfusion independence, versus 7% of the 15 placebo patients (nominal p-value of 0.04).

Roxadustat in Anemia of 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.

In collaboration with our partners Astellas and AstraZeneca, roxadustat (爱瑞卓®, EVRENZO™) is approved to treat anemia in China, Europe, Japan, and numerous other countries.

China – Roxadustat Commercial Program

On February 20, 2025, we and our subsidiary FibroGen China Anemia Holdings, Ltd. entered into a Share Purchase Agreement with AstraZeneca Treasury Limited, a subsidiary of AstraZeneca plc, pursuant to which we agreed to sell all of the issued and outstanding equity interests of FibroGen International for an aggregate purchase price of $85 million in cash for the enterprise value of FibroGen International, plus an additional cash amount equal to the net cash held in China by FibroGen International and its subsidiaries, currently estimated to be approximately $125 million, as of the closing, which totals an aggregate amount of approximately $210 million. This sale includes all of our roxadustat assets in China, including FibroGen International's subsidiary FibroGen Beijing and its 51.1% interest in Falikang. The transaction is expected to close in the third quarter of 2025, and is subject to customary closing conditions and closing deliverables, including receipt of regulatory approval from the China SAMR.

AstraZeneca is our long-time commercialization partner for roxadustat in greater China and South Korea. Upon the closing, we will assign to them all rights to roxadustat in China, Hong Kong, and Macao, including rights to manufacture, develop, distribute, and commercialize roxadustat.

U.S., Europe, Japan and Rest of World - Roxadustat Program

FibroGen has retained the rights to roxadustat in the U.S., Canada, Mexico, and in all markets not held by AstraZeneca or licensed to Astellas. Roxadustat is not approved for commercialization in any indication in the U.S., Canada, or Mexico.

Astellas is commercializing roxadustat (EVRENZO™) in Europe and Japan to treat anemia under two development and commercialization license agreements: one for Japan, and one for Europe, the Commonwealth of Independent States, the Middle East and South Africa.

Exclusive License from and Option to Acquire Fortis Therapeutics

In May 2023, we entered into an exclusive option agreement to acquire Fortis with its novel Phase 1 ADC, 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 mCRPC 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 have made four quarterly payments totaling $5.4 million to Fortis in support of its continued development obligations, of which the last payment was $1.7 million and was made during the three months ended March 31, 2024.

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 the *Consolidated Variable Interest Entity - Fortis* section in Note 4, *Variable Interest Entities*, to the condensed consolidated financial statements.

Exclusive License from HiFiBiO

In June 2021, we entered into an exclusive license and option agreement with HiFiBiO (HK) Ltd. (d.b.a. HiFiBiO Therapeutics) ("HiFiBiO"), pursuant to which we exclusively licensed from HiFiBiO all product candidates in HiFiBiO's Galectin-9 program and subsequently exclusively licensed all product candidates in HiFiBiO's CCR8 program. On June 12, 2025, FibroGen entered into a termination, asset transfer and license Agreement with HiFiBiO ("HiFiBiO Termination, Asset Transfer and License Agreement"), which terminated the exclusive license and option agreement and all rights and obligation of FibroGen thereunder ceased.

Under the HiFiBiO Termination, Asset Transfer and License Agreement, FibroGen licensed HiFiBiO the anti-CCR8 and anti-Gal-9 intellectual property developed by FibroGen. In the event HiFiBiO sublicenses the Gal-9 (FG-3165) and/or CCR8 (FG-3175) assets, FibroGen is eligible to receive a mid single-digit to low double-digit share of HiFiBiO's license revenues and low double-digit share of HiFiBiO's commercial royalties. In the case HiFiBiO commercializes either asset, FibroGen has the potential to receive single-digit royalties based upon worldwide net sales.

Exclusive License to Eluminex

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).

See the *Eluminex Agreement* section in Note 3, *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 3, *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 June 30, 2025 totaled $790.1 million. Based on the current development plans for roxadustat in Japan and Europe, we do not expect to receive most or all of the additional potential milestones under the Astellas Japan Agreement or the Astellas Europe Agreement.

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 immaterial for the three months ended June 30, 2025. The related drug product revenue was $(0.4) million for the three months ended June 30, 2024, and $1.8 million and $(2.6) million for the six months ended June 30, 2025 and 2024, 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 $1.2 million and $1.1 million for the three months ended June 30, 2025 and 2024, and $2.0 million and $2.1 million for the six months ended June 30, 2025 and 2024, 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, except for China and other territories not previously licensed to Astellas (the "AstraZeneca U.S./RoW Agreement"). 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.

On February 23, 2024, we entered into an agreement to terminate the AstraZeneca U.S./RoW Agreement with AstraZeneca, effective as of February 25, 2024. Pursuant to the AstraZeneca Termination and Transition Agreement, AstraZeneca returns all of their non-China roxadustat rights to us, with the exception of South Korea, and provides certain assistance during a transition period. In addition, as a part of this AstraZeneca Termination and Transition Agreement, AstraZeneca will receive tiered mid-single digit royalties on FibroGen's sales of roxadustat in the terminated territories, or thirty-five percent of all revenue FibroGen receives if it licenses or sells such rights to a third-party. Neither party incurred any early termination penalties. The aggregate amount of consideration for milestone and upfront payments received under the AstraZeneca U.S./RoW Agreement through the termination totaled $439.0 million. In addition, resulting from the AstraZeneca Termination and Transition Agreement, FibroGen and AstraZeneca settled the outstanding balances relating to past transactions under the AstraZeneca Master Supply Agreement. Accordingly, during the first quarter of 2024, we recorded a cumulative catch-up net adjustment of $25.7 million to the drug product revenue.

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 June 30, 2025 totaled $81.2 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 (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*.

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 2020, FibroGen Beijing and AstraZeneca completed the establishment of a jointly owned entity, Falikang, which performs roxadustat distribution, as well as conducts sales and marketing through AstraZeneca.

We account for our investment in Falikang under the equity method, and Falikang is not consolidated into our consolidated financial statements. Our proportionate share of the reported profits or losses of Falikang, is included in the discontinued operations in the condensed consolidated statement of operations, and the investment in unconsolidated subsidiary is included the held for sale assets on the condensed consolidated balance sheet. See Note 2, *Discontinued Operations*, to the condensed consolidated financial statements for details.

Product revenue, net, which is included in the discontinued operations, consists primarily of revenues from sales of roxadustat commercial product to Falikang.

Substantially all direct roxadustat product sales to distributors in China are made by Falikang, while FibroGen Beijing continues to sell roxadustat product directly in limited areas in China. FibroGen Beijing manufactures and supplies commercial product to Falikang based on an agreed upon transfer price, which includes gross transaction 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 transaction price of the China manufacturing and supply obligation ("China performance obligation") to the performance obligation satisfied during the reporting period. For our direct sales of commercial drug product, we recognize revenue when control of the promised good is transferred to the customer in an amount that reflects the consideration that we expect to be entitled to in exchange for the product. We recognized net product revenue of $19.7 million and $49.6 million for the three months ended June 30, 2025 and 2024, and $59.5 million and $80.2 million for the six months ended June 30, 2025 and 2024, respectively, majority of which were from the sales to Falikang.

