

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

Form 10-Q

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

For the quarterly period ended March 31, 2026
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

KYNTRA BIO, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

350 Bay Street, Suite 100, #6009
San Francisco, CA
(Address of Principal Executive Offices)

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

94133
(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	KYNB	The Nasdaq Global Select Market

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

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

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

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

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

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

The number of shares of common stock outstanding as of April 30, 2026 was 4,048,112.

KYNTRA BIO, INC.

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KYNTRA BIO, INC.
PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 36,997	\$ 47,872
Short-term investments	50,240	41,106
Accounts receivable, net	5,040	216
Inventories	3,384	3,743
Prepaid expenses and other current assets	5,694	6,136
Total current assets	101,355	99,073
Long-term investments	8,026	20,160
Other assets	248	361
Total assets	\$ 109,629	\$ 119,594
Liabilities, redeemable non-controlling interests and deficit		
Current liabilities:		
Accounts payable	\$ 5,094	\$ 3,745
Accrued and other current liabilities	17,340	20,183
Deferred revenue	5,680	5,314
Total current liabilities	28,114	29,242
Product development obligations	19,249	19,560
Deferred revenue, net of current	4,075	255
Liability related to sale of future revenues, non-current	67,405	65,980
Other long-term liabilities	76	82
Total liabilities	118,919	115,119
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 March 31, 2026 and December 31, 2025	—	—
Common stock, \$0.01 par value; 225,000 shares authorized at March 31, 2026 and December 31, 2025; 4,048 and 4,047 shares issued and outstanding at March 31, 2026 and December 31, 2025	40	1,012
Additional paid-in capital	1,679,295	1,677,179
Accumulated other comprehensive loss	(1,893)	(2,182)
Accumulated deficit	(1,721,245)	(1,706,047)
Total stockholders' deficit attributable to Kyntra Bio	(43,803)	(30,038)
Nonredeemable non-controlling interests	13,033	13,033
Total deficit	(30,770)	(17,005)
Total liabilities, redeemable non-controlling interests and deficit	\$ 109,629	\$ 119,594

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

KYNTRA BIO, INC.

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

	Three Months Ended March 31,	
	2026	2025
Revenue:		
Development and other revenue	\$ 246	\$ 144
Drug product revenue, net	3,492	2,595
Total revenue	3,738	2,739
Operating costs and expenses:		
Cost of goods sold	4,106	252
Research and development	7,566	9,175
Selling, general and administrative	5,862	8,106
Restructuring charge	22	126
Total operating costs and expenses	17,556	17,659
Loss from operations	(13,818)	(14,920)
Interest and other, net		
Interest expense	(2,427)	(2,257)
Interest income and other income (expenses), net	1,113	413
Total interest and other, net	(1,314)	(1,844)
Loss from continuing operations before income taxes	(15,132)	(16,764)
Provision for income taxes	—	2
Loss from continuing operations	(15,132)	(16,766)
Income (loss) from discontinued operations, net of tax	(66)	21,405
Net income (loss)	<u>\$ (15,198)</u>	<u>\$ 4,639</u>
Loss from continuing operations per share - basic and diluted	\$ (3.74)	\$ (4.15)
Income (loss) from discontinued operations per share - basic and diluted	(0.02)	5.30
Net income (loss) per share - basic and diluted	<u>\$ (3.76)</u>	<u>\$ 1.15</u>
Weighted average number of common shares used to calculate net income (loss) per share - basic and diluted	4,047	4,038

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

KYNTRA BIO, INC.**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2026	2025
Net income (loss)	\$ (15,198)	\$ 4,639
Other comprehensive income (loss):		
Foreign currency translation adjustments	395	1,299
Unrealized loss on investments, net of tax effect	(106)	(1)
Other comprehensive income, net of taxes	289	1,298
Comprehensive income (loss)	(14,909)	5,937

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

KYNTRA BIO, 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							Redeemable Non- Controlling Interests
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Nonredeemable Non- Controlling Interests	Total Deficit	
	Shares	Amount						
Balance at December 31, 2025	4,046,827	\$ 1,012	\$ 1,677,179	\$ (2,182)	\$ (1,706,047)	\$ 13,033	\$ (17,005)	\$ 21,480
Net loss	—	—	—	—	(15,198)	—	(15,198)	—
Change in unrealized gain or loss on investments	—	—	—	(106)	—	—	(106)	—
Foreign currency translation adjustments	—	—	—	395	—	—	395	—
Shares issued from stock plans, net of payroll taxes paid	1,285	—	(7)	—	—	—	(7)	—
Stock-based compensation	—	—	1,151	—	—	—	1,151	—
Other	—	(972)	972	—	—	—	—	—
Balance at March 31, 2026	4,048,112	\$ 40	\$ 1,679,295	\$ (1,893)	\$ (1,721,245)	\$ 13,033	\$ (30,770)	\$ 21,480
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 income	—	—	—	—	4,639	—	4,639	—
Change in unrealized gain or loss on investments	—	—	—	(1)	—	—	(1)	—
Foreign currency translation adjustments	—	—	—	1,299	—	—	1,299	—
Shares issued from stock plans, net of payroll taxes paid	5,080	1	(38)	—	—	—	(37)	—
Issuance cost under ATM Program	—	—	(46)	—	—	—	(46)	—
Stock-based compensation	—	—	2,852	—	—	—	2,852	—
Balance at March 31, 2025	4,041,758	\$ 1,010	\$ 1,671,388	\$ (4,434)	\$ (1,884,860)	\$ 20,487	\$ (196,409)	\$ 21,480

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

KYNTRA BIO, INC.

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

	Three Months Ended March 31,	
	2026	2025
Operating activities		
Net income (loss)	\$ (15,198)	\$ 4,639
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation	—	318
Amortization of finance lease right-of-use assets	7	9
Net accretion of premium and discount on investments	(183)	(1)
Investment loss in unconsolidated variable interest entity	—	554
Loss on divestiture	66	—
Stock-based compensation	1,151	2,852
Changes in operating assets and liabilities:		
Accounts receivable, net	(4,824)	(3,160)
Inventories	359	2,859
Prepaid expenses and other current assets	443	52,584
Operating lease right-of-use assets	—	306
Other assets	106	648
Accounts payable	1,349	(24,766)
Accrued and other liabilities	(2,453)	(31,706)
Operating lease liabilities, current	—	(220)
Deferred revenues	4,186	(4,142)
Accrued interest expense related to sale of future revenues	1,028	1,702
Accrued interest for finance lease liabilities	(7)	(6)
Operating lease liabilities, non-current	—	(169)
Other long-term liabilities	83	418
Net cash provided by (used in) operating activities	(13,887)	2,719
Investing activities		
Purchases of property and equipment	—	(16)
Cash paid related to divestiture	(60)	—
Purchases of available-for-sale securities	(11,055)	—
Proceeds from maturities of investments	14,133	—
Net cash provided by (used in) investing activities	3,018	(16)
Financing activities		
Repayments of finance lease liabilities	—	(5)
Cash paid for payroll taxes on restricted stock unit releases	(7)	(37)
Payment of issuance cost under ATM Program	—	(46)
Net cash used in financing activities	(7)	(88)
Effect of exchange rate change on cash and cash equivalents	1	1,407
Net increase (decrease) in cash and cash equivalents	(10,875)	4,022
Total cash and cash equivalents at beginning of period	47,872	102,178
Total cash and cash equivalents at end of period	\$ 36,997	\$ 106,200

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

KYNTRA BIO, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Significant Accounting Policies

Description of Operations

Kyntra Bio, Inc. (“Kyntra Bio” or the “Company”) is a biopharmaceutical company focused on development of novel therapies in oncology and rare disease.

In January 2026, the Company announced its rebranding from “FibroGen, Inc.” to “Kyntra Bio, Inc.,” representing the next step of its transformation to focus on oncology and rare disease assets. On January 8, 2026, the Company’s common stock began trading under the new Nasdaq symbol “KYNB.”

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 initiated a Phase 2 monotherapy dose optimization study of FG-3246 for the treatment of mCRPC, along with the exploratory sub-study of FG-3180, in the third quarter of 2025.

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

On August 29, 2025, the Company closed the sale of its China operations through FibroGen International (Hong Kong) Ltd. (“FibroGen International”) to AstraZeneca Treasury Limited pursuant to the share purchase agreement entered into by the Company and AstraZeneca Treasury Limited on February 20, 2025, as amended (the “Share Purchase Agreement”) for a total consideration of \$220.4 million comprised of \$85.0 million in enterprise value and \$135.4 million in net cash held in China. AstraZeneca AB (“AstraZeneca”) was the Company’s long-time commercialization partner for roxadustat in greater China. This sale included all of its 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”). For additional details, refer to Note 2, *Discontinued Operations and Divestiture*.

The Company 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”). 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 advance its development plan for roxadustat in anemia associated with lower-risk myelodysplastic syndromes (“MDS”), a high-value indication with significant unmet medical need. The Company is now finalizing the Phase 3 trial protocol for roxadustat for the treatment of anemia in patients with lower-risk MDS and high transfusion burden after receiving further comments from the FDA.

The FDA granted roxadustat Orphan Drug Designation for the treatment of MDS in December 2025.

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, 2025, filed on March 16, 2026.

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The condensed consolidated financial statements include the accounts of the Company, its wholly-owned subsidiaries and its majority-owned subsidiaries, as well as any variable interest entity (“VIE”) for which Kyntra Bio 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 the Company 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 (the “Transaction”). This sale included all of the Company’s roxadustat assets in China, including FibroGen International’s subsidiary FibroGen Beijing and its 51.1% interest in Falikang. The Transaction was closed on August 29, 2025 for a total consideration of \$220.4 million, subject to certain customary adjustments as set forth in the purchase agreement, comprised of \$85.0 million in enterprise value and \$135.4 million in net cash held in China.

