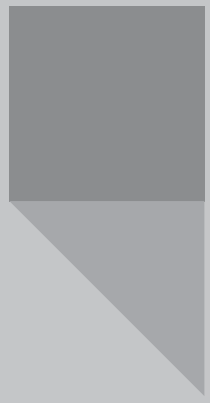
Kyntra BIO

2025 Annual Report



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

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

For the transition period from _____ to _____.

Commission file number: 001-36740

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)**

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

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

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the Registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the Registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the closing price as of the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2025, was approximately $21.0 million. Shares of common stock held by each executive officer and director have been excluded since such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of common stock outstanding as of February 28, 2026 was 4,046,827.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K for the year ended December 31, 2025 (the "Annual Report") incorporate information by reference from the definitive proxy statement for the registrant's 2026 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than after 120 days after the end of the fiscal year covered by this Annual Report.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the year ended December 31, 2025 ("Annual Report") and the information incorporated herein by reference, particularly in the sections captioned "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," contains forward-looking statements, which involve substantial risks and uncertainties. In this Annual Report, all statements other than statements of historical or present facts contained in this Annual Report, including statements regarding our future financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "believe," "will," "may," "estimate," "continue," "anticipate," "contemplate," "intend," "target," "project," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or other similar terms or expressions that concern our expectations, strategy, plans or intentions. Forward-looking statements appear in a number of places throughout this Annual Report and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, our intellectual property position, the potential safety, efficacy, reimbursement, convenience clinical and pharmaco-economic benefits of our product candidates, the potential markets for any of our product candidates, our ability to develop commercial functions, the closing of the sale of our roxadustat business in China, the potential for cash, cash equivalents and accounts receivable to fund Kyntra Bio's operating plans, expectations regarding clinical trial data, our results of operations, cash needs, spending of the proceeds from our initial public offering, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions described in the section of this Annual Report captioned "Risk Factors" and elsewhere in this Annual Report. A summary of these risk factors can be found in the following section, however, please refer to the full risk factors in Item 1A "Risk Factors." These risks are not exhaustive. Other sections of this Annual Report may include additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors 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, or implied by, any forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. The forward-looking statements made in this Annual Report are based on circumstances as of the date on which the statements are made. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report or to conform these statements to actual results or to changes in our expectations.

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 Annual Report, 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. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

This Annual Report also contains market data, research, industry forecasts and other similar information obtained from or based on industry reports and publications, including information concerning our industry, our business, and the potential markets for our product candidates, including data regarding the estimated size and patient populations of those and related markets, their projected growth rates and the incidence of certain medical conditions, as well as physician and patient practices within the related markets. Such data and information involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

You should read this Annual Report with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

RISK FACTOR SUMMARY

The success of Kyntra Bio will depend on a number of factors, many of which are beyond our control and involve risks, including but not limited to the following:

Risks Related to the Development and Commercialization of Our Product Candidates

- We are substantially dependent on the success of our lead products roxadustat and FG-3246 (in conjunction with our PET (as defined below) imaging agent FG-3180).
- Drug development and obtaining marketing authorization are very difficult endeavors, and we may ultimately be unable to obtain regulatory approval for our various product candidates in one or more jurisdictions and one or more indications.
- Preclinical, Phase 1, and Phase 2 clinical trial results may not be indicative of the results that may be obtained in larger clinical trials.
- We do not know whether our ongoing or planned clinical trials will need to be redesigned based on interim results or if we will be able to achieve sufficient patient enrollment or complete planned clinical trials on schedule.
- Our product candidates may cause or have attributed to them undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.
- If our manufacturers or we cannot properly manufacture the appropriate volume of product, we may experience delays in development, regulatory approval, launch, or successful commercialization.
- We face substantial competition in the development and commercialization of product candidates.
- Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.