RESULTS OF OPERATIONS

Revenue

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2025	2024	$	%	2025	2024	$	%
	(dollars in thousands)							
Revenue:								
Development and other revenue	$ 133	$ 269	$ (136)	(51) %	277	1,147	(870)	(76) %
Drug product revenue, net	1,215	729	486	67 %	3,811	25,216	(21,405)	(85) %
Total revenue	$ 1,348	$ 998	$ 350	35 %	$ 4,088	$ 26,363	$ (22,275)	(84) %

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 June 30, 2025, we do not expect to incur significant future co-development services. 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 2033, which reflects our best estimates. Other revenues consist of contract manufacturing revenue, patent transfer and sales of research and development material. Development and other revenue have not been material for any of the periods presented.

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.

The AstraZeneca U.S./RoW Agreement was terminated on February 23, 2024 (except for South Korea), while the AstraZeneca China Agreement and relationship continue unaffected.

In the future, we will continue generating revenue from collaboration agreements in the form of milestone payments and royalties on drug 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 $0.4 million, or 35%, for the three months ended June 30, 2025, and decreased $22.3 million, or 84%, for the six months ended June 30, 2025, respectively, compared to the same periods a year ago for the reasons discussed in the sections below.

Drug Product Revenue, Net

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2025	2024	$	%	2025	2024	$	%
	(dollars in thousands)							
Drug product revenue, net:								
Astellas Japan Agreement	$ 44	$ (366)	$ 410	(112) %	$ 1,825	$ (2,571)	$ 4,396	(171) %
Astellas Europe Agreement	1,171	1,095	76	7 %	1,986	2,116	(130)	(6) %
AstraZeneca U.S./RoW Agreement	—	—	—	NM	—	25,671	(25,671)	NM
Total drug product revenue, net:	$ 1,215	$ 729	$ 486	67 %	$ 3,811	$ 25,216	$ (21,405)	(85) %

NM = Not meaningful

Drug product revenue, net increased $0.5 million, or 67%, for the three months ended June 30, 2025, and decreased $21.4 million, or 85%, for the six months ended June 30, 2025, respectively, compared to the same periods a year ago.

Astellas Japan Agreement

During the second quarter of 2025, we updated our estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment, and the adjustment to the drug product revenue for the three months ended June 30, 2025 was immaterial.

During the first quarter of 2025, 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 $1.8 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 yield from the manufacture of bulk product tablets, among others.

During the second quarter of 2024, 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 $0.4 million. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect the foreign exchange impacts and the changes in the estimated bulk product strength mix intended to be manufactured by Astellas, among others.

During the first quarter of 2024, 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 $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, and foreign exchange impacts, among others.

As of June 30, 2025, the balances related to the API price true-up under the Astellas Japan Agreement were $0.6 million in accrued liabilities, representing our best estimate of the timing for these amounts to be paid.

Astellas Europe Agreement

We updated our estimate of variable consideration related to the bulk drug product transferred under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement 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, for the year ended December 31, 2024, we reclassified $7.2 million from the related deferred revenue to accrued liabilities. As of December 31, 2024, the related balance in accrued liabilities was $10.5 million. We further reclassified $1.3 million from the related deferred revenue to accrued liabilities during the six months ended June 30, 2025. As of June 30, 2025, the balances related to the bulk drug product price true-up under the Astellas Europe Agreement and the Astellas EU Supply Agreement were $11.9 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 $1.2 million and $1.1 million for the three months ended June 30, 2025 and 2024, and $2.0 million and $2.1 million for the six months ended June 30, 2025 and 2024, 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

As described above, pursuant to the AstraZeneca Termination and Transition Agreement related to the AstraZeneca U.S./RoW Agreement, FibroGen and AstraZeneca settled the outstanding balances relating to past transactions under the AstraZeneca Master Supply Agreement. Accordingly, during the first quarter of 2024, we accounted for the termination of the AstraZeneca U.S./RoW agreement as a contract modification under the ASC 606 and recorded a cumulative catch-up net adjustment of $25.7 million to the drug product revenue.

Operating Costs and Expenses

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2025	2024	$	%	2025	2024	$	%
	(dollars in thousands)							
Operating costs and expenses								
Cost of goods sold	$ 85	$ 140	$ (55)	(39) %	$ 337	$ 21,483	$ (21,146)	(98) %
Research and development	5,865	32,360	(26,495)	(82) %	15,040	68,848	(53,808)	(78) %
Selling, general and administrative	7,057	14,906	(7,849)	(53) %	15,164	31,622	(16,458)	(52) %
Restructuring charge	393	—	393	NM	519	—	519	NM
Total operating costs and expenses	$ 13,400	$ 47,406	$ (34,006)	(72) %	$ 31,060	$ 121,953	$ (90,893)	(75) %

NM = Not meaningful

Total operating costs and expenses decreased $34.0 million, or 72%, and decreased $90.9 million, or 75%, for the six months ended June 30, 2025, 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 was immaterial for the three months ended June 30, 2025 and 2024. Cost of goods sold decreased $21.1 million, or 98%, for the six months ended June 30, 2025, compared to the same period a year ago. As described above, during the first quarter of 2024, we recorded a cumulative catch-up net adjustment to the drug product revenue resulting from the AstraZeneca Termination and Transition Agreement related to the AstraZeneca U.S./RoW Agreement. Correspondingly, we recorded the related cost of goods sold of $21.1 million in the same period.

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. We have implemented a significant cost reduction plan in the U.S. in the third quarter of 2024. As a result, research and development expenses have overall decreased and may continue to decrease in certain areas over time.

The following table summarizes our research and development expenses incurred during the three and six months ended June 30, 2025 and 2024:

Product Candidate	Phase of Development	Three Months Ended June 30,		Six Months Ended June 30,	
		2025	2024	2025	2024
		(in thousands)			
FG-3246	Phase 2	$ 3,511	$ 5,843	$ 8,781	$ 11,304
Roxadustat	Approved / Phase 3	1,105	1,551	1,562	3,722
Pamrevlumab	Phase 2/3	627	18,391	2,796	38,617
Other research and development expenses		622	6,575	1,901	15,205
Total research and development expenses		$ 5,865	$ 32,360	$ 15,040	$ 68,848

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 $26.5 million, or 82%, for the three months ended June 30, 2025, and decreased $53.8 million, or 78%, for the six months ended June 30, 2025, respectively, compared to the same periods a year ago, primarily as a result of the net effect of the following:

- Decrease of $8.4 million and $16.2 million in employee-related costs primarily due to the impact from reduction in force action in August 2024 and cost control efforts;
- Decrease of $3.6 million and $10.5 million in clinical trials costs primarily associated with the termination of pamrevlumab programs during the second half of 2024 responding to the topline clinical data results we reported in July 2024;
- Decrease of $6.1 million and $11.9 million in facilities-related expenses due to cost control efforts including the lease termination in the third quarter of 2024;
- Decrease of $3.6 million and $6.8 million in stock-based compensation primarily resulting from significantly lower stock price and cancellations of stock options and restricted stock units due to reduced headcount; and
- Decrease of $2.6 million and $5.0 million in drug development expenses associated with drug substance activities and logistic expenses related to pamrevlumab programs which were completed and terminated.

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, recruiting fees and expenses associated with obtaining and maintaining patents. We have implemented a significant cost reduction plan in the U.S. in the third quarter of 2024. As a result, SG&A expenses have overall decreased and may continue to decrease over time.

SG&A expenses decreased $7.8 million, or 53%, for the three months ended June 30, 2025, and decreased $16.5 million, or 52%, for the six months ended June 30, 2025, respectively, compared to the same periods a year ago, primarily as a result of the net effect of the following, respectively:

- Decrease of $4.4 million and $8.0 million in employee-related costs primarily due to the impact from reduction in force action in August 2024 and cost control efforts; and
- Decrease of $3.3 million and $5.8 million in stock-based compensation primarily resulting from significantly lower stock price and cancellations of stock options and restricted stock units due to reduced headcount.