The Company analyzed the quantitative and qualitative factors and concluded that the sale of FibroGen International represents a strategic shift in the Company’s business and qualified as a discontinued operation since December 31, 2024. As a result, the Company determined that FibroGen International met the “discontinued operations” criteria in accordance with Financial Accounting Standard Board (“FASB”) Accounting Standards Codification (“ASC”) 205, Presentation of Financial Statements. Accordingly, the operating results related to FibroGen International and the gain (loss) related to the Transaction are classified as discontinued operations, and have been reflected as discontinued operations in the condensed consolidated statements of operations for all periods presented. See Note 2, *Discontinued Operations and Divestiture*, for related disclosures. Unless otherwise noted, discussion in the notes to the condensed 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. Based on its current operating plan, the Company believes that its existing cash and cash equivalents will be sufficient to fund the Company’s planned operating requirements for at least the 12 months following the issuance of the financial statements for March 31, 2026.

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. 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, 2025, filed on March 16, 2026.

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 months ended March 31, 2026 and 2025. 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 March 31,	
	2026	2025
Employee stock options	480	515
RSUs, PRSUs and TSR awards	42	48
	522	563

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.

2. Discontinued Operations and Divestiture

On February 20, 2025, the Company entered into the Share Purchase Agreement with AstraZeneca Treasury Limited, pursuant to which the Company 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. This sale included all of the Company's roxadustat assets in China, including FibroGen International's subsidiary FibroGen Beijing and its 51.1% interest in Falikang. The 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 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.

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The Transaction was closed on August 29, 2025 for a total consideration of \$220.4 million comprised of \$85.0 million in cash for the enterprise value of FibroGen International and \$135.4 million in net cash held in China. The total consideration included a \$210.4 million in cash paid at closing, and a total of \$10.0 million cash payable by AstraZeneca at the closing subject to holdbacks of: (i) a \$6.0 million holdback to offset final net cash adjustments which will be released following a customary adjustment process approximately 90 days post-closing (as such time may be extended for the parties to mutually agree upon final adjustments), and (ii) a \$4.0 million holdback to satisfy any indemnity claims, which will be released, net of any claims paid or unresolved, nine months after the closing. The Company does not expect such adjustments to be material, therefore have recorded the holdbacks as other receivable. On November 6, 2025, the Company received a \$6.4 million payment from AstraZeneca, which is in full satisfaction of the first holdback of \$6.0 million, plus \$0.4 million that was an additional payment following the final net cash adjustments after closing. The second holdback of \$4.0 million was included in the prepaid expenses and other current assets on the condensed consolidated balance sheets as of March 31, 2026 and December 31, 2025, respectively.

Historical Agreements with AstraZeneca and China Performance Obligation

In July 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 Agreement and Astellas Japan Agreement as discussed below in Note 3, *Collaboration Agreements, License Agreement and Revenues*, (“AstraZeneca U.S./RoW Agreement”). Later in 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”), as amended and restated on August 29, 2025. Neither party incurred any early termination penalties.

In July 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”).

Prior to the AstraZeneca Termination and Transition 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. The promises identified under the AstraZeneca China Agreement, including the license, co-development services and manufacturing of commercial supplies have been bundled into a single performance obligation (“China Performance Obligation”).

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 performed roxadustat distribution, as well as conducted sales and marketing through AstraZeneca.

Substantially all direct roxadustat product sales to distributors in China were made by Falikang, while FibroGen Beijing continued to sell roxadustat product directly in limited areas in China. 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 were made by Falikang. The net transaction price for FibroGen Beijing’s product sales to Falikang was 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 was based on the transaction price of the China Performance Obligation. Revenue was recognized when control of the product was 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 updated 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. Any net transaction price in excess of the revenue recognized was added to the deferred balance, and recognized in the periods as the performance obligation was satisfied.

Upon the divestiture of FibroGen International on August 29, 2025, the performance obligation to AstraZeneca was completely satisfied upon the closing of the divestiture, and all the previously deferred revenues were recognized as revenue during the third quarter of 2025.

Financial Information of the Discontinued Operations

The financial results of the discontinued operations with respect to FibroGen International reflected in the condensed consolidated statements of operations for the three months ended March 31, 2026 and 2025 were as follows (in thousands):

	Three Months Ended March 31,	
	2026	2025
Revenue:		
Product revenue, net	\$ —	\$ 39,818
Operating costs and expenses:		
Cost of goods sold	—	5,403
Research and development	—	759
Selling, general and administrative	—	7,464
Total operating costs and expenses	—	13,626
Income from operations	—	26,192
Interest and other, net		
Interest expense	—	(2,951)
Loss on divestiture	(66)	—
Interest income and other income (expenses), net	—	(1,282)
Total interest and other, net	(66)	(4,233)
Income (loss) before income taxes	(66)	21,959
Provision for income taxes	—	—
Investment loss in unconsolidated variable interest entity	—	(554)
Income (loss) from discontinued operations, net of tax	\$ (66)	\$ 21,405

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, as discussed above. Falikang was an unconsolidated VIE accounted for as an equity method investment, and considered as a related party to the Company. The net product revenue from sales to Falikang was \$36.9 million for the three months ended March 31, 2025. The other income from Falikang were immaterial for the three months ended March 31, 2025. The investment loss in Falikang was \$0.6 million for the three months ended March 31, 2025.

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 three months ended March 31, 2025 were as follows (in thousands):

	Three Months Ended March 31,	
	2025	
Depreciation	\$	318
Investment income in unconsolidated variable interest entity		554
Stock-based compensation	\$	344

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.

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The aggregate amount of consideration received under the Astellas Japan Agreement through March 31, 2026 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 months ended March 31, 2026 and 2025.

The transaction price related to consideration received through March 31, 2026 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 March 31, 2026 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, the Company 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 March 31, 2026 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 months ended March 31, 2026 and 2025.

The transaction price related to consideration received through March 31, 2026 and accounts receivable has been allocated to each of the performance obligations under the Astellas Europe Agreement, including \$619.0 million for license and \$288.9 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 March 31, 2026 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 the Company in support of commercial supplies. The related drug product revenue is described under the *Drug Product Revenue, Net* section below.

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 months ended March 31, 2026 and 2025 (in thousands):

	Three Months Ended March 31,	
	2026	2025
Astellas Japan Agreement	\$ (2,191)	\$ 1,781
Astellas Europe Agreement	5,683	814
Drug product revenue, net	<u>\$ 3,492</u>	<u>\$ 2,595</u>

Astellas Japan Agreement

The Company updates its estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment at each balance sheet date. As a result, the Company recorded a reduction to the drug product revenue of \$2.2 million for the three months ended March 31, 2026. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect changes in the listed price, among others.

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.

As of March 31, 2026, the balances related to the API price true-up under the Astellas Japan Agreement were \$3.8 million in accrued liabilities, representing the Company’s best estimate of the timing for these amounts to be paid. As of December 31, 2025, the balances related to the API price true-up under the Astellas Japan Agreement were \$1.6 million in accrued 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 three months ended March 31, 2026, the Company recorded \$3.3 million in drug product revenue for intermediates under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement, and received cash during the same quarter. Corresponding to the drug product revenue, the Company recorded the related cost of goods sold of \$3.3 million during the three months ended March 31, 2026.

In addition, during the three months ended March 31, 2026, 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 \$0.9 million as drug product revenue, and recorded \$6.2 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 three months ended March 31, 2026, the Company reclassified \$0.5 million from the related deferred revenue to accrued liabilities. As of March 31, 2026, the balances related to the bulk drug product price true-up under the Astellas Europe Agreement and the Astellas EU Supply Agreement were \$1.9 million in accrued liabilities, representing the Company’s best estimate that these amounts will be paid within the next 12 months. As of December 31, 2025, the related balance in accrued liabilities was \$5.4 million, \$3.8 million of which was paid to Astellas in the first quarter of 2026.

The Company recognized royalty revenue of \$1.5 million and \$0.8 million as drug product revenue from the deferred revenue under the Astellas Europe Agreement for the three months ended March 31, 2026 and 2025, 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.

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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, 2025	Additions	Recognized as Revenue	Reclassified to Accrued Liability / Accounts Payable	Balance at March 31, 2026
Drug product revenue - deferred revenue:					
Astellas Europe Agreement	<u>\$ (5,569)</u>	<u>\$ (6,164)</u>	<u>\$ 1,504</u>	<u>\$ 474</u>	<u>\$ (9,755)</u>

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 CD46, a novel epitope 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 the Company 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 the Company up to \$200.0 million in contingent payments associated with the achievement of various regulatory approvals. If the Company 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 the Company chooses not to acquire Fortis, its exclusive license to FG-3246 would expire.

Pursuant to an evaluation agreement entered into with Fortis concurrent with the option agreement (together the “Fortis Agreements”), the Company has exclusively licensed FG-3246 and will control and fund future research, development, including a Phase 2 clinical study sponsored by the Company, and manufacturing of FG-3246 during the option period (which ends on December 31, 2027). As part of the clinical development strategy, the Company will continue the work to develop a PET-based biomarker utilizing a radiolabeled version of the targeting antibody for patient selection.

Pursuant to the guidance under 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 March 31, 2026.

Fortis has authorized and issued common shares and Series A preferred shares. The Company owned approximately 2% of Fortis’ Series A preferred shares, which was acquired prior to the Option Acquisition Date 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 share holders upon occurrence of certain events out of the Company’s control.

