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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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	**77-0357827**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
350 Bay Street, Suite 100, #6009 San Francisco, CA	**94133**
(Address of Principal Executive Offices)	**(Zip Code)**

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

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.01 par value	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 October 31, 2026 was 4,049,985.

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)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 9,905	$ 47,872
Short-term investments	30,385	41,106
Accounts receivable, net	3,848	216
Inventories	3,255	3,743
Prepaid expenses and other current assets	1,227	6,136
Total current assets	48,620	99,073
Long-term investments	—	20,160
Other assets	231	361
Total assets	$ 48,851	$ 119,594
Liabilities, redeemable non-controlling interests and deficit		
Current liabilities:		
Accounts payable	$ 4,581	$ 3,745
Accrued and other current liabilities	31,005	20,183
Deferred revenue	6,170	5,314
Total current liabilities	41,756	29,242
Product development obligations	—	19,560
Deferred revenue, net of current	2,957	255
Liability related to sale of future revenues, non-current	11,268	65,980
Other long-term liabilities	60	82
Total liabilities	56,041	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 September 30, 2026 and December 31, 2025	—	—
Common stock, $0.01 par value; 225,000 shares authorized at September 30, 2026 and December 31, 2025; 4,050 and 4,047 shares issued and outstanding at September 30, 2026 and December 31, 2025	41	1,012
Additional paid-in capital	1,681,091	1,677,179
Accumulated other comprehensive loss	(1,208)	(2,182)
Accumulated deficit	(1,709,114)	(1,706,047)
Total stockholders' deficit attributable to Kyntra Bio	(29,190)	(30,038)
Nonredeemable non-controlling interests	520	13,033
Total deficit	(28,670)	(17,005)
Total liabilities, redeemable non-controlling interests and deficit	$ 48,851	$ 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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
Development and other revenue	$ 99	$ 119	$ 449	$ 396
Drug product revenue, net	1,663	957	3,577	4,767
Total revenue	1,762	1,076	4,026	5,163
Operating costs and expenses:				
Cost of goods sold	619	(58)	4,727	278
Research and development	8,266	1,209	22,654	16,249
Selling, general and administrative	5,757	5,295	20,951	20,459
Restructuring charge	(15)	41	(48)	560
Total operating costs and expenses	14,627	6,487	48,284	37,546
Loss from operations	(12,865)	(5,411)	(44,258)	(32,383)
Interest and other, net				
Interest expense	(1,632)	(2,083)	(6,426)	(6,346)
Gain on deconsolidation of subsidiary	—	—	30,940	—
Loss on debt extinguishments	—	(6,583)	—	(6,583)
Gain on debt restructuring	14,011	—	14,011	—
Interest income and other income (expenses), net	643	931	2,731	1,628
Total interest and other, net	13,022	(7,735)	41,256	(11,301)
Income (loss) from continuing operations before income taxes	157	(13,146)	(3,002)	(43,684)
Benefit from income taxes	—	—	(1)	(90)
Income (loss) from continuing operations	157	(13,146)	(3,001)	(43,594)
Income (loss) from discontinued operations, net of tax	—	213,782	(66)	241,266
Net income (loss)	$ 157	$ 200,636	$ (3,067)	$ 197,672
Income (loss) from continuing operations per share - basic and diluted	$ 0.04	$ (3.25)	$ (0.74)	$ (10.79)
Income (loss) from discontinued operations per share - basic and diluted	—	52.86	(0.02)	59.69
Net income (loss) per share - basic and diluted	$ 0.04	$ 49.61	$ (0.76)	$ 48.90
Weighted average number of common shares used to calculate net income (loss) per share:				
Basic	4,049	4,044	4,048	4,042
Diluted	4,050	4,044	4,048	4,042

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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net income (loss)	$ 157	$ 200,636	$ (3,067)	$ 197,672
Other comprehensive income (loss):				
Foreign currency translation adjustments	—	(2,898)	396	(1,959)
Cumulative currency translation adjustment attributable to divestiture	—	5,479	—	5,479
Unrealized income (loss) on investments, net of tax effect	(20)	2	(124)	1
Other comprehensive income (loss), net of taxes	(20)	2,583	272	3,521
Comprehensive income (loss)	137	203,219	(2,795)	201,193

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							
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Nonredeemable Non-Controlling	Total	Redeemable Non-Controlling
	Shares	Amount	Capital	Loss	Deficit	Interests	Deficit	Interests
Balance at June 30, 2026	4,049,124	$ 41	$ 1,680,274	$ (1,188)	$ (1,709,271)	$ 520	$ (29,624)	$ 21,480
Net income	—	—	—	—	157	—	157	
Change in unrealized gain or loss on investments	—	—	—	(20)	—	—	(20)	—
Distribution to non-controlling interest (Note 3)	—	—	(190)	—	—	—	(190)	—
Shares issued from stock plans, net of payroll taxes paid	861	—	(6)	—	—	—	(6)	—
Stock-based compensation	—	—	1,013	—	—	—	1,013	—
Balance at September 30, 2026	4,049,985	$ 41	$ 1,681,091	$ (1,208)	$ (1,709,114)	$ 520	$ (28,670)	$ 21,480
Balance at June 30, 2025	4,043,899	1,011 $ 1	$ 1,673,249	$ (4,794)	$ (1,892,463)	$ 20,487	$ (202,510)	$ 21,480
Net income	—	—	—	—	200,636	—	200,636	—
Change in unrealized gain or loss on investments	—	—	—	2	—	—	2	—
Foreign currency translation adjustments	—	—	—	(2,898)	—	—	(2,898)	—
Cumulative currency translation adjustment attributable to divestiture (Note 3)	—	—	—	5,479	—	—	5,479	—
Distribution to non-controlling interest (Note 3)	—	—	2,101	—	—	(7,454)	(5,353)	—
Shares issued from stock plans, net of payroll taxes paid	1,546	—	(13)	—	—	—	(13)	—
Stock-based compensation	—	—	662	—	—	—	662	—
Balance at September 30, 2025	4,045,445	1,011 $ 1	$ 1,675,999	$ (2,211)	$ (1,691,827)	$ 13,033	$ (3,995)	$ 21,480

KYNTRA BIO, INC.

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

	For The Nine Month Period							
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Nonredeemable Non-Controlling	Total	Redeemable Non-Controlling
	Shares	Amount	Capital	Loss	Deficit	Interests	Deficit	Interests
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	—	—	—	—	(3,067)	—	(3,067)	—
Change in unrealized gain or loss on investments	—	—	—	(124)	—	—	(124)	—
Foreign currency translation adjustments	—	—	—	396	—	—	396	—
Deconsolidation of foreign subsidiary (Note 2)	—	—	—	702	—	(12,513)	(11,811)	—
Distribution to non-controlling interest (Note 3)	—	—	(190)	—	—	—	(190)	—
Shares issued from stock plans, net of payroll taxes paid	3,158	1	(18)	—	—	—	(17)	—
Stock-based compensation	—	—	3,148	—	—	—	3,148	—
Other	—	(972)	972	—	—	—	—	—
Balance at September 30, 2026	4,049,985	$ 41	$ 1,681,091	$ (1,208)	$ (1,709,114)	$ 520	$ (28,670)	$ 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	—	—	—	—	197,672	—	197,672	—
Change in unrealized gain or loss on investments	—	—	—	1	—	—	1	—
Foreign currency translation adjustments	—	—	—	(1,959)	—	—	(1,959)	—
Cumulative currency translation adjustment attributable to divestiture (Note 3)	—	—	—	5,479	—	—	5,479	—
Distribution to non-controlling interest (Note 3)	—	—	2,101	—	—	(7,454)	(5,353)	—
Shares issued from stock plans, net of payroll taxes paid	8,822	2	(63)	—	—	—	(61)	—
Issuance cost under ATM Program	—	—	(46)	—	—	—	(46)	—
Redemption of fractional shares due to reverse stock split	(55)	—	—	—	—	—	—	—
Stock-based compensation	—	—	5,387	—	—	—	5,387	—
Balance at September 30, 2025	4,045,445	$ 1,011	$ 1,675,999	$ (2,211)	$ (1,691,827)	$ 13,033	$ (3,995)	$ 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)

	Nine Months Ended September 30,	
	2026	**2025**
Operating activities		
Net income (loss)	$ (3,067)	$ 197,672
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	—	713
Amortization of finance lease right-of-use assets	20	27
Net accretion of premium and discount on investments	(309)	1
Investment income in unconsolidated variable interest entity	—	(2,485)
Gain on deconsolidation of subsidiary	(30,940)	—
Loss (gain) on divestiture	66	(52,163)
Loss on debt extinguishments	—	6,583
Gain on debt restructuring	(14,740)	—
Impairment of property and equipment	—	2,062
Stock-based compensation	3,147	5,387
Dividend received from unconsolidated variable interest entity	—	3,947
Changes in operating assets and liabilities:		
Accounts receivable, net	(3,632)	(2,449)
Inventories	488	5,240
Prepaid expenses and other current assets	910	54,774
Operating lease right-of-use assets	—	808
Other assets	111	(1,072)
Accounts payable	836	(26,306)
Accrued and other liabilities	8,423	(48,148)
Operating lease liabilities, current	—	(568)
Deferred revenues	3,558	(136,321)
Accrued interest expense related to sale of future revenues	5,027	5,659
Accrued interest for finance lease liabilities	(20)	(19)
Operating lease liabilities, non-current	—	(202)
Other long-term liabilities	(1)	414
Net cash provided by (used in) operating activities	(30,123)	13,554
Investing activities		
Purchases of property and equipment	—	(38)
Proceeds from divestiture, net of cash transferred	4,000	90,204
Cash paid related to divestiture	(66)	—
Cash deconsolidated upon loss of control of subsidiary	(5)	—
Purchases of available-for-sale securities	(18,989)	(3,035)
Proceeds from maturities of investments	50,053	—
Net cash provided by investing activities	34,993	87,131
Financing activities		
Repayments of senior secured term loan facilities	—	(75,000)
Payment of senior secured term loan facilities pay-off premium and fees	—	(5,550)
Payments for debt restructuring	(42,581)	—
Cash paid for transaction costs related to debt restructuring	(20)	—
Repayments of finance lease liabilities	—	(4)
Cash paid for payroll taxes on restricted stock unit releases	(17)	(61)
Cash paid to non-controlling interest	(190)	(5,353)
Payment of issuance cost under ATM Program	—	(46)
Net cash used in financing activities	(42,808)	(86,014)
Effect of exchange rate change on cash and cash equivalents	(29)	1,126
Net increase (decrease) in cash and cash equivalents	(37,967)	15,797
Total cash and cash equivalents at beginning of period	47,872	102,178
Total cash and cash equivalents at end of period	$ 9,905	$ 117,975

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 pure play, rare disease biopharmaceutical company focused on the development of roxadustat for anemia associated with lower-risk myelodysplastic syndromes ("MDS").

In January 2026, the Company announced its rebranding from "FibroGen, Inc." to "Kyntra Bio, Inc.," representing the next step of its transformation to a rare-disease focused company. On January 8, 2026, the Company's common stock began trading under the new Nasdaq symbol "KYNB."

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 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 ("AstraZeneca Treasury") pursuant to the share purchase agreement entered into by the Company and AstraZeneca Treasury 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 3, *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 (respectively, the "Astellas Japan Agreement" and the "Astellas Europe Agreement," and collectively, the "Astellas Agreements").

The U.S. Food and Drug Administration granted roxadustat Orphan Drug Designation for the treatment of MDS in December 2025.

The Company continues to advance its development plan for roxadustat in anemia associated with lower-risk MDS, a high-value indication with significant unmet medical need. The Company has finalized the Phase 3 trial protocol for roxadustat for the treatment of anemia in patients with lower-risk MDS with high transfusion burden and is continuing preparations for the Phase 3 trial. The Company's goal is to initiate the Phase 3 trial in the first quarter of 2027, subject to the execution of either a strategic partnership or an external capital raise.

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.

The interim financial data as of September 30, 2026 and for the three and nine months ended September 30, 2026 are unaudited. In the opinion of management, the interim data includes all adjustments, consisting of normal recurring adjustments, necessary for a fair statement of the results for the interim periods. The condensed consolidated balance sheet presented as of December 31, 2025 has been derived from the consolidated audited financial statements as of that date.

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 deconsolidates its subsidiary or business in accordance with Accounting Standards Codification ("ASC") 810, *Consolidation* ("ASC 810"), as of the date the Company ceased to have a controlling financial interest in the subsidiary. Upon deconsolidation, all assets and liabilities of the former subsidiary are derecognized, any retained investment is recorded at its fair value, and any resulting gain or loss is recognized in the condensed consolidated statements of operations.

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 Share 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") 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 3, *Discontinued Operations and Divestiture*, for related disclosures. Unless otherwise noted, discussion in the notes to the condensed consolidated financial statements, relates solely to the Company's continuing operations.

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 September 30, 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

The following is a reconciliation of the basic and diluted net income (loss) per share calculation for the periods presented (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Income (loss) from continuing operations	$ 157	$ (13,146)	$ (3,001)	$ (43,594)
Income (loss) from discontinued operations, net of tax	—	213,782	(66)	241,266
Net income (loss)	157	200,636	(3,067)	197,672
Weighted average number of common shares used to calculate net income (loss) per share:				
Basic	4,049,358	4,044,319	4,048,323	4,041,628
Dilutive effect of potential common shares	209	—	—	—
Diluted	4,049,567	4,044,319	4,048,323	4,041,628
Income (loss) from continuing operations per share - basic and diluted	$ 0.04	$ (3.25)	$ (0.74)	$ (10.79)
Income (loss) from discontinued operations per share - basic and diluted	—	52.86	(0.02)	59.69
Net income (loss) per share - basic and diluted	$ 0.04	$ 49.61	$ (0.76)	$ 48.90

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 the nine months ended September 30, 2026 and the three and nine months ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Employee stock options	556	459	527	486
RSUs, PRSUs and TSR awards	50	27	50	38
ESPP	22	—	26	—
	628	486	603	524

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. Deconsolidation of European Subsidiary

In April 2026, the Company's subsidiary, FibroGen Europe Oy ("FibroGen Europe"), voluntarily filed for bankruptcy with the Finnish bankruptcy court. On April 16, 2026, the Helsinki District Court declared FibroGen Europe bankrupt and appointed an estate administrator to oversee the bankruptcy estate. As a result, the Company determined that it no longer maintained a controlling financial interest in FibroGen Europe and therefore deconsolidated the subsidiary effective April 16, 2026 in accordance with ASC 810. The Company determined that the deconsolidation did not represent a strategic shift that has a major effect on its operations and financial results. Accordingly, the results of the subsidiary have not been presented as discontinued operations.

FibroGen Europe had product development obligations to the Technology Development Center of the Republic of Finland ("TEKES"), consisting of 11 separate advances received between 1996 and 2008 pursuant to note agreements (the "TEKES Loans"). The advances were granted on a project-by-project basis to fund various product development activities undertaken solely by FibroGen Europe. Kyntra Bio was not a guarantor of the TEKES Loans, and the obligations were non-recourse to Kyntra Bio. Repayment of principal and accrued interest was not required unless FibroGen Europe had distributable funds.

FibroGen Europe's balance sheet before the deconsolidation primarily included $19.2 million of the above-mentioned TEKES Loans, $12.5 million nonredeemable non-controlling interest, and $0.7 million of cumulative foreign currency translation adjustments. Upon deconsolidation, the Company derecognized the subsidiary's assets and liabilities and recognized a $30.9 million gain on deconsolidation in the condensed consolidated statements of operations in the second quarter of 2026.

Upon deconsolidation, the Company measured any retained equity interest in FibroGen Europe at fair value in accordance with ASC 810 and determined that the fair value of such retained interest was zero as of April 16, 2026. Following deconsolidation, the Company accounts for any retained equity interest in FibroGen Europe under ASC 321, *Investments — Equity Securities*. The carrying value of the Company's retained equity interest in FibroGen Europe remained zero as of September 30, 2026.

3. 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. 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.

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 Treasury 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. As a result, during the third quarter of 2025, the Company recorded a gain on divestiture of $52.2 million which resulted from the above-mentioned total consideration of $220.4 million, less the transaction costs and fees of $7.8 million, and the derecognition of the net equity of $154.9 million of FibroGen International at the Transaction close and the cumulative currency translation adjustments of $5.5 million. On November 6, 2025, the Company received a $6.4 million payment from AstraZeneca Treasury, 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. On June 2, 2026, the Company received a $4.0 million payment from AstraZeneca Treasury, which is in full satisfaction of the final holdback. Such amount was included in the prepaid expenses and other current assets on the condensed consolidated balance sheets as of December 31, 2025.

The discontinued operations sold under the Transaction consisted substantially all the assets owned by FibroGen Cayman, therefore triggered the liquidation distribution process of FibroGen Cayman based on its Articles. Accordingly, during the third quarter of 2025, the Company distributed a total of $5.4 million to FibroGen Cayman's minority shareholders and correspondingly recorded a reduction to the related nonredeemable non-controlling interests of $7.5 million and an adjustment to additional paid-in capital of $2.1 million. After the receipt of the final holdback in the second quarter of 2026 and taking into consideration of final costs of FibroGen Cayman related to the Transaction, during the third quarter of 2026, the Company made final distributions totaling $0.2 million to FibroGen Cayman's minority shareholders on a pro-rata basis and correspondingly recorded an adjustment to additional paid-in capital of $0.2 million.

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 4, *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, *Revenue from Contracts with Customers,* 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 and nine months ended September 30, 2026 and 2025 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
Product revenue, net	$ —	167,179	$ —	$ 226,651
Operating costs and expenses:				
Cost of goods sold	—	3,761	—	13,454
Research and development	—	438	—	1,739
Selling, general and administrative	—	1,311	—	14,849
Total operating costs and expenses	—	5,510	—	30,042
Income from operations	—	161,669	—	196,609
Interest and other, net				
Interest expense	—	(1,900)	—	(7,816)
Gain (loss) on divestiture	—	52,163	(66)	52,163
Interest income and other income (expenses), net	—	475	—	(2,173)
Total interest and other, net	—	50,738	(66)	42,174
Income (loss) before income taxes	—	212,407	(66)	238,783
Provision for income taxes	—	—	—	—
Investment income in unconsolidated variable interest entity	—	1,375	—	2,483
Income (loss) from discontinued operations, net of tax	$ —	$ 213,782	$ (66)	$ 241,266

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 $165.3 million and $218.6 million for the three and nine months ended September 30, 2025, respectively. The other income from Falikang was immaterial for the three and nine months ended September 30, 2025. The investment income in Falikang was $1.4 million and $2.5 million for the three and nine months ended September 30, 2025, respectively.

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 nine months ended September 30, 2025 were as follows (in thousands):

	Nine Months Ended September 30, 2025
Depreciation	$ 713
Investment income in unconsolidated variable interest entity	(2,485)
Gain on divestiture	(52,163)
Impairment of property and equipment	2,062
Dividend received from unconsolidated variable interest entity	3,947
Stock-based compensation	$ 231

4. 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. Under this agreement, Astellas agreed to pay license fees, other upfront consideration and various milestone payments, totaling $172.6 million. The Astellas Japan Agreement also provides for tiered payments based on net sales of product (as defined) in the low 20% range of the list price published by Japan's Ministry of Health, Labour and Welfare, adjusted for certain elements, after commercial launch.

The aggregate amount of consideration received under the Astellas Japan Agreement through September 30, 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 and nine months ended September 30, 2026 and 2025.

The transaction price related to consideration received through September 30, 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 September 30, 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. 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 September 30, 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 and nine months ended September 30, 2026 and 2025.

The transaction price related to consideration received through September 30, 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 $289.1 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 three months ended September 30, 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 was as follows for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Astellas Japan Agreement	$ 17	$ (378)	$ (5,110)	$ 1,446
Astellas Europe Agreement	1,646	1,335	8,687	3,321
Drug product revenue, net	$ 1,663	$ 957	$ 3,577	$ 4,767

Astellas Japan Agreement

The Company updates its estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment at each balance sheet date. The adjustment to the drug product revenue for the three months ended September 30, 2026 was immaterial.

For the three months ended June 30, 2026, the Company updated its estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment, and accordingly recorded a reduction to the drug product revenue of $2.9 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 estimated bulk product strength mix intended to be manufactured by Astellas, and foreign exchange impacts, among others.

For the three months ended March 31, 2026, the Company updated its estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment, and accordingly recorded a reduction to the drug product revenue of $2.2 million. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect changes in the listed price, among others.

For the three months ended September 30, 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 a reduction to the drug product revenue of $0.4 million. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect foreign exchange impacts, among others.

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

For the three months ended March 31, 2025, the Company updated its estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment, and accordingly recorded an adjustment to the drug product revenue of $1.8 million. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect the changes in the estimated yield from the manufacture of bulk product tablets, among others.

As of September 30, 2026, the balances related to the API price true-up under the Astellas Japan Agreement were $2.9 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 September 30, 2026, the Company transferred bulk drug product for commercial purposes under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement, recognized the related fully-burdened manufacturing costs of $0.4 million as drug product revenue, and recorded $3.3 million as deferred revenue due to a high degree of uncertainty associated with the variable consideration for revenue recognition purposes.

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 recognized royalty revenue of $1.2 million and $1.3 million as drug product revenue from the deferred revenue under the Astellas Europe Agreement for the three months ended September 30, 2026 and 2025, and $4.1 million and $3.3 million for the nine months ended September 30, 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.

For the nine months ended September 30, 2026, 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 nine months ended September 30, 2026, the Company reclassified $1.8 million from the related deferred revenue to accrued liabilities. As of September 30, 2026, the balances related to the bulk drug product price true-up under the Astellas Europe Agreement and the Astellas EU Supply Agreement were $3.3 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 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 September 30, 2026
Drug product revenue - deferred revenue:					
Astellas Europe Agreement	$ (5,569)	$ (9,474)	$ 4,063	$ 1,853	$ (9,127)

5. Fair Value Measurements

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

	September 30, 2026			
	Level 1	Level 2	Level 3	Total
Money market funds	$ 8,011	$ —	$ —	$ 8,011
Corporate bonds	—	18,386	—	18,386
U.S. government bonds	11,999	—	—	11,999
Total	$ 20,010	$ 18,386	$ —	$ 38,396

	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	$ 56,224	$ 50,605	$ —	$ 106,829

The Company's Level 2 investments are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar investments, issuer credit spreads, benchmark investments, prepayment/default projections based on historical data and other observable inputs. There were no transfers of assets between levels during the three months ended September 30, 2026. During the nine months ended September 30, 2026, a total of $6.0 million, 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. During the three and nine months ended September 30, 2025, a total of $10.0 million and $17.8 million, respectively, of U.S. treasury notes and bills were transferred from Level 1 to Level 2 as such instruments were changed to off-the-run when they were issued before the most recent issue and were still outstanding at measurement day.

6. Balance Sheet Components

Cash and Cash Equivalents

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

	September 30, 2026	December 31, 2025
Cash	$ 1,894	$ 2,309
Commercial paper	—	11,272
Money market funds	8,011	24,302
U.S. government bonds	—	9,989
Total cash and cash equivalents	$ 9,905	$ 47,872

Investments

As of September 30, 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):

	September 30, 2026			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Corporate bonds	$ 18,447	$ —	$ (61)	$ 18,386
U.S. government bonds	12,025	—	(26)	11,999
Total investments	$ 30,472	$ —	$ (87)	$ 30,385

	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	$ 61,228	$ 38	$ —	$ 61,266

The following table summarizes, for all available-for-sale securities in an unrealized loss position as of September 30, 2026, the fair value and gross unrealized loss by length of time the security has been in a continual unrealized loss position (in thousands):

	September 30, 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	$ 18,386	$ (61)	$ —	$ —	$ 18,386	$ (61)
U.S. government bonds	11,999	(26)	—	—	11,999	(26)
Total	$ 30,385	$ (87)	$ —	$ —	$ 30,385	$ (87)

As of December 31, 2025, all available-for-sale securities in an unrealized loss position had immaterial unrealized losses.

As of September 30, 2026, the available-for-sale investments had remaining contractual maturities within one year.

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 and nine months ended September 30, 2026 and 2025.

Prepaid Expenses and Other Current Assets

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

	September 30, 2026	December 31, 2025
Holdback consideration receivable related to divestiture	$ —	$ 4,000
Prepaid assets	713	1,015
Other current assets	514	1,121
Total prepaid expenses and other current assets	$ 1,227	$ 6,136

As of 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. On June 2, 2026, the Company received a $4.0 million payment from AstraZeneca Treasury, which is in full satisfaction of the final holdback. See Note 3, *Discontinued Operations and Divestiture,* for details.

Accrued and Other Current Liabilities

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

	September 30, 2026	December 31, 2025
Preclinical and clinical trial accruals	$ 6,123	$ 3,066
API and bulk drug product price true-up	6,196	6,977
Payroll and related accruals	2,598	3,983
Accrued restructuring charge	49	537
Professional services	10,884	2,465
Current portion of liability related to sale of future revenues	3,732	1,334
Other	1,423	1,821
Total accrued and other current liabilities	$ 31,005	$ 20,183

The accrued liabilities of $6.2 million and $7.0 million for API and bulk drug product price true-up as of September 30, 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 4, *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 Morgan Stanley Tactical Value, 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.

In August 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. Accordingly, for the three and nine months ended September 30, 2025, the Company recorded a loss on debt extinguishments of $6.6 million, including the $5.5 million of premium and fees and a $1.1 million amortization of issuance costs.

The effective annual interest rate of the Initial Term Loan was 16.13% for the three and nine months ended September 30, 2025. The Company recorded interest expense of $1.9 million and $7.8 million for the three and nine months ended September 30, 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 NQ Project Phoebus, L.P. ("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 before advisory fees.

The Company accounted for the above-mentioned consideration received, net of initial issuance costs, 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 were amortized as interest expense based on the projected balance of the liability. The payments to NovaQuest were accounted for as a reduction of debt.

Under the RIFA, the Company should pay to NovaQuest up to a specified maximum amount ("Payment Cap"). Based on the Company's 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, the Company anticipated reaching a Payment Cap up to $125.0 million by 2031, including certain true-up payments in 2029 and 2031.

Effective August 31, 2026, the Company entered into an amended and restated Revenue Interest Financing Agreement (the "A&R RIFA") with NovaQuest, which reduced the maximum aggregate payments under the arrangement from $125.0 million to $65.0 million. The Company made an upfront payment of $42.6 million to NovaQuest on August 31, 2026, which, together with the total payments of $7.4 million previously made under the RIFA, aggregate to total payments of $50.0 million to NovaQuest under these agreements. After this upfront payment, the remaining payment obligation is $15.0 million (the "Remaining Cap").

Under the A&R RIFA, the Company is required to pay NovaQuest 50% of the revenue that it is entitled to under the Astellas Europe Agreement and Astellas EU Supply Agreement (Astellas territories excluding Japan). The Company may prepay or repay the remaining payment obligation at any time.