Risks Related to Our Reliance on Third Parties

- If our collaborations were terminated or if our partners were unwilling or unable to contribute or participate in the collaborations, our ability to successfully develop and commercialize the relevant product candidate could suffer.
- If our preclinical and clinical trial contractors do not properly perform their agreed-upon obligations, we may not be able to obtain or may be delayed in receiving regulatory approvals for our product candidates.
- We currently rely, and expect to continue to rely, on third parties to conduct many aspects of our product manufacturing and distribution, and these third parties may terminate these agreements or not perform satisfactorily.
- We may have shortfalls, delays, or excesses in manufacturing.
- Certain components of our products are acquired from single-source suppliers or without long-term supply agreements. The loss of these suppliers, or their failure to supply, would materially and adversely affect our business.

Risks Related to Our Intellectual Property

- If our efforts to protect our proprietary and exclusively licensed technologies are not adequate, we may not be able to compete effectively in our market.
- Our reliance on third parties and agreements with collaboration partners requires us to share our trade secrets, which increases the possibility that a competitor may discover them or that our trade secrets will be misappropriated or disclosed.
- The cost of maintaining our patent protection is high and requires continuous review and diligence. We may not be able to effectively maintain our intellectual property position throughout the major markets of the world.
- The laws of some foreign countries do not protect proprietary rights to the same extent as do the laws of the U.S., and we may encounter significant problems in securing and defending our intellectual property rights outside the U.S.

Risks Related to Government Regulation

- The regulatory approval process is highly uncertain and we may not obtain regulatory approval for our product candidates.
- Our current and future relationships with customers, physicians, and third-party payors are subject to healthcare fraud and abuse laws, false claims laws, transparency laws, and other regulations. If we are unable to comply with such laws, we could face substantial penalties.
- We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

International Risks

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

PART I

ITEM 1. BUSINESS

OVERVIEW

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

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

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

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

On August 29, 2025, we closed the sale of our China operations through FibroGen International (Hong Kong) Ltd. ("FibroGen International") to AstraZeneca Treasury Limited pursuant to the share purchase agreement entered into by the Company and AstraZeneca Treasury Limited on February 20, 2025, as amended (the "Share Purchase Agreement") for a total consideration of $220.4 million comprised of $85.0 million in enterprise value and $135.4 million in net cash held in China. AstraZeneca AB ("AstraZeneca") was our long-time commercialization partner for roxadustat in greater China. This sale included all of our roxadustat assets in China, including FibroGen International's subsidiary FibroGen (China) Medical Technology Development Co., Ltd. ("FibroGen Beijing") and its 51.1% interest in Beijing Falikang Pharmaceutical Co. Ltd. ("Falikang").

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

We continue to advance our development plan for roxadustat in anemia associated with lower-risk myelodysplastic syndromes ("MDS"), a high-value indication with significant unmet medical need. We had a positive Type-C meeting with the U.S. Food and Drug Administration ("FDA") in July 2025 and reached alignment on several elements of our proposed Phase 3 study design for roxadustat in anemia associated with lower-risk MDS, including the starting dose and the patient inclusion criteria. We are starting preparations for the Phase 3 trial, while evaluating internal development and potential partnership opportunities for this late-stage program. We submitted the Phase 3 trial protocol for roxadustat for the treatment of anemia in patients with lower-risk MDS and high transfusion burden to the FDA in December 2025.

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

Commercial, Development and Research Programs

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

FG-3246 and FG-3180 *in mCRPC*

Disease Overview

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

Current Standard of Care

Treatment choice in first and second line mCRPC significantly depends on patients' prior treatments in the castration sensitive phase. Androgen receptor signaling inhibitors or androgen receptor pathway inhibitors ("ARSIs" / "ARPIs", often used interchangeably) and chemotherapy are the preferred treatments in patients who have not been exposed to either in earlier lines of therapy. Most patients who previously progressed on an ARPI will subsequently receive chemotherapy. Switching to another ARPIs is another option for these patients but this approach is generally associated with suboptimal outcomes.

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

The recent approval of prostate-specific membrane antigen ("PSMA")-targeted radiopharmaceutical Pluvicto (lutetium Lu 177 vipivotide tetraxetan) in the post-ARPI and pre-chemotherapy setting has diversified treatment options in first and second line mCRPC for PSMA positive patients. Furthermore, PSMA-PET has been validated as standard of care diagnostic in prostate cancer, while LOCAMETZ or an approved PSMA-11 imaging agent are approved to select patients for treatment with Pluvicto.