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

As of March 31, 2026, total assets and liabilities of Fortis were immaterial. For the three months ended March 31, 2026 and 2025, 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):

	March 31, 2026			
	Level 1	Level 2	Level 3	Total
Money market funds	\$ 34,567	\$ —	\$ —	\$ 34,567
Corporate bonds	—	26,712	—	26,712
Commercial paper	—	4,585	—	4,585
U.S. government bonds	20,989	5,980	—	26,969
Total	<u>\$ 55,556</u>	<u>\$ 37,277</u>	<u>\$ —</u>	<u>\$ 92,833</u>

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Money market funds	\$ 24,302	\$ —	\$ —	\$ 24,302
Corporate bonds	—	27,817	—	27,817
Commercial paper	—	17,797	—	17,797
U.S. government bonds	31,922	4,991	—	36,913
Total	<u>\$ 56,224</u>	<u>\$ 50,605</u>	<u>\$ —</u>	<u>\$ 106,829</u>

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 months ended March 31, 2026 and 2025, a total of \$6.0 million and \$6.5 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):

	March 31, 2026	December 31, 2025
Cash	\$ 2,430	\$ 2,309
Commercial paper	—	11,272
Money market funds	34,567	24,302
U.S. government bonds	—	9,989
Total cash and cash equivalents	<u>\$ 36,997</u>	<u>\$ 47,872</u>

Investments

As of March 31, 2026, the Company's investments consist primarily of available-for-sale debt investments. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's investments by major investments type are summarized in the table below (in thousands):

	March 31, 2026			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Corporate bonds	\$ 26,763	\$ —	\$ (51)	\$ 26,712
Commercial paper	4,585	—	—	4,585
U.S. government bonds	26,986	—	(17)	26,969
Total investments	<u>\$ 58,334</u>	<u>\$ —</u>	<u>\$ (68)</u>	<u>\$ 58,266</u>

	December 31, 2025			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Corporate bonds	\$ 27,800	\$ 17	\$ —	\$ 27,817
Commercial paper	6,525	—	—	6,525
U.S. government bonds	26,903	21	—	26,924
Total investments	<u>\$ 61,228</u>	<u>\$ 38</u>	<u>\$ —</u>	<u>\$ 61,266</u>

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

	March 31, 2026					
	Less than 12 Months		12 Months or More		Total	
	Estimated Fair Value	Gross Unrealized Holding Losses	Estimated Fair Value	Gross Unrealized Holding Losses	Estimated Fair Value	Gross Unrealized Holding Losses
Corporate bonds	\$ 26,712	\$ (51)	\$ —	\$ —	\$ 26,712	\$ (51)
U.S. government bonds	\$ 20,989	\$ (17)	\$ —	\$ —	\$ 20,989	\$ (17)
Total	<u>\$ 47,701</u>	<u>\$ (68)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 47,701</u>	<u>\$ (68)</u>

As of March 31, 2026, the available-for-sale investments had remaining contractual maturities within two years.

The Company periodically assesses whether the unrealized losses on its available-for-sale investments were temporary. The Company considers factors such as the severity and the reason for the decline in value, the potential recovery period and its intent to sell. For debt securities, the Company also considers whether (i) it is more likely than not that the Company will be required to sell the debt securities before recovery of their amortized cost basis, and (ii) the amortized cost basis cannot be recovered as a result of credit losses. Based on the results of its review, the Company did not recognize any credit related losses or other impairment loss during the three months ended March 31, 2026 and 2025.

Prepaid Expenses and Other Current Assets

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

	March 31, 2026	December 31, 2025
Holdback consideration receivable related to divestiture	\$ 4,000	\$ 4,000
Prepaid assets	1,138	1,015
Other current assets	556	1,121
Total prepaid expenses and other current assets	<u>\$ 5,694</u>	<u>\$ 6,136</u>

As of March 31, 2026 and December 31, 2025, the Company recorded a \$4.0 million receivable in prepaid expenses and other current assets for the holdbacks related to the closing of the divestiture of FibroGen International. See Note 2, *Discontinued Operations and Divestiture*, for details.

Accrued and Other Current Liabilities

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

	March 31, 2026	December 31, 2025
Preclinical and clinical trial accruals	\$ 3,003	\$ 3,066
API and bulk drug product price true-up	5,716	6,977
Payroll and related accruals	1,477	3,983
Accrued restructuring charge	368	537
Professional services	4,125	2,465
Current portion of liability related to sale of future revenues	937	1,334
Other	1,714	1,821
Total accrued and other current liabilities	<u>\$ 17,340</u>	<u>\$ 20,183</u>

The accrued liabilities of \$5.7 million and \$7.0 million for API and bulk drug product price true-up as of March 31, 2026 and December 31, 2025, 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.

7. Senior Secured Term Loan Facilities

In April 2023, the Company entered into a financing agreement (“Financing Agreement”) with investment funds managed by MSTV, as lenders (the “Lenders”), and Wilmington Trust, National Association, as the administrative agent, providing for senior secured term loan facilities, and received \$74.1 million, representing a \$75.0 million initial term loan (the “Initial Term Loan”), net of \$0.9 million issuance costs.

The Initial Term Loan accrued interest at a fixed rate of 14.0% per annum, payable monthly in arrears. The Initial Term Loan would mature on May 8, 2026. The Initial Term Loan was subject to amortization payments. The Company was permitted to prepay the Initial Term Loan 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 Initial Term Loan being repaid or prepaid, plus accrued and unpaid interest of the portion of the Initial Term Loan being repaid or prepaid, plus an amount equal to the remaining scheduled interest payments due on such portion of the Initial Term Loan being repaid or prepaid as if such Initial Term Loan were to remain outstanding until the scheduled maturity date.

On August 29, 2025, upon the closing of the divestiture FibroGen International, the Company paid the Lenders a total of \$80.9 million, including \$75.0 million for paying off the senior secured term loan facilities, \$0.4 million for outstanding interest and \$5.5 million for related premium and fees.

The effective annual interest rate of the Initial Term Loan was 16.13% for the three months ended March 31, 2025. The Company recorded interest expense of \$3.0 million for the three months ended March 31, 2025, which was included in discontinued operations as the Company was required to repay the loan upon the closing of the divestiture of FibroGen International.

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. 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.

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 15.19% as of March 31, 2026.

The following table summarizes the activities of the liability related to sale of future revenues for the three months ended March 31, 2026:

	Three Months Ended March 31, 2026
Liability related to sale of future revenues - beginning balance	\$ 67,314
Interest paid	(1,316)
Interest expense recognized	2,344
Liability related to sale of future revenues - ending balance	68,342
Less: Current portion classified to accrued and other current liabilities	(937)
Liability related to sale of future revenues, non-current	<u>\$ 67,405</u>

During the three months ended March 31, 2026 and 2025, the Company recognized, under Astellas Agreements, development revenue of \$0.2 million and \$0.1 million, respectively, and drug product revenue of \$3.5 million and \$2.6 million, respectively. See Note 3, *Collaboration Agreements, License Agreement and Revenue*, for details.

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During the three months ended March 31, 2026 and 2025, the Company recognized the related interest expense of \$2.3 million and \$2.2 million, respectively. During the three months ended March 31, 2026 and 2025, the Company paid \$1.3 million and \$0.5 million accrued interest, respectively.

9. Income Taxes

Provision for income taxes for the three months ended March 31, 2026 and 2025 were immaterial.

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

10. Commitments and Contingencies

Contract Obligations

As of March 31, 2026, the Company had outstanding total non-cancelable purchase obligations of \$1.5 million for manufacture and supply of roxadustat and \$1.1 million for general purchases. 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 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, in its condensed consolidated balance sheet as of March 31, 2026.

Between April 2021 and May 2021, five putative securities class action complaints were filed against the Company and certain of its former executive officers in the U.S. District Court for the Northern District of California. On October 17, 2023, the parties reached an agreement in principle to settle the class action at \$28.5 million. The Court approved the settlement Plan of Allocation on May 28, 2024 and Plaintiffs' motion for attorney's fees on August 1, 2024. The court entered a class distribution order on January 1, 2025 and the amount was fully distributed during the first quarter of 2025. The settlement was fully covered by insurance.

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. 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. In September 2025, the agreement was approved by the Commission and the Company has been making payments to the agreed upon payment schedule.

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 derivative and securities class action lawsuits. The litigation demands have been withdrawn.

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 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.

There is currently one SEC complaint against the Company's former Chief Medical Officer in U.S. District Court. While the Company is not a party to this proceeding, pursuant to its indemnification agreement with the former officer, the Company is obligated to advance certain legal expenses and may be required to indemnify certain costs and judgments; however, certain judgments, settlements, or fines sought by the SEC would not be covered by the Company under the indemnification agreement.

As of March 31, 2026, the Company's accrued liabilities related to these obligations were not material. The Company is unable to reasonably estimate the total amount of future indemnification costs beyond amounts currently accrued due to the early stage of the litigation and significant uncertainties regarding the duration, scope, and outcome of the proceedings.

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 expenses 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 expense, interest income 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.

12. Subsequent Event

The Company's subsidiary, FibroGen Europe Oy ("FibroGen Europe"), has product development obligations to the Technology Development Center of the Republic of Finland ("TEKES"), which consist of 11 separate advances (each in the form of a note agreement) received by FibroGen Europe between 1996 and 2008 from TEKES ("TEKES loans"). These advances were granted on a project-by-project basis to fund various product development efforts undertaken by FibroGen Europe only. Kyntra Bio, Inc. is not a guarantor of these loans and they are non-recourse to Kyntra Bio, Inc. The principal or the accrued interest of these loans are not repayable by FibroGen Europe until it has distributable funds.

FibroGen Europe voluntarily submitted for bankruptcy to the Finnish bankruptcy court in April 2026. FibroGen Europe was declared bankrupt by a decision of the Helsinki District Court on April 16, 2026 and the court has appointed an estate administrator of the bankruptcy estate.

As of March 31, 2026 and December 31, 2025, the Company had U.S. Dollar equivalent of \$10.9 million and \$11.1 million of principal outstanding, respectively, and \$8.4 million and \$8.5 million of interest accrued, respectively, which were presented in the product development obligations line on the condensed consolidated balance sheets.

While the Company expects the above-mentioned bankruptcy process to result in an eventual relief of the TEKES loans, the definitive timing and the ultimate outcome of such debt relief remain uncertain. At this time, the Company cannot reasonably estimate the related financial effect on its consolidated financial position or results of operations.