The Company evaluated the A&R RIFA under ASC 470-60, and concluded that the transaction consisted of a partial cash settlement and modification of the remaining terms. Accordingly, the Company calculated the carrying value of the debt under the original RIFA as of the effective date of the A&R RIFA as $72.3 million, reduced the amount by the $42.6 million cash payment made to NovaQuest, adjusted the carrying value of the restructured liability to the Remaining Cap of $15.0 million and recognized a debt restructuring gain of $14.7 million before direct debt restructuring transaction costs. Direct debt restructuring transaction costs totaling $0.7 million, which did not affect the carrying value of the restructured liability, were recorded to reduce the debt restructuring gain, resulting in a net gain on debt restructuring of $14.0 million in the Company's condensed consolidated statements of operations for the three months ended September 30, 2026. The gain increased net income (loss) per share – basic and diluted by $3.46 for the three and nine months ended September 30, 2026, respectively.

Future royalty interest payments to NovaQuest will reduce the carrying value of the debt and no interest expense will be recorded on the restructured liability. As of September 30, 2026, the Company classified $3.7 million to accrued and other current liabilities based on its estimate of amounts expected to be paid to NovaQuest within the next 12 months.

The following table summarizes the activities of the liability related to sale of future revenues for the nine months ended September 30, 2026:

	Nine Months Ended September 30, 2026
Liability related to sale of future revenues - beginning balance	$ 67,314
Interest expense recognized	6,343
Interest paid	(1,316)
Liability related to sale of future revenues – before debt restructuring	72,341
Upfront payment	(42,581)
Gain on debt restructuring, before direct debt restructuring transaction costs	(14,760)
Liability related to sale of future revenues – ending balance	$ 15,000
Less: Current portion classified to accrued and other current liabilities	(3,732)
Liability related to sale of future revenues, non-current	$ 11,268

Associated with the original RIFA, the Company recognized, under the Astellas Agreements, development revenue of $0.3 million and drug product revenue of $1.9 million, respectively in 2026 before the A&R RIFA. Comparatively, during the three and nine months ended September 30, 2025, the Company recognized, under Astellas Agreements, development revenue of $0.1 million and $0.4 million, respectively, and drug product revenue of $1.0 million and $4.8 million, respectively. After the A&R RIFA became effective, for the three months ended September 30, 2026, the Company recognized, under Astellas Europe Agreement and Astellas EU Supply Agreement, development revenue of $0.1 million and drug product revenue of $1.6 million, respectively. See Note 4, *Collaboration Agreements, License Agreement and Revenue*, for details.

Associated with the original RIFA, during the three and nine months ended September 30, 2026, the Company recognized the related interest expense of $1.6 million and $6.3 million, respectively. During the three and nine months ended September 30, 2025, the Company recognized the related interest expense of $2.0 million and $6.1 million, respectively. No interest expense will be recorded going forward under the A&R RIFA.

During the nine months ended September 30, 2026 and 2025, the Company paid $1.3 million and $0.5 million accrued interest, respectively.

9. Income Taxes

Benefit from income taxes for the three and nine months ended September 30, 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 September 30, 2026, the Company had outstanding total non-cancelable purchase obligations of $0.4 million for manufacture and supply of roxadustat and $0.2 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. As of September 30, 2026, the Company did not have any material accruals for any active legal actions that it is named in.

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 September 30, 2026, the Company's accrued liabilities related to these obligations were approximately $9.0 million based on its best estimate. The Company is unable to reasonably estimate the total amount of future indemnification costs beyond amounts currently accrued due to significant uncertainties regarding the duration, scope, and outcome of the proceedings.

11. Segment Information

The Company has one operating and reportable 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, gain on deconsolidation of subsidiary, gain on debt restructuring, 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 Events

FG-3246 and FG-3180 Program Update

In the fourth quarter of 2026, following a review of emerging clinical data of FG-3246 from the Phase 2 trial, along with evolving competitive data and our strategic priorities, the Company decided, due to insufficient efficacy, to terminate development of FG-3246 in mCRPC and the associated companion PET imagining agent, FG-3180. Patients who are currently receiving FG-3246 and who may continue to benefit from treatment may remain on study drug in accordance with the study protocol, investigator judgment and applicable regulatory requirements. The Company will not enroll additional patients in the study and expect to complete customary clinical, regulatory, data-analysis and other wind-down activities in the coming months. At this time, the Company is evaluating and cannot reasonably estimate the potential financial effect related to this decision 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 pure play, rare disease biopharmaceutical company focused on the development of roxadustat for anemia associated with lower-risk myelodysplastic syndromes ("MDS").

In January 2026, we announced our rebranding from "FibroGen, Inc." to "Kyntra Bio, Inc.," representing the next step of our transformation to a rare-disease focused company. On January 8, 2026, our common stock began trading under the new Nasdaq symbol "KYNB."

Our oncology development portfolio has included FG-3246, a potential first-in-class antibody-drug conjugate ("ADC") targeting CD46, for the treatment of metastatic castration-resistant prostate cancer ("mCRPC") and 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, together with an exploratory sub-study of FG-3180, in the third quarter of 2025. In the fourth quarter of 2026, following a review of emerging clinical data from the Phase 2 trial, as well as a review of the evolving competitive data being generated in mCRPC, we decided to terminate the study and begin an orderly wind-down.

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.

On August 29, 2025, we closed the sale of our China operations through FibroGen International (Hong Kong) Ltd. ("FibroGen International") to AstraZeneca Treasury Limited ("AstraZeneca Treasury") pursuant to the share purchase agreement entered into with AstraZeneca Treasury 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 MDS, a high-value indication with significant unmet medical need and our internal clinical development priority.

The U.S. Food and Drug Administration ("FDA") granted roxadustat Orphan Drug Designation for the treatment of MDS in December 2025.

We have finalized the Phase 3 trial protocol for roxadustat for the treatment of anemia in patients with lower-risk MDS with high transfusion burden and are continuing preparations for the Phase 3 trial. Our goal is to initiate the Phase 3 trial in the first quarter of 2027, subject to the execution of either a strategic partnership or an external capital raise.

Recent Corporate Developments

FG-3246 and FG-3180 Program Update. In the fourth quarter of 2026, following a review of emerging clinical data of FG-3246 from the Phase 2 trial, along with evolving competitive data and our strategic priorities, we decided, due to insufficient efficacy, to terminate development of FG-3246 in mCRPC and the associated companion PET imagining agent, FG-3180. Patients who are currently receiving FG-3246 and who may continue to benefit from treatment may remain on study drug in accordance with the study protocol, investigator judgment and applicable regulatory requirements. We will not enroll additional patients in the study and expect to complete customary clinical, regulatory, data-analysis and other wind-down activities in the coming months. As a result of the termination of the FG-3246 and FG-3180 program, we expect to save over $20 million in operating expenses in 2027 and 2028.

Amendment and Restatement of Revenue Interest Financing Agreement. On August 31, 2026, Kyntra Bio entered into an amended and restated agreement (the "A&R RIFA") with NQ Project Phoebus, L.P. ("NovaQuest"), amending the Revenue Interest Financing Agreement dated November 4, 2022 (the "RIFA"). The A&R RIFA reduces the maximum aggregate payments under the agreement from $125.0 million to $65.0 million. In connection with signing, Kyntra Bio made an upfront payment of $42.6 million to NovaQuest, bringing total payments made to NovaQuest to $50.0 million under these agreements. Remaining payments are capped at $15.0 million as of August 31, 2026 (the "Remaining Cap"), and we will pay NovaQuest, on a quarterly basis, 50% of the revenue that we are entitled to under the Astellas Europe Agreement and Astellas EU Supply Agreement (defined below) in Europe and all other Astellas territories excluding Japan. Once the Remaining Cap is reached, the A&R RIFA will expire and we will retain all subsequent EVRENZO™ royalties in the Astellas territories. We may prepay or repay the remaining amount at any time. Royalties we receive for sales in Japan are no longer subject to royalty-based payments, and the intellectual property and other collateral associated with such Japan royalties have been released. See Note 8, *Liability Related to Sale of Future Revenues,* to the condensed consolidated financial statements for details.

Financial Highlights

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands, except for per share data)			
Result of Operations				
Revenue	$ 1,762	$ 1,076	$ 4,026	$ 5,163
Operating costs and expenses	14,627	6,487	48,284	37,546
Total interest and other, net	13,022	(7,735)	41,256	(11,301)
Income (loss) from continuing operations	157	(13,146)	(3,001)	(43,594)
Income (loss) from continuing operations per share - basic and diluted	$ 0.04	$ (3.25)	$ (0.74)	$ (10.79)

	September 30, 2026	December 31, 2025
	(in thousands)	
Balance Sheet		
Cash and cash equivalents	$ 9,905	$ 47,872
Short-term investments	30,385	41,106
Accounts receivable	3,848	216
Long-term investments	$ —	$ 20,160

Our revenue for the three and nine months ended September 30, 2026 primarily included $1.7 million and $3.6 million, respectively, of drug product revenue from commercial-grade active pharmaceutical ingredient ("API") or bulk drug product sales to Astellas. As a comparison, our revenue for the three and nine months ended September 30, 2025 primarily included $1.0 million and $4.8 million, respectively, of drug product revenue from commercial-grade API or bulk drug product sales to Astellas. Revenue increased for the three months ended September 30, 2026 compared to the same period in 2025, primarily due to bulk drug product sales to Astellas in current period. The revenue decreased for the nine months ended September 30, 2026 compared to the same period in 2025, primarily due to the change in estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment (as defined below).

Operating costs and expenses for the three and nine months ended September 30, 2026 increased compared to the same periods a year ago primarily as a result of the net effect of the following, respectively:

- $5.5 million and $7.6 million higher clinical trial expenses associated with FG-3246 Phase 2 trials and preparations for roxadustat MDS Phase 3 trials;
- $2.2 million and $6.5 million higher legal expenses primarily related to estimated indemnification costs associated with a former officer;
- $1.1 million and $2.7 million higher research and development outside services due to higher activities associated with FG-3246 and roxadustat MDS studies;
- $0.6 million and $4.4 million higher cost of goods sold corresponding to drug product revenue;
- $0.6 million and $2.9 million lower equipment expenses due to cost control efforts;

- $0.4 million and $2.0 million lower stock-based compensation primarily resulting from lower stock price and reduced headcount; and
- $2.2 million lower employee-related expenses during the nine months ended September 30, 2026 primarily due to reduced headcount.

On August 31, 2026, we entered into an A&R RIFA with NovaQuest, amending the RIFA. The A&R RIFA reduces the maximum aggregate payments under the agreement from $125.0 million to $65.0 million. Pursuance to the A&R RIFA, we made an upfront payment of $42.6 million to NovaQuest on August 31, 2026, which, together with the total payments of $7.4 million previously made under the RIFA, brought the total payments made to NovaQuest to $50.0 million under these agreements. After this upfront payment, the Remaining Cap is $15.0 million.As a result, we recorded a gain on debt restructuring of $14.0 million in the Company's condensed consolidated statements of operations for the three months ended September 30, 2026. See Note 8, *Liability Related to Sale of Future Revenues,* to the condensed consolidated financial statements for details.

In April 2026, our subsidiary, FibroGen Europe Oy ("FibroGen Europe"), voluntarily filed for bankruptcy with the Finnish bankruptcy court. On April 16, 2026, the Helsinki District Court declared FibroGen Europe bankrupt and appointed an estate administrator to oversee the bankruptcy estate. As a result, we determined that we no longer maintained a controlling financial interest in FibroGen Europe and therefore deconsolidated the subsidiary effective April 16, 2026. Upon deconsolidation, we derecognized the subsidiary's assets and liabilities and recognized a $30.9 million gain on deconsolidation. See Note 2, *Deconsolidation of European Subsidiary*, to the condensed consolidated financial statements for details.

For the three months ended September 30, 2026, we had income from continuing operations of $0.2 million, or an earnings per basic and diluted share of $0.04, as compared to a loss of $13.1 million, or a loss per basic and diluted share of $3.25, for the same period a year ago, primarily due to the gain on debt restructuring, offset by increases in operating costs and expenses. For the nine months ended September 30, 2026, we had a loss from continuing operations of $3.0 million, or a loss per basic and diluted share of $0.74, as compared to a loss of $43.6 million, or a loss per basic and diluted share of $10.79, for the same period a year ago, primarily due to the gain on debt restructuring and the gain on deconsolidation of subsidiary, offset by increases in operating costs and expenses and decreases in revenue.

Cash and cash equivalents, investments and accounts receivable totaled $44.1 million at September 30, 2026, a decrease of $65.2 million from December 31, 2025, primarily due to the above-mentioned $42.6 million upfront payment to NovaQuest and 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.

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 approximately 74,000, and continues to rise as more therapies become available and patients are living longer with MDS. Annual incidence rates are estimated to be 20,000 adults in the U.S., 70% of whom are considered lower-risk MDS.

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 70% of the total diagnosed MDS population. National Comprehensive Cancer Network guidelines recommend the use of erythropoiesis-stimulating agents ("ESAs"), luspatercept and imetelstat in lower risk MDS patients, depending on patients' treatment history, serum erythropoietin ("EPO") levels and *ring sideroblast* ("RS") *status*. Current FDA approved treatment options are effective in less than 50% of 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 RS status. Roxadustat, our orally administered small molecule hypoxia-inducible factor prolyl hydroxylase inhibitor, stimulates the body's natural mechanism of RBC production and iron homeostasis 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 have finalized 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. Our goal is to initiate the Phase 3 trial in the first quarter of 2027, subject to the execution of either a strategic partnership or an external capital raise.

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 key Phase 3 design elements, including the patient population (high transfusion burden patients requiring ≥4 units of packed RBC (pRBCs) within an 8-week period, for each of 2 consecutive 8-week periods in the 16 weeks immediately prior to randomization, who are refractory to, intolerant to, or ineligible for prior ESA therapy), dose regimen, and placebo control group with a 2:1 randomization. We have selected 8-week transfusion independence (over the first 24 weeks) as the primary endpoint of the study. The FDA recommended a longer duration of transfusion independence as the primary endpoint (16-weeks over 48 weeks), however, an 8-week primary endpoint is consistent with past and current placebo-controlled studies in this indication. We are including 12-week, 16-week, and 24-week transfusion independence (each over 48 weeks) as key secondary endpoints. Based on consultation with medical professionals, we believe the design of the study should provide sufficient evidence of patient benefit in this population of high-transfusion burden lower-risk MDS patients. The study is powered to detect meaningful statistically significant differences for the primary endpoint and all key secondary endpoints.

Phase 2/3 Clinical Trial in MDS

As previously disclosed from MATTERHORN, our Phase 2/3 placebo-controlled, double-blind clinical trial of roxadustat for the treatment of anemia in MDS, 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. Treatment-emergent adverse events were generally lower grade and managed medically with no new safety signals.

Our European Hematology Association Congress 2026 presentation highlighted data from post hoc analyses. In 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 (8 weeks within the first 28 weeks), versus 7% of the 15 placebo patients (nominal p-value of 0.04). In addition, roxadustat subgroups had similar rates of transfusion independence in both RS+ and RS- patients. In RS- patients, which comprised 84 of the 140 patients enrolled in the trial, treatment with roxadustat led to transfusion independence for ≥8 weeks (within the first 28 weeks) in 48% of patients vs. 28% for placebo.

We also conducted a post hoc analysis of MATTERHORN patients who were considered refractory to prior ESA therapy. In this subgroup, treatment with roxadustat was associated with higher rates of red blood cell RBC transfusion independence of at least eight weeks compared with placebo. The difference was greatest among patients with high transfusion burden at baseline, defined as ≥4 units of packed RBC (pRBCs) within an 8-week period (30.8% vs 0%). Among patients requiring at least two RBC units per eight weeks, 38.9% of roxadustat-treated patients achieved at least eight-week RBC transfusion independence compared with 12.5% of placebo-treated patients (14/36 versus 3/24; p=0.03).

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 3, *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.

FG-3246 and FG-3180 in mCRPC

FG-3246 has been evaluated in the post-androgen receptor pathway inhibitor ("ARPI"), pre-chemotherapy mCRPC setting, an area of high unmet need, where radiographic progression-free survival is short. FG-3180 has been evaluated as a potential patient-selection biomarker for FG-3246. As described below, in the fourth quarter of 2026, we decided to terminate our ongoing Phase 2 study and begin an orderly wind-down.

Phase 2 Monotherapy Clinical Trial of FG-3246 and FG-3180 for the Treatment of 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 attractive target for an ADC . The cytotoxic payload of FG-3246 is monomethyl auristatin E, an anti-mitotic agent that has been utilized in five commercially approved ADC drugs.

In the fourth quarter of 2026, we decided to terminate 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, and to begin an orderly wind-down of the study. Patients currently receiving FG-3246 who may continue to benefit from treatment may remain on study drug in accordance with the study protocol, investigator judgment and applicable regulatory requirements. We do not plan to enroll additional patients in the study. We expect to complete customary clinical, regulatory, data-analysis and other wind-down activities and to analyze available data from enrolled patients.

The trial also included an exploratory sub-study of FG-3180, a companion PET imaging agent that shares the same CD46-targeted antibody used in FG-3246, to assess its diagnostic and predictive performance. We are also winding down the FG-3180 sub-study.

The Phase 2 trial (NCT06842498) is randomized and open label, and was designed to evaluate the safety, efficacy, tolerability, and pharmacokinetics ("PK") of FG-3246. Prior to the decision to discontinue enrollment, the trial was designed to enroll 75 patients randomized 1:1:1 to receive 1.8, 2.4 or 2.7 mg/kg AJBW of FG-3246, with a primary objective of determining an optimal dose for potential further development based on efficacy, safety and PK parameters. Secondary endpoints include radiographic progression-free survival, prostate-specific antigen ("PSA") 50 response and PSA90 response. Because we have discontinued enrollment, no additional patients will be enrolled in the study or the FG-3180 companion PET imaging agent sub-study as part of the study wind-down.

Exclusive License and Option to Acquire Fortis

In May 2023, we 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 was 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 held an exclusive license to FG-3246. In the fourth quarter of 2026, we decided to discontinue development of FG-3246, and we notified Fortis that we will terminate the evaluation agreement, at which time our exclusive license to FG-3246 will terminate and the option to acquire Fortis will terminate. Following termination, we are required to wind-down, at our cost, our remaining development activities under the study plan or, at Fortis's election, transfer them to Fortis; to transfer collaboration data, regulatory materials, manufacturing documentation, and inventory to Fortis.

As a result of our decision to discontinue the development of FG-3246, we will not pay the option exercise payment or any contingent payments to Fortis, and we will not be responsible for the milestone fees and royalties owed to University of California, San Francisco, an upstream licensor to Fortis, which would have applied had we acquired Fortis.

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 4, *Collaboration Agreements, License Agreement and Revenues*, to the condensed consolidated financial statements for details.

Astellas

In June 2005, we entered into a collaboration agreement with Astellas for the development and commercialization (but not manufacture) of roxadustat for the treatment of anemia in Japan ("Astellas Japan Agreement"). In April 2006, we entered into a separate collaboration agreement with Astellas for roxadustat for the treatment of anemia in Europe, the Commonwealth of Independent States, the Middle East, and South Africa ("Astellas Europe Agreement"). Under these agreements, the aggregate amount of consideration received through September 30, 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 immaterial for the three months ended September 30, 2026. The related drug product revenue was ($0.4) million for the three months ended September 30, 2025, and ($5.1) million and $1.4 million for the nine months ended September 30, 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 $1.6 million and $1.3 million for the three months ended September 30, 2026 and 2025, and $8.7 million and $3.3 million for the nine months ended September 30, 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 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.

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. 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 3, *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 3, *Discontinued Operations and Divestiture*, to the condensed consolidated financial statements for details.

Product revenue, net, was $167.2 million and $226.7 million for the three and nine months ended September 30, 2025, respectively, majority of which were from the sales to Falikang, and was included in the discontinued operations. As discussed in Note 3, *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 September 30,		Change		Nine Months Ended September 30,		Change	
	2026	2025	$	%	2026	2025	$	%
	(dollars in thousands)							
Revenue:								
Development and other revenue	$ 99	$ 119	$ (20)	(17)%	$ 449	$ 396	$ 53	13 %
Drug product revenue, net	1,663	957	706	74 %	3,577	4,767	(1,190)	(25)%
Total revenue	$ 1,762	$ 1,076	$ 686	64 %	$ 4,026	$ 5,163	$ (1,137)	(22)%

Development revenue includes co-development and other development related services. We recognize development services as revenue in the period in which they are billed to our partners, excluding China. As of September 30, 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 $0.7 million, or 64%, for the three months ended September 30, 2026, and decreased $1.1 million, or 22%, for the nine months ended September 30, 2026, respectively, compared to the same periods a year ago for the reasons discussed in the sections below.

Drug Product Revenue, Net

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2026	2025	$	%	2026	2025	$	%
	(dollars in thousands)							
Drug product revenue, net:								
Astellas Japan Agreement	$ 17	$ (378)	$ 395	104 %	$ (5,110)	$ 1,446	$ (6,556)	(453) %
Astellas Europe Agreement	1,646	1,335	311	23 %	8,687	3,321	5,366	162 %
Total drug product revenue, net:	$ 1,663	$ 957	$ 706	74 %	$ 3,577	$ 4,767	$ (1,190)	(25) %

Drug product revenue, net increased $0.7 million, or 74%, for the three months ended September 30, 2026, and decreased $1.2 million, or 25%, for the nine months ended September 30, 2026, respectively, compared to the same periods a year ago.

Astellas Japan Agreement

During the third quarter of 2026, the adjustment to the drug product revenue was immaterial.

During the second 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 $2.9 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 estimated bulk product strength mix intended to be manufactured by Astellas, and foreign exchange impacts, among others.

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 third 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 a reduction to the drug product revenue of $0.4 million. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect foreign exchange impacts, 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 September 30, 2026, the balances related to the API price true-up under the Astellas Japan Agreement were $2.9 million in accrued liabilities, representing our best estimate of the timing for these amounts to be paid.

Astellas Europe Agreement

We recognized royalty revenue as drug product revenue, from the deferred revenue under the Astellas Europe Agreement, of $1.2 million and $1.3 million for the three months ended September 30, 2026 and 2025, and $4.1 million and $3.3 million for the nine months ended September 30, 2026 and 2025, respectively. It is our 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.

During the third quarter of 2026, 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 $0.4 million as drug product revenue, and recorded $3.3 million as deferred revenue due to a high degree of uncertainty associated with the variable consideration for revenue recognition purposes.

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.

For the nine months ended September 30, 2026, we updated our estimate of variable consideration related to the bulk drug product transferred in prior years. Specifically, the change in estimated variable consideration was based on the bulk drug product held by Astellas at the period end, adjusted to reflect the changes in the estimated transfer price, forecast information, shelf-life estimates and other items. As a result, we further reclassified $1.8 million from the related deferred revenue to accrued liabilities. As of September 30, 2026, the balances related to the bulk drug product price true-up under the Astellas Europe Agreement and the Astellas EU Supply Agreement were $3.3 million in accrued liabilities, representing our best estimate that these amounts will be paid within the next 12 months. 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.

Operating Costs and Expenses

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2026	2025	$	%	2026	2025	$	%
	(dollars in thousands)							
Operating costs and expenses								
Cost of goods sold	$ 619	$ (58)	$ 677	1,167 %	$ 4,727	$ 278	$ 4,449	1,600 %
Research and development	8,266	1,209	7,057	584 %	22,654	16,249	6,405	39 %
Selling, general and administrative	5,757	5,295	462	9 %	20,951	20,459	492	2 %
Restructuring charge	(15)	41	(56)	(137) %	(48)	560	(608)	(109) %
Total operating costs and expenses	$ 14,627	$ 6,487	$ 8,140	125 %	$ 48,284	$ 37,546	$ 10,738	29 %

Total operating costs and expenses increased $8.1 million, or 125%, for the three months ended September 30, 2026, and increased $10.7 million, or 29%, for the nine months ended September 30, 2026, respectively, compared to the same periods a year ago for the reasons discussed in the sections below.

Cost of Goods Sold

Cost of goods sold increased $0.7 million, or 1,167%, for the three months ended September 30, 2026 compared to the same period a year ago, primarily due to the costs of bulk drug product transferred to Astellas of $0.4 million. Cost of goods sold increased $4.4 million, or 1,600%, for the nine months ended September 30, 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 $1.3 million during the nine months ended September 30, 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 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. As a result of the termination of the FG-3246 and FG-3180 program, we expect to save over $20 million in operating expenses in 2027 and 2028.

The following table summarizes our research and development expenses incurred during the three and nine months ended September 30, 2026 and 2025:

Product Candidate	Phase of Development	Three Months Ended September 30,		Nine Months Ended September 30,	
		2026	2025	2026	2025
		(in thousands)			
Roxadustat	Approved / Phase 3	$ 3,470	$ 287	$ 8,153	$ 1,849
FG-3246	Phase 2	4,684	1,571	13,761	10,352
Other research and development expenses		112	(649)	740	4,048
Total research and development expenses		$ 8,266	$ 1,209	$ 22,654	$ 16,249

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 increased $7.1 million, or 584%, for the three months ended September 30, 2026, compared to the same period a year ago, primarily as a result of the net effect of the following:

- Increase of $5.5 million in clinical trials expenses associated with the FG-3246 Phase 2 trial and preparations for the roxadustat MDS Phase 3 trial; and
- Increase of $1.1 million in outside services due to higher activities associated with FG-3246 and roxadustat MDS studies in the current year period.

Research and development expenses increased $6.4 million, or 39%, for the nine months ended September 30, 2026, compared to the same period a year ago, primarily as a result of the net effect of the following:

- Increase of $7.6 million in clinical trials expenses associated with the FG-3246 Phase 2 trial and preparations for the roxadustat MDS Phase 3 trial;
- Increase of $2.7 million in outside services due to higher activities associated with FG-3246 and roxadustat MDS studies in the current year period;
- Decrease of $1.8 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;
- Decrease of $0.7 million in drug development expenses due to lower drug substance activities and lower logistic expenses associated with manufacturing activities for FG-3246 clinical trials; and
- Decrease of $0.7 million in equipment expenses due to cost control efforts.

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.

SG&A expenses increased $0.5 million, or 9%, for the three months ended September 30, 2026, compared to the same period a year ago, primarily as a result of the net effect of the following, respectively:

- Increase of $2.2 million in legal expenses primarily related to estimated indemnification costs associated with a former officer;
- Decrease of $1.0 million in outside services due to cost control efforts; and
- Decrease of $0.7 million in stock-based compensation primarily resulting from lower stock price.

SG&A expenses remained relatively flat for the nine months ended September 30, 2026, compared to the same period a year ago, primarily as a result of the net effect of the following, respectively:

- Increase of $6.5 million in legal expenses primarily related to estimated indemnification costs associated with a former officer;
- Decrease of $2.2 million in equipment expenses and decrease of $2.1 million in outside services due to cost control efforts; and
- Decrease of $1.3 million in stock-based compensation primarily resulting from lower stock price and reduced headcount.