Kyntra Bio is developing FG-3246 in the post-ARPI, pre-chemotherapy mCRPC setting. This is an area of high unmet need, where radiographic progression free survival is short: Approximately 5-6 months after switching to a different ARPI, approximately 8 months with chemotherapy, and 9.3 months with Pluvicto in PSMA-positive patients, who are considered appropriate to delay taxane-based chemotherapy. Novel mechanisms of action that extend survival are critical in this setting as well as biomarker driven treatment approaches. FG-3246 and the potential patient selection biomarker FG-3180 are being developed to address these unmet medical needs.

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

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

We are actively enrolling our Phase 2 monotherapy dose optimization study of FG-3246 for the treatment of patients with mCRPC in the post-ARPI and pre-chemotherapy setting, with interim results expected in the second half of 2026.

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

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

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

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

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

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

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

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

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

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

ROXADUSTAT IN ANEMIA ASSOCIATED WITH MDS

Disease Overview

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

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

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

Limitations of the Current Standard of Care for Anemia in MDS

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

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

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

Market Opportunity for Roxadustat in MDS

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

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

Roxadustat in MDS Clinical Trials

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

We had a positive Type-C meeting with the FDA in July 2025, and reached alignment on several elements of our proposed Phase 3 study design for roxadustat in anemia associated with lower-risk MDS, including the starting dose and the patient inclusion criteria.

We are advancing preparations for the Phase 3 trial, while evaluating internal development and potential partnership opportunities for this late-stage program. We submitted the Phase 3 trial protocol for roxadustat for the treatment of anemia in patients with lower-risk MDS and high transfusion burden to the FDA in December 2025.

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 the Orphan Drug Designation.

The Phase 3 trial is planned to assess the safety and efficacy of roxadustat in a randomized, double-blind, placebo-controlled design in approximately 200 patients with lower-risk MDS. Alignment was reached with the FDA on the patient population (patients requiring ≥ 4 RBC units in two consecutive 8-week periods prior to randomization, who are refractory to, intolerant to, or ineligible for prior erythropoiesis-stimulating agents (ESA) therapy), dose regimen, as well as management of potential thrombotic risk through eligibility, dose modification and discontinuation criteria. For the primary endpoint of RBC transfusion independence, the Company is considering independence over either an 8-week period or 16-week period.

Phase 2/3 Clinical Trial in MDS

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

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

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

Roxadustat in Anemia of CKD

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

China – Roxadustat Commercial Program

On August 29, 2025, we closed the sale of our China operations through FibroGen International to AstraZeneca Treasury Limited pursuant to the Share Purchase Agreement for a total consideration of $220.4 million, comprised of $85.0 million in enterprise value and $135.4 million in net cash held in China. This sale included all of our roxadustat assets in China, including FibroGen International's subsidiary FibroGen Beijing and its 51.1% interest in Falikang.

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.

COLLABORATIONS

Collaboration Partnerships for Roxadustat

Our revenue to date has been generated primarily from our collaboration agreements with Astellas and AstraZeneca for the development and commercialization of roxadustat. For the years ended December 31, 2025 and 2024, our revenue for continuing operations was substantially related to our collaboration agreements.

Astellas

We have two agreements with Astellas for the development and commercialization of roxadustat, one for Japan, and one for Europe, the Commonwealth of Independent States, the Middle East and South Africa. Under these agreements, we provided Astellas the right to develop and commercialize roxadustat for anemia in these territories.

We share responsibility with Astellas for clinical development activities required for U.S. and Europe regulatory approval of roxadustat, and equally share those development costs under the agreed development plan for such activities. Astellas will be responsible for clinical development activities and all associated costs required for regulatory approval in all other countries in the Astellas territories. Astellas will hold and have responsibility for regulatory filings in its territories. We are responsible, either directly or through our contract manufacturers, for the manufacture and supply of all quantities of roxadustat to be used in development and commercialization under the agreements, other than roxadustat drug product for Japan. Astellas is responsible for roxadustat commercialization activities in the Astellas territories.