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, 2025 filed with the SEC on March 16, 2026 (“2025 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

Kyntra Bio, Inc. (“Kyntra Bio” or “we”) is a biopharmaceutical company focused on development of novel therapies in oncology and rare disease.

In January 2026, we announced our rebranding from “FibroGen, Inc.” to “Kyntra Bio, Inc.,” representing the next step of our transformation and focus on oncology and rare disease assets. On January 8, 2026, our common stock began trading under the new Nasdaq symbol “KYNB.”

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 initiated a Phase 2 monotherapy dose optimization study of FG-3246 for the treatment of mCRPC, along with the exploratory sub-study of FG-3180, in the third quarter of 2025.

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

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On August 29, 2025, we closed the sale of our China operations through FibroGen International (Hong Kong) Ltd. (“FibroGen International”) to AstraZeneca Treasury Limited pursuant to the share purchase agreement entered into with AstraZeneca Treasury Limited on February 20, 2025, as amended (the “Share Purchase Agreement”) for a total consideration of \$220.4 million comprised of \$85.0 million in enterprise value and \$135.4 million in net cash held in China. AstraZeneca AB (“AstraZeneca”) was our long-time commercialization partner for roxadustat in greater China. This sale included 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”).

Kyntra Bio 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”). 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 advance 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, including the starting dose and the patient inclusion criteria. We are starting preparations for the Phase 3 trial, while evaluating internal development and potential partnership opportunities for this late-stage program. We are now finalizing the Phase 3 trial protocol for roxadustat for the treatment of anemia in patients with lower-risk MDS and high transfusion burden after receiving further comments from the FDA.

The FDA granted roxadustat Orphan Drug Designation for the treatment of MDS in December 2025.

Financial Highlights

	Three Months Ended March 31,	
	2026	2025
	(in thousands, except for per share data)	
Result of Operations		
Revenue	\$ 3,738	\$ 2,739
Operating costs and expenses	17,556	17,659
Loss from continuing operations	(15,132)	(16,766)
Loss from continuing operations per share - basic and diluted	\$ (3.74)	\$ (4.15)
	March 31, 2026	December 31, 2025
	(in thousands)	
Balance Sheet		
Cash and cash equivalents	\$ 36,997	\$ 47,872
Short-term investments	50,240	41,106
Accounts receivable	5,040	216
Long-term investments	\$ 8,026	\$ 20,160

Our revenue for the three months ended March 31, 2026 and 2025 primarily included \$3.5 million and \$2.6 million, respectively, of drug product revenue from commercial-grade active pharmaceutical ingredient (“API”) or bulk drug product sales to Astellas.

Operating costs and expenses for the three months ended March 31, 2026 remained relatively flat compared to the same period a year ago primarily as a result of the net effect of the following, respectively:

- \$1.4 million lower employee-related expenses primarily due to reduced headcount;
- \$1.4 million lower equipment and facilities-related expenses due to cost control efforts;
- \$1.3 million lower stock-based compensation primarily resulting from lower stock price and reduced headcount; and
- \$3.9 million higher cost of goods sold recorded during the three months ended March 31, 2026 corresponding to the drug product revenue.

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For the three months ended March 31, 2026, we had a loss from continuing operations of \$15.1 million, or a loss per basic and diluted share of \$3.74, as compared to a loss of \$16.8 million, or a loss per basic and diluted share of \$4.15, for the same period a year ago, primarily due to the increase in revenue as discussed above.

Cash and cash equivalents, investments and accounts receivable totaled \$100.3 million at March 31, 2026, a decrease of \$9.1 million from December 31, 2025, primarily due to the cash used 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 mCRPC

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. In any given year, there are approximately 65,000 drug treatable mCRPC cases in the U.S. across the various lines of therapy, 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 in the castration sensitive phase. Androgen receptor signaling inhibitors or androgen receptor pathway inhibitors ("ARSI" / "ARPIs," often used interchangeably) and chemotherapy are the preferred treatments in patients who have not been exposed to either in earlier lines of therapy. Most patients who previously progressed on an ARPI will subsequently receive chemotherapy. Switching to another ARPIs is another option for these patients but this approach is generally associated with suboptimal outcomes.

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

The recent approval of prostate-specific membrane antigen ("PSMA")-targeted radiopharmaceutical Pluvicto (lutetium Lu 177 vipivotide tetraxetan) in the post-ARPI and pre-chemotherapy setting has diversified treatment options in first and second line mCRPC for PSMA positive patients. 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.

Kyntra Bio is developing FG-3246 in the post-ARPI, pre-chemotherapy mCRPC setting. This is an area of high unmet need, where radiographic progression free survival is short: Approximately 5-6 months after switching to a different ARPI, approximately 8 months with chemotherapy, and 9.3 months with Pluvicto in PSMA-positive patients, who are considered appropriate to delay taxane-based 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.

Phase 2 Monotherapy Clinical Trial of FG-3246 and FG-3180 for the Treatment of mCRPC

We are developing FG-3246 in mCRPC. FG-3246 is a potential first-in-class ADC targeting CD46, a novel epitope expressed on the surface of prostate and other cancer cells. 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 are actively enrolling our Phase 2 monotherapy dose optimization study of FG-3246 for the treatment of patients with mCRPC in the post-ARPI and pre-chemotherapy setting, with interim results expected in the fourth quarter of 2026.

The trial is also assessing the diagnostic and predictive performance of FG-3180, a companion PET imaging agent, which shares the same CD46-targeted antibody used in FG-3246. The ability of FG-3180 to identify mCRPC lesions and predict response to FG-3246 is being evaluated.

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Our ongoing Phase 2 monotherapy trial ([NCT06842498](#)) is a randomized, open label, dose optimization trial designed to evaluate the safety, efficacy, tolerability, and pharmacokinetics (PK) of FG-3246 for the treatment of patients with mCRPC who have progressed following ARPI treatment and who have not received chemotherapy for their mCRPC. The trial is scheduled to enroll 75 patients who will be randomized 1:1:1 to receive either 1.8, 2.4 or 2.7 mg/kg AJBW of FG-3246. The primary endpoint of the trial is the determination of the optimal dose for the Phase 3 trial based on efficacy, safety, and PK parameters. Secondary endpoints include radiographic progression-free survival (“rPFS”), prostate-specific antigen (“PSA”) 50 response, and PSA90 response. An interim analysis, made up of a composite response rate of PSA50 response and overall response rate, is currently planned once 12 patients enrolled in each of the three dose arms have completed up to 12 weeks on study or discontinued and is anticipated in the fourth quarter of 2026.

An exploratory sub-study will evaluate FG-3180, a companion PET imaging agent, as a diagnostic radiopharmaceutical. All patients deemed eligible for participation in the Phase 2 trial will participate in the sub-study evaluating FG-3180 prior to randomization.

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

In March 2025, Kyntra Bio 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 Clinical 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 mCRPC. 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 February 2026, the University of California, San Francisco (“UCSF”) presented positive results from the investigator-sponsored Phase 1b/2 study of FG-3246 in combination with enzalutamide in patients with mCRPC at the 2026 American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU). The presentation includes data from 44 biomarker unselected patients with progressive mCRPC, 17 of which were enrolled in the Phase 1b dose escalation portion of the study with 27 enrolled in the dose expansion phase of the study. Eligibility criteria for the trial included patients who progressed on at least one prior ARPI while patients who were treated with prior chemotherapy in the castration-resistant setting were excluded. Over 60% of the patients progressed on two or more prior ARPIs prior to enrollment, which included prior enzalutamide treatment. The primary endpoint of the escalation phase was assessment of dose-limiting toxicities (“DLT”) and determination of the maximum tolerated dose and recommended dose for the Phase 2 portion of the study – which was determined to be 2.1 mg/kg of FG-3246 and 160mg/day of enzalutamide. The primary endpoint of the Phase 2 expansion portion of the study was composite response rate (PSA50 response and/or objective response per RECIST v1.1). Secondary endpoints were PSA50 response rate, objective response rate, rPFS, overall survival, and treatment-related adverse events (“TRAEs”).

FG-3246 combined with enzalutamide demonstrated anti-tumor activity with a composite response rate of 21% in the overall cohort and 40% in patients who had progressed on only one prior ARPI. Median rPFS of 7.0 months was observed in the overall cohort. Notably, median rPFS of 10.1 months was observed in patients who had progressed on only one prior ARPI, a result which was consistent across the different prior ARPIs administered.

Additionally, in an exploratory analysis, tumor uptake of FG-3180 (our CD46-targeting PET imaging agent) was numerically associated with PSA50 response (nominal $p=0.053$), highlighting its potential as a biomarker for patient selection.

Combination therapy of FG-3246 and enzalutamide demonstrated a similar safety profile as was observed in the previous Phase 1 monotherapy trial of FG-3246. Neutropenia risk was successfully mitigated with use of granulocyte colony-stimulating factor (“G-CSF”) prophylaxis.

The most frequent TRAEs with the combination therapy included fatigue, peripheral neuropathy, anorexia, and dysgeusia. Cumulative toxicities, including peripheral neuropathy, led to treatment discontinuation for some patients.

ROXADUSTAT IN ANEMIA ASSOCIATED WITH MDS

Disease Overview

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 MDS

Stem cell transplantation 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 (“RBC”) 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 RBC 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, 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 lower-risk MDS.

Market Opportunity for Roxadustat in MDS

We believe there is a significant need for a safe and convenient option to address anemia in patients with lower-risk MDS that is effective agnostic of ring sideroblast status. Roxadustat, our orally administered small molecule hypoxia-inducible factor prolyl hydroxylase inhibitor, stimulates the body’s natural mechanism of RBC 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 RBC 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 lower-risk 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 lower-risk MDS anemia patients, where it is not uncommon for patients to present with autoimmune and inflammatory conditions.