Interest and Other, Net

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2026	2025	$	%	2026	2025	$	%
	(dollars in thousands)							
Interest and other, net:								
Interest expense	$ (1,632)	$ (2,083)	$ 451	(22) %	$ (6,426)	$ (6,346)	$ (80)	1 %
Gain on deconsolidation of subsidiary	—	—	—	NM	30,940	—	30,940	NM
Loss on debt extinguishments	—	(6,583)	6,583	NM	—	(6,583)	6,583	NM
Gain on debt restructuring	14,011	—	14,011	NM	14,011	—	14,011	NM
Interest income and other income (expenses), net	643	931	(288)	(31) %	2,731	1,628	1,103	68 %
Total interest and other, net	$ 13,022	$ (7,735)	$ 20,757	(268) %	$ 41,256	$ (11,301)	$ 52,557	(465) %

NM = Not meaningful

Interest Expense

Interest expense represents the interest associated with our liability related to sale of future revenues with NovaQuest and interest related to the Technology Development Center of the Republic of Finland product development obligations. Interest expense decreased $0.5 million, or 22% for the three months ended September 30, 2026, compared to the same period a year ago, primarily due to the above-mentioned debt restructuring with NovaQuest in August 2026. Under the A&R RIFA, future royalty interest payments to NovaQuest will reduce the carrying value of the debt and no interest expense will be recorded on the restructured liability. See Note 8, *Liability Related to Sale of Future Revenues,* to the condensed consolidated financial statements for details. In addition, we no longer incur interest expenses for product development obligations in Finland, following the deconsolidation of FibroGen Europe in April 2026. See Note 2, *Deconsolidation of European Subsidiary*, to the condensed consolidated financial statements for details.

Interest expense remained relatively flat for the nine months ended September 30, 2026, compared to the same period a year ago.

Gain on deconsolidation of subsidiary

In April 2026, our subsidiary, FibroGen Europe, voluntarily filed for bankruptcy with the Finnish bankruptcy court. On April 16, 2026, the Helsinki District Court declared FibroGen Europe bankrupt and appointed an estate administrator to oversee the bankruptcy estate. As a result, we determined that we no longer maintained a controlling financial interest in FibroGen Europe and therefore deconsolidated the subsidiary effective April 16, 2026. Upon deconsolidation, we derecognized the subsidiary's assets and

liabilities and recognized a $30.9 million gain on deconsolidation in the second quarter of 2026. See Note 2, *Deconsolidation of European Subsidiary*, to the condensed consolidated financial statements for details.

Loss on debt extinguishments

In August 2025, upon the completion of the sale of our China operations through FibroGen International to AstraZeneca Treasury Limited, we paid a total of $80.9 million to Morgan Stanley Tactical Value ("MSTV"), 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. Accordingly, we recorded a loss on debt extinguishments of $6.6 million for the three and nine months ended September 30, 2025. See Note 7, *Senior Secured Term Loan Facilities*, to the condensed consolidated financial statements for details.

Gain on debt restructuring

On August 31, 2026, we entered into the A&R RIFA with NovaQuest, amending the RIFA. The A&R RIFA reduces the maximum aggregate payments under the agreement from $125.0 million to $65.0 million. Pursuance to the A&R RIFA, we made an upfront payment of $42.6 million to NovaQuest on August 31, 2026. After this upfront payment, the Remaining Cap is $15.0 million. As a result, we recorded a gain on debt restructuring of $14.0 million in the Company's condensed consolidated statements of operations for the three months ended September 30, 2026. See Note 8, *Liability Related to Sale of Future Revenues,* to the condensed consolidated financial statements for details.

Interest Income and Other Income (Expenses), Net

Interest income and other income (expenses), net primarily include interest income earned on our cash, cash equivalents and investments, foreign currency transaction gains (losses), remeasurement of certain monetary assets and liabilities in non-functional currency of our subsidiaries into the functional currency, realized gains (losses) on sales of investments, and other non-operating income and expenses.

Interest income and other income (expenses), net decreased $0.3 million, or 31%, for three months ended September 30, 2026, compared to the same period a year ago, primarily due to lower interest income resulting from lower cash equivalents and investment balances during the current year period. Interest income and other income (expenses), net increased $1.1 million, or 68%, for the nine months ended September 30, 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 period.

Income Taxes

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(dollars in thousands)			
Income (loss) from continuing operations before income taxes	$ 157	$ (13,146)	$ (3,002)	$ (43,684)
Benefit from income taxes	—	—	(1)	(90)
Effective tax rate	— %	— %	— %	0.2 %

Benefit from income taxes for the three and nine months ended September 30, 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 3, *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 closing of the Transaction 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 Treasury 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 Treasury, 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. On June 2, 2026, we received a $4.0 million payment from AstraZeneca Treasury, which is in full satisfaction of the final holdback. See Note 3, *Discontinued Operations and Divestiture*, to the condensed consolidated financial statements for details.

In April 2023, we entered into a 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 the RIFA with NovaQuest with respect to our revenues from Astellas' sales of roxadustat in Europe, Japan and the other Astellas territories. Pursuant to the RIFA, in the fourth quarter of 2022, we received $49.8 million from NovaQuest, representing the gross proceeds of $50.0 million net of initial issuance costs, in consideration for a portion of future revenues we will receive from Astellas. On August 31, 2026, we entered into an A&R RIFA with NovaQuest. Pursuance to the A&R RIFA, we made an upfront payment of $42.6 million to NovaQuest on August 31, 2026, which, together with the total payments of $7.4 million previously made under the RIFA, brought the total payments made to NovaQuest to $50.0 million under these agreements. After this upfront payment, the Remaining Cap is $15.0 million. Under the A&R RIFA, we are required to pay NovaQuest 50% of the revenue that we are entitled to under the Astellas Europe Agreement and Astellas EU Supply Agreement (Astellas territories excluding Japan). For additional details about this financing transaction, see Note 8, *Liability Related to Sale of Future Revenues*, to the condensed consolidated financial statements.

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 in discontinued operations in our 2024 and 2025 10-Ks. On September 30, 2026, we received a determination letter (the "Determination") from the Staff notifying us that we had not yet demonstrated compliance with Listing Rule 5450(b) as of the September 29, 2026 deadline and that, as a result, the Staff had determined to delist our common stock from the Nasdaq Global Select Market. However, this Determination has no immediate effect on the listing of Kyntra Bio's common stock on Nasdaq Global Select Market.

We timely requested a hearing before a Nasdaq Hearings Panel (the "Panel") to review the Determination and to seek additional time to regain compliance. The hearing request stays the suspension of trading of our common stock and the filing of a Form 25-NSE with the Securities and Exchange Commission pending the Panel's written decision.

We had a hearing before a Nasdaq Hearings Panel ("Panel") on November 5, 2026, and are awaiting the Panel's decision. Kyntra Bio may also consider applying to transfer our securities to the Nasdaq Capital Market. If we are unable to obtain an extension 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 $44.1 million at September 30, 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) the A&R RIFA, under which, until the Remaining Cap is reached, we are required to pay 50% of the roxadustat revenue that we are entitled to for sales in Europe and the other Astellas territories (excluding Japan). These remaining payments are payable from that specified revenue stream and, in the ordinary course, do not require us to use our other cash resources, but they reduce the amount of such royalty revenue available to fund our operations.

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:

	Nine Months Ended September 30,	
	2026	2025
Net cash provided by (used in):		
Operating activities	$ (30,123)	$ 13,554
Investing activities	34,993	87,131
Financing activities	(42,808)	(86,014)
Effect of exchange rate changes on cash and cash equivalents	(29)	1,126
Net increase (decrease) in cash and cash equivalents	$ (37,967)	$ 15,797

Operating Activities

Net cash used in operating activities was $30.1 million for the nine months ended September 30, 2026 and consisted primarily of net loss of $3.1 million adjusted for non-operating cash items of $42.8 million, and a net increase in operating assets and liabilities of $15.7 million. The significant non-operating cash items included gain on deconsolidation of subsidiary of $30.9 million, gain on debt restructuring of $14.7 million, and stock-based compensation expense of $3.1 million. The significant items in the changes in operating assets and liabilities included the following:

- Accrued and other liabilities increased $8.4 million, driven by higher accrued legal expenses;
- Accrued interest expense related to sale of future revenues increased $5.0 million due to the interest expense of $6.3 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;
- Deferred revenue increased $3.6 million, driven by $9.5 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 nine months ended September 30, 2026; partially offset by $4.0 million royalty revenue recognized, and $1.8 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 4, *Collaboration Agreements, License Agreement and Revenues*, to the condensed consolidated financial statements for details; and
- Accounts receivable increased $3.6 million driven by the billing to Astellas for the bulk drug product transferred during the third quarter of 2026.

Net cash provided by operating activities was $13.6 million for the nine months ended September 30, 2025 and consisted primarily of net income of $197.7 million adjusted for non-operating cash items of $35.9 million, and a net decrease in operating assets and liabilities of $148.2 million. The significant non-operating cash items included gain on divesture of FibroGen International of $52.2 million, loss on debt extinguishments of $6.6 million and stock-based compensation expense of $5.4 million. The significant items in the changes in operating assets and liabilities included the following:

- Deferred revenue decreased $136.3 million, due to the recognition of all the previously deferred balance related to our China performance obligation under our agreements with AstraZeneca during the three months ended September 30, 2025 upon the completion of the divestiture of FibroGen International on August 29, 2025, as the performance obligation to AstraZeneca were completely satisfied upon the closing of the divestiture;
- Accrued and other liabilities decreased $48.1 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, $7.8 million of the transaction costs related to the divestiture, and the $3.2 million payments of accrued restructuring charge. The accrued and other liabilities were also impacted by cost control efforts and the timing of invoicing and payment;
- Accounts payable decreased $26.3 million, primarily driven by the payments made during the current year period to AstraZeneca under the settlement agreements entered in September 2024 between FibroGen China and AstraZeneca to settle certain historical items;
- Prepaid expenses and other current assets decreased $54.8 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 current year period based on the arrangements under the above-mentioned settlement agreements between FibroGen China and AstraZeneca to settle certain historical items, which was unbilled receivables as of December 31, 2024;
- Accrued interest expense related to sale of future revenues increased $5.7 million due to the interest expense of $6.1 million accrued, offset by the interest paid of $0.5 million during the period; and
- Inventory decreased $5.2 million primarily driven by lower inventory production in China as we have decommissioned our API manufacturing facility in Cangzhou, China in late 2024. Inventory in China was part of the held-for-sale assets as of December 31, 2024.

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 $35.0 million for the nine months ended September 30, 2026 and consisted primarily of $50.1 million proceeds from maturity of investments and $4.0 million cash payment received from AstraZeneca, which is in full satisfaction of the final holdback related to divestiture of FibroGen International; partially offset by $19.0 million cash used in purchases of available-for-sale securities.

Net cash provided by investing activities was $87.1 million for the nine months ended September 30, 2025 and consisted primarily of $90.2 million net proceeds from the divestiture of FibroGen International on August 29, 2025, which included the $210.4 million of cash received at closing, net of the $120.2 million cash in China at the closing that were derecognized upon the divestiture; partially offset by $3.0 million cash used in purchases of available-for-sale securities.

Financing Activities

Financing activities primarily reflect proceeds from strategic financing arrangements, proceeds from the issuance of our common stock, cash paid for debt restructuring of our liability related to sale of future revenues, cash paid related to our senior secured term loan facilities, cash paid to shareholders and cash paid for payroll taxes on restricted stock unit releases.

Net cash used in financing activities was $42.8 million for the nine months ended September 30, 2026, primarily related to the $42.6 million upfront payment to NovaQuest in connection with the debt restructuring. See Note 8, *Liability Related to Sale of Future Revenues,* to the condensed consolidated financial statements for details.

Net cash used in financing activities was $86.0 million for the nine months ended September 30, 2025 and consisted primarily of $75.0 million of cash used to pay off our senior secured term loan facilities with MSTV and $5.5 million of cash paid for the related premium and fees associated with the early pay-off. See Note 7, *Senior Secured Term Loan Facilities*, to the condensed consolidated financial statements for details. Net cash used in financing activities also included $5.4 million of cash paid to FibroGen Cayman's minority shareholders during the third quarter of 2025.

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 September 30, 2026, we had outstanding total non-cancelable purchase obligations of $0.4 million for manufacture and supply of roxadustat and $0.2 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 A&R RIFA with NovaQuest, as of September 30, 2026, our remaining payment obligation of liability related to sale of future revenues was $15.0 million, $3.7 million of which we anticipate to pay within the next 12 months. See Note 8, *Liability Related to Sale of Future Revenues*, to the condensed consolidated financial statements for details.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

There have been no material changes in our critical accounting policies, estimates and judgments during the three and nine months ended September 30, 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 September 30, 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 September 30, 2026.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended September 30, 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 September 30, 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 Candidate

- We are substantially dependent on the success of our product roxadustat.*
- Drug development and obtaining marketing authorization are very difficult endeavors, and we may ultimately be unable to obtain regulatory approval for our product candidate 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 candidate may cause or have attributed to it undesirable side effects or have other properties that delay or prevent its regulatory approval or limit its 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 candidate.
- Our product candidate 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 collaboration is terminated or if our partner is unwilling or unable to contribute or participate in the collaboration, 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 candidate.
- 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 partner 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 candidate.
- 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

- 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.*

RISK FACTORS

Risks Related to the Development and Commercialization of Our Product Candidate

We are substantially dependent on the success of our product roxadustat.*

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, and the potential of roxadustat for anemia associated with lower-risk myelodysplastic syndromes (“MDS”).

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 product candidate in one or more jurisdictions and in one or more indications.*

The development, manufacturing, marketing, and selling of our product and product candidate 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 the product candidate. Before obtaining regulatory approval for the commercial sale of the 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. Accordingly, we may be unable to successfully develop our product candidate 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 Practice ("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 candidate 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 candidate 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 candidate 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 partner 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 ability to obtain regulatory approval for our product candidate.

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 candidate 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 candidate produces 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 product, if any, and impose burdensome implementation that impact commercial performance.

Any of the foregoing scenarios could materially harm the commercial prospects for our product candidate.

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 candidate;
- delay or failure to obtain required regulatory or institutional review board approval or guidance;
- failure of the drug to pass interim futility criteria for efficacy in a clinical trial design;
- adverse side effects that meet safety stopping rules for the study in a clinical trial design;
- delay or failure to reach timely agreement on acceptable terms with prospective CROs and clinical trial sites;
- delay or failure to recruit, enroll and retain patients through the completion of the trial;
- patient recruitment, enrollment, or retention, clinical site initiation, or retention problems associated with civil unrest, military conflicts around the world, or natural disasters;
- delay or failure to maintain clinical sites in compliance with clinical trial protocols or to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- delay or failure to initiate or add a sufficient number of clinical trial sites;
- delay or failure to manufacture sufficient quantities of product candidate for use in clinical trials;
- difficulty enrolling a sufficient number of patients to conduct our clinical trials, as well as, investigator-sponsored trials as planned;
- inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, warning letter, or other regulatory action; and
- changes in laws or regulations.

In particular, identifying and qualifying patients to participate in clinical trials of our product candidate 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 candidate. Patients may be unwilling to participate in clinical trials of our product candidate 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 candidate 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 candidate may cause or have attributed to it undesirable side effects or have other properties that delay or prevent its regulatory approval or limit its commercial potential.

Undesirable side effects caused by our product candidate or that may be identified as related to our product candidate 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 candidate or specific indications affected;
- regulatory authorities increasing the data and information required to approve our product candidate and imposing other requirements; and
- our collaboration partner terminating our existing agreements.

The occurrence of any or all of these events may cause the development of our product candidate to be delayed or terminated, which could materially and adversely affect our business and prospects.

Clinical trials of our product candidate 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 candidate will be 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 candidate 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 candidate. If safety problems occur or are identified after our product candidate 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 candidate 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 from 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 candidate or product 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 our drug or drug candidate, include, but are not limited to, demonstration of comparability to approved/ in approval products and processes, additional clinical trials, delays in development or commercialization, earlier expiration dates, shorter shelf life, or specification failures, and those changes may materially impact our operations and potential profitability. This includes the scenario that the change may be unsuccessful and cause delays or other negative impact.

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

- costs and challenges associated with scale-up and attaining sufficient manufacturing yields;
- contracting with additional suppliers and validation/qualification of additional facilities to meet growing demand;
- supply chain issues, including coordination of multiple contractors in our supply chain and securing necessary licenses (such as export licenses);
- the timely availability and shelf-life requirements of raw materials and supplies;
- limited stability and product shelf life;

- equipment maintenance issues or failure;
- quality control and quality assurance issues;
- shortages of qualified personnel and capital required to manufacture large quantities of product;
- compliance with regulatory requirements that vary in each country where a product might be sold;
- capacity or forecasting limitations and scheduling availability in contracted facilities;
- natural disasters, such as pandemics, floods, storms, earthquakes, tsunamis, and droughts, or accidents such as fire, that affect facilities, possibly limit or postpone production, and increase costs; and
- failure to obtain a license to procure 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 our product candidate 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 would likely reduce our potential revenue.

We face substantial competition in the development and commercialization of product candidate.

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 partner to achieve and maintain a competitive advantage with respect to the development and commercialization of our product candidate. 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 partner 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 candidate 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 candidate receives 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 candidate and obtaining regulatory approvals will not guarantee future revenue. The degree of market acceptance of our approved product candidate 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 candidate 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 candidate may cause or have attributed to it undesirable side effects or have other properties that delay or prevent its regulatory approval or limit its 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 candidate, 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 candidate to other available products in order to obtain or maintain reimbursement or pricing approval. In the U.S., the current administration has pursued Most Favored Nation ("MFN") pricing policies, which tie or seek to tie the price of certain drugs to the lowest price paid for the same drug in other economically comparable countries, through executive action, voluntary pricing agreements with manufacturers and Center for Medicare and Medicaid Innovation ("CMMI") models. On September 30, 2026, the Centers for Medicare & Medicaid Services ("CMS") finalized the Global Benchmark for Efficient Drug Pricing ("GLOBE") Model, a mandatory Medicare Part B model that, after a reporting period beginning January 1, 2027 and performance period beginning April 1, 2027, will require manufacturers of certain high-spend, single source drugs to pay rebates tied to international reference prices. CMS has not yet finalized the companion Medicare Part D GUARD Model, and the GLOBE Model has already faced challenges in court. If these models are expanded, or if similar policies are adopted and applied to our products, they could result in downward pricing pressure domestically. The Inflation Reduction Act of 2022 established a Medicare drug price negotiation program administered by CMS, under which selected drugs are subject to government-negotiated "maximum fair prices." Small-molecule drugs, including roxadustat if approved in the United States, become eligible for selection earlier in their lifecycle than biologics. In January 2026, CMS selected drugs payable under Medicare Part B for negotiation for the first time (with negotiated prices effective in 2028), and legislation enacted in 2025 broadened the exclusion for orphan drugs, which may affect whether and when our product or product candidate could become subject to negotiation. If any of our products become subject to this program, or if this framework is expanded, our revenue and our collaboration partner's commercialization economics could be adversely affected. 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. In addition, on September 28, 2026, the Council of the European Union adopted a comprehensive reform of the EU pharmaceutical legislation that, once approved by the European Parliament and published, would among other things reduce the baseline period of regulatory protection for new medicines to eight years of data protection plus one year of market protection (subject to conditional extensions and an overall cap of eleven years), impose enhanced supply and shortage-prevention obligations, and require environmental risk assessments, with most provisions applying approximately two years after entry into force. These changes could affect the exclusivity, pricing and commercial prospects of roxadustat and our product candidate in Europe.

Risks Related to Our Reliance on Third Parties

If our collaboration is terminated or if our partner is unwilling or unable to contribute or participate in the collaboration, our ability to successfully develop and commercialize the relevant product candidate could suffer.*

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 AB ("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 (Hong Kong) Ltd. ("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.

In addition, if our collaboration partner Astellas is unsuccessful in their commercialization efforts in Europe and Japan, our financial results will be negatively affected.

If we do not establish and maintain strategic collaborations related to our product candidate, we will bear all of the risk and costs related to the development and commercialization of any such product candidate, which could trigger the need for us to seek additional financing, hire additional employees and otherwise develop expertise at significant cost.

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 partner in the event that our collaboration partner takes the position that our internal activities overlap with those areas that are exclusive to our collaboration agreements. Moreover, disagreements with our collaboration partner 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 partner 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 partner, as well as potentially impacting our commercial results.

Our collaboration partner could also become our competitors in the future. If our collaboration partner develops 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 candidate, the development and commercialization of our product candidate 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 candidate.

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 candidate. 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 candidate 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 candidate, 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 candidate 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 candidate 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 partner 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 that may negatively impact our planned development and commercialization activities;
- significant financial commitments we may be required to make with third-party manufacturers for early-stage clinical or pre-clinical programs that may fail to produce scientific results that would justify further development (without the ability to mitigate the manufacturing investments);
- the possible misappropriation of our proprietary technology, including our trade secrets and know-how;
- 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 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 candidate. 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 candidate, but are still responsible for cGMP adherence, if our contract manufacturers cannot successfully manufacture material that conforms to our or our collaboration partner's 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 product candidate 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 candidate 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 candidate or product, which in turn may delay, prevent or impair our development and commercialization efforts. We also carry the risk that we may need to pay termination fees to other manufacturers in the event that we have to manufacture lower volumes or not at all depending on the results of our clinical trials. We may be subject to payments to other third-party manufacturers to cover portions or all of the committed manufacturing campaigns even if we do not need the material for clinical or commercial usage. In addition, third-party manufacturers tend to change their upfront fees or postponement/cancelation fees over time or upon initiation of additional contracts, and this may lead to unanticipated financial loss for 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 candidate. 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 candidate. While we have in the past maintained sufficient inventory of materials, active pharmaceutical ingredient (“API”), and drug product to meet our and our collaboration partner’s 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 candidate 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 candidate, and there can be no assurance that our intellectual property will create and sustain the competitive position of our product candidate.

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 candidate. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidate is threatened, generic manufacturers and competitors with significantly greater resources could threaten our ability to commercialize our product candidate.

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 candidate without infringing the patent rights of others.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how, information, or technology that is not covered by our patents. Although our agreements require employees to acknowledge ownership by us of inventions conceived as a result of employment from the point of conception and, to the extent necessary, perfect such ownership by assignment, and we require employees, consultants, advisors and third parties who have access to our trade secrets, proprietary know-how and other confidential information and technology to enter into appropriate confidentiality agreements, we cannot be certain that our trade secrets, proprietary know-how and other confidential information and technology will not be subject to unauthorized disclosure, use, or misappropriation or that our competitors will not otherwise gain access to or independently develop substantially equivalent trade secrets, proprietary know-how and other information and technology. Furthermore, the laws of some foreign countries 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 candidate 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 partner or we may be subject to patent infringement claims from third parties. We attempt to ensure that our product candidate 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 candidate, roxadustat. 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 partner 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 candidate 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 candidate is expected to compete, protecting our trade secrets, including our strategies for addressing competing products and generic competition, is imperative, and any unauthorized use or disclosure could impair our competitive position and may have a material adverse effect on our business and operations.

In addition, our collaboration partner is a larger, more complex organization 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 partner 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 candidate, 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 candidate but that are not covered by the claims of the patents that we own or have exclusively licensed.

- Patent protection on our product candidate 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 candidate.

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 candidate.

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 any product candidate 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 our product candidate, 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 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. Regulations under the CCPA addressing risk assessments, cybersecurity audits and automated decision-making technology took effect on January 1, 2026, with phased compliance deadlines extending through 2030, and additional applicable comprehensive state privacy laws also took effect on January 1, 2026. 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. For example, the EU AI Act has applied in stages since 2025; although the EU's Digital Omnibus on AI, which entered into force on July 27, 2026, postponed the application of the high-risk AI system requirements to December 2027 and August 2028, other obligations, including certain transparency requirements, have applied since August 2, 2026. 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. The current PDUFA authorization expires on September 30, 2027, and Congress must pass legislation to reauthorize it. In August 2026, the FDA released a proposed commitment letter for the next reauthorization (PDUFA VIII), which the FDA expects to transmit to Congress by January 15, 2027; the final terms, including any changes to fee structures and review performance goals, are uncertain, and a failure to reauthorize PDUFA on a timely basis, or the FDA's inability to retain experienced review staff, could delay regulatory reviews and interactions.

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 draft framework, which has not been finalized. 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 partner 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

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. In February 2026, the U.S. Supreme Court invalidated tariffs imposed under the International Emergency Economic Powers Act, and the administration has since relied on other legal authorities, including Section 232 and Section 301, to impose or maintain tariffs and trade restrictions. In September 2026, the U.S. and China announced an extension of their trade truce from November 10, 2026 to January 10, 2027; the truce may not be extended further, and if it lapses, previously suspended tariffs, export controls and other measures could be reinstated. 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 candidate.

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 candidate 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 candidate, 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.*

The climate of geopolitical tensions in China affecting global supply chains may impact our ability to continually meet market demand. 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 candidate. 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 a lead product candidate in clinical development, roxadustat for anemia in lower-risk MDS in the U.S. and elsewhere. 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 September 30, 2026, we had an accumulated deficit of $1.7 billion. As of September 30, 2026, we had capital resources from cash and cash equivalents of $9.9 million and short-term investments of $30.4 million. Based on our current operating plans, we expect that our cash, cash equivalents, investments and accounts receivable will be sufficient to fund our operations into 2028; however, we may exhaust our capital resources sooner than expected and may need additional funding earlier than planned. 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 candidate and effectively manufacture, market and sell the product candidate that is 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 product and product candidate 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 any future product candidate. Our operating plans or third-party collaboration 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 our product candidate. 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 candidate 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.

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) the A&R RIFA (as defined below), under which, until the Remaining Cap (as defined below) is reached, we are required to pay 50% of the roxadustat revenue that we are entitled to for sales in Europe and the other Astellas territories (excluding Japan). These remaining payments are payable from that specified revenue stream and, in the ordinary course, do not require us to use our other cash resources, but they reduce the amount of such royalty revenue available to fund our operations.

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 amended revenue interest financing agreement with NovaQuest requires us to pay 50% of our recognized drug product revenue associated with the Astellas territories excluding Japan and subjects specified assets to a security interest until the remaining $15 million payment cap is reached.*

In November 2022, we entered into a $50 million revenue interest financing agreement (the “RIFA”) with NovaQuest with respect to our revenues from Astellas’ sales of roxadustat in Europe, Japan and the other Astellas territories.

On August 31, 2026, we entered into an amended and restated agreement (the “A&R RIFA”) with NovaQuest, amending the RIFA originally entered into on November 4, 2022. The A&R RIFA reduced the maximum aggregate payments under the agreement from $125 million to $65 million and eliminated all future true-up payments, including the potential balloon payments under the original agreement. In exchange, we paid NovaQuest an upfront payment of $42.6 million, plus NovaQuest’s expenses, upon signing, bringing total payments made to date to $50 million, a full return of NovaQuest’s invested capital. As of August 31, 2026, we had $15 million in remaining revenue-interest payment obligations (the “Remaining Cap”), which will be satisfied by paying NovaQuest 50% of the roxadustat revenue recognized from Astellas, on a quarterly basis, for sales in Europe and all other Astellas territories excluding Japan. Once the Remaining Cap is reached, the A&R RIFA will expire and we will retain all subsequent roxadustat royalties in the Astellas territories. The royalties we receive for sales in Japan are no longer subject to the royalty-based payments, and the intellectual property and other collateral associated with the Japan royalties were released.