Restructuring Charge

In response to the topline clinical results for pamrevlumab in patients with pancreatic cancer we announced in July 2024, we implemented an immediate and significant cost reduction plan in the U.S., including terminating pamrevlumab research and development investment and expeditiously winding down remaining obligations, and reducing our U.S. workforce by approximately 75%. As a result, we recorded majority of the related non-recurring restructuring charge during the third quarter of 2024, primarily consisting of notice period and severance payments, accrued vacation, and employee benefits contributions. The related restructuring charge for the three and six months ended June 30, 2025 was not material.

Interest and Other, Net

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2025	2024	$	%	2025	2024	$	%
	(dollars in thousands)							
Interest and other, net:								
Interest expense	$ (2,009)	$ (1,868)	$ (141)	8 %	$ (4,265)	$ (3,960)	$ (305)	8 %
Interest income and other income (expenses), net	286	900	(614)	(68) %	698	3,135	(2,437)	(78) %
Total interest and other, net	$ (1,723)	$ (968)	$ (755)	78 %	$ (3,567)	$ (825)	$ (2,742)	332 %

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 remained relatively flat for the three and six months ended June 30, 2025, compared to the same periods a year ago.

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 decreased $0.6 million, or 68%, and decreased $2.4 million, or 78%, for the six months ended June 30, 2025, respectively, compared to the same periods a year ago, primarily due to lower interest income resulting from lower cash equivalents and investment balances.

Income Taxes

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	(dollars in thousands)			
Loss from continuing operations before income taxes	$ (13,775)	$ (47,376)	$ (30,539)	$ (96,415)
Benefit from income taxes	(92)	(281)	(90)	(274)
Effective tax rate	0.7 %	0.6 %	0.3 %	0.3 %

Benefits for income taxes for the three and six months ended June 30, 2025 and 2024 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.

Discontinued Operations

On February 20, 2025, we entered into the Share Purchase Agreement with AstraZeneca Treasury Limited pursuant to which we and our subsidiary FibroGen China Anemia Holdings, Ltd. agreed to sell all of the issued and outstanding equity interests of FibroGen International to AstraZeneca Treasury Limited. AstraZeneca is our long-time commercialization partner for roxadustat in greater China and South Korea. This sale includes all of our roxadustat assets in China, including FibroGen International's subsidiary FibroGen Beijing and its 51.1% interest in Falikang. The transaction is expected to close in the third quarter of 2025, and is subject to customary closing conditions and closing deliverables, including receipt of regulatory approval from the China State Administration for Market Regulation.

We determined that FibroGen International met the "held for sale" criteria and the "discontinued operations" criteria in accordance with Financial Accounting Standard Board Accounting Standards Codification ASC 205, *Presentation of Financial Statements*, as of June 30, 2025 and December 31, 2024. Accordingly, the operating results related to FibroGen International are classified as discontinued operations, and have been reflected as discontinued operations in the condensed consolidated statements of operations. See Note 2, *Discontinued Operations*, 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.

In November 2022, we entered into a Revenue Interest Financing Agreement ("RIFA") with NovaQuest Capital Management ("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.

In April 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 a $75.0 million 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. For additional details about this financing transaction, see Note 7, *Senior Secured Revolving Line of Credit*, to the condensed consolidated financial statements. Upon the closing of the sale of FibroGen International and its subsidiaries to AstraZeneca Treasury Limited, we intend to repay our term loan facility with the Lenders.

In February 2025, we entered into an Equity Distribution Agreement with BofA Securities, Inc. pursuant to which we may issue and sell, from time to time and through BofA Securities, Inc., shares of our common stock having an aggregate offering price of up to $30.0 million. We did not sell any shares of common stock under this agreement during the three and six months ended June 30, 2025.

As of June 30, 2025, we had cash and cash equivalents of $23.4 million for our continuing operations, compared to $50.5 million as of December 31, 2024. Cash is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. In addition, as of June 30, 2025, we had $96.5 million of cash and cash equivalents and $22.1 million of accounts receivable in China, which were included in the held for sale assets on the condensed consolidated balance sheet. We will have access to the entirety of the cash, cash equivalents and accounts receivable balances in China upon the close of the sales of FibroGen International to AstraZeneca Treasury Limited.

We have evaluated measures to access additional cash from our China operations and we believe the above-mentioned sale of FibroGen International represents the most efficient way to access the entirety of our cash from China upon closing of the transaction. The completion of the sale of FibroGen International, access to additional cash from our China operations and 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), including both continuing operations and discontinued operations:

	Six Months Ended June 30,	
	2025	2024
Net cash provided by (used in):		
Operating activities	$ 15,401	$ (99,157)
Investing activities	(29)	123,515
Financing activities	(97)	(133)
Effect of exchange rate changes on cash and cash equivalents	2,388	2,801
Net increase in cash and cash equivalents	$ 17,663	$ 27,026

Operating Activities

Net cash provided by operating activities was $15.4 million for the six months ended June 30, 2025 and consisted primarily of net loss of $3.0 million adjusted for non-operating cash items of $6.2 million, and a net increase in operating assets and liabilities of $12.1 million. The significant non-operating cash items included stock-based compensation expense of $4.7 million. The significant items in the changes in operating assets and liabilities included the following:

- Prepaid expenses and other current assets decreased $51.5 million, primarily due to the $28.5 million distribution of the above-mentioned litigation settlement during the quarter, which is fully recoverable under our insurance policies. The decrease in prepaid expenses and other current assets was also related to the collection from Falikang during the quarter based on the arrangements under the above-mentioned settlement agreements between FibroGen China and AstraZeneca to settle certain historical items, which was unbilled receivables as of December 31, 2024;
- Deferred revenue increased $7.5 million, primarily related to the $10.0 million additional deferred revenue during the quarter due to changes in estimate associated with the China performance obligation; offset by the $2.0 million royalty revenue recognized from the deferred revenue under the Astellas Europe Agreement during the period. See the *Drug Product Revenue, Net* section in Note 3, *Collaboration Agreements, License Agreement and Revenues*, to the condensed consolidated financial statements for details;
- Inventory decreased $4.2 million primarily driven by lower inventory production in China as we have decommissioned our API manufacturing facility in Cangzhou, China in late 2024. Inventory in China is part of the held-for-sale assets resulting from the Share Purchase Agreement with AstraZeneca Treasury Limited as discussed above and in Note 2, *Discontinued Operations,* to the condensed consolidated financial statements;
- Accrued interest expense related to sale of future revenues increased $3.7 million due to the interest expense of $4.1 million accrued, offset by the interest paid of $0.5 million during the period. See Note 8, *Liability Related to Sale of Future Revenues*, to the condensed consolidated financial statements for details;
- Accrued and other liabilities decreased $30.7 million, primarily driven by the $28.5 million distribution of litigation settlement related to our agreement in principle with plaintiffs to settle the class action lawsuit. The accrued and other liabilities were also impacted by cost control efforts and the timing of invoicing and payment;
- Accounts payable decreased $21.7 million, primarily driven by the payments made during the quarter to AstraZeneca under the settlement agreements entered in September 2024 between FibroGen China and AstraZeneca to settle certain historical items; and
- Accounts receivable increased $3.0 million, primarily driven by the billings to Falikang based on the arrangements under the above-mentioned settlement agreements and related to the increase product sales. Accounts receivable from Falikang is part of the held-for-sale assets resulting from the Share Purchase Agreement with AstraZeneca Treasury Limited as discussed above and in Note 2, *Discontinued Operations* to the condensed consolidated financial statements.