According to Grand View Research, the global MDS market was estimated at approximately \$3 billion in 2023 and is projected to reach approximately \$5 billion by 2030 (approximately 9% CAGR from 2024 to 2030), attributed primarily to the rise in novel therapeutics.

Roxadustat in MDS Clinical Trials

We maintain our rights to roxadustat in the U.S., Canada, Mexico and in all markets not licensed to Astellas or held by AstraZeneca.

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, including the starting dose and the patient inclusion criteria.

We are advancing preparations for the Phase 3 trial, while evaluating internal development and potential partnership opportunities for this late-stage program. We are now finalizing the Phase 3 trial protocol for roxadustat for the treatment of anemia in patients with lower-risk MDS and high transfusion burden after receiving further comments from the FDA.

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The FDA granted roxadustat Orphan Drug Designation for the treatment of MDS in December 2025. If roxadustat is approved for lower-risk MDS, Orphan Drug Designation would provide seven years regulatory exclusivity for roxadustat in lower-risk MDS in the U.S., along with additional economic and other benefits associated with Orphan Drug Designation.

The Phase 3 trial is planned to assess the safety and efficacy of roxadustat in a randomized, double-blind, placebo-controlled design in approximately 200 patients with lower-risk MDS. Alignment was reached with the FDA on the patient population (patients requiring ≥ 4 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. For the primary endpoint of RBC transfusion independence, we are considering independence over either an 8-week period or 16-week period.

Phase 2/3 Clinical Trial in MDS

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.

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 CKD

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

China – Roxadustat Commercial Program

On August 29, 2025, we closed the sale of our China operations through FibroGen International to AstraZeneca Treasury Limited pursuant to the Share Purchase Agreement for a total consideration of \$220.4 million, comprised of \$85.0 million in enterprise value and \$135.4 million in net cash held in China. This sale included all of our roxadustat assets in China, including FibroGen International's subsidiary FibroGen Beijing and its 51.1% interest in Falikang. For additional details, refer to Note 2, *Discontinued Operations and Divestiture*, to the condensed consolidated financial statements.

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

Kyntra Bio has retained the rights to roxadustat in the U.S., Canada, Mexico, and in all markets not held by AstraZeneca or licensed to Astellas.

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 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, FOR46 (now referred to as “FG-3246”) that targets CD46, a novel epitope 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, Kyntra Bio has exclusively licensed FG-3246 and will control and fund future research and development, including a Phase 2 clinical study sponsored by Kyntra Bio, and manufacturing of FG-3246 during the option period (which ends on December 31, 2027). 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.

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If we exercise the option to acquire Fortis, we will pay Fortis \$80.0 million, and thereafter, Fortis would be eligible to receive from Kyntra Bio 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 Kyntra Bio 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 to Eluminex

In April 2023, we entered into an Amended and Restated Exclusive License Agreement with Eluminex (“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).

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 the Europe Agreement with Astellas for roxadustat for the treatment of anemia in Europe, the Commonwealth of Independent States, the Middle East, and South Africa (“Astellas Europe Agreement”). Under these agreements, the aggregate amount of consideration received through March 31, 2026 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 (\$2.2) million and \$1.8 million for the three months ended March 31, 2026 and 2025, 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 us in support of commercial supplies (the “Astellas EU Supply Agreement”). The related drug product revenue was \$5.7 million and \$0.8 million for the three months ended March 31, 2026 and 2025, 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 us in support of commercial supplies.

In February 2024, we entered into an agreement to terminate the AstraZeneca U.S./RoW Agreement with AstraZeneca, as amended and restated on August 29, 2025. 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.

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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”). On August 29, 2025, we closed the sale of our China operations through FibroGen International to AstraZeneca Treasury Limited pursuant to the Share Purchase Agreement. For additional details, refer to Note 2, *Discontinued Operations and Divestiture*, to the condensed consolidated financial statements. Under the AstraZeneca China Agreement, the aggregate amount of consideration received through the sale of our China operations totaled \$81.2 million.

In July 2020, FibroGen China 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”). Accordingly, 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 accounted for our investment in Falikang under the equity method, and Falikang was not consolidated into our consolidated financial statements. Our proportionate share of the reported profits or losses of Falikang, was included in the discontinued operations in the condensed consolidated statement of operations. See Note 2, *Discontinued Operations and Divestiture*, to the condensed consolidated financial statements for details.

Product revenue, net, was \$39.8 million for the three months ended March 31, 2025, majority of which were from the sales to Falikang, and was included in the discontinued operations. As discussed in Note 2, *Discontinued Operations and Divestiture*, to the condensed consolidated financial statements, the divestiture of FibroGen International was completed on August 29, 2025 and accordingly, the performance obligation to AstraZeneca was completely satisfied upon the closing of the divestiture.

RESULTS OF OPERATIONS

Revenue

	Three Months Ended March 31,		Change	
	2026	2025	\$	%
	(dollars in thousands)			
Revenue:				
Development and other revenue	\$ 246	\$ 144	\$ 102	71 %
Drug product revenue, net	3,492	2,595	897	35 %
Total revenue	\$ 3,738	\$ 2,739	\$ 999	36 %

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 March 31, 2026, we do not expect to incur significant future co-development services. 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 Astellas in support of pre-commercial preparation prior to the new drug application or marketing authorization application approval, and for ongoing commercial launch in Japan and Europe. We recognize drug product revenue when we fulfill the inventory transfer obligations. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the drug product revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period when the uncertainty associated with the variable consideration is subsequently resolved. Actual amounts of consideration ultimately received in the future may differ from our estimates, for which we will adjust these estimates and affect the drug product revenue in the period such variances become known.

In the future, we will continue generating revenue from collaboration agreements in the form of 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 \$1.0 million, or 36%, for the three months ended March 31, 2026, compared to the same period a year ago for the reasons discussed in the sections below.

Drug Product Revenue, Net

	Three Months Ended March 31,		Change	
	2026	2025	\$	%
	(dollars in thousands)			
Drug product revenue, net:				
Astellas Japan Agreement	\$ (2,191)	\$ 1,781	\$ (3,972)	(223) %
Astellas Europe Agreement	5,683	814	4,869	598 %
Total drug product revenue, net:	<u>\$ 3,492</u>	<u>\$ 2,595</u>	<u>\$ 897</u>	35 %

Drug product revenue, net increased \$0.9 million, or 35%, for the three months ended March 31, 2026, compared to the same period a year ago.

Astellas Japan Agreement

During the first quarter of 2026, 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 changes in the listed price, among others.

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.

As of March 31, 2026, the balances related to the API price true-up under the Astellas Japan Agreement were \$3.8 million in accrued liabilities, representing our best estimate of the timing for these amounts to be paid.

Astellas Europe Agreement

During the first quarter of 2026, we recorded \$3.3 million to the drug product revenue for intermediates under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement, and received cash during the same quarter. In addition, we 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 \$0.9 million as drug product revenue, and recorded \$6.2 million as deferred revenue due to a high degree of uncertainty associated with the variable consideration for revenue recognition purposes. In addition, we updated our estimate of variable consideration related to the bulk drug product transferred in prior years. Specifically, the change in estimated variable consideration was based on the bulk drug product held by Astellas at the period end, adjusted to reflect the changes in the estimated transfer price, forecast information, shelf-life estimates and other items. As a result, for the three months ended March 31, 2026, we reclassified \$0.5 million from the related deferred revenue to accrued liabilities. As of March 31, 2026, the balances related to the bulk drug product price true-up under the Astellas Europe Agreement and the Astellas EU Supply Agreement were \$1.9 million in accrued liabilities, representing our best estimate that these amounts will be paid within the next 12 month. As of December 31, 2025, we recorded \$5.4 million related balance in accrued liabilities, \$3.8 million of which was paid to Astellas in the first quarter of 2026.

We recognized royalty revenue as drug product revenue, from the deferred revenue under the Astellas Europe Agreement, of \$1.5 million and \$0.8 million for the three months ended March 31, 2026 and 2025, 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.

Operating Costs and Expenses

	Three Months Ended March 31,		Change	
	2026	2025	\$	%
	(dollars in thousands)			
Operating costs and expenses				
Cost of goods sold	\$ 4,106	\$ 252	\$ 3,854	1,529 %
Research and development	7,566	9,175	(1,609)	(18) %
Selling, general and administrative	5,862	8,106	(2,244)	(28) %
Restructuring charge	22	126	(104)	(83) %
Total operating costs and expenses	<u>\$ 17,556</u>	<u>\$ 17,659</u>	<u>\$ (103)</u>	<u>(1) %</u>

Total operating costs and expenses decreased \$0.1 million, or 1%, for the three months ended March 31, 2026, compared to the same period a year ago for the reasons discussed in the sections below.

Cost of Goods Sold

Cost of goods sold increased \$3.9 million, or 1,529%, for the three months ended March 31, 2026, compared to the same period a year ago, primarily due to the cost associated with the intermediates drug product revenue of \$3.3 million and the costs of bulk drug product delivered to Astellas of \$0.9 million during the three months ended March 31, 2026.

Research and Development Expenses

Research and development expenses consist of independent research and development costs and the gross 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 months ended March 31, 2026 and 2025:

Product Candidate	Phase of Development	Three Months Ended March 31,	
		2026	2025
		(in thousands)	
FG-3246	Phase 2	\$ 4,323	\$ 5,270
Roxadustat	Approved / Phase 3	2,642	457
Other research and development expenses		601	3,448
Total research and development expenses		<u>\$ 7,566</u>	<u>\$ 9,175</u>

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 \$1.6 million, or 18%, for the three months ended March 31, 2026, compared to the same period a year ago, primarily as a result of the net effect of the following:

- Decrease of \$1.1 million employee-related costs primarily due to lower headcount;
- Decrease of \$0.7 million in stock-based compensation primarily resulting from lower stock price and reduced headcount; and
- Increase of \$1.1 million in outside services due to higher activities associated with FG-3246 studies in the current year period, as compared to activities related to pamrevlumab programs, which were completed and terminated in the prior year period.