NovaQuest's security interest under the A&R RIFA is limited to the applicable revenue interests and product intellectual property rights for the remaining Astellas territories (excluding Japan) until the Remaining Cap is reached or paid, at which time the remaining security interests will be automatically released.

Unlike the original RIFA, the A&R RIFA eliminated the potential balloon and true-up payments that we previously disclosed. Our remaining revenue-interest payments are capped at $15 million as of August 31, 2026 and will be satisfied from 50% of the roxadustat recognized revenue for sales from applicable territories. Accordingly, in the ordinary course, these remaining payments do not require us to use cash from other sources. However, until the Remaining Cap is reached, we will retain only half of that specified revenue, and the timing over which the revenue share and related security interest remain outstanding will depend on Astellas' commercialization efforts and sales, which we do not control. We may prepay the Remaining Cap at any time, but any such voluntary prepayment would reduce our available cash.

The A&R RIFA also includes customary reporting obligations and events of default, mostly focused on the $15 million remaining payment cap as of August 31, 2026. Upon an uncured event of default, NovaQuest may exercise remedies available to it under the A&R RIFA with respect to the remaining collateral. Although the A&R RIFA materially reduced our payment obligations and collateral exposure, such remedies could adversely affect our rights in the covered assets.

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

The A&R RIFA is filed as an exhibit to this Quarterly Report on Form 10-Q.

The A&R RIFA includes certain risks, including: (2) a possible extension of the period during which the recognized revenue payments and related security interest remain outstanding if Astellas sales in the applicable territories are lower or occur later than we currently anticipate; (3) limits on our ability to dispose of or encumber the covered roxadustat revenue interests and product intellectual property while NovaQuest's security interest remains outstanding; (4) the remedies available to NovaQuest in the event an uncured event of default were to occur under the A&R RIFA; and (5) a reduction in our available cash if we elect to prepay all or a portion of the Remaining Cap rather than allowing it to be satisfied from the specified royalty stream.

The A&R RIFA does not require the future balloon or true-up payments contemplated by the original RIFA, and Japan royalties and the associated intellectual property and other collateral have been released. Nevertheless, the remaining payments based on the Astellas revenue, covenant and collateral provisions described above could adversely affect our cash flows or rights in the covered assets until the Remaining Cap is reached or paid.

We may encounter difficulties in managing our growth and expanding our operations, successfully.

As we seek to advance our product candidate 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 product, product candidate, 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 include indemnification for proceedings against our current or former officers, and there is one ongoing proceeding against a former officer where costs are now material as set forth in the *Indemnification Agreements* section under Note 10, *Commitments and Contingencies*. 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 partner 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 candidate. 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 candidate or significantly reduced demand for any approved products;
- material costs and expenses to defend the related litigation;
- a diversion of time and resources across the entire organization, including our executive management;
- product recalls, product withdrawals or labeling restrictions;
- termination of our collaboration relationship or disputes with our collaboration partner; and
- reputational damage negatively impacting our product candidate.

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 candidate. We maintain product liability insurance in a customary amount for the stage of development of our product candidate. Although we believe that we have sufficient coverage based on the advice of our third-party advisors, there can be no assurance that such levels will be sufficient for our needs. Moreover, our insurance policies have various exclusions, and we may be in a dispute with our carrier as to the extent and nature of our coverage, including whether we are covered under the applicable product liability policy. If we are not able to ensure coverage or are required to pay substantial amounts to settle or otherwise contest the claims for product liability, our business and operations would be negatively affected.

Our business and operations would suffer in the event of computer system failures.

Despite implementing security measures, our internal computer systems, and those of our CROs, collaboration partners, and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We upgraded our disaster and data recovery capabilities in 2022 and continue to maintain and upgrade these capabilities. However, to the extent that any disruption or security breach, in particular with our partners' operations, results in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and it could result in a material disruption and delay of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

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

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

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

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

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

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

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

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

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

Applicable data privacy and security obligations may require us to 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 September 30, 2026, the closing price of our common stock on the Nasdaq Global Select Market has ranged from $6.46 per share to $12.02 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 candidate;
- 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 candidate or clinical development programs;
- results of clinical trials of our competitors' products;
- safety issues with respect to our product candidate or our competitors' products;
- regulatory actions with respect to our product candidate 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 candidate 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 Securities Exchange Act of 1934, as amended (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 our common stock may be delisted if the Nasdaq hearing panel does not provide us more time to regain compliance with the continued listing requirements of the Nasdaq Global Select 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 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). On September 30, 2026, we received a determination letter (the "Determination") from the Staff notifying us that we had not yet demonstrated compliance with Listing Rule 5450(b) as of the September 29, 2026 deadline and that, as a result, the Staff had determined to delist our common stock from the Nasdaq Global Select Market. However, this Determination has no immediate effect.

We timely requested a hearing before a Nasdaq Hearings Panel (the "Panel") to review the Determination and to seek additional time to regain compliance. The hearing request stays the suspension of trading of our common stock and the filing of a Form 25-NSE with the Securities and Exchange Commission pending the Panel's written decision. Accordingly, our common stock will remain listed and continue to trade on the Nasdaq Global Select Market under the symbol "KYNB" pending the Panel's decision. We had a hearing on November 5, 2026, and are awaiting the Panel's decision.

We prepared a compliance plan for the Panel. However, there can be no assurance that the Panel will grant our request for continued listing or that we will be able to regain compliance with the applicable continued listing requirements within any extension period that may be granted by the Panel. If the Panel does not grant our request, or if we do not satisfy the terms of any exception the Panel grants, our common stock would be subject to delisting from the Nasdaq Global Select Market.

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

To remain listed on the Nasdaq Capital Market, we would need to satisfy one of three standards (stockholders' equity of at least $2.5 million, market value of listed securities of at least $35 million, or net income from continuing operations of at least $500,000), among other requirements, and there can be no assurance that we could do so.

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 decreased 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 the Panel does not grant continued listing or we are otherwise unable to regain compliance with the Nasdaq Global Select Market, our common stock would be delisted from the applicable Nasdaq market. 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 product candidate and business or otherwise offer opportunities for us. In connection with these acquisitions or investments, we may:

- issue stock that would dilute our existing stockholders' percentage of ownership;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We may not be able to complete acquisitions on favorable terms, if at all. If we do complete an acquisition, we cannot assure you that it will ultimately strengthen our competitive position or that it will be viewed positively by customers, financial markets or investors. Furthermore, future acquisitions could pose numerous additional risks to our operations, including:

- problems integrating the purchased business, products or technologies, or employees or other assets of the acquisition target;
- increases to our expenses;
- disclosed or undisclosed liabilities of the acquired asset or company;
- diversion of management's attention from their day-to-day responsibilities;
- reprioritization of our development program and even cessation of development and commercialization of our current product candidate;

- harm to our operating results or financial condition;
- entrance into markets in which we have limited or no prior experience; and
- potential loss of key employees, particularly those of the acquired entity.

We may not be able to complete any acquisitions or effectively integrate the operations, products or personnel gained through any such acquisition.

Provisions in our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others and may prevent attempts by our stockholders to replace or remove our current directors or management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board of Directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Among other things, these provisions:

- authorize "blank check" preferred stock, which could be issued by our Board of Directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified Board of Directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our Board of Directors pursuant to a resolution adopted by a majority of the total number of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our Board of Directors;
- provide that our directors may be removed prior to the end of their term only for cause;
- provide that vacancies on our Board of Directors may be filled only by a majority of directors then in office, even though less than a quorum;
- require a supermajority vote of the holders of our common stock or the majority vote of our Board of Directors to amend our bylaws; and
- require a supermajority vote of the holders of our common stock to amend the classification of our Board of Directors into three classes and to amend certain other provisions of our certificate of incorporation.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management by making it more difficult for stockholders to replace members of our Board of Directors, which is responsible for appointing the members of our management.

Moreover, because we are incorporated in Delaware, we are governed by certain anti-takeover provisions under Delaware law which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. We are subject to the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, our amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Changes in our tax provision or exposure to additional tax liabilities could adversely affect our earnings and financial condition.

As a multinational corporation, we are subject to income taxes in the U.S. and various foreign jurisdictions. Significant judgment is required in determining our global provision for income taxes and other tax liabilities. In the ordinary course of a global business, there are intercompany transactions and calculations where the ultimate tax determination is uncertain. Our income tax returns are subject to audits by tax authorities. Although we regularly assess the likelihood of adverse outcomes resulting from these examinations to determine our tax estimates, a final determination of tax audits or tax disputes could have an adverse effect on our results of operations and financial condition.

We are also subject to non-income taxes, such as payroll, withholding, excise, customs and duties, sales, use, value-added, net worth, property, gross receipts, and goods and services taxes in the U.S., state and local, and various foreign jurisdictions. We are subject to audit and assessments by tax authorities with respect to these non-income taxes and the determination of these non-income taxes is subject to varying interpretations arising from the complex nature of tax laws and regulations. Therefore, we may have exposure to additional non-income tax liabilities, which could have an adverse effect on our results of operations and financial condition.

The tax regulations in the U.S. and other jurisdictions in which we operate are extremely complex and subject to change. Changes in tax regulations could have an adverse effect on our results of operations and financial condition. On July 4, 2025, the One Big Beautiful Bill Act was signed into law in the U.S. which contains a broad range of tax reform provisions affecting businesses. We are still in the process of evaluating the legislation and an estimate of the financial impact cannot be made at this time.

Federal and state tax laws impose substantial restrictions on the utilization of net operating loss ("NOL") and credit carryforwards in the event of an "ownership change" for tax purposes, as defined in Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the "IRC"). 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 IRC Section 382 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, IRC Section 382 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 NOL 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. For example, on April 2, 2026, the President issued a proclamation under Section 232 of the Trade Expansion Act of 1962 imposing a 100% tariff on imports of certain patented pharmaceuticals and associated ingredients, which took effect on July 31, 2026 for certain listed companies and on September 29, 2026 for other companies, subject to reduced rates for products of specified jurisdictions (including the European Union and Japan) and of companies with approved onshoring plans or pricing agreements, to zero-rate treatment for certain categories of products (such as orphan-designated drugs and antibody-drug conjugates, which may be conditioned on country of origin or other criteria), and to an exception for products imported solely for clinical trials, research and development or other noncommercial use. We source active pharmaceutical ingredient, other materials from suppliers in China for our programs, and the application of these tariffs to us, the availability of exceptions, and any future expansion of Section 232 or other tariffs to additional products or countries is uncertain. In addition, the U.S. Supreme Court invalidated tariffs imposed under the International Emergency Economic Powers Act in February 2026, the administration has relied on other legal authorities to impose tariffs, and the U.S.–China trade truce currently runs only through January 10, 2027. 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 candidate 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
10.1*†	Amended and Restated Revenue Interest Financing Agreement by and between Kyntra Bio, Inc. and NQ Project Phoebus, L.P., dated as of August 28, 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 is the type of information the Company treats as private and 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: November 16, 2026

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

Date: November 16, 2026

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

Execution Version

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Exhibit 10.1

AMENDED AND RESTATED REVENUE INTEREST FINANCING AGREEMENT

This Amended and Restated Revenue Interest Financing Agreement (this "***Agreement***") is entered into as of August 28, 2026 (the "***A&R Effective Date***"), by and between Kyntra Bio, Inc. (f/k/a FibroGen, Inc.), a Delaware corporation having an address of 350 Bay Street, Suite 100 #6009, San Francisco, CA 94133 ("***Company***") and NQ Project Phoebus, L.P., a Delaware limited partnership having an address of 4208 Six Forks Road, Suite 920, Raleigh, NC 27609 ("***NovaQuest***"). Company and NovaQuest are each referred to herein by name or, individually, as a "***Party***" or, collectively, as "***Parties***."

INTRODUCTION

A. Company and NovaQuest entered into that certain Revenue Interest Financing Agreement, dated as of November 4, 2022 (the "***Original Agreement***"), pursuant to which NovaQuest was granted an undivided percentage interest in Company's revenue received under the Astellas Agreements, including, without limitation: (i) twenty-two and one-half percent (22.5%) of each of the Astellas EMEA Revenue, Astellas Japan Revenue and Replacement Net Sales Revenue recognized during each Fiscal Year; (ii) the applicable percentages of Astellas Other Revenue and (iii) the applicable percentages of Replacement Other Revenue. The interests attributable to the Astellas Japan Agreement granted under the Original Agreement, being twenty-two and one-half percent (22.5%) of Astellas Japan Revenue and Replacement Net Sales Revenue associated therewith recognized during each Fiscal Year and the applicable percentages of Astellas Other Revenue and Replacement Other Revenue attributable to the Astellas Japan Agreement, together with all related Revenue Interests Collateral (as defined in the Original Agreement) and other Collateral (as defined in the Original Agreement) associated therewith, are referred to herein as the "***Japan Revenue Interests***".

B. As a material inducement for NovaQuest's entry into the Original Agreement, Company granted to NovaQuest a security interest in the Collateral (as defined in the Original Agreement), including the Revenue Interests Collateral (which include the Japan Revenue Interests) (in each case, as defined in the Original Agreement), pursuant to Section 4.5 of the Original Agreement.

C. Pursuant to the Original Agreement, NovaQuest paid Company the Investment Amount of Fifty Million Dollars ($50,000,000) in exchange for the Revenue Interest Payments

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(as defined in the Original Agreement), including the Japan Revenue Interests, pursuant to and in accordance with the terms of the Original Agreement.

D. Company desires to repurchase all Repurchased Interests (as defined below in this Agreement), and NovaQuest desires to sell and return the Repurchased Interests to Company, in each case on the terms and conditions set forth in this Agreement. Company desires to repurchase the Repurchased Interests from NovaQuest (and receive the other rights and benefits afforded to the Company in this Agreement) in exchange for payment of the Repurchase Price and the Expense Payment, and NovaQuest desires to sell and return the Repurchased Interests to Company (and to be bound by the other obligations and agreements applicable to NovaQuest in this Agreement) in exchange for Company's payment of the Repurchase Price and the Expense Payment, and, in connection therewith, the Parties desire to amend and restate the Original Agreement in its entirety on the terms and conditions set forth in this Agreement.

E. In connection with the repurchase of the Repurchased Interests and the amendment and restatement of the Original Agreement, Company is paying NovaQuest the Repurchase Price of Forty-Two Million, Five Hundred and Eighty Thousand, Five Hundred and Ninety Dollars and Sixty Six Cents ($42,580,590.66) plus the Expense Payment simultaneously with the execution of this Agreement.

F. Following the payment, and NovaQuest's receipt, of the Repurchase Price, the Parties have agreed that the only remaining financial obligation of Company to NovaQuest under this Agreement and otherwise shall be the Capped Return Amount, being Fifteen Million Dollars ($15,000,000), plus any Adjusted Amount, reduced on a dollar-for-dollar basis by the aggregate amount of all Revenue Interest Payments received by NovaQuest after the A&R Effective Date and any full or partial prepayments of the Capped Return Amount made pursuant to Section 4.1(d) or otherwise. The Parties acknowledge and agree that all other payment obligations that would otherwise have been owed by Company under the Original Agreement (including, without limitation, all True-Up Payments, minimum amount payments under Section 4.1(b) of the Original Agreement, any Prepayment Amount (as defined in the Original Agreement), the Event of Default Fee (as defined in the Original Agreement), and any other amounts) other than the Revenue Interest Payments (for the avoidance of doubt, excluding the Japan Revenue Interests) and, in each case, subject to and capped by the Capped Return Amount, are by this Agreement eliminated in their entirety and shall have no force or effect from and after the A&R Effective Date.

G. As additional material inducement for Company's entry into this Agreement, NovaQuest has agreed that (i) the Astellas Japan Agreement, all Astellas Japan Revenue (as defined in the Original Agreement), all Japan Revenue Interests, all Repurchased Interests and all other Collateral (as defined in the Original Agreement) related or ancillary thereto shall be forever excluded from the Collateral, the Collateral Revenue Interests, the Revenue Interest Payments from and after the A&R Effective Date and NovaQuest's receipt of the Repurchase Price and the Expense Payment (the items, amounts and property covered by this clause (i), collectively, the "***Japan Related Collateral***"), (ii) Japan is not part of the Territory from and after the A&R Effective Date and (iii) NovaQuest's security interest and Lien in the Collateral

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shall no longer extend (or applicable) to the Astellas Japan Agreement, any revenue or other amounts derived therefrom or any Japan Related Collateral and all such security interests and subject to NovaQuest's receipt of the Repurchase Price and the Expense Payment, Liens with respect to the Japan Related Collateral are hereby automatically and irrevocably forever released, terminated and discharged.

H. The Parties have agreed that the only amounts payable to NovaQuest from and after the A&R Effective Date shall be Revenue Interest Payments (for the avoidance of doubt, excluding the Japan Revenue Interests), calculated as fifty percent (50%) of Astellas EMEA Revenue and Astellas Other Revenue (excluding the Japan Revenue Interests) recognized during each Fiscal Quarter, in each case, subject to and capped by the Capped Return Amount; provided that any Adjusted Amount shall be payable in addition to the Capped Return Amount and shall not be subject to or reduce the Capped Return Amount; provided, further, that amounts paid pursuant to clause (i) Section 4.3(a) shall reduce the Capped Return Amount on a dollar-for-dollar basis. Except for any Adjusted Amount, no other amounts shall be owed to NovaQuest under this Agreement or otherwise.

I. The Parties have agreed that Company may (but is not required to) pay the then-current Capped Return Amount to NovaQuest at any time, for any reason and without penalty, interest or any additional fee or amount, and that upon NovaQuest's receipt of such payment (and the payment of any Adjusted Amount), this Agreement (other than Company's indemnification obligations under ARTICLE X and any actionable claims of fraud by either of Company or NovaQuest) and all other Transaction Documents shall immediately and automatically forever terminate, all security interests and Liens granted to NovaQuest hereunder, under any other Transaction Document or otherwise (including, without limitation, on all of the Collateral) shall immediately and automatically forever be released, terminated and discharged, and NovaQuest irrevocably authorizes Company and its counsel and designees to (and, upon Company request, NovaQuest shall promptly) file termination statements and release documents and take such other actions necessary or appropriate to effectuate the foregoing and also NovaQuest shall promptly take such other actions as may be reasonably requested by Company to effectuate the release, termination and discharge of all such security interests and Liens and the foregoing.

J. Once any remedies on the Collateral are exhausted up to the Capped Return Amount (and the payment of any Adjusted Amount), no other amounts shall be owed, due or payable to NovaQuest at any time thereafter (including, with respect to any uncollected Revenue Interest payments), and this Agreement (other than Company's indemnification obligations under ARTICLE X and any actionable claims of fraud by either of Company or NovaQuest) and all other Transaction Documents shall immediately and automatically forever terminate.

NOW, THEREFORE, in consideration of the representations, warranties, covenants and agreements set forth herein, the mutual concessions described in the foregoing recitals, and for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Company and NovaQuest hereby agree as follows:

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ARTICLE I

DEFINITIONS

1.1 Defined Terms. Except as otherwise expressly stated in this Agreement, when used and capitalized in this Agreement (other than the headings of the Articles and Sections), including the foregoing preamble, recitals, exhibits and schedules hereto, the following terms shall have the meanings assigned to them in this ARTICLE I and include the plural as well as the singular and include all participles of each such term, as applicable.

"***A&R Effective Date***" has the meaning set forth in the preamble hereto.

"***Adjusted Amount***" means, collectively, (a) the Expense Payment (it being agreed that the Expense Payment was paid in full in cash on the A&R Effective Date), (b) any default interest owed, due and payable pursuant to Section 4.4, (c) any Applicable Withholding Payment, (d) any amount owed, due and payable pursuant to Section 11.2(g), and (e) any amounts owed, due and payable pursuant to Company's indemnification obligations under ARTICLE X, in each case, if any.

"***Applicable Withholding Payment***" means any owed, due and payable Gross-Up Amount required to be paid by Company to (or on behalf of) NovaQuest pursuant to clause (ii) of Section 4.3(a).

"***AAA***" has the meaning set forth in Section 11.2(b).

"***AAA Rules***" has the meaning set forth in Section 11.2(b).

[*]

"***Acquiring Party***" means a Third Party that obtains control of Company in connection with a Change of Control of Company. For purposes of this definition, the term "control" shall have the meaning set forth in the definition of Affiliate.

"***Act***" means, collectively, the United States Federal Food, Drug, and Cosmetic Act of 1938, including any amendments thereto, and all regulations promulgated thereunder and any successor laws.

"***Affiliate***" means, with respect to an entity, any business entity controlling, controlled by, or under common control with, such entity, but only for so long as such control exists. For the purposes of this definition, "controlling," "controlled," and "control" mean the possession, directly (or indirectly through one or more intermediary entities), of the power to direct the management or policies of an entity, including through ownership of fifty percent (50%) or more of the voting securities of such entity (or, in the case of an entity that is not a corporation, ownership of fifty percent (50%) or more of the corresponding interest for the election of the entity's managing authority). Notwithstanding the foregoing, for purposes of this Agreement, NovaQuest Capital Management, L.L.C. shall be deemed to have no control Persons.

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"***Agreement***" has the meaning set forth in the preamble hereto.

"***Applicable Law***" means any applicable law, rule, or regulation of any Governmental Authority, or judgment, order, writ, decree, permit, or license of any Governmental Authority.

"***Arbitration***" has the meaning set forth in Section 11.2(b).

"***Arbitration Notice***" has the meaning set forth in Section 11.2(b).

"***Arbitrator***" has the meaning set forth in Section 11.2(c).

"***Astellas***" means Astellas Pharma Inc., a Japanese corporation with a principal place of business at 3-11 Nihonbashi-Honcho, 2-Chome, Chuo-ku, Tokyo, 103-8411 Japan.

"***Astellas Agreement***" means (A) prior to the A&R Effective Date, each or any of the Astellas EMEA Agreement or the Astellas Japan Agreement ("***Astellas Agreements***" means both of the foregoing, collectively); and (B) from and after the A&R Effective Date, solely the Astellas EMEA Agreement. For the avoidance of doubt, from and after the A&R Effective Date, the Astellas Japan Agreement shall not be an Astellas Agreement for any purpose under this Agreement.

"***Astellas EMEA Agreement***" means (a) that certain Anemia License and Collaboration Agreement by and between Astellas Pharma Inc. and FibroGen, Inc. dated April 28, 2006, as amended and supplemented by that certain Amendment to Anemia License and Collaboration Agreement, dated August 31, 2006, that certain Amendment No. 2, dated December 1, 2006, and that certain Amendment No. 3, dated May 10, 2012, attached hereto as Exhibit B, and as may be further amended from time to time in accordance with this Agreement and (b) that certain Astellas EU Supply Agreement dated Jan 1, 2021, as amended ("***Astellas EMEA Supply Agreement***").

"***Astellas EMEA Revenue***" means, [*].

"***Astellas Japan Agreement***" means that certain Collaboration Agreement by and between Astellas Pharma Inc. and FibroGen, Inc. dated June 1, 2005, as amended January 1, 2013 and as otherwise amended from time to time. From and after the A&R Effective Date, the Astellas Japan Agreement is not an Astellas Agreement for purposes of this Agreement, and NovaQuest has no rights or interests with respect thereto.

"***Astellas Japan Revenue***" means, [*].

"***Astellas Other Revenue***" means [*] For the avoidance of doubt, from and after the A&R Effective Date, Astellas Other Revenue shall not include any amounts attributable to the Astellas Japan Agreement or any Japan Revenue Interests.

"***Astellas Revenue***" means (A) prior to the A&R Effective Date, collectively, the Astellas EMEA Revenue, the Astellas Japan Revenue, and the Astellas Other Revenue; and (B) from and

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after the A&R Effective Date, collectively, the Astellas EMEA Revenue and the Astellas Other Revenue (as narrowed by clause (B) of the definition thereof). For the avoidance of doubt, from and after the A&R Effective Date, Astellas Revenue shall not include any Astellas Japan Revenue or any Japan Revenue Interests.

"***Bankruptcy Event of Default***" means any of: (a) the liquidation or dissolution of Company; (b) a Voluntary Bankruptcy; or (c) an Involuntary Bankruptcy.

"***Bankruptcy Laws***" means, collectively, bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, fraudulent transfer, or other similar laws affecting the enforcement of creditors' rights generally.

"***Business Day***" means any day other than Saturday, Sunday, or any day on which banking institutions located in the State of New York are permitted or obligated by law to close.

"***Capped Return Amount***" means, as of any date of determination after the A&R Effective Date, (i) Fifteen Million Dollars ($15,000,000) minus (ii) the aggregate amount of (A) Revenue Interest Payments actually received in cash by NovaQuest after the A&R Effective Date [*] (B) any full or partial prepayments of the Capped Return Amount [*].

"***Capped Return Payoff***" has the meaning set forth in Section 4.1(d).

"***Change of Control***" means, with respect to Company a transaction with one or more Third Parties that is: (a) a merger, share exchange, or other reorganization of Company; (b) the sale, by one or more stockholders or holders of equity securities, of stock or equity securities representing a majority of the voting power of Company; or (c) the sale or exclusive license of all or substantially all of the assets of the Company, or a sale of Company's business and assets related to the Product; or (d) the acquisition of majority control of the board of directors or equivalent governing body of Company, for which, in each of cases of clauses (a) and (b) of this definition, the stockholders or holders of other equity securities of Company prior to such transaction do not own a majority of the voting power of the acquiring, surviving, or successor entity, as the case may be.

"***Collateral***" means the Revenue Interest Collateral and the Product IP Rights. Notwithstanding anything to the contrary in this Agreement and for the avoidance of doubt, the Collateral shall exclude any Japan Related Collateral.

"***Collateral Revenue Interests***" means, in each case, as further described in Section 4.1(a): (A) for each Fiscal Quarter ending on or prior to June 30, 2026, (i) twenty-two and one-half percent (22.5%) of each of the Astellas EMEA Revenue, Astellas Japan Revenue, and Replacement Net Sales Revenue, (ii) ten percent (10%) of Astellas Other Revenue recognized during such period, and (iii) ten percent (10%) of Replacement Other Revenue; and (B) beginning with the Fiscal Quarter ending September 30, 2026, and solely until the Capped Return Amount is reduced to zero, (i) fifty percent (50%) of Astellas EMEA Revenue recognized during each Fiscal Quarter, (ii) fifty percent (50%) of Astellas Other Revenue (as narrowed by clause (B) of the definition thereof) recognized during each Fiscal Quarter, (iii) fifty percent

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(50%) of Replacement Net Sales Revenue recognized during each Fiscal Quarter, and (iv) fifty percent (50%) of Replacement Other Revenue recognized during each Fiscal Quarter. For the avoidance of doubt, from and after the A&R Effective Date, (a) the Collateral Revenue Interests shall not include any interest in Astellas Japan Revenue, Japan Revenue Interests or Japan Related Collateral and (b) all Collateral Revenue Interests (including those attributable to Replacement Net Sales Revenue and Replacement Other Revenue) received for each Fiscal Quarter ending on or after September 30, 2026 shall be subject to and capped by the Capped Return Amount.