AstraZeneca

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. AstraZeneca was our long-time commercialization partner for roxadustat in greater China. This sale includes all of our roxadustat assets in China, including FibroGen International's subsidiary FibroGen Beijing and its 51.1% interest in Falikang.

Upon the closing, we assigned to AstraZeneca Treasury Limited all rights to roxadustat in China, Hong Kong, and Macao, including rights to manufacture, develop, distribute, and commercialize roxadustat.

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. Roxadustat is not approved for commercialization in any indication in the U.S., Canada, or Mexico. Astellas is commercializing roxadustat (EVRENZO™) in Europe and Japan to treat anemia under two development and commercialization license agreements: one for Japan, and one for Europe, the Commonwealth of Independent States, the Middle East and South Africa.

Our collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in the U.S. and all territories except for China and those territories previously licensed to Astellas (the "AstraZeneca U.S./RoW Agreement") was terminated (except South Korea) on February 25, 2024, as amended and restated on August 29, 2025.

Additional Information Related to Collaboration Agreements

Additional information related to our collaboration agreements is set forth in Item 7 of this Annual Report, and Note 4, *Collaboration Agreements, License Agreement and Revenues,* to our consolidated financial statements under Item 8 of this Annual Report. Information about collaboration partners that accounted for more than 10% of our total revenue for the last two fiscal years is set forth in Note 15, *Segment and Geographic Information*, to our consolidated financial statements under Item 8 of this Annual Report.

Exclusive License and Option to Acquire Fortis Therapeutics

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

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

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

STRATEGIC FINANCING AGREEMENTS

In November 2022, we entered into a revenue interest financing agreement (the "RIFA") with NQ Project Phoebus, L.P. ("NovaQuest") with respect to our revenues from Astellas' sales of roxadustat in Europe, Japan and the other Astellas territories.

Pursuant to the RIFA, we received $49.8 million from NovaQuest, representing the gross proceeds of $50.0 million net of initial issuance costs, in consideration for a portion of future revenues we will receive from Astellas. For additional details about this financing transaction, see Note 9, *Liability Related to Sale of Future Revenues*, to the consolidated financial statements.

On August 29, 2025, we repaid our term loan facility with Morgan Stanley Tactical Value that was entered into in April 2023. For additional details about this financing transaction, see Note 8, *Senior Secured Term Loan Facilities*, to the consolidated financial statements.

COMPETITION

The pharmaceutical and biotechnology industries are highly competitive, particularly in some of the indications of our developing drug candidates. We face competition from multiple other pharmaceutical and biotechnology companies, many of which have significantly greater financial, technical and human resources and experience in product development, manufacturing and marketing. These potential advantages of our competitors are particularly a risk in pancreatic cancer, where we do not currently have a development or commercialization partner.

We expect any products that we develop and commercialize to compete based on, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic competition, and the availability of reimbursement from government and other third-party payors.

We expect that in many cases, the products that we commercialize will compete with existing marketed products, as well as product candidates that may be approved in the future, from companies that have large, established commercial organizations. In addition, we will likely face competition in patient recruitment and enrollment for clinical trials from other companies developing or seeking to pursue products or treatments in the same diseases or indications as us.

MANUFACTURE AND SUPPLY

We continue to enter into contractual arrangements with qualified third-party manufacturers to manufacture and package our products and product candidates. We believe this manufacturing strategy enables us to more efficiently direct financial resources to the research, development and commercialization of product candidates rather than diverting resources to establishing a significant internal manufacturing infrastructure, unless there is additional strategic value for establishing manufacturing capabilities. As our product candidates proceed through development, we explore or enter into longer-term commercial supply agreements with key suppliers and manufacturers in order to meet the ongoing and planned clinical and commercial supply needs for ourselves and our partners. Our timing of entry into these agreements is based on the current development and commercialization plans.