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 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 \$2.2 million, or 28%, for the three months ended March 31, 2026, compared to the same period a year ago, primarily as a result of the net effect of the following, respectively:

- Decrease of \$1.1 million in equipment and facilities-related expenses due to cost control efforts; and
- Decrease of \$0.6 million in stock-based compensation primarily resulting from lower stock price and reduced headcount.

Interest and Other, Net

	Three Months Ended March 31,		Change	
	2026	2025	\$	%
	(dollars in thousands)			
Interest and other, net:				
Interest expense	\$ (2,427)	\$ (2,257)	\$ (170)	8 %
Interest income and other income (expenses), net	1,113	413	700	169 %
Total interest and other, net	<u>\$ (1,314)</u>	<u>\$ (1,844)</u>	<u>\$ 530</u>	<u>(29) %</u>

Interest Expense

Interest expense represents the 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 months ended March 31, 2026, compared to the same period 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 increased \$0.7 million, or 169%, for the three months ended March 31, 2026, compared to the same period a year ago, primarily due to higher interest income resulting from overall higher cash equivalents and investment balances during the current year periods.

Income Taxes

	Three Months Ended March 31,	
	2026	2025
	(dollars in thousands)	
Loss from continuing operations before income taxes	\$ (15,132)	\$ (16,764)
Provision for income taxes	—	2
Effective tax rate	— %	— %

Provision for income taxes for the three months ended March 31, 2026 and 2025 were immaterial.

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.

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. 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 was closed on August 29, 2025.

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 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 and Divestiture*, to the condensed consolidated financial statements for details.

LIQUIDITY AND CAPITAL RESOURCES

Financial Condition

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

Upon the close of the sale of FibroGen International and its subsidiaries to AstraZeneca Treasury Limited on August 29, 2025, we received \$210.4 million in cash paid at closing, and a total of \$10.0 million cash payable by AstraZeneca at the closing subject to holdbacks of: (i) a \$6.0 million holdback to offset final net cash adjustments which will be released following a customary adjustment process approximately 90 days post-closing (as such time may be extended for the parties to mutually agree upon final adjustments), and (ii) a \$4.0 million holdback to satisfy any indemnity claims, which will be released, net of any claims paid or unresolved, nine months after the closing. On November 6, 2025, we received a \$6.4 million payment from AstraZeneca, which is in full satisfaction of the first holdback of \$6.0 million, plus \$0.4 million that was an additional payment following the final net cash adjustments after closing. See Note 2, *Discontinued Operations and Divestiture*, to the condensed consolidated financial statements for details.

In April 2023, we entered into the Financing Agreement with investment funds managed by MSTV (“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. Upon the closing of the sale of FibroGen International and its subsidiaries to AstraZeneca Treasury Limited on August 29, 2025, we repaid our term loan facility with the Lenders. For additional details about this financing transaction, see Note 7, *Senior Secured Term Loan Facilities*, to the condensed consolidated financial statements.

In November 2022, we entered into a Revenue Interest Financing Agreement (“RIFA”) with an affiliate of 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.

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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 to date.

As previously disclosed, in April 2026, we received a letter from the Nasdaq Listing Qualifications Staff of the Nasdaq Stock Market notifying us that Kyntra Bio no longer complies with the Nasdaq Global Select Market continued listing requirement of \$50 million in total assets and total revenue for the most recently completed fiscal year (or two of the last three most recently completed fiscal years) per Listing Rule 5450(b)(3)(A). This is due to the revenue of FibroGen International being presented as held for sale (in discontinued operations) in our 2024 and 2025 10-Ks. The notification has no immediate effect on the listing of Kyntra Bio's common stock on Nasdaq Global Select Market.

Kyntra Bio intends to timely submit a compliance plan to Nasdaq. Kyntra Bio may also consider applying to transfer our securities to the Nasdaq Capital Market. If we are unable to maintain compliance or transfer and regain compliance, our common stock could become subject to delisting, which could adversely affect share price, liquidity, and ability to raise capital.

Cash and cash equivalents, investments and accounts receivable totaled \$100.3 million at March 31, 2026, compared to \$109.4 million as of December 31, 2025. Cash is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting of available-for-sale securities, and stated at fair value, are also available as a source of liquidity.

Our liquidity is subject to specific risks, including: (i) indemnification obligations to current and former officers and directors, which may require us to advance legal expenses or satisfy judgments or settlements that are not fully covered by insurance, as our insurance policies are subject to exclusions, coverage limits, and potential disputes with insurers; and (ii) our obligations under the RIFA with NovaQuest, pursuant to which we may be required to make substantial payments if the revenue interest payments do not perform sufficiently, including potential balloon payments in 2029 and 2031, which could place significant demands on our cash resources relative to our current liquidity position. There can be no assurance that our cash resources will be sufficient to satisfy these obligations, and we may be required to seek additional financing.

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:

	Three Months Ended March 31,	
	2026	2025
Net cash provided by (used in):		
Operating activities	\$ (13,887)	\$ 2,719
Investing activities	3,018	(16)
Financing activities	(7)	(88)
Effect of exchange rate changes on cash and cash equivalents	1	1,407
Net increase (decrease) in cash and cash equivalents	<u>\$ (10,875)</u>	<u>\$ 4,022</u>

Operating Activities

Net cash used in operating activities was \$13.9 million for the three months ended March 31, 2026 and consisted primarily of net loss of \$15.2 million adjusted for non-operating cash items of \$1.0 million, and a net increase in operating assets and liabilities of \$0.3 million. The significant non-operating cash items included stock-based compensation expense of \$1.2 million. The significant items in the changes in operating assets and liabilities included the following:

- Deferred revenue increased \$4.2 million, driven by \$6.2 million 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 first quarter of 2026; partially offset by \$1.5 million royalty revenue recognized, and \$0.5 million reclassified to accrued liabilities, resulting from changes in estimated variable consideration associated with the bulk drug product transferred to Astellas. See the *Drug Product Revenue, Net* section in Note 3, *Collaboration Agreements, License Agreement and Revenues*, to the condensed consolidated financial statements for details;
- Accounts payable increased \$1.3 million driven by timing of invoicing and payments.

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- Accrued interest expense related to sale of future revenues increased \$1.0 million due to the interest expense of \$2.3 million accrued, offset by the interest payment of \$1.3 million during the period. See Note 8, *Liability Related to Sale of Future Revenues*, to the condensed consolidated financial statements for details.
- Accounts receivable increased \$4.8 million driven by the billing to Astellas for the bulk drug product transferred during the first quarter of 2026; and
- Accrued and other liabilities decreased \$2.5 million, driven by the bonus payment during the quarter.

Net cash provided by operating activities was \$2.7 million for the three months ended March 31, 2025 and consisted primarily of net income of \$4.6 million adjusted for non-operating cash items of \$3.7 million, and a net decrease in operating assets and liabilities of \$5.7 million. The significant non-operating cash items included stock-based compensation expense of \$2.9 million. The significant items in the changes in operating assets and liabilities included the following:

- Accrued and other liabilities decreased \$31.7 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, and bonus and severance payouts totaling \$5.1 million during the quarter. The accrued and other liabilities were also impacted by cost control efforts and the timing of invoicing and payment;
- Accounts payable decreased \$24.8 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;
- Deferred revenue decreased \$4.1 million, primarily related to the reclassification of \$2.1 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 year. In addition, the decrease in deferred revenue was also related to the \$1.3 million product revenue recognized, which is included in the discontinued operations, from the previously deferred revenue of the China performance obligation during the quarter;
- Accounts receivable increased \$3.2 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;
- Prepaid expenses and other current assets decreased \$52.6 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 settlement agreements between FibroGen China and AstraZeneca to settle certain historical items, which was unbilled receivables as of December 31, 2024;
- Inventory decreased \$2.9 million primarily driven by lower inventory production in China as we have decommissioned our API manufacturing facility in Cangzhou, China in late 2024; and
- Accrued interest expense related to sale of future revenues increased \$1.7 million due to the interest expense of \$2.2 million accrued, offset by the interest paid, during the quarter.

Investing Activities

Investing activities primarily consist of purchases of investments, proceeds from the maturity and sale of investments, and net proceeds from divestiture.

Net cash provided by investing activities was \$3.0 million for the three months ended March 31, 2026 and consisted primarily of \$14.1 million proceeds from maturity of investments; partially offset by \$11.1 million cash used in purchases of available-for-sale securities.

Net cash used in investing activities was immaterial for the three months ended March 31, 2025.

Financing Activities

Financing activities primarily reflect proceeds from strategic financing arrangements, cash paid to shareholders and 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 three months ended March 31, 2026 and 2025, respectively.

Material Cash Requirements

We generate revenue from commercial sales of roxadustat product in Japan and Europe. Even with these revenues, we anticipate that we will continue to generate losses for the foreseeable future. To date, we have funded certain portions of our research and development and manufacturing efforts globally through collaboration partners, debt financings, and equity financing. We expect to continue to incur significant research and development expenses to invest in our development 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.

Commitments and Contingencies

Contractual Obligations

As of March 31, 2026, we had outstanding total non-cancelable purchase obligations of \$1.5 million for manufacture and supply of roxadustat and \$1.1 million for general purchases, 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 RIFA with NovaQuest, as of March 31, 2026, we had \$68.3 million of liability related to sale of future revenues in the condensed consolidated balance sheets, \$0.9 million of which we anticipate to pay within the next 12 month. Based on our current estimates of drug product revenue and revenue from milestone payments under the Astellas Agreements, and taking into the consideration of the terms under the RIFA, we anticipate to reach a payment cap up to \$125.0 million by 2031. See Note 8, *Liability Related to Sale of Future Revenues*, to the condensed consolidated financial statements for details.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

There have been no material changes in our critical accounting policies, estimates and judgments during the three months ended March 31, 2026 compared with the disclosures in Part II, Item 7 of our 2025 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 March 31, 2026, 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 March 31, 2026.