"***Commercially Reasonable Efforts***" means, [*].

"***Commercialize***" or "***Commercialization***" means any and all activities directed to marketing, promoting, distributing, importing, exporting, offering to sell, or selling the Product, including commercial manufacturing activities.

"***Company***" has the meaning set forth in the preamble hereto.

"***Company Competitor***" means any Person that, in the Fiscal Year preceding the date of determination, derived more than [*] of its revenue from its or its Affiliates' direct sales of pharmaceutical products.

"***Compound***" means Roxadustat, as more particularly described in Exhibit D.

"***Confidential Information***" has the meaning set forth in Section 6.1.

"***Cover***" means that the use, manufacture, sale, offer for sale, development, commercialization, or importation of the subject matter in question by an unlicensed entity would infringe a claim of an issued Patent, or a claim, if issued, of a patent application that constitutes a Patent.

"***Custodian***" means any receiver, trustee, assignee, liquidator, custodian, or similar official under any Bankruptcy Law.

"***Default***" means any event that, with the giving of notice or passage of time, or both, could result in an Event of Default.

"***Defaulting Party***" has the meaning set forth in Section 8.6(d)(iii).

"***Dispute***" has the meaning set forth in Section 11.2(a).

"***Dispute Notice***" has the meaning set forth in Section 11.2(a).

"***Dollars***" or "***$***" means U.S. dollars.

"***Effective Date***" means November 4, 2022, being the date of the Original Agreement.

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"***Encumbrance***" means any lien, charge, security interest, mortgage, option, privilege, pledge, right of first refusal, hypothecation, adverse ownership interest, charge, trust or deemed trust (whether contractual, statutory, or otherwise arising), or any other encumbrance, right, or claim of any other Person of any kind whatsoever whether choate or inchoate. "***Encumber***" means to restrict, impose, suffer, or otherwise create any Encumbrance.

"***ESG Questionnaires***" has the meaning set forth in Section 5.4.

"***Event of Default***" means each or any of: (a) the failure by Company to pay any Revenue Interest Payment or any Adjusted Amount due to NovaQuest under this Agreement when required to be paid, which failure continues for more than [*] after Company's receipt of written notice from NovaQuest specifying such failure; (b) a Bankruptcy Event of Default; (c) a Change of Control occurs and Company fails to comply with Section 8.4; (d) the sale, transfer, or other disposition of a material portion of the Collateral by Company (other than in the ordinary course of business) without NovaQuest's prior written consent; or (e) Company materially breaches its obligations under Section 8.6(d) with respect to the Astellas EMEA Agreement and such breach remains uncured for [*] after Company's receipt of written notice from NovaQuest specifying such breach and where such breach, if not cured, would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

"***Excluded Taxes***" means any of the following Taxes imposed on or with respect to NovaQuest or required to be withheld or deducted from payment to NovaQuest: (a) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case (i) imposed as a result of NovaQuest being organized under the laws of, or having its principal office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (ii) that are Other Connection Taxes and (b) Taxes to the extent solely attributable to NovaQuest or any of its Affiliates changing its jurisdiction of domicile or form of legal entity or from NovaQuest assigning its rights or obligations under the Funding Agreement. For the purposes of the definition of "Excluded Taxes," the term "NovaQuest" includes any successors or assignees of NovaQuest according to Section 11.6.

"***Expense Payment***" has the meaning set forth in Section 11.4.

"***FDA***" means the United States Food and Drug Administration, or any successor agency thereto.

"***Fiscal Quarter***" means each of the following three (3)-month periods during each Fiscal Year: January 1 through March 31; April 1 through June 30; July 1 through September 30; and October 1 through December 31.

"***Fiscal Year***" means the twelve (12)-month period from January 1 through December 31.

"***GAAP***" means U.S. generally accepted accounting principles, as in effect on the date or for the period with respect to which such standards are applied.

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"***Governmental Authority***" means any national, supra-national (*e.g.*, the European Commission or the Council of the European Union), federal, state, local, or foreign court or governmental agency, authority, instrumentality, regulatory body, department, bureau, political subdivision, or other governmental entity (including the FDA, the European Medicines Agency, the Japanese Ministry of Health, Labour and Welfare or Pharmaceuticals and Medical Devices Agency, and the Medicines and Health Products Regulatory Agency, as well as any similar regulatory body in any country in the Territory) or any arbitrational tribunal, in each case of a competent jurisdiction, including any such authority that is responsible for taxation or for issuing approvals, licenses, registrations, or authorizations necessary for the manufacture, import, sale, pricing, or use of the Product for human therapeutic use in any applicable regulatory jurisdiction.

"***Gross-Up Amount***" has the meaning set forth in Section 4.3(a).

"***GxP***" means all relevant Governmental Authority requirements for: (a) current Good Clinical Practices for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials; (b) current Good Laboratory Practice for laboratory activities for pharmaceuticals; and (c) current Good Manufacturing Practices, including in each case, as set forth in Title 21 of the United States Code of Federal Regulations.

"***IFRS***" means international accounting standards, as in effect on the date or for the period with respect to which such standards are applied, as established by the International Financial Reporting Standards.

"***Indebtedness***" means, with respect to a Person: (a) all obligations of such Person for borrowed money; (b) all obligations of such Person evidenced by a note, bond, debenture, or similar instrument; (c) all obligations of such Person upon which interest charges are customarily paid; (d) all obligations of such Person under conditional sale or other title retention agreements relating to property acquired by such Person; (e) all obligations of such Person in respect of the deferred purchase price of property or services (excluding deferred compensation and accounts payable incurred in the ordinary course of business and not overdue by more than [*]; (f) all Indebtedness as described in clauses (a) through (e) or clauses (h) through (l) of others secured by (or for which the holder of such indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien on property owned or acquired by such Person if the Indebtedness secured thereby has been assumed; (g) all guarantees by such Person of Indebtedness as described in clauses (a) through (e) or clauses (h) through (l) of others; (h) all capital lease obligations of such Person; (i) all obligations, contingent or otherwise, of such Person as an account party in respect of letters of credit and letters of guaranty; (j) all net obligations of such Person under any interest rate exchange agreement, foreign currency exchange agreement, commodity price protection agreement, currency swap, forward, future or derivative transactions or other interest or currency exchange rate or commodity price hedging arrangement; (k) all obligations, contingent or otherwise, of such Person in respect of bankers' acceptances; and (l) any disqualified equity interests of such Person.

"***Investment Amount***" has the meaning set forth in Section 3.1(a).

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"***Investor Return Payment***" means each or any of the Revenue Interest Payments. For the avoidance of doubt, from and after the A&R Effective Date, Investor Return Payments shall not include any True-Up Payments, minimum amount payments under Section 4.1(b) of the Original Agreement, any Prepayment Amount (as defined in the Original Agreement), the Event of Default Fee (as defined in the Original Agreement), any payment with respect to Japan Revenue Interests and any other amounts.

"***Investor Return Payment Satisfaction***" means the earlier to occur of: (a) such time as the Capped Return Amount has been finally reduced to $0; and (b) such time as Company has paid the then-current Capped Return Amount to NovaQuest pursuant to Section 4.1(d).

"***Involuntary Bankruptcy***" means a court of competent jurisdiction enters an order or decree under any Bankruptcy Law that: (a) is for relief against Company in an involuntary case; (b) appoints a Custodian of Company or for any substantial part of its property; or (c) orders the winding up or liquidation of Company; or any similar relief is granted under any non-U.S. laws, and in each case ((a)–(c)), such order or decree remains unstayed and in effect for [*].

"***Japan Related Collateral***" has the meaning set forth in Recital G.

"***Japan Revenue Interests***" has the meaning set forth in Recital A.

"***Knowledge of Company***" or "***Knowledge***" means the actual knowledge, after making reasonable inquiry, of [*].

"***Liabilities***" means any and all indebtedness, liabilities, and obligations, whether accrued, fixed, or contingent, mature or inchoate, known or unknown, reflected on a balance sheet or otherwise, including those arising under any law or judgment of any court of any kind or any award of any arbitrator of any kind, and those arising under any contract, commitment, or undertaking.

"***License***" means (i) prior to the A&R Effective Date, a grant of any Product IP Rights or Regulatory Approvals for making, developing, Commercializing or otherwise exploiting the Product in the Territory, including, for the avoidance of doubt, each of the Astellas EMEA Agreement, the Astellas Japan Agreement, and any Replacement Agreement; and (ii) from and after the A&R Effective Date, a grant of any Product IP Rights or Regulatory Approvals for making, developing, Commercializing or otherwise exploiting the Product in the Territory, including, for the avoidance of doubt, the Astellas EMEA Agreement and any Replacement Agreement, but excluding in all cases the Astellas Japan Agreement, the Japan Related Collateral and any agreement, arrangement, or revenue derived therefrom, which shall not be a License for any purpose under this Agreement from and after the A&R Effective Date.

"***Licensee***" means a Third Party or an Affiliate of Company that is granted a License, by Company, an Affiliate of Company, or another Licensee. For the avoidance of doubt, (a) Astellas is a Licensee and (b) any Third Party that enters into a Replacement Agreement with Company or with any Affiliate of Company shall be a Licensee.

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"***Lien***" means any mortgage, lien, pledge, participation interest, charge, adverse claim, security interest, encumbrance or restriction of any kind, whether voluntarily incurred and arising by operation by law or otherwise, including any restriction on use, transfer or exercise of any other attribute of ownership of any kind.

"***Losses***" has the meaning set forth in Section 10.1.

"***Material Adverse Effect***" means any material adverse effect on: (a) the ability of the Company to make the Revenue Interest Payments required to be made by this Agreement; (b) the Commercialization of the Product in the Territory; (c) for the purpose of Section 7.1 only, any of the Product IP Rights, including Company's rights in or to any Product IP Rights; (d) for the purpose of Section 7.1 only, any Regulatory Approval granted prior to the Effective Date for the Product in the Territory; (e) for the purpose of Section 7.1 only, the legality, validity, or enforceability of any Astellas Agreement or Transaction Document; (f) the ability of Company to perform any of its material obligations under any Astellas Agreement or Transaction Document, or to consummate the transactions contemplated hereby or thereby; or (g) the rights or remedies of NovaQuest under any Transaction Document; provided that no material adverse effect on anything related to the Astellas Japan Agreement or any agreement related to Japan Revenue Interests or Japan Related Collateral shall be a Material Adverse Effect unless it also constitutes a material adverse effect under clause (a) above.

"***Material Contract***" means: (a) any agreement to which Company or any Affiliate of Company is a party and is material to the Commercialization of the Product in the Territory; or (b) any other agreement to which Company or any Affiliate of Company is a party for which breach, non-performance, or failure to renew by a Responsible Party could reasonably be expected to result in a Material Adverse Effect; [*].

"***NDA***" means a new drug application (as defined in Title 21 of the U.S. Code of Federal Regulations, as amended from time to time) submitted to the FDA seeking approval to introduce, distribute, sell, or market a drug product for human therapeutic use in the U.S. (including a new drug application submitted under Section 505(b)(2) of the Act) and the foreign equivalent in any country in the Territory.

"***NovaQuest***" has the meaning set forth in the preamble hereto.

"***NovaQuest Indemnitees***" has the meaning set forth in Section 10.1.

"***Original Agreement***" has the meaning set forth in Recital A.

"***Other Connection Taxes***" means, with respect to NovaQuest, Taxes imposed as a result of a present or former connection between NovaQuest and the jurisdiction imposing such Tax (other than connections arising from NovaQuest having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced this Agreement). For the purposes of the definition of "Other Connection Taxes," the term "NovaQuest" includes any successors or assignees of NovaQuest according to Section 11.6.

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"***Parties***" has the meaning set forth in the preamble hereto.

"***Party***" has the meaning set forth in the preamble hereto.

"***Patents***" means all patents (including all reissues, extensions, substitutions, confirmations, re-registrations, re-examinations, revalidations, supplementary protection certificates, and patents of addition) and patent applications (including all provisional applications, continuations, continuations-in-part, and divisions) and all counterparts and equivalents of any of the foregoing in any country or jurisdiction.

"***Payment Cap***" has the meaning given to "Capped Return Amount."

"***Payment Report***" has the meaning set forth in Section 4.1(f).

"***Permitted Company***" means [*].

"***Permitted Encumbrance***" means

(a) Encumbrances imposed by law, such as carriers', warehousemen's, landlords', materialmen's, repairman's, construction contractors', mechanics', airports', navigation authority's or other like Encumbrances, in each case for sums not yet overdue by more than [*] or being contested in good faith by appropriate proceedings or other Encumbrances arising out of judgments or awards against such Person with respect to which such Person shall then be proceeding with an appeal or other proceedings for review (or which, if due and payable, are being contested in good faith by appropriate proceedings and for which adequate reserves are being maintained, to the extent required by IFRS);

(b) Encumbrances for taxes, assessments or other governmental charges or levies (i) which are not yet overdue for [*] or not yet due or payable, (ii) which are being contested in good faith by appropriate proceedings and (iii) for which adequate reserves are being maintained to the extent required by IFRS or GAAP;

(c) Encumbrances securing indebtedness (including, without limitation, capital lease obligations and purchase money obligations) incurred by the Company to finance all or any part of the purchase, lease, construction, installation, repair or improvement of property (real or personal), plant or equipment or other fixed or capital assets; provided such lien extends only to the assets the acquisition, lease, construction, repair, replacement or improvement of which is financed thereby and any replacements, additions and accessions thereto and any income or profits thereof;

(d) Encumbrances on specific items of inventory or other goods and proceeds of any Person securing such Person's obligations in respect of bankers' acceptances or letters of credit entered into in the ordinary course of business issued or created for the account of such Person to facilitate the purchase, shipment or storage of such inventory or other goods;

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(e) grants of software, technology and other intellectual property licenses in the ordinary course of business;

(f) Encumbrances in favor of customs and revenue authorities arising as a matter of law to secure payment of customs duties in connection with the importation and exportation of goods in the ordinary course of business;

(g) [*];

(h) the Encumbrances or Liens granted in favor of NovaQuest pursuant to this Agreement; and

(i) Encumbrances arising solely by virtue of any statutory or common law provision or customary business provision relating to banker's encumbrances, rights of set-off or similar rights.

"***Person***" means any natural person, corporation, trust, joint venture, association, unincorporated organization, cooperative, company, partnership, trust, limited liability company, government (domestic or foreign), and any agency or instrumentality thereof, or any other entity recognized by law.

"***Prepayment***" has the meaning given to "Capped Return Payoff" in Section 4.1(d).

"***Prepayment Amount***" has the meaning given to "Capped Return Amount."

"***Prime Rate***" has the meaning set forth in Section 4.4.

"***Product***" means any prescription pharmaceutical product that contains the Compound.

"***Product IP Rights***" means all of the following intellectual property owned or licensed by the Company, in each case, as they exist in the Territory and solely as necessary or useful to the manufacturing, development or Commercialization of the Product in the Territory: (a) the Product Know-How; (b) the Product Patents; and (c) all trademarks, service marks, trade names, and works protectable under copyright laws.

"***Product Know-How***" means, with respect to the Product in the Territory, all trade secrets, technology, processes, practices, formulae, instructions, procedures, assembly procedures, results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data, including study designs and protocols), know-how, methods, treatments, techniques, systems, designs, artwork, drawings, plans, specifications, data and information, in each case whether or not confidential, proprietary, patentable, copyrightable, or susceptible to any other form of legal protection, in written, electronic or any other form.

"***Product Patents***" has the meaning set forth in Section 7.1(e).

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"***Quarterly Report***" means a report submitted by Company to NovaQuest in accordance with the provisions of Section 3.1(b), that contains (a) the information from quarterly reports in respect of the preceding Fiscal Quarter or other reports and material correspondence received from Astellas during the preceding Fiscal Quarter under its obligations under the Astellas Agreements relating to Commercialization of the Product in the Territory; (b) a statement setting forth Company's good faith qualitative assessment of Astellas's performance of its obligations under the Astellas Agreements relating to Commercialization of the Product in the Territory during the preceding Fiscal Quarter; and (c) at any time after the termination of any Astellas Agreement and Company's entry into a Replacement Agreement, information similar to the information set forth in clauses (a) and (b) of this definition to the extent received from any Responsible Party or to the extent pertaining to such Responsible Party's performance under the applicable Replacement Agreement. All amounts in each Quarterly Report shall be denominated in Dollars. Notwithstanding the foregoing, Company may, at its election, deliver the information contemplated herein and therein via disclosures made pursuant to Company's public reporting requirements, by delivery of summaries, reports, or presentations to NovaQuest, or by providing excerpts of materials presented to the Company's board of directors or executive leadership team.

"***Recordkeeping Period***" has the meaning set forth in Section 5.2(a).

"***Register***" has the meaning set forth in Section 11.6.

"***Regulatory Approval***" means, with respect to the Product, in any country or jurisdiction, any approval, registration, license, or authorization that is required by the applicable Governmental Authority to market and sell such Product in such country or jurisdiction.

"***Regulatory Filing***" means any application, filing, or submission required by or provided to a Governmental Authority relating to the development, manufacture, Commercialization, pricing, or other exploitation of the Product, including any supporting documentation, correspondence, meeting minutes, amendments, supplements, registrations, licenses, regulatory drug lists, advertising and promotion documents, adverse event files, complaint files, and manufacturing, shipping, or storage records with respect to any of the foregoing, including an NDA, drug master filing, clinical trial application, and any counterparts or equivalents of any of the foregoing.

"***Replacement Agreement***" means an agreement entered into between Company or any Affiliate of Company and a Third Party following the termination (in whole or in part) of any Astellas Agreement in which Company grants a License or otherwise transfers any of the Product IP Rights in the Territory or other rights that are relevant to making, using, selling, offering for sale, or importation of the Product in the Territory. Agreements expressly considered Replacement Agreements include: (x) exclusive licenses, option agreements, right of first refusal agreements, non-assertion agreements, distribution agreements that grant or otherwise transfer any Product IP Rights in the Territory, or similar agreements; and (y) agreements that grant or otherwise transfer rights in the Product IP Rights along with rights owned by Company or any Affiliate of Company or granted to Company or any Affiliate of Company by a Third Party. For the avoidance of doubt, (I) Replacement Agreement excludes any or all of the Astellas

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Agreements, (II) the Astellas Japan Agreement and all of the agreements, documents and other terms used in this definition related thereto or associated therewith or related solely to or associated solely with Japan are excluded from this definition and (III) no Replacement Agreement shall solely relate to or be solely associated with Japan, the Astellas Japan Agreement or Japan Revenue Interests.

"***Replacement Net Sales Revenue***" means any payments based on sales of the Product in the Territory received by Company or any of its Affiliates under or pursuant to a Replacement Agreement. For the avoidance of doubt, (a) Replacement Net Sales Revenue excludes Astellas EMEA Revenue, Astellas Japan Revenue, and Astellas Other Revenue, (b) the Japan Revenue Interests and any replacement of such revenue or amounts by anything else, and any other payments or amounts related solely to or associated solely with Japan, are excluded from Replacement Net Sales Revenue, and (c) any Replacement Net Sales Revenue shall be subject to and capped by the Capped Return Amount.

"***Replacement Other Revenue***" means any revenue, other than Replacement Net Sales Revenue, recognized by Company or any of its Affiliates under or pursuant to a Replacement Agreement attributable to payments for the Product in the Territory. For the avoidance of doubt, (a) Replacement Other Revenue excludes Astellas EMEA Revenue, Astellas Japan Revenue, and Astellas Other Revenue, (b) the Japan Revenue Interests and any other revenue related solely to or associated solely with Japan are excluded from Replacement Other Revenue, and (c) any Replacement Other Revenue shall be subject to and capped by the Capped Return Amount.

"***Repurchase Price***" means Forty-Two Million, Five Hundred and Eighty Thousand, Five Hundred and Ninety Dollars and Sixty Six Cents ($42,580,590.66).

"***Repurchased Interests***" means all of NovaQuest's right, title and interest in and to the Astellas Japan Agreement, the Astellas Japan Revenue (including the portion of Astellas Other Revenue attributable to the Astellas Japan Agreement), the Japan Revenue Interests and all related Collateral Revenue Interests, Revenue Interest Payments and Revenue Interest Collateral associated therewith, which rights, title and interests are being repurchased by Company from NovaQuest in exchange for the Repurchase Price pursuant to this Agreement.

"***Responsible Party***" means Company, Astellas, its and their respective Affiliates and Licensees, and any Acquiring Party.

"***Revenue Interest Collateral***" means the [*]; provided that no Japan Revenue Interests or Japan Related Collateral shall constitute Revenue Interest Collateral.

"***Revenue Interests***" means [*] and (b) excludes all Japan Revenue Interests.

"***Revenue Interest Payment***" has the meaning set forth in Section 4.1(a). "***Revenue Interest Payments***" means the Revenue Interest Payment, collectively. Notwithstanding anything to the contrary and for the avoidance of doubt, the Revenue Interest Payment and the Revenue Interest Payments exclude all rights and payments with respect to the Japan Revenue Interests.

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"***Sales Forecast***" has the meaning set forth in Section 5.1(b).

[*]

[*]

[*]

"***Senior Officer***" means: (a) in the case of NovaQuest, its chief investment officer; and (b) in the case of Company, its Chief Executive Officer.

[*]

"***Tax***" means any present or future tax, levy, impost, duty, assessment, charge, fee, deduction, or withholding in the nature of a tax and whatever called (including interest and penalties thereon) imposed, levied, collected, withheld, or assessed by any Governmental Authority.

"***Term***" has the meaning set forth in Section 9.1.

"***Territory***" means each or any of the following countries, individually or collectively: Albania, Andorra, Armenia, Austria, Azerbaijan, Belarus, Belgium, Bosnia & Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Egypt, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Kazakhstan, Kyrgyzstan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Monaco, Netherlands, Norway, North Macedonia, Poland, Portugal, Romania, Russia, San Marino, Serbia and Montenegro (Yugoslavia), Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Tajikistan, Turkey, Turkmenistan, Ukraine, United Kingdom, Uzbekistan, Vatican City, Bahrain, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, Syria, United Arab Emirates, Yemen (and solely prior to the A&R Effective Date, Japan), and any other country in which Astellas has rights to Commercialize the Product (an "Additional Country") (provided that any such Additional Country shall be included in the Territory only if and to the extent Astellas is Commercializing the Product in such Additional Country); provided, however, that from and after the A&R Effective Date, Japan shall be excluded from the Territory for all purposes under this Agreement.

"***Third Party***" means any Person, including a Governmental Authority, other than Company, NovaQuest, and each of their respective Affiliates. "***Third-Party***" has the corresponding meaning.

"***Transaction Documents***" means this Agreement, [*], and any other documents, instruments, or financing statements required to be delivered hereunder or thereunder or in connection herewith or therewith.

"***True-Up Payment***" has the meaning set forth in the Original Agreement.

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"***UCC***" means the Uniform Commercial Code as in effect from time to time in the State of New York, provided that if, with respect to any financing statement or by reason of any provisions of applicable law, the perfection or the effect of perfection or non-perfection of the security interest or any portion thereof granted pursuant to Section 4.5 is governed by the Uniform Commercial Code as in effect in a jurisdiction of the United States other than the State of New York, then "***UCC***" means the Uniform Commercial Code as in effect from time to time in such other jurisdiction for purposes of the provisions of this Agreement and any financing statement relating to such perfection or effect of perfection or non-perfection.

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

"***Voluntary Bankruptcy***" means Company, pursuant to or within the meaning of any Bankruptcy Law: (a) commences a voluntary case; (b) consents to the entry of an order for relief against it in an involuntary case; (c) consents to the appointment of a Custodian of it or for any substantial part of its property; or (d) makes a general assignment for the benefit of its creditors or takes any comparable action under any non-U.S. laws relating to insolvency.

"***Voluntary Transfer***" means with respect to NovaQuest, or any of its Affiliates (to the extent relevant): (a) the sale or disposition of all or substantially all of the assets of such Party; (b) the sale or transfer of more than [*] of the voting power of the outstanding voting securities of such Party or any Affiliate of such Party that directly or indirectly controls (as defined in the definition of Affiliate) such Party; (c) the merger or consolidation of such Party or any Affiliate of such Party that directly or indirectly controls (as defined in the definition of Affiliate) such Party, with or into another entity Person; or (d) the assignment by such Party of this Agreement or all or any portion of the rights and obligations hereunder.

"***Withholding Payment***" has the meaning set forth in Section 4.3(a).

ARTICLE II

SCOPE OF AGREEMENT

2.1 General Agreement. Each Party represents and warrants to the other Party that, as of the A&R Effective Date, to such Party's Knowledge, no breach, violation, Default or Event of Default exists under the Original Agreement, this Agreement or any other Transaction Document (including any facts, circumstances, or events that, alone or together with other facts, circumstances, or events, such Party reasonably expects would, with the giving of notice or passage of time, or both, give rise to a breach, violation, Default or Event of Default). In addition to the Repurchase Price and the Expense Payment paid simultaneously by Company to NovaQuest with the execution of this Agreement, and in consideration for the Parties' entry into this Agreement: (a) Company shall make payments to NovaQuest as expressly set forth in and subject to the limitations of Article IV, including Section 4.1(e), and subject to the Capped Return Amount, and (b) except for any Adjusted Amount, NovaQuest shall be entitled under this Agreement and otherwise to no more than the Capped Return Amount.

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2.2 Preamble, Recitals and Definitions. Notwithstanding anything to the contrary in this Agreement or otherwise, the preamble, recitals, definitions and all of the other foregoing provisions in this Agreement shall be deemed to be incorporated into the body of this Agreement and shall be deemed to be agreements that all Parties are bound.

2.3 Limitations. Company accepts, acknowledges, and agrees that NovaQuest is agreeing, on the terms and conditions set forth in this Agreement, only to satisfy the funding obligations set forth in Section 3.1(a) and its other obligations expressly set forth herein and is not assuming any Liability of Company, of whatever nature, whether presently in existence or arising or asserted hereafter.

ARTICLE III

NOVAQUEST FUNDING; COMMERCIALIZATION

3.1 NovaQuest's Funding Obligation.

(a) Investment Amount. On the Effective Date, NovaQuest paid Company an amount equal to Fifty Million Dollars ($50,000,000) (the "***Investment Amount***"). The Investment Amount has been paid in full and NovaQuest has no further funding obligations under this Agreement.