Net cash used in operating activities was $99.2 million for the six months ended June 30, 2024 and consisted primarily of net loss of $48.5 million adjusted for non-operating cash items of $15.8 million, and a net decrease in operating assets and liabilities of $66.5 million. The significant non-operating cash items included stock-based compensation expense of $17.4 million. The significant items in the changes in operating assets and liabilities included the following:

- Accrued and other liabilities decreased $52.7 million, primarily driven by payment of $35.3 million to Astellas and $11.5 million to AstraZeneca related to accrued API and bulk drug product price true-up; bonus and severance payouts totaling $19.1 million, offset by accrued inventory related cost of $8.5 million as of June 30, 2024, as part of the cost of goods sold resulting from the above-mentioned termination of the AstraZeneca U.S./RoW agreement. The accrued and other liabilities were also impacted by the timing of invoicing and payment;
- Deferred revenue decreased $29.5 million, primarily related to the $20.6 million product revenue recognized from the previously deferred revenue of the China performance obligation during the six months ended June 30, 2023. In addition, the decrease in deferred revenue was also related to the $2.1 million royalty revenue recognized from the deferred revenue under the Astellas Europe Agreement, and the reclassification of $5.4 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 six months ended June 30, 2023;
- Accounts payable decreased $8.0 million, primarily driven by the timing of invoicing and payments;

- Accrued interest expense related to sale of future revenues decreased $1.9 million due to the $5.7 million interest paid, offset by the interest expense of $3.7 million accrued during the six months ended June 30, 2024;
- Inventory decreased $15.6 million primarily driven by the $12.6 million of work-in-progress inventory that was reimbursed as part of the above-mentioned termination of the AstraZeneca U.S./RoW agreement;
- Accounts receivable decreased $6.0 million, primarily driven by the receipt of the billings under our collaboration and license agreements; and
- Prepaid expenses and other current assets decreased $4.5 million, primarily due to the reimbursements from the insurance for the legal fees associated with the class action lawsuit, which is recoverable under our insurance policies.

Investing Activities

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

Net cash used in investing activities was immaterial for the six months ended June 30, 2025.

Net cash provided by investing activities was $123.5 million for the six months ended June 30, 2024 and consisted primarily of $132.2 million of proceeds from maturities of investments, partially offset by $8.6 million of cash used in purchases of available-for-sale securities.

Financing Activities

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

Net cash used in financing activities was immaterial for the six months ended June 30, 2025 and 2024.

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 and the sale of FibroGen International and its subsidiaries to AstraZeneca Treasury Limited, 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.

If we are unable to complete the above mentioned sale of FibroGen International and its subsidiaries to AstraZeneca Treasury Limited, access additional cash from our China operations, or raise additional capital in the U.S., we would not have sufficient liquidity to continue operations in the U.S. for the 12 months from the date that the financial statements are issued and would not be able to comply with its financial covenant that requires a minimum balance of $18.75 million of unrestricted cash and cash equivalents to be held in accounts in the U.S. Upon an event of default, our senior secured term loan facilities could become immediately due and payable. We have evaluated measures to access additional cash from our China operations and believe the sale of FibroGen International represents the most efficient way to access the entirety of our cash from China upon closing of the transaction. There is also the potential that we raise additional funds in the U.S. at any time through equity, equity-linked, or debt financing arrangements or from other sources. There can be no assurances that these plans will be successful. As a result of these factors, we have determined that there is substantial doubt about our ability to continue as a going concern within 12 months after the date that the financial statements are issued. 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 funding, we could delay, reduce or eliminate research and development programs, product portfolio development or future commercialization efforts which could adversely affect our business prospects.

Commitments and Contingencies

Contractual Obligations

As of June 30, 2025, we had outstanding total non-cancelable purchase obligations of $3.1 million for general purchases and other programs and $0.5 million for manufacture and supply of roxadustat, all of which are expected to be paid within the next 12 months. We expect to fulfill our commitments under these agreements in the normal course of business, and as such, no liability has been recorded.

Under the Financing Agreement with Morgan Stanley Tactical Value, as of June 30, 2025, we had $73.7 million of senior secured term loan facilities balance on the condensed consolidated balance sheets, which is subject for repayment within the next 12 months. In addition, we are obliged to pay interest on a monthly basis, for which we expect to pay a total of $9.0 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 June 30, 2025, we had $63.0 million of liability related to sale of future revenues in the condensed consolidated balance sheets, $1.7 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.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

There have been no material changes in our critical accounting policies, estimates and judgments during the three and six months ended June 30, 2025 compared with the disclosures in Part II, Item 7 of our 2024 Form 10-K.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are a smaller reporting company as defined in Rule 12b-2 of the Exchange Act; therefore, pursuant to Item 305(e) of Regulation S-K, we are not required to provide the information required by this Item.

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 June 30, 2025, 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 June 30, 2025.

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 June 30, 2025 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 June 30, 2025, as we could not predict the ultimate outcome of these matters, or reasonably estimate the potential exposure. See Note 10, *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, 2024, filed on March 17, 2025.

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 roxadustat and FG-3246 (in conjunction with our positron emission tomography imaging agent FG-3180).
- Drug development and obtaining marketing authorization are very difficult endeavors, and we may ultimately be unable to obtain regulatory approval for our various product candidates in one or more jurisdictions and 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 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 the 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 and exclusively licensed 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 United States, and we may encounter significant problems in securing and defending our intellectual property rights outside the United States.

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 United States and foreign laws, regulations, rules, contractual obligations, industry standards, 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 (including class claims) and mass arbitration demands; 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

- If we are unable to consummate the sale of FibroGen International to AstraZeneca Treasury Limited, our operations, business conditions, and the trading price of our common stock and our business may be harmed.*
- We have established operations in China and there are 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.
- Changes in U.S. and China relations, as well as relations with other countries, and/or regulations may adversely impact our business.*
- We use our own manufacturing facility in China to produce roxadustat drug product for the market in China. There are risks inherent to operating commercial manufacturing facilities and we may not be able to continually meet market demand.
- There is a risk of manufacturing disruption due to geopolitical tensions in China and related to United States legislation impacting WuXi AppTec, Wuxi Biologics, and Wuxi XDC.*
- 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 roxadustat and FG-3246 (in conjunction with our positron emission tomography ("PET") imaging agent FG-3180).

The future value drivers for FibroGen, Inc. ("FibroGen" or the "Company") depend in large part on the continued commercial success of roxadustat in Europe, Japan, and the People's Republic of China ("China"), the potential of roxadustat anemia associated with lower-risk myelodysplastic syndromes ("MDS"), and the development of FG-3246 (in conjunction with our PET imaging agent FG-3180), which is in clinical development for metastatic castration-resistant prostate cancer ("mCRPC").

If our efforts in these programs are unsuccessful, it may materially and adversely affect our business and financial condition.