Changes in Internal Control over Financial Reporting

During the quarter ended March 31, 2026, we completed the implementation of an enterprise resource planning ("ERP") system, with which we expect to improve the efficiency of certain financial and transactional processes. As a result, we have updated the design and documentation of internal controls, processes and procedures, which occurred following the ERP implementation to ensure we continue to maintain effective internal control over financial reporting.

Except as described in the previous paragraph, 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 March 31, 2026 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 March 31, 2026, 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, 2025, filed on March 16, 2026.

SUMMARY RISK FACTORS

The success of Kyntra Bio 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 PET (as defined below) 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 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 could 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.

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- 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 U.S., and we may encounter significant problems in securing and defending our intellectual property rights outside the U.S.

Risks Related to Government Regulation

- The regulatory approval process is highly uncertain and we may not obtain regulatory approval for our product candidates.
- Our current and future relationships with customers, physicians, and third-party payors are subject to healthcare fraud and abuse laws, false claims laws, transparency laws, and other regulations. If we are unable to comply with such laws, we could face substantial penalties.
- We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, 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.

International Risks

- Within the next year, we may face costs from the wind-up of the Cayman Subsidiary (as defined below), and may not receive some of the AZ Holdbacks (as defined below) related to the sale of FibroGen International and its subsidiaries.
- Changes in U.S. and China relations, as well as relations with other countries, and/or regulations may adversely impact our business.
- We depend on third party suppliers in China, and there are risks inherent to utilizing third party manufacturing facilities.
- 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.

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 PET (as defined below) imaging agent FG-3180).

The future value drivers for Kyntra Bio, Inc. (“Kyntra Bio” or the “Company”) depend in large part on the continued commercial success of roxadustat in Europe and Japan, the potential of roxadustat for anemia associated with lower-risk myelodysplastic syndromes (“MDS”), and the development of FG-3246 (in conjunction with our positron emission tomography (“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 partner for roxadustat may influence development decisions in their respective territories and they may make decisions with respect to development or regulatory authorities that limit or increase the cost of development. Accordingly, we may be unable to successfully develop 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;
- 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 or delay in approval of one of our clinical trial investigational new drug applications or protocol or protocol amendments (in particular, due to a government shutdown or other factor outside of our control);
- 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 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.

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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 narrower 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 Kyntra Bio 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;

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- 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;

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- 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 a license to proprietary starting materials.

Kyntra Bio 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 narrower 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 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 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.

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, particularly for the prostate cancer market. 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 Kyntra Bio 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 could 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 for the 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) could be delayed.

We have active collaboration agreements with respect to the development and commercialization of roxadustat with Astellas Pharma Inc. (“Astellas”).

Our current agreements with Astellas provide them with the right to terminate their agreements for convenience or for breach, either of which could have an adverse effect on our business and operations. Moreover, if Astellas, 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 collaboration agreement between the Company and AstraZeneca, effective as of July 2013, 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 the People’s Republic of China (“China”), not previously licensed to Astellas (the “AstraZeneca U.S./RoW Agreement”) was terminated on February 25, 2024 as amended and restated on August 29, 2025 (except for South Korea). Our collaboration agreement with AstraZeneca for the development and commercialization of roxadustat for the treatment of anemia in China (the “AstraZeneca China Agreement”) culminated as a result of the completion of the sale of FibroGen International and its subsidiaries pursuant to the share purchase agreement entered into by the Company and AstraZeneca Treasury Limited on February 20, 2025, as amended on August 29, 2025 (the “Share Purchase Agreement”). This eliminates any additional potential milestones or other payments AstraZeneca could have made under the AstraZeneca U.S./RoW Agreement or the AstraZeneca China Agreement. 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 partner Astellas is unsuccessful in their commercialization efforts in Europe and Japan, 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 our own operating manufacturing facilities at this time. 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. 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, fees associated with such termination, or nonrenewal of manufacturing agreements with third parties may negatively impact our planned development and commercialization activities;

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- 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;
- potential regulatory actions taken against one of our contract manufacturers for failure to adhere to GMP;
- 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 Kyntra Bio 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 Kyntra Bio.

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/cancellation fees over time or upon initiation of additional contracts, and this may lead to unanticipated financial loss for Kyntra Bio.

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.

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.

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.

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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 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.

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, certain 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. 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, can be a significant problem. 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. 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”) and the United Kingdom’s GDPR 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.

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 utilizing artificial intelligence (“AI”) within 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. 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. 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.

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.

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. 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.

International Risks

Within the next year, we may face costs from the wind-up of the Cayman Subsidiary (as defined below), and may not receive some of the AZ Holdbacks (as defined below) related to the sale of FibroGen International and its subsidiaries.

As disclosed in our Current Report on Form 8-K filed in February 20, 2025, we agreed to two holdback amounts from the consideration paid by AstraZeneca Treasury Limited (the “AZ Holdbacks”) in connection with the sale of FibroGen International and its subsidiaries. The AZ Holdbacks were subject to specified conditions, potential set-offs, indemnification claims, and dispute processes. While we received all of the \$6.0 million holdback (plus an additional \$0.4 million favorable net cash adjustment), we may not receive all of the \$4.0 million remaining AZ holdback. We may not receive some of the second AZ Holdback, the amount may be reduced, and/or the timing of any release may be delayed, including due to claims or issues that are outside our control. In addition, there is a possibility that liabilities related to the sale of FibroGen International and its subsidiaries — such as post-closing adjustments, taxes, third-party or employee claims, product or commercial liabilities, compliance matters, or other indemnifiable losses—could exceed the AZ Holdback or fall outside its scope.

After the final AZ Holdback is received or finalized, we are planning on winding up FibroGen International (Cayman) Limited (the “Cayman Subsidiary”). The wind-up involves legal, regulatory, tax, accounting, and administrative steps. The timing, cost, and outcome of these steps are uncertain and may be impacted by claims or demands from stakeholders, which could require us to establish or increase reserves, provide additional documentation, or engage in dispute resolution or litigation. Any of these issues could delay any further distributions to shareholders of the Cayman Subsidiary and require additional management attention.

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 China, including imposing several rounds of tariffs affecting certain products manufactured in China. 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 connections to China. We have business operations in the U.S., and conduct contract manufacturing in both the U.S. and China. Any unfavorable government policies on cross-border relations and/or international trade, including tariffs, may affect the import of products and product components from China. While we have thus far imported products manufactured in China under exemptions from tariffs, if we are unable to do so in the future, the Company could encounter additional costs to supply our product and product candidates.

We depend on third party suppliers in China, and there are risks inherent to utilizing third-party manufacturing facilities.

Our suppliers are obligated to comply with cGMP requirements but there can be no assurance that they will maintain all of the appropriate licenses required to manufacture our product candidates for clinical and commercial use. Our product suppliers must continually spend time, money and effort in production, record-keeping and quality assurance and appropriate controls in order to ensure that any products manufactured in their facilities meet applicable specifications and other requirements for product safety, efficacy and quality but there can be no assurance that their 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 we do not yet have a secondary source supplier for either roxadustat API. Consequently, we carry single source supplier risk for all countries we or our partners are selling in. 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 suppliers’ abilities to operate their manufacturing facilities. Certain equipment, records and other materials located in such facilities would be difficult to replace or would require substantial replacement lead-time that would impact our ability to successfully commercialize supply roxadustat API or other clinical products.

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 (“ADC”) drug substance and ADC 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 be subject to currency exchange rate fluctuations and currency exchange restrictions with respect to 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 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.

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

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

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

On December 22, 2017, the Tax Cuts and Jobs Act 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.

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 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 loss from continuing operations were \$58.2 million and \$153.1 million for the year ended December 31, 2025, and 2024, respectively. As of March 31, 2026, we had an accumulated deficit of \$1.7 billion. As of March 31, 2026, we had capital resources from cash and cash equivalents of \$37.0 million and short-term and long-term investments of \$58.3 million. Despite the commercialization efforts of Astellas for roxadustat for the treatment of anemia caused by chronic kidney disease, we anticipate we will continue to incur losses on an annual basis for the foreseeable future. Furthermore, due to 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. 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. Furthermore, 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. 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.

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Our liquidity is subject to specific risks, including: (i) indemnification obligations to current and former officers and directors, which may require us to advance legal expenses or satisfy judgments or settlements that are not fully covered by insurance, as our insurance policies are subject to exclusions, coverage limits, and potential disputes with insurers; and (ii) our obligations under the Revenue Interest Financing Agreement (the “RIFA”) with an affiliate of NovaQuest Capital Management (“NovaQuest”), pursuant to which we may be required to make substantial payments if the revenue interest payments do not perform sufficiently, including potential balloon payments in 2029 and 2031, which could place significant demands on our cash resources relative to our current liquidity position. There can be no assurance that our cash resources will be sufficient to satisfy these obligations, and we may be required to seek additional financing.

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 transaction with 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 in the Astellas territories.

Our obligations under the RIFA with NovaQuest, pursuant to which we may be required to make substantial payments if the revenue interest payments do not perform sufficiently, including potential balloon payments in 2029 and 2031, which could place significant demands on our cash resources relative to our current liquidity position. There can be no assurance that our cash resources will be sufficient to satisfy these obligations, and we may be required to seek additional financing.

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.

For additional details about this financing transaction, see Note 8, *Liability Related to Sale of Future Revenues*, to the condensed consolidated financial statements.

Our obligations under this financing transaction 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.

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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, 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 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. Any of the above risks would negatively impact our ability to operate our business and obtain additional debt or equity financing on favorable terms.

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.

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 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.

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.