(b) Quarterly Reports. Beginning with the first full Fiscal Quarter that commences after the A&R Effective Date and for each subsequent Fiscal Quarter during the Term, Company shall deliver a complete and accurate Quarterly Report to NovaQuest within [*] following the first Business Day of such Fiscal Quarter; provided that, in the event that Astellas is delayed in providing the Company with any information required to be contained in a Quarterly Report, the Company will notify NovaQuest of such delay in the Quarterly Report and will subsequently provide NovaQuest with the relevant delayed Quarterly Report information within [*] after Company receives the relevant delayed Quarterly Report information from Astellas.

(c) Miscellaneous. For the avoidance of doubt, NovaQuest has no further payment obligations under this Section 3.1.

3.2 Diligence. During the Term, Company shall use [*] to ensure that a Permitted Company is Commercializing the Product in the Territory in each country where the Product has received Regulatory Approval (other than, for the avoidance of doubt, Japan).

ARTICLE IV

PAYMENTS TO NOVAQUEST

4.1 Payments and Reports.

(a) Revenue Interest Payments. [*], Company shall pay to NovaQuest a payment (each such payment, a "***Revenue Interest Payment***") in an amount equal to the Collateral

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Revenue Interests for such Fiscal Quarter, calculated in accordance with the definition of Collateral Revenue Interests. Revenue Interest Payments [*] shall be subject to and applied against the Capped Return Amount. Each Revenue Interest Payment calculated under clause (B) of the definition of Collateral Revenue Interests are, for the avoidance of doubt, as follows:

(i) fifty percent (50%) of Astellas EMEA Revenue recognized during such Fiscal Quarter; plus

(ii) fifty percent (50%) of Astellas Other Revenue recognized during such Fiscal Quarter; plus

(iii) fifty percent (50%) of Replacement Net Sales Revenue recognized during such Fiscal Quarter; plus

(iv) fifty percent (50%) of Replacement Other Revenue recognized during such Fiscal Quarter.

In no event shall the aggregate Revenue Interest Payments actually received in cash by NovaQuest [*] exceed Fifteen Million Dollars ($15,000,000) (i.e., the Capped Return Amount in effect as of the A&R Effective Date) (for the avoidance of doubt, any owed, due and payable Adjusted Amount is in excess of the Capped Return Amount). Only Revenue Interest Payments actually received in cash by NovaQuest [*] shall reduce the Capped Return Amount on a dollar-for-dollar basis. The Repurchase Price and all amounts attributable to [*] shall be separately treated and shall not reduce the Capped Return Amount. No adjustment, true-up or other calculation shall require NovaQuest to make any affirmative payment or repayment to Company, whether before or after the Capped Return Amount has been reduced to zero.

[*].

(b) [Reserved].

(c) [Reserved].

(d) Capped Return Payoff. Notwithstanding any other provision of this Agreement, Company may pay the then-current remaining Capped Return Amount to NovaQuest at any time during the Term, for any reason and without penalty or premium, by wire transfer of immediately available funds and written notice designating such payment as a Capped Return Payoff pursuant to this Section 4.1(d) (such payment, a "***Capped Return Payoff***"). Company and NovaQuest agree that any Capped Return Payoff shall be deemed to be due and payable to NovaQuest upon its receipt.

(e) Capped Return Amount; Termination.

(i) Company's obligation to make any Investor Return Payments to NovaQuest will terminate upon the achievement of Investor Return Payment Satisfaction. For

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clarity, upon the achievement of Investor Return Payment Satisfaction, this Agreement and the other Transaction Documents will terminate in accordance with Section 9.2(b).

(ii) Notwithstanding anything to the contrary in this Agreement or any other Transaction Document, all Revenue Interest Payments received by NovaQuest from (or on behalf of) Company shall be applied first to reduce the Capped Return Amount, and, after the occurrence and during the continuance of an Event of Default upon the foreclosure of the Collateral by NovaQuest, NovaQuest shall be entitled to receive one hundred percent (100%) of the amounts from exercising rights and remedies on the Collateral until the Capped Return Amount has been reduced to zero, plus any Adjusted Amount, at which point all further amounts from the Collateral and the Revenue Interest Payments shall belong solely to (and be held in trust for and immediately paid over to) Company.

(f) Payment Reports. Commencing with the Fiscal Quarter in which the A&R Effective Date occurs and continuing for each Fiscal Quarter until the achievement of Investor Return Payment Satisfaction, Company shall, simultaneously with its delivery of a Revenue Interest Payment pursuant to Section 4.1(a) or, if no Revenue Interest Payment is due, [*] of the end of the applicable Fiscal Quarter, prepare and deliver a written report to NovaQuest that includes (to the extent received from a Responsible Party or otherwise reasonably available to the Company) reasonably detailed information regarding the total monthly sales of the Product on a country-by-country basis in such Fiscal Quarter in the Territory, including the amounts of gross sales of the Product per country in the Territory, and a calculation of the Astellas EMEA Revenue, Astellas Other Revenue, and the applicable Revenue Interest Payment payable to NovaQuest which are attributable to each country for such Fiscal Quarter (including any foreign exchange rates employed) (such written report, a "***Payment Report***").

4.2 NovaQuest's Account. All payments under this Agreement to NovaQuest shall be made in Dollars by wire transfer in immediately available funds to such accounts as NovaQuest designates in writing from time to time.

4.3 Taxes; Withholding.

(a) If any Governmental Authority requires (i) Company to deduct or withhold any amount from any payment by Company to NovaQuest, or (ii) NovaQuest to pay any present or future Tax, assessment, or other governmental charge on, any payment by Company to NovaQuest (in each case, a "***Withholding Payment***"), then Company shall, in addition to paying NovaQuest the amount reduced by such Withholding Payment, simultaneously pay NovaQuest an additional amount such that NovaQuest receives the full contractual amount of the applicable payment as if no such Withholding Payment had occurred (such additional amount, the "***Gross-Up Amount***"); provided, that Company shall not be required to pay such additional amounts with respect to any Withholding Payment that is attributable to any Excluded Taxes.

(b) Notwithstanding Section 4.3(a), if a Withholding Payment is required solely as a result of (i) a Voluntary Transfer by NovaQuest after the Effective Date of this Agreement or (ii) the failure to provide an IRS Form W-9 pursuant to Section 4.3(c), then Company shall not be obligated to pay NovaQuest the Gross-Up Amount with respect to such Withholding Payment.

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(c) NovaQuest and any permitted transferee or assignee hereunder shall deliver at the closing, and at any other times as reasonably requested by the Company or required by law to reduce the amount of withholding, a properly completed IRS Form W-9 certifying that NovaQuest (or such permitted transferee or assignee) is exempt from "backup" withholding tax.

(d) If Company is required to make a Withholding Payment to a Governmental Authority, Company shall deliver to NovaQuest the original or a certified copy of a receipt issued by such Governmental Authority evidencing its payment of such Withholding Payment.

(e) After the A&R Effective Date, the contingent Revenue Interest Payments that have yet to become owed, due and paid as of any applicable time are not intended by the Parties to be treated as debt or equity for Tax purposes. If there is an inquiry by any Governmental Authority of Company or NovaQuest related to this Section 4.3(e), the Parties shall cooperate with each other in responding to such inquiry in a commercially reasonable manner consistent with this Section 4.3(e) and Applicable Law.

4.4 Interest. If any payment required to be paid by Company to NovaQuest under this Agreement is not made when due, then such outstanding payment will accrue interest, beginning on the date when the payment was due and ending (but not including) the date such payment is made, at an annual rate equal to [*] plus the Prime Rate, subject to any limitation under Applicable Law. Such rate will be compounded every [*], commencing on the date on which such payment was due and ending (but not including) the date such payment is made. Payment of accrued interest will accompany payment of the outstanding payment. "***Prime Rate***" means the prime rate as reported in *The Wall Street Journal*, New York edition, on the date such payment is due.

4.5 Grant of Security Interest.

(a) For value received and to secure the prompt and complete payment and performance of all payment obligations of Company now or hereafter owing, due and payable to NovaQuest under Section 4.1 and in respect of any Adjusted Amount, the Company does hereby: (i) grant to NovaQuest a security interest in and to all right, title and interest in, to and under the Collateral; and (ii) authorize NovaQuest, from and after the Effective Date, to file such financing statements and continuation statements with respect to such financing statements when applicable, in such manner and such jurisdictions as are necessary or appropriate to perfect the security interest granted hereunder; provided, that the description of the Collateral in such financing statements and continuation statements shall not be broader than the definition of the Collateral hereunder (for the avoidance of doubt, after giving effect to this Agreement).

(b) Subject to Section 4.5(d), Company agrees that from time to time, Company will, in a commercially reasonable manner, execute and deliver all further instruments and documents, and take all further actions, that NovaQuest may reasonably request and that are required in order to perfect and protect the security interest granted in the Collateral hereby, to create, perfect or protect the security interest purported to be granted hereby or to enable NovaQuest to exercise and enforce its rights and remedies hereunder with respect to any of the Collateral, including, but not limited to, entering into United States law governed intellectual property security agreements

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with respect to the Product IP Rights and filing such agreements with the United States Patent and Trademark Office, as necessary, [*].

(c) Following the payment of the Capped Return Amount (and the payment of any Adjusted Amount), this Agreement (other than Company's indemnification obligations under ARTICLE X and any actionable claims of fraud by either of Company or NovaQuest) and all other Transaction Documents shall immediately and automatically forever terminate, all security interests and Liens granted to NovaQuest hereunder, under any other Transaction Document or otherwise (including, without limitation, on all of the Collateral) shall immediately and automatically forever be released, terminated and discharged, and NovaQuest irrevocably authorizes Company and its counsel and designees to (and, upon Company request, NovaQuest shall promptly) file termination statements and release documents and take such other actions necessary or appropriate to effectuate the foregoing and also NovaQuest shall promptly take such other actions as may be reasonably requested by Company to effectuate the release, termination and discharge of all such security interests and Liens and the foregoing. [*].

(d) Notwithstanding any provision herein to the contrary, the Company shall not be required to execute or deliver any instrument or document or take any further actions, in each case, with respect to any Collateral (other than the filing of a UCC-1 financing statement against the Company in its jurisdiction of incorporation and an intellectual property security agreement to be filed with the United States Patent and Trademark Office) if any of the following apply:

(i) [*];

(ii) the burden or cost of obtaining a grant of a security interest therein or perfection thereof (including any burden resulting from a change to the ordinary course business operations of Company or from any third party consent required for any such grant or perfection) exceeds the practical benefit to NovaQuest afforded thereby as reasonably mutually determined by Company and NovaQuest;

(iii) such actions would contravene, violate, cause a breach or default under or give rise to a right of early termination under or require any third party consent, authorization or approval by any Person (including any Governmental Authority) that is not an Affiliate of the Company (other than which have already been obtained or that Company reasonably determines would not be burdensome to obtain upon NovaQuest's reasonable request to obtain), any Applicable Law or contract to which the Company or any of its assets are bound (other than any contract entered into for purposes of contravening or avoiding the Company's obligations hereunder), including, for the avoidance of doubt, any intercreditor agreement; or

(iv) would result in adverse tax consequences to the Company or any of its Affiliates.

(e) For the avoidance of doubt, the security interest granted to NovaQuest pursuant to this Section 4.5 (and any perfection, priority or protection thereof) shall be subject to the terms of any [*] executed from time to time after the date hereof, and with respect to any conflict between this Agreement and any [*].

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ARTICLE V

INFORMATION RIGHTS; RECORD KEEPING

5.1 Information Rights.

(a) In addition to Company's other reporting and disclosure obligations contained in this Agreement, and, with respect to information Company has the right to receive under the Astellas Agreements and information that Company is provided under the Astellas Agreements, Company shall, and shall cause all other Responsible Parties to, upon NovaQuest's reasonable request, promptly prepare and provide NovaQuest with reasonable notice and information regarding each of the following matters relating to the Product and to promptly respond to NovaQuest's reasonable inquiries with respect thereto and promptly provide, upon NovaQuest's reasonable request, information and documents related to each of the following matters, in each case, to the extent relating to, or that could be reasonably expected to materially affect, the Commercialization of the Product in the Territory:

(i) general Commercialization overview and updates, including any material issues regarding manufacturing of the Product;

(ii) finalized briefing packages and minutes from meetings with a Governmental Authority, notifications, letters, and other material communications with a Governmental Authority;

(iii) material Regulatory Filings, including any NDA;

(iv) any material actual or anticipated issues with the supply of the Product;

(v) any matters arising from Patents Covering the Product and other intellectual property rights protecting the Product, including intellectual property rights owned or controlled by Third Parties, that would reasonably be expected to materially and adversely impact the Commercialization of the Product;

(vi) any decision or anticipated decision to cease marketing, selling, or otherwise Commercializing the Product;

(vii) receipt of Regulatory Approvals; and

(viii) each Sales Forecast to be provided pursuant to Section 5.1(b).

Notwithstanding the foregoing, Company may, at its election, deliver the information contemplated herein and therein via disclosures made pursuant to Company's public reporting requirements, by delivery of summaries, reports, or presentations to NovaQuest, or by providing excerpts of materials presented to the Company's board of directors or executive leadership team, provided that upon NovaQuest's reasonable request, Company promptly shall provide

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reasonable access to any material information and documents encompassing the information provided by Company pursuant to this Section 5.1(a).

(b) To the extent that Company is able to forecast and track, and actually does forecast and track orders for the Product in the Territory, Company will, on an annual basis during the Term and within [*] after approval from the Company's board of directors, provide NovaQuest with a copy of Company's good faith forecasted sales of the Product in the Territory for the then-current Fiscal Year (each such Fiscal Year forecast, a "***Sales Forecast***"). The form and format of the Sales Forecasts shall be as reasonably determined by the Company, provided, however, that each such Sales Forecast shall take into account any forecasts provided by Responsible Parties if such forecast is provided by any Responsible Party. This Section 5.1(b) does not, with respect to obtaining information from Astellas, require Company to take any actions beyond which Company has the right to take under the Astellas Agreements.

(c) [*], upon NovaQuest's reasonable advance request, NovaQuest shall be entitled to an update call or meeting (via teleconference or videoconference or at a location reasonably designated by NovaQuest) to discuss (i) the Quarterly Reports and the Payment Reports, (ii) [*], the progress of Commercialization efforts with respect to the Product in the Territory, (iii) [*], the status and the historical and potential performance of the Product in the Territory, (iv) [*], any regulatory developments with respect to any Product in the Territory; and (v) such other matters that the Parties mutually deem reasonably appropriate.

5.2 Company's Record Keeping; NovaQuest's Audit Rights.

(a) Records. Company shall, and shall ensure that the Responsible Parties shall, consistent with GAAP or IFRS, as applicable, keep and maintain for a period of at least [*] from the end of any Fiscal Quarter (except as otherwise provided herein) accounts and records of all data reasonably required to verify (and, with respect to periods prior to the A&R Effective Date, including data relating to Astellas Japan Revenue to the extent necessary to verify Revenue Interest Payments attributable to such periods):

(i) information required to be provided to NovaQuest under this Agreement, including pursuant to Section 5.1; and

(ii) (A) the gross amount received by any Responsible Party from Third Parties for sales of the Product, and (B) the calculation of the Revenue Interest Payments.

Company's and the Responsible Parties' recordkeeping obligations under this Section 5.2 shall survive the termination of this Agreement until the date that is [*] following the last day on which a payment is due under this Agreement (the "***Recordkeeping Period***").

(b) Audit. From the Effective Date until the expiration of the Recordkeeping Period, upon prior written notice to Company: (i) NovaQuest shall have the right to review and audit, through an independent certified public accountant selected by NovaQuest and reasonably satisfactory to Company, those accounts and records of Company as NovaQuest determines is reasonably necessary to verify Company's and Responsible Parties' compliance with this

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Agreement; and (ii) Company shall, upon the reasonable request of NovaQuest, [*] review and audit each Responsible Party, through an independent certified public accountant reasonably approved by NovaQuest, those accounts and records of each such Responsible Party as NovaQuest determines is reasonably necessary to verify such Responsible Party's compliance with this Agreement. Such review and audits shall occur during normal business hours and no more than once per Fiscal Year, provided that NovaQuest shall be entitled to conduct a reasonable number of follow-up reviews and audits if NovaQuest finds that Company or a Responsible Party is not in material compliance with this Agreement. In addition, Company shall, upon reasonable request by NovaQuest (which request NovaQuest shall be permitted to make one time every [*], promptly exercise its audit rights pursuant to the Section of the Astellas EMEA Agreement titled "Reporting and Audit Rights," to the extent necessary to verify the calculations of Astellas EMEA Revenue or Astellas Other Revenue, and shall furnish the results of such audit to NovaQuest. With respect to any Replacement Agreement entered into by Company that would reasonably be expected to generate Replacement Net Sales Revenue or Replacement Other Revenue, Company shall use reasonable efforts to ensure that such Replacement Agreement grants Company audit rights which are substantially similar in all material respects to Company's audit rights pursuant to the section of the Astellas EMEA Agreement titled "Reporting and Audit Rights." With respect to any such Replacement Agreement described in the foregoing sentence, Company shall, upon request by NovaQuest (which request NovaQuest shall be permitted to make one time every [*], promptly exercise its audit rights to the extent necessary to verify the calculations of Replacement Net Sales Revenue or Replacement Other Revenue and shall furnish the results of such audit to NovaQuest. NovaQuest shall be solely responsible for all of the expenses of any audit conducted pursuant to this Section 5.2(b), unless the independent certified public accountant's report shows, in respect of any Fiscal Year then being reviewed, an underpayment of amounts due to NovaQuest hereunder for such Fiscal Year by more than [*], in which case Company shall be responsible for the reasonable expenses incurred by NovaQuest for the independent certified public accountant's services. If the report shows an underpayment of amounts due to NovaQuest hereunder, then Company will pay NovaQuest an amount equal to such underpayment, plus interest on such amounts in accordance with Section 4.4, within [*] after receipt of notice of such underpayment and copy of the relevant portion of the audit report.

5.3 Notice of Certain Events. Company will notify NovaQuest in writing with respect to the following matters promptly upon Company's Knowledge thereof (and Company shall be responsible for ensuring that each Responsible Party notifies Company of such matters upon such Responsible Party becoming aware thereof), in each case, to the extent relating to the Commercialization of the Product in the Territory:

(a) Company's or any other Responsible Party's submission of a material Regulatory Filing for the Product, including any NDA;

(b) Company's or any other Responsible Party's receipt of Regulatory Approval for the Product;

(c) the occurrence of any Material Adverse Effect;

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(d) any decision by Company or any other Responsible Party to cease the Commercialization of the Product in the Territory;

(e) the actual or written threat of revocation, withdrawal, suspension, cancellation, termination, or material modification of any approvals or authorizations, including any Regulatory Approval, from any Governmental Authority with respect to the Product in the Territory;

(f) Company's or, to the Knowledge of Company, any other Responsible Party's being debarred, excluded, suspended, or otherwise ineligible to participate in government health care programs;

(g) Company's or, to the Knowledge of Company, any other Responsible Party's becoming a party to a settlement, consent, or similar agreement with any Governmental Authority regarding the Product in the Territory;

(h) Company's or, to the Knowledge of Company, any other Responsible Party's being charged with, or convicted of, violating any Applicable Law regarding the Product in the Territory;

(i) any recall, suspension, market withdrawal, seizure, warning letter, other written communication asserting lack of compliance with any Applicable Law in any material respect, or any serious adverse event in each case, with respect to the Product in the Territory; and

(j) any clinical trial of the Product being suspended, put on hold, or terminated prior to completion as a result of any action by a Governmental Authority, or as a result of a Responsible Party's voluntary decision in the Territory; and

(k) the receipt by Company or any other Responsible Party of any adverse written notice from any Governmental Authority regarding the approvability or approval of the Product in the Territory.

(l) Any notice provided pursuant to this Section 5.3 shall include a reasonably detailed description of the event giving rise to the requirement to provide such notice, along with complete copies of all material documentation related thereto unless prohibited by Applicable Law.

Notwithstanding the foregoing, Company may, at its election, deliver the information contemplated herein and therein via disclosures made pursuant to Company's public reporting requirements, by delivery of summaries, reports, or presentations to NovaQuest, or by providing excerpts of materials presented to Company's board of directors or executive leadership team.

5.4 ESG Questionnaires. The Company will provide, to the Knowledge of Company and solely as permitted by Applicable Law, true and complete responses to any ESG Questionnaires submitted to Company by NovaQuest no more than once per each Fiscal Year during the Term. For the purposes of this Section 5.4 and this Agreement, "***ESG Questionnaires***" means any

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questionnaire, survey, request for information, or other similar inquiry, relating to environmental, social, or governance issues and Company's policies and practices in connection therewith.

5.5 [**Reserved**].

ARTICLE VI

CONFIDENTIAL INFORMATION

6.1 Definition of Confidential Information.

(a) For purposes of this Agreement, the term "***Confidential Information***" of a Party means the terms of this Agreement and any information or materials furnished by or on behalf of such Party or its Affiliates to another Party or its Affiliates pursuant to this Agreement or learned through observation during visit(s) to any facility of the Party or its Affiliates.

(b) Notwithstanding Section 6.1(a), the term "Confidential Information" shall not include information that:

(i) was already known to the receiving Party, other than under a legal, contractual, or fiduciary obligation of confidentiality to or for the benefit of the disclosing Party, at the time it was disclosed to or learned by the receiving Party hereunder;

(ii) was generally available to the public at the time it was disclosed to or learned by the receiving Party hereunder;

(iii) became generally available to the public after it was disclosed to or learned by the receiving Party hereunder, other than through any act or omission of the receiving Party or its Affiliates or representatives in breach of this Agreement;

(iv) was lawfully disclosed to the receiving Party, after it was disclosed to or learned by the receiving Party hereunder, by a Third Party that, to the receiving Party's knowledge, was not bound by any legal, contractual, or fiduciary obligation of confidentiality to or for the benefit of the disclosing Party with respect to such information; or

(v) is independently developed by the receiving Party without the benefit or use of the Confidential Information of the disclosing Party.

6.2 Obligations. Except as authorized in this Agreement or except upon obtaining the other Party's prior written consent, each Party agrees that for the Term and for [*] thereafter, it will:

(a) maintain in confidence, and not disclose to any Person, the other Party's Confidential Information;

(b) not use the other Party's Confidential Information for any purpose, except for performing its obligations and exercising its rights and remedies under this Agreement; and

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(c) protect the other Party's Confidential Information in its possession by using substantially the same or higher degree of care that it uses to protect its own Confidential Information (but no less than a reasonable degree of care).

Notwithstanding anything to the contrary in this Agreement, a Party is entitled to seek injunctive relief to restrain the breach or threatened breach by the other Party of this ARTICLE VI without having to prove actual damages or threatened irreparable harm or post any bond. Such injunctive relief will be in addition to any rights and remedies available to the aggrieved Party at law, in equity, and under this Agreement for such breach or threatened breach.

6.3 Permitted Disclosures.

(a) Permitted Persons. A Party may disclose the other Party's Confidential Information, without the other Party's prior written permission, to:

(i) its Affiliates and its and its Affiliates' limited partners, members, managers, directors and individuals or bodies responsible for governance of receiving Party (including, with respect to NovaQuest, NovaQuest's investment committee and limited partner advisory committee), banks and other actual or potential financing sources, and actual or potential permitted assignees, purchasers, transferees, or successors-in-interest under Sections 8.2 or 11.6 or its or their employees, agents, consultants, attorneys or accountants, in each case, who need to know such Confidential Information (including to provide financing to receiving Party, to assist receiving Party in evaluating or monitoring receiving Party's interests in the transactions contemplated hereby, or in fulfilling its obligations or exploiting its rights hereunder (or to determine their interest in providing such financing or assistance)) and who are, prior to receiving such disclosure, bound by customary contractual or professional confidentiality and non-use obligations;

(ii) other Persons who are (A) investors or potential investors (or advisors or fiduciaries (including trustees) or underwriters or placement agents to such Persons) in connection with a private placement or other equity, debt, or other investment or potential investment transaction in or with receiving Party (including, with respect to NovaQuest, an investment or potential investment in or with NovaQuest or a NovaQuest Affiliate), who need to know such Confidential Information in connection with making or monitoring such equity, debt, or other investment or potential investment transaction, or (B) in the case of NovaQuest, potential investment targets (provided that (1) for the purpose of this Section 6.3(a)(ii), receiving Party may disclose only Confidential Information of disclosing Party pertinent to the investment or potential investment transaction and may make such disclosures only in anticipation, and during the period, of such investment or potential investment transaction, and (2) for the purpose of clause (B) of this Section 6.3(a)(ii), NovaQuest may disclose the identity of Company, the Product that is the subject of this Agreement, and the fact that this Agreement provides for the Investor Return Payments) provided that in the case of clauses (A) and (B) of this Section 6.3(a)(ii), such Persons are, prior to receiving such disclosure, bound by customary contractual or professional obligations of confidentiality, nondisclosure, and nonuse; and

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(iii) officers, employees, or advisors of any Governmental Authorities for the purpose of submitting Regulatory Filings for the Product and obtaining or maintaining Regulatory Approval, or in connection with any routine examination of a Party by a Governmental Authority.

[*].

(b) Legally Required. A Party may disclose the other Party's Confidential Information, without the other Party's prior written permission, to any Person to the extent such disclosure is necessary to comply with Applicable Law, applicable stock exchange requirements, or an order or subpoena from a court of competent jurisdiction. In the case of any compelled disclosure, the compelled Party, to the extent legally permissible, shall give reasonable advance notice to the other Party of such disclosure and, at such other Party's reasonable request and expense, the compelled Party shall use its reasonable efforts to secure confidential treatment of such Confidential Information prior to its disclosure (whether through protective orders or otherwise). However, if a Party receives a request from an authorized representative of a U.S. or foreign tax or financial reporting authority (including the U.S. Securities and Exchange Commission) for a copy of this Agreement, then that Party may provide a copy of this Agreement to such authority representative without advance notice to, or the permission or cooperation of, the other Party, but the disclosing Party shall notify the other Party of the disclosure as soon as reasonably practical.

(c) NovaQuest Consent. Notwithstanding anything to the contrary in this Section 6.3, Company shall not, and Company agrees to ensure that Responsible Parties shall not, without the prior written consent of NovaQuest (not to be unreasonably, withheld, conditioned or delayed), disclose to a Third Party any: [*].

6.4 Terms of Agreement. The Parties agree that they will each treat the existence, contents and terms of this Agreement as confidential, and neither Party shall make any press release or other disclosure to the general public that discloses or otherwise concerns this Agreement or any terms hereof, without the prior written consent of the other Party (not to be unreasonably, withheld, conditioned or delayed), except to the extent permitted under Section 6.3 or as otherwise permitted in accordance with this Section 6.4 or Section 6.5. Notwithstanding anything to the contrary in this Agreement, NovaQuest acknowledges and agrees that it will be necessary for Company to file this Agreement with the SEC and to make other public disclosures regarding the terms of this Agreement and payments made under this Agreement in its reports filed with the SEC and consents to such public filing and the making of such public disclosures, and Company agrees that it will provide NovaQuest a reasonable opportunity to review and comment on any proposed redactions to the copy of this Agreement to be filed with the SEC, as well as on such other public disclosures made by Company relating to NovaQuest or this Agreement or the transactions contemplated thereby, which comments Company shall consider in good faith, provided that Company shall not be required to provide NovaQuest the opportunity to review and comment on any disclosure substantively identical to any disclosure previously reviewed and commented upon by NovaQuest. For purposes of clarity, Company shall not be required to provide NovaQuest the opportunity to review and comment on any disclosure substantively

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identical to any disclosure previously reviewed and commented upon by NovaQuest and each Party is free to republish or discuss with Third Parties the information regarding the Agreement and the Parties' relationship disclosed in such securities filings and any other authorized public announcements. For the avoidance of doubt, any consent or approval given by a Party with respect to any press release or general public disclosure under or in connection with Section 6.4 of the Original Agreement prior to the A&R Effective Date shall not be deemed to constitute a consent or approval for purposes of this Section 6.4.