Drug development and obtaining marketing authorization are very difficult endeavors, 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 United States of America ("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 effective and has an acceptable safety profile 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 effective and has an acceptable safety profile 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) is necessary to demonstrate the safety and efficacy of a product candidate;
- disagreement over the design or implementation of our clinical trials;
- our product candidates exhibiting an unacceptable safety signal at any stage of development;

- failure either by us or the clinical research organizations ("CROs") or investigators that conduct clinical trials on our behalf, to comply with regulations or GCPs, clinical trial protocols, or contractual agreements, which may adversely impact our clinical trials, as well as, investigator-sponsored 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.;
- failure either by us or third-party contractors manufacturing our product candidates to maintain current good manufacturing practices ("cGMP"), successfully pass inspection, or meet other applicable manufacturing regulatory requirements;
- requirements by regulatory authorities to exclude the use of patient data from unreliable clinical trials, or disagreement with our interpretation of the data from our preclinical trials and clinical trials;
- failure by collaboration partners or other third parties such as clinical investigators to perform or complete their clinical programs in a timely manner, or at all; or
- Failure of data from investigator-sponsored clinical trials, which are used as supportive evidence for our initial IND studies, to meet GCP standards.

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, as well as, investigator-sponsored 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.

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.

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.

When we have an investigator-sponsored trial, we would have to rely on sponsor's data generated independently under sponsor's institutional practices. As a result, there is an additional risk that results may differ in future trials run by FibroGen as the sponsor.

We do not know whether our ongoing or planned clinical trials 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;

- failure of the drug to pass interim futility criteria for efficacy in a clinical trial design;
- adverse side effects that meet safety stopping rules for the study in a clinical trial design;
- 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, clinical site initiation, or retention problems associated with civil unrest, military conflicts around the world, or natural disasters;
- 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 well as, investigator-sponsored 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, as well as, investigator-sponsored 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, as well as, investigator-sponsored 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 our clinical trials, as well as, investigator-sponsored 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. Our drug candidates are being studied in patient populations that are at high risk of death and adverse events, and even if unrelated to our drug candidate, 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. 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, as well as, investigator-sponsored 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 scale. We may need to enter into additional manufacturing agreements and may be unable to do so on satisfactory terms or in a timely manner. In addition, we may experience delays or technical problems associated with technology transfer of manufacturing processes to any new suppliers.

We, or our collaboration partner, may not be able to accurately forecast clinical or commercial supply requirements and we may not meet or we may exceed our requirements as to quantities, scale-up, yield, cost, potency or quality in compliance with cGMP.

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. Any delay or interruption in the supply of our product candidates or products could have a material adverse effect on our business and operations.

In addition, due to delays in, or not obtaining, marketing approval for any one of our clinical programs, we may have excess supply or excess waste of expiring product supply. Or if product expires due to delays, we may have a shortfall of supply of non-expired product as manufacturing of such product has significant lead times.

Please see also our risk factor titled "*We may have shortfalls, delays, or excesses in manufacturing.*"

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. Manufacturing changes made to one of our drugs or drug candidates, include, but are 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, and those changes may materially impact our operations and potential profitability. This includes the scenario that the change may be unsuccessful and cause delays or other negative impact.

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;
- 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;
- 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; and
- failure to obtain license to proprietary starting materials.

FibroGen may also elect to transition its manufacturing responsibilities to another party. There may be risks underlying this manufacturing transition, as well as new risks that may emerge after the new organization takes over manufacturing, if that were to happen.

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, regulatory authorities conduct their own benefit-risk analysis and may reach different conclusions. Regulatory authorities may use, among other things, different statistical methods, different endpoints or definitions thereof, and 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. 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. The China Health Authority has accepted abbreviated new drug applications (“NDAs”) for over 20 generic roxadustat applicants and approved multiple for marketing in China.

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 and enrollment for clinical trials.

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.

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 University of California, San Francisco, for the continued development of FG-3246 (in conjunction with our PET biomarker). While we control development of FG-3246 up to the 4-year evaluation period, we will be doing so under our investigational new drug application that references Fortis's investigational new drug application. If Fortis were unwilling to cooperate with development efforts, our ability to develop FG-3246 (in conjunction with our PET biomarker) would be delayed.

While we terminated our collaboration agreement with AstraZeneca AB ("AstraZeneca") for roxadustat for the treatment of anemia in the U.S. and all territories except for China and those territories previously licensed to Astellas (the "AstraZeneca U.S./RoW Agreement"), we have active collaboration agreements with respect to the development and commercialization of roxadustat with Astellas Pharma Inc. ("Astellas") and with AstraZeneca in China and South Korea. These agreements provide for reimbursement of our development costs by our collaboration partners and also provide for the commercialization of roxadustat throughout the major territories of the world.

On February 20, 2025, we entered into a share purchase agreement (the "Share Purchase Agreement") with AstraZeneca Treasury Limited pursuant to which we agreed to sell all of the issued and outstanding equity interests of FibroGen International (Hong Kong) Ltd. ("FibroGen International") to AstraZeneca Treasury Limited. The transaction is expected to close in the third quarter of 2025, and is subject to customary closing conditions and closing deliverables. Until closing, the collaboration agreement with AstraZeneca, and associated reimbursement of our development costs, will remain in effect.

Our current agreements with Astellas and AstraZeneca provide them with the right to terminate their 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 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 any 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 profit from the commercialization of roxadustat could suffer.

For instance, the AstraZeneca U.S./RoW Agreement was terminated on February 23, 2024 (except for South Korea). Although our ongoing collaboration agreement with AstraZeneca for the development and commercialization of roxadustat for the treatment of anemia in China (the "AstraZeneca China Agreement") continues through closing of the Share Purchase Agreement, this eliminates any additional potential milestones or other payments AstraZeneca would have made under the AstraZeneca U.S./RoW Agreement except for potentially in South Korea. The likelihood receiving such payments was remote due to our withdrawal of the U.S. new drug application for chronic kidney disease ("CKD") anemia. And while we are now investigating new licensing opportunities for roxadustat, there can be no assurance that we will find such a partner or be able to agree to a license on reasonable terms.

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 take 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, as well as potentially impacting our commercial results.

Certain 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, as well as, investigator-sponsored trials in accordance with GCP, clinical protocols, and designs. We also rely on a number of third-party CROs or other third parties to assist in undertaking, managing, monitoring, imaging and testing, and otherwise executing our ongoing clinical trials. We expect to continue to rely on CROs, clinical data management organizations, medical institutions, clinical investigators, and other third parties 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, cGMP, and good laboratory practices 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 and clinical investigators or clinical partners 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 facility 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;
- 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; and
- inability for FibroGen to meet timing and volume obligations to Astellas or other partners due to insufficient resources.

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. Furthermore, premature termination of third-party manufacturers may result in additional cost burden for FibroGen.

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

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 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 other third-party manufacturers to cover portions or all of the 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.

Entering into new long-term commercial supply arrangements on commercially reasonable terms, could take significant time or may not be possible. We currently rely on our contract manufacturers to purchase from third-party suppliers some of the materials necessary to produce our product candidates. We do not have direct control over the acquisition of those materials by our contract manufacturers.

The logistics of our supply chain, which include shipment of materials and intermediates from countries such as China and India add additional time and risk (including risk of loss) to the manufacture of our product candidates. While we have in the past maintained sufficient inventory of materials, active pharmaceutical ingredient ("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.

In addition, one of our suppliers, Catalent, was recently acquired by a private company, which could add additional risk to our ability to manufacture at such supplier, including entering into new or extended agreements with this supplier.

Risks Related to Our Intellectual Property

If our efforts to protect our proprietary and exclusively licensed 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 our proprietary information or technology could compromise our competitive position.

We have in the past and may in the future be involved in initiating legal or administrative proceedings involving the product candidates and intellectual property of our competitors. Moreover, we are, have been, and may in the future be involved in legal proceedings initiated by third parties involving our intellectual property. 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 or defending our intellectual property.