Legal proceedings, 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. Such costs may include indemnification for proceedings against our current or former officers, and there is one ongoing proceeding against a former officer where costs could be material but are uncertain at this time. Although we maintain insurance for certain potential liabilities, such insurance does not cover all types and amounts of potential liabilities and is subject to various exclusions and caps on amounts recoverable. Even if we believe a claim is covered by insurance, insurers may dispute its entitlement to recovery for a variety of potential reasons, which may affect the timing and, if the insurers prevail, the amount of our recovery. There can be no assurance that our cash resources will be sufficient to satisfy these obligations, and we may be required to seek additional financing.

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;

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- 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.

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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 file timely public reports and 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 March 31, 2026, the closing price of our common stock on the Nasdaq Global Select Market has ranged from \$5.16 per share to \$12.38 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;
- 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 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.

There is a risk that our common stock could be delisted if we are unable to regain compliance with the Nasdaq Global Select Market or, if we are unable to transfer to the Nasdaq Capital Market.*

As previously disclosed, on April 2, 2026, we received a letter from the Nasdaq Listing Qualifications Staff of the Nasdaq Stock Market notifying us that Kyntra Bio no longer complies with the Nasdaq Global Select Market continued listing requirement of \$50 million in total assets and total revenue for the most recently completed fiscal year (or two of the last three most recently completed fiscal years) per Listing Rule 5450(b)(3)(A). This is due to the revenue of FibroGen International being presented as held for sale (in discontinued operations) in our 2024 and 2025 10-Ks. We do not currently meet the alternative requirements of Listing Rule 5450(b) (either the shareholders’ equity or the market value of listed securities standards).

The notification received has no immediate effect on the listing of Kyntra Bio’s common stock on Nasdaq Global Select Market. Under the Nasdaq Rules, we have 45 days (May 18, 2026) to submit a plan to regain compliance and if such plan is accepted, Nasdaq may grant us with an extension of up to 180 days (September 29, 2026) to evidence compliance.

Per Listing Rule 5810(c)(2)(D), we may submit a plan that demonstrates current or near-term compliance with the listing requirements relating to stockholders’ equity or market value of listed securities. In determining whether to accept our plan, Nasdaq will consider such things as the likelihood that the plan will result in compliance with Nasdaq’s continued listing criteria, our past compliance history, the reasons for our current non-compliance, other corporate events that may occur within the review period, our overall financial condition, and our public disclosures.

We may also consider applying to transfer our securities to the Nasdaq Capital Market.

If our stock is transferred from the Nasdaq Global Select Market to the Nasdaq Capital Market, we would continue to be listed on a Nasdaq market; however, such a transfer could be perceived negatively by investors. The Nasdaq Capital Market has less stringent listing requirements than the Nasdaq Global Select Market, and a transfer could signal to investors that we no longer meet the higher standards associated with the Nasdaq Global Select Market. As a result, the market price of our common stock could decline and the trading volume and liquidity could be adversely affected.

While our common stock would continue to be listed on a Nasdaq market following such a transfer, we could experience decrease analyst coverage and reduced market visibility compared to companies listed on the Nasdaq Global Select Market. This could make it more difficult for investors (including institutional investors) to obtain research coverage or accurate market information regarding our common stock. Any reduced liquidity or market interest could also result in negative publicity and could also make it more difficult for us to raise additional capital.

If we are unable to maintain compliance with the continued listing requirements of the Nasdaq Capital Market following such a transfer, or if we are unable to transfer and unable to regain compliance with the Nasdaq Global Select Market, our common stock could become subject to delisting. Delisting from the Nasdaq Global Select Market or any Nasdaq market could make trading our common stock more difficult for investors, potentially leading to declines in our share price and liquidity. In that event, the risks with respect to delisting include limited trading markets, ineligibility to sell securities under our current S-3 registration statement under certain circumstances, potential quotation on over-the-counter markets, and the possible application of “penny stock” rules (as “penny stock” is defined in the Exchange Act, and including coverage under Rule 15g-9 of the Exchange Act), and could further adversely affect the market for and value of our common stock.

We may engage in acquisitions that could dilute stockholders and harm our business.

We may, in the future, make acquisitions of or investments in companies that we believe have products or capabilities that are a strategic or commercial fit with our present or future product candidates and business or otherwise offer opportunities for us. In connection with these acquisitions or investments, we may:

- issue stock that would dilute our existing stockholders’ percentage of ownership;

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- 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.

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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. 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 Kyntra Bio 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.	8-K	001-36740	3.1	11/21/2014
3.2	Amended and Restated Bylaws.	8-K	001-36740	3.1	04/04/2025
3.3	First Amendment to Amended and Restated Bylaws.	8-K	001-36740	3.2	01/07/2026
3.4	Certificate of Amendment of the Amended and Restated Certificate of Incorporation.	8-K	001-36740	3.1	06/12/2025
3.5	Certificate of Amendment of the Amended and Restated Certificate of Incorporation.	8-K	001-36740	3.1	01/07/2026
4.1	Form of Common Stock Certificate.	8-K	001-36740	4.1	11/21/2014
101.*+	Non-Employee Director Compensation Policy, as amended April 10, 2026.	—	—	—	—
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.

KYNTRA BIO, INC.

Date: May 12, 2026

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

Date: May 12, 2026

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

Kyntra Bio, Inc.
Non-Employee Director Compensation Policy

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

Eligible Directors

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

Annual Cash Compensation

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

1. Annual Board Service Retainer:
 - a. All Directors: \$50,000
2. Annual Committee Chair Service Fee (in lieu of non-Chair Service fee):
 - a. Chairman of the Audit Committee: \$20,000
 - b. Chairman of the Compensation Committee: \$17,500
 - c. Chairman of the Nominating and Governance Committee: \$10,000
3. Annual Committee Member (non-Chair) Service Fee:
 - a. Audit Committee: \$10,000
 - b. Compensation Committee: \$7,500
 - c. Nominating and Governance Committee: \$5,000
4. Annual Non-Executive Chairperson/Lead Independent Director Service Retainer:
 - a. Lead Independent Director: \$22,500
 - b. Non-Executive Chairperson: \$50,000
5. Annual Scientific Advisory Board Service Fee:
 - a. \$25,000

Equity Compensation

Equity awards will be granted under the Kyntra Bio, Inc. 2024 Equity Incentive Plan (or any successor thereto, the “**Plan**”). All stock options granted under this policy will be non-statutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying Company common stock on the date of grant, and a term of ten (10) years from the date of grant (subject to earlier termination in connection with a termination of service or a corporate transaction as provided in the Plan). All equity awards granted under this Policy will be documented on the applicable form of equity award agreement most recently approved for use by the Board

(or a duly authorized committee thereof) for Directors. The terms of the equity awards described in this Policy will be automatically adjusted upon any Capitalization Adjustment (as defined and provided for under the Plan).

1. **Initial Grant.** On the date of the Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Director will be automatically, and without further action by the Board, granted a stock option award of 14,000 shares. Such awards will vest in equal quarterly installments over three years from the grant date, subject to the Director's Continuous Service. A Director who, in the one year prior to his or her initial election to serve on the Board as a Director, served as an employee of Kyntra Bio or one of its subsidiaries, will not be eligible for an initial grant.
2. **Annual Grant.** Except as set forth in Paragraph 3 below, on the date of each Company annual stockholder meeting, each person who is elected or appointed as a Director, and each other Director who continues to serve as a Director immediately after such annual stockholder meeting, will be automatically, and without further action by the Board, granted a stock option award of award of 7,000 shares. Such options vest in equal quarterly installments over one year from the grant date or on the annual meeting of the following year, whichever comes first.
3. **Prorated Annual Grants.** For any Director that is appointed on the day of an annual stockholder meeting, their initial grant (twice an annual grant) will be in lieu of their first annual grant. For any other newly elected or appointed Director, at their first annual stockholder meeting, their first annual grant will be automatically, and without further action by the Board, a stock option award of 7,000 shares multiplied by the Applicable Fraction (as defined below) (a "**Prorated Annual Grant**"). The "**Applicable Fraction**" means a fraction with (a) a numerator equal to the number of days between the date of the Director's initial election or appointment to the Board and their first annual stockholder meeting, and (b) a denominator equal to 365.
4. **Option Value.** The value of a stock option to be granted under the Director Compensation Policy shall be determined using the same method the Company uses to calculate stock option awards to its employees, as approved by the Compensation Committee of the Board, using the grant date fair value, rounding down to the nearest share.
5. **RSU Value.** The number of shares subject to RSUs granted under the Director Compensation Policy shall be determined based on the closing price on the NASDAQ of the Company's common on the grant date, rounded down to the nearest share.
6. **Vesting.** Vesting of awards granted under this Policy will cease if the Director resigns from the Board or otherwise ceases to serve as a Director, unless the Board determines that the circumstances warrant continuation of vesting. All equity awards granted under this Policy will vest in full immediately prior to a Change in Control (as defined in the Plan), subject to the Director's Continuous Service (as defined in the Plan) as of the day prior to the closing of the Change in Control.

Reimbursement of Expenses

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

Philosophy

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

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

Adopted: September 17, 2014

Amended: March 4, 2015

Amended: February 23, 2016, Effective as of the 2016 Annual Meeting of Stockholders

Amended: June 5, 2018

Amended: June 5, 2019

Amended: February 10, 2020

Amended: April 13, 2022

Amended: February 14, 2023

Amended: January 1, 2024

Amended: April 22, 2024

Amended: April 10, 2026

CERTIFICATION

I, Thane Wettig, certify that:

1. I have reviewed this Form 10-Q of Kyntra Bio, 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: May 12, 2026

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

CERTIFICATION

I, David DeLucia, certify that:

1. I have reviewed this Form 10-Q of Kyntra Bio, 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: May 12, 2026

/s/ David DeLucia

David DeLucia

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

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Thane Wettig, Chief Executive Officer of Kyntra Bio, 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 March 31, 2026, 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: May 12, 2026

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 12th day of May, 2026.

/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 Kyntra Bio, 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.