6.5 Use of Names. Neither Party shall mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other Party or its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, publicly available promotional material, or other form of publicity without the prior written approval of such other Party in each instance. Notwithstanding the foregoing, the restrictions imposed by this Section 6.5 shall not prohibit a Party from making any disclosure identifying any such Person to the extent required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted) or to the extent that such information is already public information. Further, notwithstanding the foregoing except for disclosures required by Applicable Law or the rules of a stock exchange or to the extent such information is already public information, the Parties agree that each Party shall have the right to publicly disclose the existence of this Agreement as a revenue interest financing agreement with revenue interest payments, Company's prepayment option, the name of the Parties, the name and a description of the Product, and the amount of the Investment Amount and the Repurchase Price.

ARTICLE VII

REPRESENTATIONS AND WARRANTIES; LIMITATION OF LIABILITY

7.1 Company's Representations and Warranties. Except as set forth in the applicable Schedules attached hereto, Company represented and warranted to NovaQuest previously on the Effective Date (but not on any other date and not on the A&R Effective Date, except as expressly set forth below) as follows:

(a) Organization. As of the A&R Effective Date, Company is a corporation duly incorporated, validly existing, and in good standing under the laws of the State of Delaware and is qualified to do business and legally permitted to perform its obligations under this Agreement in each jurisdiction where failure to be so qualified could result in a Material Adverse Effect.

(b) Authorization. As of the A&R Effective Date, Company has all necessary corporate or other power, right, and authority to carry on its business as it is presently carried on by Company and as contemplated by this Agreement, to enter into, to execute and deliver this Agreement, and to perform all of the covenants, agreements, and obligations to be performed by Company hereunder. As of the A&R Effective Date, this Agreement has been duly executed and delivered by Company and, when executed and delivered by NovaQuest, constitutes Company's valid and binding obligation, enforceable against Company in accordance with its terms, subject

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to bankruptcy, insolvency, reorganization, or similar laws affecting the rights of creditors generally and equitable principles.

(c) No Conflicts. As of the A&R Effective Date, the execution and delivery of this Agreement by Company and the performance by Company of its obligations hereunder does not and will not: (i) violate any provision of the organizational documents of Company; (ii) conflict with or violate any Applicable Law that applies to Company or its assets or properties; (iii) require any permit, authorization, consent, approval, exemption, or other action by, notice to, or filing with any entity or Governmental Authority (other than as expressly contemplated hereby); (iv) violate, conflict with, result in a material breach of, or constitute (with or without notice or lapse of time or both) a material default under, or an event that would give rise to any right of notice, modification, acceleration, payment, cancellation, or termination under, or in any manner release any party thereto from any obligation under, any permit or contract to which Company or any Affiliate of Company is a party or by which any of its properties or assets are bound; or (v) except as provided in Section 4.5, result in the creation or imposition of any Encumbrance on any part of the Collateral of Company (other than Permitted Encumbrances)[*].

(d) No Consent. As of the A&R Effective Date, except for (i) any consents required to be provided from Astellas under the Astellas Agreements, (ii) any filings necessary to perfect the security interest granted in favor of NovaQuest under Section 4.5 and (iii) other consents which have already been obtained, no other consent, approval, license, order, authorization, registration, declaration, or filing with or of any Person, other than Regulatory Approvals required with respect to the Product, is required by Company in connection with the execution and delivery by Company of this Agreement, the performance by Company of its obligations under this Agreement, or the consummation of any of the transactions contemplated hereby[*].

(e) Product Property. A list of the Patents owned or controlled by Company that Cover the Product in the Territory as currently Commercialized is set forth in Schedule 7.1(e) (the "***Product Patents***"). To the Knowledge of Company, all of the Product Patents are in full force and effect and have not lapsed, expired, or otherwise terminated. Except as set forth in Schedule 7.1(e), no Person has made a written claim to Company or, to the Knowledge of Company, to any other Party, to be an inventor under any of the Product Patents who is not a named inventor thereof. Company has good and valid title to and solely owns all right, title, and interest in and to the Product Patents subject to Permitted Encumbrances and the License. To Company's Knowledge, the Product Patents are all of the Patents reasonably necessary for the Commercialization of the Product in Territory as currently Commercialized or contemplated to be Commercialized. [*].

(f) Litigation. Except as set forth in Schedule 7.1(f), there is no action, suit, claim, proceeding, interference, reexamination, opposition, *inter partes* or post-grant review, or investigation pending or, to the Knowledge of Company, threatened against Company, any other Responsible Party, or any of its or their licensors, at law or in equity, in an arbitration proceeding to which Company, any other Responsible Party, or any of its or their licensors is a party, or Governmental Authority inquiry pending or, to the Knowledge of Company, threatened against Company, any other Responsible Party, or any of its or their licensors, that, in each case, if

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adversely determined, would: (i) question or defeat the validity or enforceability of any Product IP Rights; (ii) prevent, interfere with, or delay the consummation of the transactions contemplated by this Agreement; (iii) otherwise adversely affect any Product IP Rights or NovaQuest's rights under this Agreement; or (iv) have, or reasonably be expected to result in, a Material Adverse Effect.

(g) Infringement and Intellectual Property. As of the A&R Effective Date, to the Knowledge of Company, the making, use, sale, offer for sale, or import of the Product as currently Commercialized or contemplated to be Commercialized by any Responsible Party, Licensees, or sublicensees in the Territory does not, and will not, during the Term, infringe any issued Patent of any Third Party or misappropriate or make any unauthorized use of any other intellectual property or proprietary asset of any Third Party. To the Knowledge of Company, the Product Patents are, or will be upon issuance, valid and enforceable and no Third Party is infringing, misappropriating, or making any unauthorized use of a Product Patent or Product Know-How. None of the Product Patents or Product Know-How is subject to any outstanding decree, order, judgment, or stipulation restricting in any manner the use or licensing thereof by Company.

(h) Material Contracts. As of the A&R Effective Date, [*] to which Company or its Affiliates are a party are listed in Schedule 7.1(h) and are enforceable and in full force and effect, except as such enforceability may be limited due to applicable Bankruptcy Laws affecting the enforcement of creditors' rights generally, and general principles of equity. Company has provided correct and complete copies of all such Material Contracts to NovaQuest, and such copies remain correct and complete as of the A&R Effective Date. As of the A&R Effective Date, each Responsible Party is in compliance with and has not materially breached, violated, or defaulted under, or received written notice that it has materially breached, violated, or defaulted under any of the terms or conditions of any such Material Contract. As of the A&R Effective Date, Company is not aware of any event that has occurred or circumstance or condition that exists that would, or would reasonably be expected to, constitute such a breach, violation, or default with the lapse of time, giving of notice, or both. To the Knowledge of Company, as of the A&R Effective Date, the counterparty of each Material Contract is in compliance in all material respects with the terms and conditions of such Material Contract. Except as set forth in Schedule 7.1(h), as of the A&R Effective Date, Company has not granted an Encumbrance on any of its Product IP Rights, on the Revenue Interests, or on any of Company's payments to NovaQuest under this Agreement (in each case, solely to the extent constituting Collateral), except Permitted Encumbrances.

(i) Certain Regulatory Matters.

(i) To the Company's Knowledge, a Responsible Party holds all or is seeking the applicable approvals and authorizations from Governmental Authorities necessary for Company or, to the Knowledge of Company, such Responsible Party to conduct its business in the manner in which such business is being conducted and as contemplated hereunder with respect to the Product in the Territory, including the manufacture, testing, and Commercialization of the Product. To the Knowledge of the Company, the countries in which a

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Responsible Party holds an applicable approval and authorization for the Product in the Territory is as set forth on Schedule 7.1(i) and all such issued approvals and authorizations are in good standing and in full force and effect. Company or, to the Knowledge of Company, a Responsible Party has not received any written notice or any other communication from any Governmental Authority regarding any actual or possible revocation, withdrawal, suspension, cancellation, termination, or material modification of any such issued or pending approvals or authorizations for the Product in the Territory.

(ii) Company has not, and, to the Knowledge of Company, no other Responsible Party has, with respect to the Product in the Territory, knowingly made any untrue statement of a material fact or fraudulent statement to any Governmental Authority, failed to disclose a material fact required to be disclosed to any Governmental Authority, or committed an act, made a statement or failed to make a statement, that provides or could reasonably be expected to provide a basis for the FDA or other Governmental Authority to invoke the FDA's policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" set forth in 56 Fed. Reg. 46191 (September 10, 1991) or any similar policy of any other Governmental Authority.

(iii) Company is not and has never been, and, to the Knowledge of Company, no Responsible Party is or has ever been: (A) debarred by a Governmental Authority; (B) a party to a settlement agreement, consent decree, or similar agreement with a Governmental Authority regarding the Product in the Territory; or (C) charged with, or convicted of, violating Applicable Law regarding the Product in the Territory.

(iv) To the Knowledge of Company, the Product has not been the subject of or subject to (as applicable) any recall, suspension, market withdrawal, seizure, warning letter, other written communication asserting lack of compliance with any Applicable Law in any material respect in the Territory. No clinical trial of the Product in the Territory has been suspended, put on hold, or terminated prior to completion as a result of any action by any Governmental Authority or voluntarily.

(v) Neither Company nor its Affiliates have, and, to the Knowledge of Company, no other Responsible Party or exclusive licensor of any Product Patent, has received any adverse written notice from any Governmental Authority regarding the approvability or approval of the Product in the Territory.

(j) Financial Condition. All financial statements for Company delivered to NovaQuest fairly present, in conformity with GAAP or IFRS, as applicable, in all material respects Company's financial condition and Company's results of operations. There has not been any material deterioration in Company's financial condition since the date of the most recent financial statements delivered to NovaQuest.

(k) Supply. The Company has on hand or has made adequate provisions to secure sufficient quantities of Product to meet its obligations under the Astellas Agreements. The Company has on hand or has made adequate provisions to secure sufficient quantities of Product to support the Commercialization of the Product in the Territory.

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(l) Lien Representations and Warranties. As of the A&R Effective Date, the Company's exact legal name is "Kyntra Bio, Inc." (formerly known as "FibroGen, Inc."). As of the A&R Effective Date, the Company is, and has been since its incorporation, incorporated in the State of Delaware.

(m)Taxes. Company and its subsidiaries have: (i) filed all federal and state income Tax returns and other material Tax returns that they are required to file and (ii) duly paid all federal and state income Taxes and other material Taxes or installments thereof that they are required to pay, except Taxes being contested in good faith by appropriate proceedings and for which Company and its subsidiaries maintain adequate reserves in accordance with GAAP.; With respect to Company and its subsidiaries, there are no proposed or pending Tax assessments, deficiencies, audits, or other proceedings that have had, or could reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

(n)Brokers' Fees. Except for Morgan Stanley & Co. LLC, there is no investment banker, broker, finder, financial advisor, or other intermediary who has been retained by or is authorized to act on behalf of Company who might be entitled to any fee or commission in connection with the transactions contemplated by the Transaction Documents.

(o)Ownership. As of the A&R Effective Date, Company is the exclusive owner of the entire right, title (legal and equitable), and interest in, to, and under the Revenue Interests, and has good and valid title thereto.

(p)Solvency. Upon consummation of the transactions contemplated by the Transaction Documents and the application of the proceeds therefrom: (i) the fair saleable value of Company's assets (on a consolidated basis) will be greater than the sum of its Indebtedness, liabilities and other obligations, including contingent liabilities; (ii) the present fair saleable value of Company's assets (on a consolidated basis) will be greater than the amount that would be required to pay its probable liabilities on its existing Indebtedness, liabilities and other obligations, including contingent liabilities, as they become absolute and matured; (iii) Company will be able to realize upon its assets (on a consolidated basis) and pay its Indebtedness, liabilities and other obligations, including contingent obligations, as they mature; (iv) Company (on a consolidated basis) will not be rendered insolvent (within the meaning of any applicable law or otherwise), will not have unreasonably small capital with which to engage in its business and will not be unable to pay its Indebtedness as it matures; and (v) Company will not have become subject to any Voluntary Bankruptcy or Involuntary Bankruptcy. No step has been taken by Company or, to the Knowledge of Company, any other Person, to make Company subject to a Voluntary Bankruptcy or Involuntary Bankruptcy.

(q)Full Disclosure. With respect to the Product in the Territory, Company has previously delivered to NovaQuest true and complete copies of all agreements, contracts, documents, or other information referred to in this Agreement or that have been requested by NovaQuest, in each case, that has not been publicly disclosed by the Company. No representation or warranty or other statement made by Company in this Agreement, the Exhibits, the Schedules, any supplements, attachments, or annexes to the Exhibits or Schedules, or any certificates delivered in connection with the transactions contemplated in this Agreement

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contains any untrue statement or omits to state a material fact necessary to make any of them, in light of the circumstances in which it was made, not misleading. To the Knowledge of Company, there is no fact, event, or condition that has specific application to Company and that materially adversely affects the Product that has not been set forth in this Agreement, the Exhibits, and the Schedules hereto.

(r) Applicable Astellas Agreements and Product IP Rights. As of the A&R Effective Date, the Astellas EMEA Agreement and the Astellas EU Supply Agreement specifically referenced in Schedule 7.1(h) have not been amended, modified, supplemented or waived since the Effective Date and the Product IP Rights have not been amended in a manner that would reasonably be expected to materially adversely affect the amount of any Revenue Interest Payments that otherwise would have been payable to NovaQuest in the absence of any such amendment since the Effective Date.

7.2 NovaQuest's Representations and Warranties. NovaQuest represents, warrants, and covenants to Company as of the A&R Effective Date as follows:

(a) Organization. NovaQuest is a Delaware limited partnership duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization.

(b) Authorization. NovaQuest has all necessary power, right, and authority to carry on its business as it is presently carried on by NovaQuest, to enter into, execute, and deliver this Agreement and perform all of the covenants, agreements, and obligations to be performed by NovaQuest hereunder. This Agreement has been duly executed and delivered by NovaQuest and constitutes, when executed and delivered by Company, NovaQuest's valid and binding obligation, enforceable against NovaQuest in accordance with its terms, subject to bankruptcy, insolvency, reorganization, or similar laws affecting the rights of creditors generally and equitable principles.

(c) No Conflict. Neither the execution and delivery of this Agreement nor the performance or consummation of it or the transactions contemplated hereby will: (i) conflict with any Applicable Law; (ii) in any material respect, violate, conflict with, result in a material breach of, or constitute a material default under any material contract, agreement, commitment, or instrument to which NovaQuest is a party or by which NovaQuest or any of its assets are bound or committed; or (iii) violate the applicable formation documents for NovaQuest.

(d) No Consent. No consent, approval, license, order or authorization, registration, declaration, or filing with or of any Person is required by NovaQuest in connection with the execution and delivery by NovaQuest of this Agreement, the performance by it of its obligations under this Agreement, or the consummation by it of any of the transactions contemplated hereby or thereby.

(e) Litigation. There is no action, suit, claim, proceeding, or investigation pending or, to the knowledge of NovaQuest, which, for the purpose of this Section 7.2(e) means the actual knowledge of [*], threatened against NovaQuest or any of its Affiliates, at law or in equity, in an arbitration proceeding to which NovaQuest or any of its Affiliates is a party, or pursuant to the

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procedures of a Governmental Authority having jurisdiction over NovaQuest or its Affiliates, that, if adversely determined, would: (i) prevent the consummation of the transactions contemplated by this Agreement; or (ii) otherwise materially adversely affect Company's rights under this Agreement.

(f) Financing. NovaQuest has the contractual right to call, from amounts contractually committed by its investors, sufficient cash to pay the Investment Amount in accordance with this Agreement. NovaQuest acknowledges that its obligations under this Agreement are not contingent on obtaining financing.

7.3 [*].

ARTICLE VIII

COVENANTS

8.1 Notifications.

(a) Defaults, Termination and Litigation.

(i) Company shall promptly upon obtaining Knowledge thereof notify NovaQuest in writing and with reasonable detail of any actual or threatened (or any receipt of notice of any actual or threatened): (A) default or material breach by Company or the counterparty under any Material Contract, (B) default or breach by Company or Astellas under the Astellas Agreements if such default or breach would reasonably be expected to have a material adverse effect on the amount of the Revenue Interest Payments; or [*]. For avoidance of doubt, as this section relates to the Astellas Agreements, such notification shall be limited to information Company has the right to receive under the Astellas Agreements or information of which the Company has Knowledge.

(ii) Company shall promptly upon obtaining Knowledge thereof notify NovaQuest in writing and with reasonable detail of the actual or threatened commencement of (or receipt of notice of the actual or threatened commencement of) any dispute, claim, suit, litigation, injunction, or arbitration proceeding related to the Product, [*], or a Material Contract, including those disputes, claims, suits, litigation, or arbitration proceedings alleging a Third Party's infringement or misappropriation of any of the Product IP Rights owned or licensed by a Responsible Party and those alleging a Responsible Party's (or any of their respective Affiliates', licensees', or sublicensees') infringement or misappropriation of a Third Party's intellectual property in the making, use, sale, offer for sale, or importation of the Product. Each such notification shall contain a reasonably detailed summary of the event described therein. At the request of NovaQuest, Company shall promptly discuss with NovaQuest, or provide in writing to NovaQuest, full particulars of the applicable matter. For avoidance of doubt, as this section relates to the Astellas Agreements, such notification shall be limited to information Company has the right to receive under the Astellas Agreements or information of which the Company has Knowledge.

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(b) Intellectual Property Updates. Company shall keep NovaQuest reasonably informed, in accordance with its obligations under ARTICLE V, with regard to all material developments in the status, validity, prosecution efforts, or change thereto, of any of the Product Patents in the Territory owned, licensed, or sublicensed by a Responsible Party, in each case to the extent Company has Knowledge thereof. For avoidance of doubt, as this section relates to the Astellas Agreements, such notification shall be limited to information Company has the right to receive under the Astellas Agreements or information of which the Company has Knowledge.

8.2 No Disposition of Rights. Notwithstanding anything to the contrary herein, but without limiting Company's obligations under Section 8.6(d), without NovaQuest's prior written consent (not to be unreasonably, withheld, conditioned or delayed), Company shall not (and Company shall ensure that each of its Affiliates does not) Encumber any: (a) Revenue Interest Payments or (b) Product IP Rights, in each case, solely to the extent constituting Collateral, other than Permitted Encumbrances.

8.3 Event of Default.

(a) The Company shall notify NovaQuest in writing as soon as possible, and in any event within [*] of the occurrence and continuance of any Event of Default during the Term, identifying the nature of such Event of Default. [*].

(b) Subject to the terms and conditions of [*], if an Event of Default has occurred and is continuing and [*], NovaQuest may exercise remedies available at law or in equity in respect of the Collateral, including directing Company and its Affiliates to assemble and deliver the Collateral as directed by NovaQuest, notifying any Third Party holding such Collateral (or portion thereof) of NovaQuest's rights in such Collateral (or portion) and directing such Third Party to transfer such Collateral or make payments in respect thereof to NovaQuest (and Company hereby consents to such transfer or payment); [*]. For the avoidance of doubt, [*], NovaQuest shall have no right to exercise any remedies in respect of the Collateral, and all security interests and Liens granted to NovaQuest hereunder shall be immediately and automatically terminated, released and discharged (and all other actions shall be taken by the applicable Persons) in accordance with Section 4.5(c).

8.4 Change of Control of Company. In the event of a Change of Control of Company, at Company's option, Company shall either: (a) cause its obligations under this Agreement to be assumed by the Acquiring Party if all of the following conditions have been met (i) NovaQuest has been provided with a true, complete, and accurate copy of the primary definitive agreement (and any ancillary documents reasonably required for a complete understanding thereof) relating to the Change of Control (subject to redaction and omission to the same extent as the publicly-filed version of such agreement), (ii) solely with respect to a Change of Control in which the Acquiring Party is not a Permitted Company, NovaQuest has provided its prior written consent to the Change of Control, which consent may not be unreasonably withheld, conditioned, or delayed, and (iii) the Acquiring Party has agreed in writing, in form and substance reasonably acceptable to NovaQuest, to assume all of Company's obligations under this Agreement; or (b) elect to pay the then-current Capped Return Amount to NovaQuest in full pursuant to Section 4.1(d); provided that Company shall have [*] following written notice from NovaQuest to make

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such election and, if Company elects clause (b), to pay the then-current Capped Return Amount; provided, further that, this Section 8.4 shall not apply in the event a Change of Control pursuant to subsection (d) of the definition of Change of Control occurs; provided, further, however, that Company shall provide notice promptly upon such occurrence.

8.5 Company IP Obligations. Company shall use [*] to (and shall cause each Responsible Party to):

(a) prosecute and maintain in full force and effect all Product Patents in the Territory owned or controlled by it on or after the Effective Date and all Regulatory Approvals related to the Product in the Territory;

(b) maintain, keep in full force and effect, and seek available patent term extensions for any such Product Patents;

(c) defend any challenge to the validity, patentability, enforceability, or non-infringement of any such Product Patents or any opposition to any such Product Patents;

(d) if a Third Party is infringing such Product Patents, cause such infringement to cease, including by initiating legal proceedings against any Third-Party infringer as necessary;

(e) promptly provide NovaQuest with written notice of any (i) action or settlement discussions relating to any alleged, actual, or potential infringement of Product Patents to the extent reasonably necessary to Commercialize the Product in the Territory, and (ii) damages award or settlement with respect thereto; and

(f) maintain all Product Know-How in confidence.

This Section 8.5 does not require Company to take any actions beyond which Company has the right to take under the Astellas Agreements in effect as of the Effective Date.

8.6 Additional Covenants and Agreements of Company.

(a) Compliance with Law. With respect to the performance of this Agreement and the activities contemplated by this Agreement, Company shall comply, and shall cause each Responsible Party to comply, with all Applicable Laws.

(b) Noncontravention. Except as set forth in [*] or as otherwise set forth in this Agreement, during the Term, Company shall not grant any right to any Affiliate or Third Party that would conflict with the rights granted to NovaQuest hereunder or enter into any agreement that would impair Company's ability to perform its obligations under this Agreement.

(c) Material Contracts and Licenses. Company shall comply with all terms and conditions of, and fulfill all of its obligations under, all of the Material Contracts, except for such noncompliance that would not reasonably be expected to result in a Material Adverse Effect. Company shall use [*] to enforce against the other party(ies) to each Material Contract all

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material terms and conditions thereunder, except where the failure of the other party(ies) to perform would not reasonably be expected to have a Material Adverse Effect. Company shall ensure that all Licenses contain provisions that require the Licensees to notify Company of any Material Adverse Effect and that allow Company to share information pertaining to the Commercialization of the Product to NovaQuest as contemplated by this Agreement. [*].

(d) Astellas Agreements.

(i) Without limiting any of Company's other obligations under this Agreement, Company shall comply with all material terms and conditions of, and fulfill all of its material obligations under, the Astellas EMEA Agreement. Company may not materially amend the Astellas EMEA Agreement, waive any material term thereof, or terminate the Astellas EMEA Agreement without NovaQuest's prior written consent (not to be unreasonably withheld, conditioned or delayed). Company shall use [*] to enforce all terms of the Astellas EMEA Agreement that, individually or collectively, would reasonably be expected to have a material adverse impact on the amount or timing of any payment to NovaQuest under this Agreement and shall exercise its available rights and remedies at law or in equity in the event of a breach of the Astellas EMEA Agreement with respect to any such terms.

(ii) Promptly after receiving notice from Astellas, or any other Person (A) terminating an Astellas Agreement (in whole or in part); (B) alleging any breach of or material default under an Astellas Agreement by Company; or (C) asserting the existence of any facts or circumstances that Company reasonably expects to give rise to an Event of Default, Company shall, in each case ((A) through (C)), (X) promptly give a written notice to NovaQuest describing in reasonable detail the relevant breach, default, facts, circumstances, or termination event, including a copy of any written notice received from Astellas or the other relevant Person, and, in the case of any breach, default, or alleged breach or default by Company, describing in reasonable detail any corrective action Company proposes to take, and (Y) in the case of any breach, default, alleged breach or default by Company, use its best efforts to promptly cure such breach or default and give written notice to NovaQuest upon curing such breach or default.

(iii) Promptly after Company becomes aware of a breach of, default under, or an alleged breach of or default under, an Astellas Agreement by Astellas or any other Person, including, for the avoidance of doubt, by Company or an Affiliate of Company (each, a "***Defaulting Party***"), or of the existence of any facts, circumstances, or events that, alone or together with other facts, circumstances, or events, Company reasonably expects (with or without the giving of notice or passage of time, or both) to give rise to a breach of or default under an Astellas Agreement by a Defaulting Party or the right to terminate an Astellas Agreement (in whole or in part) by Company, in each case, Company shall promptly (but in any event within [*]) give a written notice to NovaQuest describing in reasonable detail the relevant breach, default, or termination event.

(iv) Company shall, at NovaQuest's request and expense, make available its relevant records and personnel to NovaQuest in connection with any prosecution of litigation by Company or NovaQuest against any party to the Astellas Agreements to enforce any of Company's rights under the Astellas Agreements, and provide reasonable assistance and

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authority to file and bring such litigation, including, if required to bring such litigation, being joined as a party or plaintiff. All reasonable and documented out-of-pocket Third-Party expenses of Company (including reasonable and documented attorneys' fees) incurred pursuant to this Section 8.6(d)(iv) shall be reimbursed by NovaQuest.

ARTICLE IX

TERM AND TERMINATION

9.1 Term of Agreement. The term of this Agreement shall commence as of the A&R Effective Date and continue until terminated in accordance with this ARTICLE IX (the "***Term***").

9.2 Termination.

(a) Mutual Termination. This Agreement may be terminated by mutual written agreement of Company and NovaQuest.

(b) Automatic Termination. This Agreement shall immediately and automatically terminate upon the achievement of Investor Return Payment Satisfaction.

(c) Termination for Event of Default. NovaQuest may terminate this Agreement upon the occurrence and during the continuance of an Event of Default by Company, provided that Company has received written notice from NovaQuest of the occurrence and continuance of such Event of Default, specifying in reasonable detail the particulars of the alleged Event of Default and such Event of Default has not been cured within [*]. NovaQuest will have the right to pursue remedies it may have at law or equity for the occurrence and continuance of such Event of Default, including the right to seek damages from Company.