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 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, generic manufacturers and competitors with significantly greater resources could threaten our ability to commercialize our product candidates.

Intellectual property protecting our roxadustat product is either being challenged or will expire at various times in the coming years, raising the possibility of generic competition. The China Health Authority has approved multiple generic forms of our EVRENZO™ product (爱瑞卓®, roxadustat) for marketing in China. The introduction of generic competition for a patented branded medicine typically results in a significant and rapid reduction in net sales and operating income for the branded product because generic manufacturers typically offer their unpatented versions at sharply lower prices. Such competition can occur after successful challenges to intellectual property rights or the regular expiration of the term of the patent or other intellectual property rights. Such competition can also result from a Declaration of Public Interest or the compulsory licensing of our drugs by governments, or from a general weakening of intellectual property laws in certain countries around the world. In addition, generic manufacturers sometimes take an aggressive approach to challenging intellectual property rights, including conducting so-called "launches at risk" of products that are still under legal challenge for infringement before final resolution of legal proceedings.

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, *inter partes* review, opposition, invalidation, 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, pending the sale of FibroGen International to AstraZeneca Treasury Limited, 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 FG-3246 (in conjunction with our PET imaging agent FG-3180). 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. In particular, patent challenges have been filed against our crystal form patents in Europe and China, and against our photostable formulations patent in Europe. In Europe, our European Patent No. 3470397 (the "`397 Patent"), which claims formulations comprising the commercial crystalline form of roxadustat was upheld in opposition, the opponents have appealed the decision in this case. In China, three roxadustat crystal form patents were revoked in first-round proceedings and the revocations were upheld on first appeal; however, all decisions currently remain on appeal. Final resolution of these proceedings in Europe and China will take time and we cannot be assured that these patents will survive these proceedings 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 and generic competition, 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. For example, in China, we have had substantial difficulty effectively maintaining, prosecuting and enforcing our intellectual property rights. As we have experienced in multiple jurisdictions, 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, 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 existence of and any increase in the sales and production of counterfeit pharmaceuticals, or the technological capabilities of counterfeiters, could negatively impact our revenues, brand reputation, business and results of operations.

Risks Related to Government Regulation

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

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that our 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 or indication.

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, imprisonment, 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, industry standards, 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 (including class claims) and mass arbitration demands; 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 data, 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, as amended by the California Privacy Rights Act of 2020 (collectively, "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. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. These developments further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the U.S., laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom'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 ("PIPL") impose strict requirements for processing personal data, including health-related information. Specifically, under the EU 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 brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. We also target customers in Asia and have operations in China and are subject to new and emerging data privacy regimes in Asia, including China's PIPL, Japan's Act on the Protection of Personal Information, and Singapore's Personal Data Protection Act.

Additionally, companies that transfer personal data out of the European Economic Area and the United Kingdom to other jurisdictions are subject to scrutiny from regulators, individual litigants, and activities groups.

We are planning to bring artificial intelligence ("AI") into our IT platforms and services. However, our competitors might integrate AI faster or more effectively than us, which could put us at a disadvantage. Additionally, if AI helps create content, analyses, or recommendations that turn out to be flawed or biased, or even just perceived that way, it could hurt our business and financial health. AI can also lead to cybersecurity issues, potentially exposing personal data of users. Such incidents could damage our reputation and affect our performance. As AI technology rapidly evolves, and with the possibility of new regulations, we may need additional resources to ensure we use AI responsibly and ethically to avoid unforeseen negative consequences. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials and other statements, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

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; restrictions on use of AI tools which may involve 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; interruptions or stoppages in our business operations including clinical trials; 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 can be 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.

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 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. In addition, if our internal control over financial reporting is deemed ineffective, 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.

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.

Healthcare reform in the U.S. in the future may include changes to Prescription Drug User Fee Act (PDUFA) funding, or other actions that impact FDA programs or personnel funded by user fees. If user fees are cut or eliminated, or if personnel funded by user fees are terminated at FDA, the result could increase uncertainty on review timelines or extend FDA review timelines (e.g., new drug applications, Biologics License Applications), which can result in delays for regulatory action and adversely impact drug development timelines.

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 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 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 take effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid ("CMS") Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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, or otherwise adversely affect our business.

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

If we are unable to consummate the sale of FibroGen International to AstraZeneca Treasury Limited, our operations, business conditions, and the trading price of our common stock and our business may be harmed.*

The consummation of the sale of FibroGen International is subject to the satisfaction or waiver of various customary closing conditions, including the receipt of regulatory approval from the China State Administration for Market Regulation ("SAMR"). We cannot guarantee that the closing conditions set forth in the Share Purchase Agreement will be satisfied and if we are unable to satisfy the closing conditions, AstraZeneca Treasury Limited will not be obligated to purchase FibroGen International. In the event that the sale is not completed, the announcement of the termination of the Share Purchase Agreement may adversely affect the trading price of our common stock and our business, including that we will not have sufficient liquidity to continue operations in the U.S. for twelve months from the date of this Quarterly Report and will not be able to comply with our debt covenant under our senior secured term loan facilities that requires a minimum of $18.75 million of unrestricted cash and cash equivalents to be held in accounts in the U.S. If the sale is not completed within eight months of entering into the Share Purchase Agreement, both parties have a right to terminate the transaction. If the sale of FibroGen International is delayed past the third quarter of 2025, we may need to delay initiation of our planned Phase 2 monotherapy dose optimization study of FG-3246 for the treatment of mCRPC, currently expected in the third quarter of 2025. If the sale of FibroGen International to AstraZeneca Treasury Limited is not completed, our Board of Directors, may evaluate other strategic alternatives with respect to FibroGen International, if any are available, which alternatives may not be as favorable to our stockholders as the proposed sale to AstraZeneca Treasury Limited, and may not result in any definitive transaction or enhance stockholder value.

We have established operations in China and there are 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, or natural disasters, including 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.

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 are attempting to import future quantities of drug substance from certain suppliers ahead of any new tariffs, if we are unable to do so before such new tariffs are introduced for clinical or commercial pharmaceuticals from China, the Company could encounter moderate additional costs to transfer remaining quantities of FG-3246 for completion of its clinical Phase 2 clinical study, and potentially significant additional costs for the transfer of commercial roxadustat inventory for commercial supply for Europe.

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 facility in China to produce roxadustat drug product for the market in China. There are risks inherent to operating commercial manufacturing facilities, and we may not be able to continually meet market demand.

We are obligated to comply with cGMP requirements but 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 to our product suppliers, 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 facility meet applicable specifications and other requirements for product safety, efficacy and quality but 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 facility. Certain equipment, records and other materials located in such facility 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.

There is a risk of manufacturing disruption due to geopolitical tensions in China and related to U.S. legislation impacting WuXi AppTec, WuXi Biologics, and WuXi XDC.*

The climate of geopolitical tensions in China affecting global supply chains may impact our ability to continually meet market demand. For example, certain U.S. lawmakers have encouraged sanctions and introduced legislation that could affect WuXi AppTec (Hong Kong) Limited and our current supplier of FG-3246, WuXi Biologics (Hong Kong) Limited ("WuXi Biologics"), Wuxi XDC (Hong Kong) Limited ("WuXi XDC") and companies that do business with WuXi Biologics and WuXi XDC. Shanghai SynTheAll Pharmaceutical Co., Ltd. ("WuXi STA"), our supplier of roxadustat drug substance, is also included in this legislation since it is a branch of WuXi Apptec. This can impact the FG-3246 program as we source the linker and payload from WuXi STA and we manufacture antibody, antibody drug conjugate drug substance and antibody drug conjugate drug product at WuXi Biologics and WuXi XDC. This legislation is being developed and it is possible that the content in the legislation continues to change prior to becoming law. There are also risks that new legislation comes up in the future that imposes further restrictions on our ability to source FG-3246 from WuXi Biologics, WuXi XDC, and WuXi STA for U.S. based clinical and commercial demand. This legislation may prevent us from launching FG-3246 in the U.S. or conducting clinical trials after the period specified in the legislation. This may also force us to consider alternative suppliers for which additional time, money and resources may be required without a guarantee of producing comparable product in a timely fashion. The occurrence of any such event could materially and adversely affect our business, financial condition, results of operations, timing of supply deliveries, cash flows and prospects.