Roxadustat

Roxadustat is a small-molecule drug manufactured from generally available commercial starting materials and chemical technologies and multi-purpose equipment available from many third-party contract manufacturers. We have entered into commercial supply arrangements with Shanghai SynTheAll Pharmaceutical Co., Ltd. (“WuXi STA”) and Catalent Pharma Solutions, LLC (“Catalent”) as our primary manufacturers of roxadustat drug substance (also known as active pharmaceutical ingredient (“API”)) and roxadustat drug product, respectively. WuXi STA is located in China and currently supplies our API globally. WuXi STA has passed inspections by several regulatory agencies, including the FDA and NMPA, and is Current Good Manufacturing Practice (“cGMP”) compliant. Catalent is located in the U.S. and supplies our drug product tablets globally except for Japan, where they are manufactured by Astellas. Catalent has passed several regulatory inspections, including by the FDA, and manufactures commercial products for other clients.

GOVERNMENT REGULATION

Our business activities and operations, including the clinical testing, manufacturing, labeling, storage, distribution, record keeping, advertising, promotion, import, export and marketing of our product candidates, among other things, are subject to extensive regulation by governmental authorities in the U.S., China, and other countries. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations, including in Europe and China, requires the expenditure of substantial time and financial resources. Compliance with environmental laws, rules, and regulations has not had, and is not expected to have, a material effect on our capital expenditures, results of operations, or competitive position, and we do not currently anticipate material capital expenditures for environmental control facilities.

Failure to comply with the applicable requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the applicable regulatory authority to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by FDA and the Department of Justice, or other governmental entities.

U.S. Product Approval Process

In the U.S., the FDA regulates drugs and biological products, or biologics, under the Public Health Service Act, as well as the FDCA, which is the primary law for regulation of drug products. Both drugs and biologics are subject to the regulations and guidance implementing these laws.

The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of the Investigational New Drug Application ("IND"), which includes a protocol detailing, among other things, the objectives of the clinical trial. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the trials as outlined in the IND prior to that time. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed.

While we have an Exclusive Option Agreement and Evaluation Agreement with Fortis, Fortis currently holds the IND for FG-3246/FOR46.

Further, the protocol for each clinical trial must be reviewed and approved by an independent institutional review board, either centrally or individually at each institution at which the clinical trial will be conducted.

The results of preclinical studies and clinical trials, together with detailed information on the manufacture, composition and quality of the product candidate, are submitted to the FDA in the form of an NDA (for a drug) or Biologics License Application ("BLA") (for a biologic), requesting approval to market the product. The application must be accompanied by a significant user fee payment. The FDA has substantial discretion in the approval process and may refuse to accept any application or decide that the data is insufficient for approval and require additional preclinical, clinical or other studies.

Review of Application

Once the NDA or BLA submission is accepted for filing, which occurs, if at all, 60 days after submission, the FDA informs the applicant of the specific date by which the FDA intends to complete its review. During the approval process, the FDA reviews NDAs and BLAs to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is manufactured in accordance with cGMPs to assure and preserve the product's identity, strength, quality and purity. The FDA may require Risk Evaluation and Mitigation Strategy to assure safe use of the product, and inspections of manufacturing facilities (for cGMP compliance) and clinical trial sites (for integrity of data supporting safety and efficacy). The FDA may also convene an advisory committee of external experts to review issues relating to risk, benefit and interpretation of clinical trial data. The FDA may require post-marketing testing and surveillance to monitor safety or efficacy of a product. FDA will issue either an approval of the NDA or BLA or a CRL detailing the deficiencies and information required in order for reconsideration of the application.

Post-Approval Requirements

Even after approval, drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to continuous regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product distribution, advertising and promotion and reporting of adverse experiences with the product.

In addition, entities involved in the manufacture and distribution of approved drugs and biologics are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. The FDA requires prior approval before implementing any changes to the manufacturing process, investigations and corrections of any deviations from cGMP, and impose reporting and documentation requirements on the sponsor and any third-party manufacturer the sponsor may use. Accordingly, manufacturers must expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company in violation may be subject to significant liability.

Federal and State Fraud and Abuse and Healthcare and Transparency Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state healthcare laws restrict certain business practices in the biopharmaceutical industry. These laws include, but are not limited to, anti-kickback, false claims, data privacy and security, and transparency statutes and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any good, facility, item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly. The intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 (collectively "PPACA"), to a stricter intent standard such that a person or entity no longer needs to have actual knowledge of this statute or the specific intent to violate it in order to have committed a violation. In addition, PPACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below).