(d) Termination for Bankruptcy. NovaQuest may terminate this Agreement in its entirety upon written notice to Company upon the occurrence of a Bankruptcy Event of Default.

9.3 Effects of Termination. Expiration or termination of this Agreement for any reason will not release either Party from any obligation or liability which, at the time of such expiration or termination, has already accrued to the other Party; provided that, notwithstanding anything to the contrary, Company shall never have any obligation or liability under this Agreement, any other Transaction Document or otherwise to NovaQuest, any of its Affiliates or related Persons for an amount greater than the Capped Return Amount, plus any Adjusted Amount; provided, further, that the foregoing shall not limit any liability of either Party resulting from breaches of ARTICLE VI, any non-payment indemnification obligations expressly covered by ARTICLE X, or any liability of either Party arising from fraud or bad faith. Notwithstanding the foregoing or anything else to the contrary, no obligation or liability attributable to any period before the A&R Effective Date shall survive termination or expiration of this Agreement (other than any fraudulent actions of Company or NovaQuest that such Person is unaware of as of the A&R

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Effective Date), all such obligations having been fully and irrevocably satisfied by the Repurchase Price and the Expense Payment paid on the A&R Effective Date.

9.4 Survival. Notwithstanding anything to the contrary contained in this Agreement, Sections 4.1(d) (Capped Return Payoff), 4.1(e) (Capped Return Amount; Termination), 4.3 (Taxes; Withholding), 4.4 (Interest) and 4.5(c) (release of security interests), this Section 9.4 shall survive any termination of this Agreement or any other Transaction Document until the Capped Return Amount and any accrued, owed, due and unpaid default interest pursuant to Section 4.4 have been paid or reduced to zero and all security interests and Liens granted to NovaQuest hereunder have been terminated, released and discharged. In addition, Section 5.2 (for the duration of the Recordkeeping Period), ARTICLE VI, ARTICLE X, any liability of either Party arising from fraud or bad faith (for the duration of any applicable statute of limitations), and ARTICLE XI shall survive the termination of this Agreement for any reason.

ARTICLE X INDEMNIFICATION

10.1 Company's Indemnification Obligations. Company hereby agrees to indemnify, defend, hold harmless, and reimburse NovaQuest and its Affiliates and their respective managers, directors, officers, employees, agents, and its and their respective successors, heirs, and assigns (collectively, the "***NovaQuest Indemnitees***") from and against any losses, costs, claims, damages, Liabilities, or expenses (including reasonable attorneys' and professional fees and other expenses of litigation) (each, a "***Loss***" and collectively, "***Losses***") actually sustained or incurred by NovaQuest Indemnitees arising out of claims, suits, actions, or demands, in each case brought by a Third Party, or settlements or judgments arising therefrom (including personal injury, products liability, and intellectual property infringement or misappropriation claims) (each a "***Third-Party Claim***") as a result or arising out of:

(a) a Responsible Party's, or its or their respective agent's or contractor's actions or inactions in connection with the Development, promotion, marketing, handling, manufacture, Commercialization, packaging, labeling, storage, distribution, pricing, reimbursement, transport, use, sale, or other disposition of the Product;

(b) any breach by Company of a representation or warranty of Company contained in this Agreement or in any other agreement between the Parties contemplated by this Agreement or the breach or default by a Responsible Party of any covenant, agreement, or obligation of Company contained in this Agreement or in any other agreement between the Parties contemplated by this Agreement;

(c) a Responsible Party's failure to comply with Applicable Law or GxP; or

(d) [*] recklessness, or intentional wrongful acts or omissions related to this Agreement of a Responsible Party, or contractors or any of their respective directors, employees, or agents.

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10.2 Procedures.

(a) Notice. If one or more NovaQuest Indemnitees seek indemnification (each, an "***Indemnified Party***") under Section 10.1, then NovaQuest shall give prompt written notice to Company of the assertion of any Third-Party Claim in respect of which indemnity may be sought hereunder. Such notice shall include a description of the Third-Party Claim, the nature and amount of the applicable Loss, to the extent known at such time, and NovaQuest's decision with respect to whether Company will assume the defense of the Third-Party Claim. The failure NovaQuest to notify Company on a timely basis or provide such information as set forth above will not relieve Company of any liability that it may have to an Indemnified Party unless Company demonstrates that Company's defense of such action is materially prejudiced by NovaQuest's failure to give such notice and then solely to the extent thereof. The Indemnified Party shall provide Company with complete and correct copies of reasonably relevant papers and official documents received from or on behalf of the Third Party asserting the Third-Party Claim in connection with any Third-Party Claims for which indemnity is sought hereunder and such other information with respect thereto as Company may reasonably request. The Parties shall keep each other reasonably informed of any facts or circumstances that may be of material relevance in connection with the Loss for which indemnification is sought.

(b) Appointment of Counsel. If NovaQuest elects to have Company assume the defense of any Third-Party Claim for which indemnification is sought hereunder, then Company will promptly appoint a lead counsel in the defense of such Third-Party Claim any legal counsel selected by Company that is reasonably acceptable to the Indemnified Party.

(c) Right to Participate in Defense. Without limiting Section 10.2(b), any Indemnified Party shall be entitled to participate in the defense of such Third-Party Claim assumed by Company and to employ counsel of its choice for such purpose. However, such employment shall be at the Indemnified Party's own expense unless: (i) the employment thereof has been specifically authorized by Company in writing; (ii) Company has failed to assume the defense, diligently defend the claim, and employ counsel in accordance with Section 10.2(b) (in which case the Indemnified Party may control the defense); or (iii) the interests of the Indemnified Party and Company with respect to such Third-Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Laws, ethical rules, or equitable principles, in which case such employment shall be at the expense of Company.

(d) Settlement. With respect to the defense of any Third-Party Claim assumed by Company, Company will only have the right to consent to the entry of any judgment or enter into any settlement with respect to such Third-Party Claim upon the prior written consent of the Indemnified Party (not to be unreasonably, withheld, conditioned or delayed).

(e) Cooperation. With respect to the defense of any Third-Party Claim for which indemnification is sought and for which NovaQuest elects the defense thereof to be assumed by Company, the Indemnified Party shall reasonably cooperate in the defense or prosecution thereof, and Company shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith. In the event NovaQuest elects not to have Company assume

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the defense of any Third-Party Claim for which indemnification is sought, then Company shall cooperate with the Indemnified Party in the defense or prosecution thereof, including by furnishing such records, information, and testimony, providing such witnesses and attending such conferences, discovery proceedings, hearings, trials, and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnified Party to, and reasonable retention by Company of, records and information that are reasonably relevant to such Third-Party Claim, and making Company employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder.

(f) NovaQuest Indemnified Party's Defense of Third-Party Claims. If either: (i) Company fails to timely (and in any event [*] assume and diligently conduct the defense of any Third-Party Claim upon NovaQuest's election pursuant to Section 10.2(a); or (ii) NovaQuest elects not to have Company assume the defense of a Third-Party Claim, then the Indemnified Party may assume the defense of, and settle, such Third-Party Claim with counsel of its own choice and on such terms as it deems appropriate, without any obligation to obtain the consent of Company, at Company's expense.

10.3 Limitations. The Company's obligations pursuant to this ARTICLE X shall not apply to the extent such Third-Party Claims result from gross negligence or willful misconduct by any of the Indemnified Parties.

ARTICLE XI

MISCELLANEOUS

11.1 Governing Law; Waiver of Jury Trial. This Agreement shall be governed by and construed, interpreted, and enforced in accordance with the laws of the State of New York, as applied to agreements executed and performed entirely in the State of New York, without giving effect to the principles of conflicts of law thereof. EACH PARTY IRREVOCABLY WAIVES ANY RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING IN CONNECTION WITH OR RELATING TO THIS AGREEMENT OR ANY AGREEMENT ENTERED INTO PURSUANT HERETO AND AGREES THAT ANY SUCH SUIT, ACTION, OR PROCEEDING SHALL BE TRIED BEFORE A COURT AND NOT BEFORE A JURY.

11.2 Dispute Resolution.

(a) Subject to Section 11.3, prior to the initiation of any Arbitration between the Parties, any dispute, controversy, or claim arising under, out of, or in connection with this Agreement, including any subsequent amendments (a "***Dispute***") shall be first discussed in good faith between the Parties' Senior Officers. Either Party shall have the right to refer a Dispute to the Parties' Senior Officers for attempted resolution by sending a written notice to the other Party setting forth in reasonable detail the nature of the Dispute (the "***Dispute Notice***"). If either Party provides a Dispute Notice, then the Senior Officer (or his or her designee) from each Party shall, by phone or in-person, discuss the Dispute in good faith, commencing within [*] after the

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delivery of the Dispute Notice and continuing until at least [*] after the delivery of the Dispute Notice.

(b) If the two Senior Officers (or their designees) have not reached a mutually acceptable resolution to the Dispute within [*] after the delivery of the Dispute Notice, then either Party may submit the Dispute to arbitration by delivering a written notice to the other Party (an "***Arbitration Notice***"), and the Dispute shall be resolved by final, binding arbitration conducted in accordance with the then-current Commercial Rules (the "***AAA Rules***") of the American Arbitration Association or any successor entity (the "***AAA***") including the Procedures for Large, Complex Commercial Disputes (including, as appropriate, the Optional Rules for Emergency Measures of Protection), as amended from time to time, except as provided in this Section 11.2 ("***Arbitration***").

(c) Selection of Arbitrators. The Arbitration tribunal shall consist of three (3) arbitrators, who shall be selected as follows: (i) [*] shall be selected by Company; (ii) [*] shall be selected by NovaQuest; and (iii) [*] shall be selected by the [*] (each such arbitrator, an "***Arbitrator***"). Each of the Arbitrators shall have prior experience in connection with the biopharmaceutical industry, or shall be a retired judge. No Arbitrator shall be a current or former employee, shareholder, officer, or director of, or consultant, or advisor to, or other representative of, either Party. [*].

(d) Venue and Language. The venue of the Arbitration shall be New York, New York, USA. The Arbitration shall be conducted in English, and all foreign language documents shall be submitted in the original language and shall be accompanied by a certified translation into English.

(e) Time Periods. The Arbitration shall be conducted expeditiously and efficiently, and absent good cause shown as determined by the Arbitrators, the Arbitrators shall conduct any evidentiary hearing within [*] of confirmation of the panel of Arbitrators. Upon the written mutual agreement of both Parties, any time period specified in this Section 11.2 or the [*] shall be extended or accelerated according to the Parties' written mutual agreement. The Arbitrators shall take into account both the desirability of making discovery efficient and cost-effective and the needs of the Parties for an understanding of any legitimate issue raised in the Arbitration. The Arbitrators shall, upon the request of one or both parties, permit the exchange of documents relevant to the claims and defenses raised in the Arbitration. Unless the Parties mutually agree, no depositions or other discovery devices shall be permitted, absent extraordinary circumstances as determined by the Arbitrators.

(f) Consolidation of Disputes. In order to facilitate the comprehensive resolution of related disputes, and upon request of any Party to the Arbitration proceeding, the Arbitrators may consolidate the Arbitration proceeding with any other Arbitration proceeding relating to this Agreement. The Arbitrators shall not consolidate such Arbitrations unless they determine that: (i) there are issues of fact or law common to the proceedings so that a consolidated proceeding would be more efficient than separate proceedings; and (ii) no Party would be prejudiced as a result of such consolidation through undue delay or otherwise. The Arbitrators shall have jurisdiction to decide matters of arbitrability.

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(g) Costs. The costs of the Arbitration, including reasonable fees plus expenses to be paid to the Arbitrator(s) and the reasonable out-of-pocket costs (including the costs incurred for translation of the documents into English, reasonable attorneys' and expert witness fees, and reasonable travel expenses) of the prevailing Party shall be borne by: (i) the losing Party, if the Arbitrator(s) rule in favor of one Party on all disputed issues in the Arbitration; and (ii) the Parties, as allocated in writing by the Arbitrator(s) in a manner with a reasonable relationship to the outcome of the Arbitration, if the Arbitrator(s) rule in favor of one Party with respect to some issues and in favor of the other Party with respect to other issues and, in either case ((i) or (ii)), paid within [*] from the final decision by the Arbitrator.

(h) Decision to be Binding. The Arbitrators shall render a reasoned arbitral award. The award by the Arbitrators shall be final and binding on the Parties, non-reviewable and non-appealable, and judgment upon any arbitral award may be entered and enforced by any court or other judicial authority of competent jurisdiction. The Parties' agreement to arbitrate, and any arbitral award, shall be enforced under the Federal Arbitration Act.

(i) Confidentiality. All Disputes under this Agreement shall be kept confidential. All settlement negotiations, proceedings, and any award and any information obtained from the other Party in connection with the Arbitration shall be deemed Confidential Information subject to ARTICLE VI, provided that the Parties further agree that such Confidential Information may be disclosed to the extent necessary to enforce any award or enforce this Agreement to arbitrate; provided that either Party may disclose such settlement information if required by the U.S. Securities and Exchange Commission, and such disclosing Party shall use its reasonable efforts to secure confidential treatment of such Confidential Information prior to its disclosure (whether through protective orders or otherwise) or with respect to any filing required by a securities agency, the Parties agree to use reasonable efforts to provide the other with a copy of any filing required by a securities agency that will be made publicly available regarding the Agreement or its terms to review prior to filing and to consider any comments of the other Party in good faith, and to the extent either Party is required to file or disclose this Agreement with a securities agency, if the Agreement may become publicly available, such Party shall consider in good faith the other Party's comments with respect to confidential treatment of the Agreement's terms and shall redact the Agreement in a manner allowed by the securities agency to protect sensitive terms, and shall be permitted to file the Agreement, as so redacted, with the securities agency.

11.3 Equitable Relief. Each of the Parties hereto acknowledges that the other Party may have no adequate remedy at law if it fails to perform any of its obligations under ARTICLE VI of this Agreement. In such event each of the Parties agrees that the other Party shall have the right, in addition to any other rights it may have (whether at law or in equity), to pursue equitable remedies such as injunction and specific performance for the breach or threatened breach of any provision of such ARTICLE VI from any court of competent jurisdiction.

11.4 Expenses. Simultaneously with its payment of the Repurchase Price, Company shall pay NovaQuest for NovaQuest's actual and documented out-of-pocket costs and expenses (including reasonable legal fees and accountants' fees) incurred solely in connection with the negotiation of this Agreement up to a maximum amount of [*] (the "***Expense Payment***"). Except as expressly

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set forth herein, each Party shall be responsible for and bear all of its own costs and expenses with regard to the negotiation and consummation of the transactions contemplated by this Agreement. Notwithstanding the foregoing, each Party represents and warrants to the other that the other Party will not be liable for any brokerage commission, finder's fee, or other like payment in connection with the transactions contemplated hereby because of any action taken by, or agreement or understanding reached by, that Party. If, after the A&R Effective Date, Company requests an amendment of this Agreement in connection with any restructuring, reorganization, or similar transaction to which Company or any Affiliate of Company is a party, [*].

11.5 Relationship of the Parties. Nothing in this Agreement is intended to be construed so as to suggest that either Party (except as expressly set forth herein) is obligated to provide, directly or indirectly, any advice, consultations, or other services to the other Party. Neither Party shall have any responsibility for the hiring, termination, or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever or to create or impose any contractual or other liability on the other Party without such Party's approval. For all purposes and notwithstanding any other provision of this Agreement to the contrary, each Party's legal relationship under this Agreement to the other Party shall be that of independent contractor. This Agreement is not a partnership agreement, and nothing in this Agreement shall be construed to establish a relationship of co-partners or joint venturers between the Parties for any purpose, including any Tax purpose.

11.6 Successors and Assigns. Neither this Agreement nor any rights or obligations hereunder may be assigned in whole or in part by either Party, by operation of law or otherwise, without the prior written consent of the other Party (not to be unreasonably withheld, conditioned or delayed), provided that, notwithstanding the foregoing: (a) subject to the terms of any [*], NovaQuest may, upon delivery of reasonable written notice to Company, (i) assign, sell, or otherwise transfer this Agreement to an Affiliate of NovaQuest, and (ii) assign, sell, pledge, contribute, or otherwise transfer, in whole or in part, its rights to receive any payments under this Agreement, its rights to enforce such payment rights, and its rights to conduct or request audits or receive information and audit findings under ARTICLE V to any Person that is not a Company Competitor, and such Person may assign, sell, pledge, contribute, or otherwise transfer such rights to another Person that is not a Company Competitor; and (b) Company may assign, sell, pledge, contribute or otherwise transfer its rights or obligations hereunder in accordance with Section 8.2 and Section 8.4. This Agreement shall be binding upon, and subject to the terms of this Section 11.6, inure to the benefit of the Parties hereto, their permitted successors, legal representatives and assigns, provided that [*]. Any assignment or attempted assignment not in accordance with this Section 11.6 shall be null and void. Company shall maintain at one of its offices a register for the recordation of the names and addresses of the Parties and the commitments of, and principal amounts (and stated interest) under the Agreement owing to, each Party pursuant to the terms hereof from time to time (the "***Register***"). The entries in the Register shall be conclusive absent manifest error, and the Parties shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as a Party hereunder for all purposes of this Agreement. The Register shall be available for inspection by the Parties, at any reasonable time

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and from time to time upon reasonable prior notice. The Parties agree that the foregoing is intended to ensure that the Agreement is in "registered form" within the meaning of Treasury Regulation Section 5f.103-1(c) and shall be interpreted consistently therewith. For avoidance of doubt, Company may assign, sell, pledge, contribute or otherwise transfer its rights or obligations under such portions of Astellas Revenue that are not part of the Revenue Interest Payments due and payable to NovaQuest.

11.7 Notices. All notices, consents, waivers, requests, and other communications hereunder shall be in writing and shall be delivered in person, sent by confirmed electronic mail, sent by overnight courier (*e.g.*, Federal Express), confirmed facsimile transmission or posted by registered or certified mail, return receipt requested, with postage prepaid, to following addresses of the Parties:

If to Company:

Kyntra Bio, Inc.
350 Bay Street, Suite 100 #6009
San Francisco, CA 94133
[*]

with a copy (which shall not constitute notice)to:

Goodwin Procter LLP
520 Broadway, Suite 500
Santa Monica, CA 90401
[*]

If to NovaQuest:

NQ Project Phoebus, L.P.
4208 Six Forks Road, Suite 920
Raleigh, NC 27609
[*]

with a copy to:

Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail, Suite 300
Raleigh, North Carolina 27607
[*]

or to such other address or addresses as NovaQuest or Company may from time to time designate by notice as provided herein. Any such notice shall be deemed given: (a) when actually received when so delivered personally or by overnight courier; (b) if mailed, other than during a period of general discontinuance or disruption of postal service due to strike, lockout or otherwise, on the [*] after its postmarked date thereof; or (c) if sent by e-mail with acknowledgement of receipt,

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transmission on the date sent if such day is a Business Day or the next following Business Day if such day is not a Business Day.

11.8 Severability. If any provision hereof should be held invalid, illegal, or unenforceable in any jurisdiction, then the Parties shall negotiate in good faith a valid, legal, and enforceable substitute provision that most nearly reflects the original intent of the Parties. All other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties as nearly as may be possible. Such invalidity, illegality, or unenforceability shall not affect the validity, legality, or enforceability of such provision in any other jurisdiction. Nothing in this Agreement shall be interpreted so as to require a Party to violate any Applicable Law.

11.9 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be, or construed as, a waiver of the same or any other term or condition of this Agreement on any future occasion.

11.10 Entire Agreement. This Agreement, and any [*], including any Exhibits or Schedules to any the foregoing, set forth all of the covenants, promises, agreements, warranties, representations, conditions, and understandings between the Parties relating to the subject matter hereof and thereof and supersedes and terminates all prior agreements and understandings between the Parties. There are no covenants, promises, agreements, warranties, representations, conditions, or understandings, either oral or written, between the Parties relating to the subject matter hereof other than as set forth in this Agreement or [*]. The Parties acknowledge and agree that the Parties' respective rights and obligations with regard to the subject matter herein are enshrined in this Agreement. Any conflict or inconsistency between the main body of this Agreement, the Exhibits, or Schedules, or any other documents to be delivered pursuant hereto shall be resolved in accordance with the following order of priority: (a) main body of this Agreement; (b) Exhibits and Schedules; and (c) other documents.

11.11 Third-Party Beneficiaries. Except with regard to the NovaQuest Indemnitees under ARTICLE X, all rights, benefits, and remedies under this Agreement are solely intended for the benefit of the Parties (including their permitted successors and assigns), and no Third Party (except the NovaQuest Indemnitees with regard to their rights, benefits, and remedies under ARTICLE X and except for the Parties' permitted successors and assigns) shall have any rights whatsoever to: (a) enforce any obligation contained in this Agreement; (b) seek a benefit or remedy for any breach of this Agreement; or (c) take any other action relating to this Agreement under any legal theory, including actions in contract, tort (including negligence, gross negligence and strict liability), or as a defense, setoff, or counterclaim to any action or claim brought or made by the Parties (or any of their permitted successors and assigns).

11.12 Interpretation. When a reference is made in this Agreement to Articles, Sections, Schedules, or Exhibits, such reference shall be to an Article, Section, Schedule, or Exhibit to this Agreement unless otherwise indicated. The words "include," "includes," and "including" when

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used herein shall be deemed in each case to be followed by the words "without limitation" and shall not be construed to limit any general statement that it follows to the specific or similar items or matters immediately following it. The headings and captions in this Agreement are for convenience and reference purposes only and shall not be considered a part of or affect the construction or interpretation of any provision of this Agreement. Unless specified otherwise, all statements of, or references to, monetary amounts in this Agreement are to Dollars. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under GAAP or IFRS, as applicable, but only to the extent consistent with its usage and the other definitions in this Agreement. Provisions that require that a Party or the Parties "agree," "consent," "approve," or the like shall require that such agreement, consent, or approval be specific and in writing, whether by written agreement, letter, approved minutes, or otherwise. Words of any gender include the other gender, and words using the singular or plural number also include the plural or singular number, respectively. Neither Party hereto shall be deemed to be the drafter of this Agreement for the purposes of construing this Agreement against one Party or the other. If any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day, then such notice or other action or omission shall be deemed to require to be taken on the next occurring Business Day.

11.13 Amendments. This Agreement may be amended, modified, or supplemented only by a written amendment or agreement signed by an authorized officer of both NovaQuest and Company.

11.14 No Implied Licenses. Each Party acknowledges that the rights granted in this Agreement are limited to the scope expressly granted, and all other rights to each Party's respective technologies and intellectual property rights are expressly reserved to the Party owning or controlling such technologies and intellectual property rights.

11.15 Time. Time is of the essence with respect to this Agreement and each of its provisions.

11.16 Counterparts. This Agreement may be executed in any number of counterparts with the same effect as if each of the parties hereto had signed the same document. All counterparts shall be construed together and shall constitute one agreement. This Agreement, to the extent signed and delivered by means of a facsimile machine or via e-mail in .pdf file format, shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.

11.17 Electronic Signatures. Any signature (including any electronic symbol or process attached to, or associated with, a contract or other record and adopted by a Person with the intent to sign, authenticate, or accept such contract or record) hereto or to any other certificate, document, or instrument related to this Agreement, and any contract formation or record-keeping through electronic means, shall have the same legal validity and enforceability as a manually executed signature or use of a paper-based recordkeeping system to the fullest extent permitted by applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any similar state law based on the Uniform Electronic Transactions Act, and the Parties hereby waive any objection to the contrary.

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11.18 Further Assurances. Each of the Parties hereto shall execute and deliver such additional documents, certificates, and instruments and shall perform such additional acts as may be reasonably requested and necessary or appropriate to carry out the purposes and intent and all of the provisions of this Agreement and to consummate all of the transactions contemplated by this Agreement.

11.19 Remedies. Neither the failure nor any delay by any Party in exercising any right, power, or privilege under this Agreement will operate as a waiver of such right, power, or privilege, and no single or partial exercise of such right, power, or privilege will preclude any other or further exercise of such right, power, or privilege or the exercise of any other right, power, or privilege. Unless specifically and expressly stated in this Agreement as exclusive, each remedy of the Parties specified in this Agreement is not exclusive, and, subject to the terms of this Agreement, is cumulative. The Parties shall be entitled to pursue any available legal or equitable remedy for breach of this Agreement or any provision hereof.

[Signature page follows]

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

KYNTRA BIO, INC.

By: \s\ [*]

Name: [*]

Title: [*]

[Signature Page to NovaQuest – Kyntra Amended & Restated Revenue Interest Financing Agreement]

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

NQ PROJECT PHOEBUS, L.P.

By: NQ POF V GP, Ltd, its general partner

By: \s\ [*]

Name: [*]

Title: [*]

[Signature Page to NovaQuest – Kyntra Amended & Restated Revenue Interest Financing Agreement]

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Exhibit A

Reserved

[Exhibit A to NovaQuest – Kyntra Amended & Restated Revenue Interest Financing Agreement]

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Exhibit B

Astellas EMEA Agreement

[Attached]

[Exhibit B to NovaQuest – NovaQuest – Kyntra Amended & Restated Revenue Interest Financing Agreement]

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Exhibit C

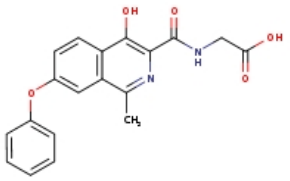
[Reserved]

[Exhibit C to NovaQuest – NovaQuest – Kyntra Amended & Restated Revenue Interest Financing Agreement]

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Exhibit D

Compound



The chemical compound or bulk active pharmaceutical compound, known as FG-4592, whose specific INN name is roxadustat with CAS number 808118-40-3

[Exhibit D to NovaQuest – NovaQuest – Kyntra Amended & Restated Revenue Interest Financing Agreement]

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Schedule 7.1(e)

Product Patents

[*].

[Schedule 7.1(e) to NovaQuest – NovaQuest – Kyntra Amended & Restated Revenue Interest Financing Agreement]

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Schedule 7.1(f)

Litigation

[*].

[Schedule 7.1(f) to NovaQuest – NovaQuest – Kyntra Amended & Restated Revenue Interest Financing Agreement]

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Schedule 7.1(h)

Material Contracts

[*].

[Schedule 7.1(h) to NovaQuest – NovaQuest – Kyntra Amended & Restated Revenue Interest Financing Agreement]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted or excluded from this exhibit because it is both (i) not material and (ii) the type of information that the registrant treats as private and confidential.

Schedule 7.1(i)

Certain Regulatory Matters

- [*]

[Schedule 7.1(i) to NovaQuest – NovaQuest – Kyntra Amended & Restated Revenue Interest Financing Agreement]

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Exhibit 31.1

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: November 16, 2026

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

Exhibit 31.2

CERTIFICATION

I, David DeLucia, certify that:

1. I have reviewed this Form 10-Q of 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: November 16, 2026

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

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Thane Wettig, Chief Executive Officer of 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 September 30, 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: November 16, 2026

In Witness Whereof, the undersigned have set their hands hereto as of the 16th day of November, 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.