We may experience difficulties in successfully growing and sustaining sales of roxadustat in China.*

Pending the sale of FibroGen International to AstraZeneca Treasury Limited, 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. Roxadustat's recent inclusion in the 2023 National Reimbursement Drug List came with a limited 7% price reduction. Such reimbursement pricing for China is effective for a standard two-year period (between January 1, 2024, and December 31, 2025). The China Health Authority has since accepted abbreviated NDAs for over 20 generics roxadustat applicants and approved multiple for marketing in China. In the third quarter, roxadustat was announced as being included in the 11th round of the country's volume-based purchasing program whereby a national tender has been called. We expect this to occur in the second half of 2025. As a result, we expect our access to the China market as the originator drug will be significantly impacted and our price would be further reduced, resulting in significant reductions in the topline revenue for roxadustat.

Sales of roxadustat in China may also 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 of 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 are 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.*

Pending the sale of FibroGen International to AstraZeneca Treasury Limited, 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 June 30, 2025, approximately $96.5 million of our cash and cash equivalents is held in China, and was included in the held for sale assets on the condensed consolidated balance sheet, the entirety of which we will have access to upon the close of the sale of FibroGen International to AstraZeneca Treasury Limited.

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 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 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 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 SAMR. 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.

Pending the sale of FibroGen International to AstraZeneca Treasury Limited, 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 chemotherapy-induced anemia in China, potentially anemia in lower-risk MDS in the U.S. and elsewhere, and FG-3246 (in conjunction with our PET imaging agent FG-3180) for mCRPC. Most of our revenue generated to date has been based on our collaboration agreements. 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, 2024 and 2023 were $47.6 million and $284.2 million, respectively. As of June 30, 2025, we had an accumulated deficit of $1.9 billion. As of June 30, 2025, we had capital resources from cash and cash equivalents of $23.4 million for our continuing operations. In addition, as of June 30, 2025, we had $96.5 million of cash and cash equivalents and $22.1 million of accounts receivable in China, which were included in the held for sale assets on the condensed consolidated balance sheet. We will have access to the entirety of the cash, cash equivalents, and accounts receivable balances in China upon the close of the sales of FibroGen International to AstraZeneca Treasury Limited. 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. Furthermore, upon closing of the sale of FibroGen International to AstraZeneca Treasury Limited, we will not be due any royalty, development or milestone payments under the AstraZeneca China Agreement. 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 our clinical development efforts. 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. If we are unable to complete the sale of FibroGen International, access additional cash from our China operations, or raise additional capital in the U.S., we will not have sufficient liquidity to continue operations in the U.S. for the twelve months from the date of this Quarterly Report and will not be able to comply with our debt covenant under our senior secured term loan facilities that requires a minimum balance of $18.75 million of unrestricted cash and cash equivalents to be held in accounts in the U.S. Upon an event of default, our senior secured term loan facilities could become immediately due and payable. We have evaluated measures to access additional cash from our China operations and we believe the sale of FibroGen International represents the most efficient way to access the entirety of our cash from China upon closing of the transaction. There is also the potential that we raise additional funds in the U.S. at any time through equity, equity-linked, or debt financing arrangements or from other sources. There can be no assurances that these plans will be successful. As a result of these factors, we have determined that there is substantial doubt about our ability to continue as a going concern within 12 months after the date that the financial statements are issued. 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. 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 imposes 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 we are unable to obtain funding, we could delay, reduce or eliminate research and development programs, product portfolio development or future commercialization efforts which could adversely affect our business prospects.

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.*

In November 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.

In April 2023, we entered into a financing agreement ("Financing Agreement") with a $75 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.

Our Financing Agreement with Morgan Stanley Tactical Value requires us to maintain a minimum balance of $18.75 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 through our roxadustat collaborations.

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 help fund our operations. 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 managing our growth and expanding our operations, successfully.

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, commercialization and administration capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to increase the responsibilities of management. Our failure to accomplish any of these steps could prevent us from successfully implementing our strategy and maintaining the confidence of investors in us.

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

In August 2024, we approved a reduction to our U.S. workforce of approximately 75% to lower our operating expenses, causing the loss of senior management and employees with valuable skills, experience, and productivity. If we are unable to continue to attract and retain personnel with the quality and experience necessary to advance the development of our product candidates, our ability to pursue our strategy will be limited and our business and operations would be adversely affected.

Retaining and recruiting 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. 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.

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 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"). All seven Derivative Lawsuits have been dismissed. 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. While the Securities Class Action Litigation has been settled, we intend to vigorously defend the claims made in the Derivative Litigation; however, the outcome of these matters cannot be predicted.

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, we received a subpoena from the SEC requesting documents related to roxadustat's pooled cardiovascular safety data. The SEC followed up with a subpoena for additional documents in the second quarter of 2024. In May 2025, the Company entered into a settlement with the SEC, subject to Commission approval. As part of the settlement, and without admitting or denying the findings in the settlement offer or administrative order to be issued by the SEC, the Company agreed to pay a $1.25 million civil penalty.

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 additional similar 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 10, *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 by a cybersecurity incident, 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 cybersecurity 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. While it is possible that extortion payments may alleviate the negative impact of a ransomware attack, 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.

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 designated 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 reveal competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Our third party service providers may be exposed to natural disasters and other catastrophes.*

Our third party service, cloud and software-as-a-services (SaaS) platform providers, who we rely on for critical support functions, may be exposed to significant risks from natural disasters and other catastrophic events, including earthquakes, power outages, and unforeseen disruptions. Many of these providers are in regions prone to earthquakes and fires, such as the San Francisco Bay Area. These risks could severely impact their operations, infrastructures, or abilities to deliver services, which could in turn disrupt our business continuity and have a material adverse effect on our operations and financial results. Although we have conducted comprehensive risk assessments, the vulnerability of our third-party partners to these events remains a significant risk, particularly as many operate from single sites with limited disaster recovery capabilities. Their inability to recover promptly from such events could result in service delays or interruptions, leading to operational challenges, and increased costs for us.

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 the 12-month period ended June 30, 2025, the closing price of our common stock on the Nasdaq Global Select Market has ranged from $5.16 per share to $31.50 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;
- the timing of the release of results of and regulatory updates regarding our clinical trials, as well as, investigator-sponsored 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 10, *Commitments and Contingencies*, to the condensed consolidated financial statements.

We are a smaller reporting company, and the reduced disclosure requirements applicable to us may make our common stock less attractive to investors.

We are a "smaller reporting company," and we are therefore eligible for certain provisions of the Exchange Act, including only being required to provide two years of audited financial statements and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. If some investors find our common shares less attractive as a result of our reliance on these reduced disclosure obligations, there may be a less active trading market for our common shares and our price of our common shares may be more volatile.