The federal false claims laws and federal civil monetary penalties statute prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of, or payment for, healthcare benefits, items or services.

In addition, we may be subject to federal and state healthcare privacy and security laws. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, imposes certain requirements on covered entities, business associates and their covered subcontractors relating to the privacy, security and transmission of individually identifiable health information. In addition, state laws complicate compliance efforts by the way they govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and with varying effects.

Additionally, the federal Physician Payments Sunshine Act within the PPACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians, other healthcare professionals, and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, such healthcare professionals and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

Also, many states have similar healthcare statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion of products from reimbursement under government programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products will be sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Data Privacy and Security

In the ordinary course of our business, we may process confidential, proprietary, and sensitive information, including personal data. Accordingly, we are, or may become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy and security. Such obligations may include, without limitation, the Federal Trade Commission Act, the California Consumer Privacy Act of 2018 ("CCPA"), the Canadian Personal Information Protection and Electronic Documents Act, Canada's Anti-Spam Legislation, the European Union's General Data Protection Regulation 2016/679 ("EU GDPR"), the EU GDPR as it forms part of United Kingdom ("UK") law by virtue of section 3 of the European Union (Withdrawal) Act 2018 ("UK GDPR"), China's Personal Information Protection Law, the ePrivacy Directive, and the Payment Card Industry Data Security Standard. Several states within the U.S. have enacted or proposed data privacy and security laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act. Additionally, we are, or may become, subject to various U.S. federal and state consumer protection laws that require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data.

The CCPA, EU GDPR, and UK GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing that may increase our compliance obligations and exposure for any noncompliance. For example, the CCPA imposes obligations on covered businesses to provide specific disclosures related to a business's collection, use, and disclosure of personal data and to respond to certain requests from California residents related to their personal data (for example, requests to know of the business's personal data processing activities, to delete the individual's personal data, and to opt out of certain personal data disclosures). Also, the CCPA provides for civil penalties and a private right of action for data breaches which may include an award of statutory damages. In addition, the California Privacy Rights Act of 2020 ("CPRA"), effective January 1, 2023, expanded the CCPA by, among other things, giving California residents the ability to limit use of certain sensitive personal data, establishing restrictions on personal data retention, expanding the types of data breaches that are subject to the CCPA's private right of action, and establishing a new California Privacy Protection Agency to implement and enforce the new law.

Foreign data privacy and security laws (including but not limited to the EU GDPR and UK GDPR) impose significant and complex compliance obligations on entities that are subject to those laws. As one example, the EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances.

See the section titled "Risk Factors" for additional information about the laws and regulations to which we may become subject and about the risks to our business associated with such laws and regulations.

Pharmaceutical Coverage, Pricing and Reimbursement

In both domestic and foreign markets, our sales of any approved products will depend in part on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Third-party payors are increasingly focused on containing healthcare costs by challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the coverage and reimbursement status of newly approved healthcare product candidates.

Because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming, costly and sometimes unpredictable process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval would be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. We cannot be certain that our products and our product candidates will be considered cost-effective. If we are unable to obtain coverage of, and adequate reimbursement and payment levels for, our product candidates from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition and future success.

In addition, in many foreign countries, particularly the countries of the European Union and China, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. We may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with our own products.

Healthcare Reform and Pricing Pressure

Healthcare reform and cost-containment measures in the United States and abroad could affect the coverage, pricing, reimbursement and commercial potential of any product candidates for which we obtain marketing approval. In the U.S., federal and state lawmakers, regulators and payors continue to focus on drug pricing, reimbursement, transparency and patient access, and may adopt or expand measures that reduce reimbursement, impose manufacturer discounts or rebates, or otherwise limit the prices we may charge for our products.

The U.S. healthcare environment has already been affected by major legislation, including the Affordable Care Act and the Inflation Reduction Act of 2022. Among other things, the Inflation Reduction Act established Medicare drug price negotiation for selected products, inflation-based rebate obligations, and a redesign of the Medicare Part D benefit, including a manufacturer discount program that became effective January 1, 2025. In addition, the first negotiated Medicare prices became effective on January 1, 2026. These and other current or future healthcare reform measures may reduce the commercial opportunity for our products, increase our compliance burdens, or otherwise adversely affect our business, financial condition and results of operations.