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. On July 4, 2025, the One Big Beautiful Bill Act was signed into law in the U.S. which contains a broad range of tax reform provisions affecting businesses. We are still in the process of evaluating the legislation and an estimate of the financial impact cannot be made at this time.

Federal and state tax laws impose substantial restrictions on the utilization of net operating loss and credit carryforwards in the event of an "ownership change" for tax purposes, as defined in IRC Section 382. We would undergo an ownership change if, among other things, the stockholders who own, directly or indirectly, 5% or more of our common stock, or are otherwise treated as "5% shareholders" under Section 382 of the U.S. Internal Revenue Code and the regulations promulgated thereunder, increase their aggregate percentage ownership of our stock by more than 50 percentage points over the lowest percentage of the stock owned by these stockholders at any time during the testing period, which is generally the three-year period preceding the potential ownership change. In the event of an ownership change, Section 382 of the U.S. Internal Revenue Code imposes an annual limitation on the amount of taxable income a corporation may offset with NOL carryforwards. The annual limitation is generally equal to the value of the stock of the corporation immediately before the ownership change, multiplied by the long-term tax-exempt rate for the month in which the ownership change occurs (the long-term tax-exempt rate for March 2015 is 2.67%). Any unused annual limitation may generally be carried over to later years until the NOL carryforwards expire. The Company performed an IRC Section 382 analysis and do not believe there were ownership changes as of December 31, 2024. Thus, IRC Section 382 will not limit the use of our net operating loss and tax credit carryforwards. We continue to monitor trading activities in our shares which could cause ownership change in future years.

Tariffs or other trade policy changes could harm our business.

Changes in trade policies, tariffs, and geopolitical tensions may impact our business, supply chain, and costs of operations. Governments worldwide, including the U.S. and key trade partners like China, have imposed and may continue to impose tariffs, export controls, trade restrictions, and other measures that could impact our supply chain and our costs of doing business. If we are impacted by the changing trade relations between the U.S. and other countries, our business and results of operations may be negatively impacted.

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.

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

Rule 10b5-1 Trading Arrangements

None.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of FibroGen, Inc.	8-K	001-36740	3.1	11/21/2014
3.2	Amended and Restated Bylaws of FibroGen, Inc.	8-K	001-36740	3.1	04/04/2025
3.3	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of FibroGen, Inc.	8-K	001-36740	3.1	06/12/2025
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* †	Amendment No.2 to the Collaboration Agreement by and between Astellas Pharma, Inc. and FibroGen, Inc., dated as of June 6, 2025.	—	—	—	—

10.2	Second Amendment to Financing Agreement, by and among FibroGen, Inc., NHTV Fairview Holding LLC, NHTV II Fairview Holding LLC, MSTV Fund II ESC Fairview Holding LLC, and Wilmington Trust, National Association, dated as of June 5, 2025.	8-K	001-36740	10.1	06/09/2025
10.3	Third Amendment to Financing Agreement, by and among FibroGen, Inc., NHTV Fairview Holding LLC, NHTV II Fairview Holding LLC, MSTV Fund II ESC Fairview Holding LLC, and Wilmington Trust, National Association, dated as of July 14, 2025.	8-K	001-36740	10.1	07/14/2025
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 With Embedded Linkbase Documents.	—	—	—	—
104	Cover Page formatted as inline XBRL and contained in Exhibits 101.	—	—	—	—

* Filed herewith.

† Portions of this exhibit (indicated by asterisks) have been omitted as the Company has determined that (i) the omitted information is not material and (ii) the omitted information would likely cause competitive harm if publicly disclosed 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: August 11, 2025

By: /s/ Thane Wettig
Thane Wettig
Chief Executive Officer
(Principal Executive Officer)

Date: August 11, 2025

By: /s/ David DeLucia
David DeLucia
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

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

Exhibit 10.1

AMENDMENT NO. 2 TO COLLABORATION AGREEMENT

THIS AMENDMENT NO. 2 (the "**Second Amendment**") is effective as of the 6th June 2025 (the "**Second Amendment Effective Date**") by and between Astellas Pharma, Inc. ("**Astellas**") and FibroGen, Inc. ("**FG**"). This Second Amendment amends the Collaboration Agreement entered into by and between Astellas and FG on 1st June 2005, as subsequently amended by the First Amendment, effective 1st January 2013 (collectively, the "**Agreement**"). Astellas and FG shall be referred to individually herein as a "**Party**" and collectively as the "**Parties**".

WHEREAS, under the Agreement, Astellas and FG have agreed to modify the calculation of the API Batch Transfer Price as set forth in the Agreement; and

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

1) Unless otherwise defined herein, all capitalized terms and phrases used in this Second Amendment shall have the meanings ascribed to them in the Agreement.

2) With respect to the calculation of the API Batch Transfer Price as set forth in the second paragraph to Item Number 16 of the First Amendment, such paragraph will be replaced in its entirety with the following:
"*The "**API Batch Transfer Price**" shall be calculated based on (a) [*] to be manufactured by Astellas for the upcoming Astellas fiscal year derived from the manufacturing plan presented in the then-current Astellas supply forecast, and (ii) the [*], and (b) the [*] less (c) Bulk Product Manufacturing Cost.*"

   In addition, the definition for "**FG Yield**" shall be deleted from Item Number 16 of the First Amendment.

3) With respect to updates of the API Batch Transfer Price as set forth in Item Number 17 of the First Amendment, subparagraph (a) shall be replaced in its entirety with the following:
"*(a) No later than the end of February of each calendar year, FG shall provide to Astellas [*] for the upcoming Astellas fiscal year based on the manufacturing plan presented in the then-current Astellas supply forecast.*"

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

4) Section 20.6 (Notices) of the Agreement is hereby amended to reflect the Parties' current notice information, including email addresses which may be utilized to provide notice via email transmission (with acknowledgement of receipt of such email) as follows:

Astellas:	[*]
with a copy to:	[*]
FG :	[*]
With a copy to:	[*]

5) The Agreement, as amended by this Second Amendment, contains the entire understanding of the Parties with respect to the subject matter hereof. The Parties acknowledge that the amendments to the Agreement contained in this Second Amendment are and shall be of no force or effect with respect to the EU Agreement.

6) Except as otherwise provided herein this Second Amendment, the Agreement has not been modified or amended and remains in full force and effect. All express or implied agreements and understandings, either oral or written, heretofore made that conflict with respect to the subject matter herein are expressly superseded in this Second Amendment.

7) This Second Amendment may be executed in counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Counterparts may be signed, including electronic signature, and delivered by facsimile, via portable document format (.pdf), or by any other electronic means and that each Party may use such electronic document as evidence of the execution and delivery of this Second Amendment by all Parties to the same extent that an original signature could be used.

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

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

FIBROGEN, INC.	**ASTELLAS PHARMA, INC.**
By: /s/ [*]	By: /s/ [*]
Name: [*]	Name: [*]
Title: [*]	Title: [*]
Date: 2025-Jun-06	Date: 2025 June 25

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

Exhibit 31.1

CERTIFICATION

I, 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: August 11, 2025

/s/ Thane Wettig
Thane Wettig
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, David DeLucia, 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: August 11, 2025

/s/ David DeLucia
David DeLucia
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION

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

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2025, 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: August 11, 2025

In Witness Whereof, the undersigned have set their hands hereto as of the 11th day of August, 2025.

/s/ Thane Wettig
Thane Wettig
Chief Executive Officer

/s/ David DeLucia
David DeLucia
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.