Foreign Regulation Outside of China

In order to market any product outside of the U.S., we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, manufacturing, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the U.S. apply similarly in the context of other countries we are seeking approval in, including Europe and China, the approval process varies between countries and jurisdictions and can involve different amounts of product testing and additional administrative review periods. For example, in Europe and in China, a sponsor must submit a clinical trial application, much like an IND prior to the commencement of human clinical trials. A clinical trial application must be submitted to each national health authority and an independent ethics committee.

For other countries outside of the European Union, such as China and the countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory approval process in other countries.

Regulatory Exclusivity for Approved Products

U.S. Patent Term Restoration

Depending upon the timing, duration, and specifics of the FDA approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. The patent term restoration period is generally one-half the time between the effective date of an initial IND and the submission date of an NDA or BLA, plus the time between the submission date of the NDA or BLA and the approval of that product candidate application, to the extent such period occurs after grant of the patent. Patent term restoration cannot, however, extend the remaining term of a patent beyond a total of 14 years from the product's approval date. In addition, only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves applications for any patent term extension or restoration. In the future, we expect to apply for restoration of patent term for patents relating to each of our product candidates in order to add patent life beyond the current expiration date of such patents, depending on the length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

Market exclusivity provisions under the U.S. federal Food, Drug & Cosmetic Act can also delay the submission or the approval of certain applications of companies seeking to reference another company's NDA or BLA. The Hatch-Waxman Act provides a 5-year period of exclusivity to any approved NDA for a product containing a New Chemical Entity ("NCE") never previously approved by FDA either alone or in combination with another active moiety. No application or abbreviated NDA directed to the same NCE may be submitted during the 5-year exclusivity period, except that such applications may be submitted after four years if they contain a certification of patent invalidity or non-infringement of the patents listed with the FDA by the innovator NDA.

Biologic Price Competition and Innovation Act

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") established an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated regulatory approval pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on similarity to an existing branded product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement with respect to the patents listed with the FDA by the innovator BLA holder.

Orphan Drug Act

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the U.S., or if it affects more than 200,000 individuals in the U.S. there is no reasonable expectation that the cost of developing and making a drug product available in the U.S. for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. The designation of such drugs also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or biological product as defined by the FDA or if our drug candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity in any indication.

Products receiving orphan designation in Europe can receive ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation; for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; the initial applicant consents to a second orphan medicinal product application; or the initial applicant cannot supply enough orphan medicinal product. An orphan product can also obtain an additional two years of market exclusivity in Europe for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

Foreign Country Data Exclusivity

Europe also provides opportunities for additional market exclusivity. For example, in Europe, upon receiving marketing authorization, a NCE or new biologic generally receives eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in Europe from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity.

INTELLECTUAL PROPERTY

We own or license numerous patents in the U.S. and foreign countries primarily covering our products. We have also developed and are developing brand names and trademarks for our products. We consider the overall protection of our patents, trademarks, licenses, and other intellectual property rights to be of material value and act to protect these rights from infringement. Our success depends in part upon our ability to obtain and maintain patent and other intellectual property protection for our product candidates including compositions-of-matter, dosages, and formulations, manufacturing methods, and novel applications, uses and technological innovations related to our product candidates and core technologies. We also rely on trade secrets, know-how and continuing technological innovation to further develop and maintain our competitive position.

Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technologies, inventions and any improvements that we consider important to the development and implementation of our business and strategy. Our ability to maintain and solidify our proprietary position for our products and technologies will depend, in part, on our success in obtaining and enforcing valid patent claims. Additionally, we may benefit from a variety of regulatory frameworks in the U.S., Europe, China, and other territories that provide periods of non-patent-based exclusivity for qualifying drug products. Refer to *"Government Regulation — Regulatory Exclusivity for Approved Products."*

We cannot ensure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications that may be filed by us in the future, nor can we ensure that any of our existing or subsequently granted patents will be useful in protecting our drug candidates, technological innovations, and processes. Additionally, any existing or subsequently granted patents may be challenged, invalidated, circumvented or infringed. We cannot guarantee that our intellectual property rights or proprietary position will be sufficient to permit us to take advantage of current market trends or otherwise to provide or protect competitive advantages. Furthermore, our competitors may be able to independently develop and commercialize similar products, or may be able to duplicate our technologies, business model, or strategy, without infringing our patents or otherwise using our intellectual property.

The protection afforded by any particular patent depends upon many factors, including the type of patent, scope of coverage encompassed by the granted claims, availability of extensions of patent term, availability of legal remedies in the particular territory in which the patent is granted, and validity and enforceability of the patent. Changes in either patent laws or in the interpretation of patent laws in the U.S. and other countries could diminish our ability to protect our inventions and to enforce our intellectual property rights. Accordingly, we cannot predict with certainty the enforceability of any granted patent claims or of any claims that may be granted from our patent applications.

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Our ability to maintain and solidify our proprietary position for our products and core technologies will depend on our success in obtaining effective claims and enforcing those claims once granted. We have been in the past and are currently involved in various legal proceedings with respect to our patents and patent applications and may be involved in such proceedings in the future. Additionally, we may claim that a third party infringes our intellectual property, or a third party may claim that we infringe its intellectual property. Such legal proceedings may be associated with significant expenses, damages, attorneys' fees, costs of proceedings, and experts' fees, and management and employees may be required to spend significant time in connection with these actions.

Because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that any patent related to our product candidates may expire before any of our product candidates can be commercialized, or may remain in force for only a short period of time following commercialization, thereby reducing the advantage afforded by any such patent.

The patent positions for our most advanced programs are summarized below.

Roxadustat Patent Portfolio

While the composition-of-matter patents covering roxadustat expired in 2024 (except in the U.S., where they expire in 2025), the roxadustat patent portfolio includes additional patents providing protection for roxadustat, including protection for the commercial crystalline form, pharmaceutical compositions, and key intermediates in roxadustat synthesis. Subject to the additional details outlined below for particular territories, and exclusive of any patent term extension, U.S. and foreign patents relating to crystalline forms of roxadustat and key intermediates in roxadustat synthesis are due to expire in 2033, and U.S. and foreign patents relating to photostable formulations of roxadustat are due to expire in 2034.

Supplemental Protection Certificates (SPCs) are pending or have been granted in European Union member states, where roxadustat has been granted marketing approval, on our European Patent No. 3470397 (the "`397 Patent"), which claims formulations comprising the commercial crystalline form of roxadustat, thereby extending patent protection to 2036. The `397 Patent was upheld in opposition and at the subsequent appeal. Patent term extensions (PTEs) have also been granted for several roxadustat-related patents in Japan, where roxadustat has been granted marketing approval, including on composition-of-matter and crystal form patents extending patent protection to 2029 and 2035, respectively.

FG-3246 Patent Portfolio

Our FG-3246 patent portfolio includes U.S. and foreign patents and pending patent applications providing, upon grant, composition-of-mater protection for FG-3246 that are due to expire in 2035 exclusive of any patent term extension. In addition, U.S. patents, and US and foreign pending patent applications directed to pharmaceutical compositions and dosing of FG-3246 provide protection through an expiry date of 2041 exclusive of any patent term adjustment or extension that may be available in a particular country.

Trade Secrets and Know-How

In addition to patents, we rely upon proprietary trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality and other terms in agreements with our commercial partners, collaboration partners, consultants, and employees. Such agreements are designed to protect our proprietary information and may also grant us ownership of technologies that are developed through a relationship with a third party, such as through invention assignment provisions. Agreements may expire and we could lose the benefit of confidentiality, or our agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

To the extent that our commercial partners, collaboration partners, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

In-Licenses

Fortis Therapeutics / UCSF

Effective May 5, 2023, we entered into an Evaluation Agreement with Fortis Therapeutics, Inc., under which the Company was granted an exclusive license to certain Fortis intellectual property (IP) and additional IP in-licensed by Fortis from UCSF for the purpose of performing evaluation activities associated with use of FG-3246/FOR46 particularly for treatment of mCRPC. The IP includes know-how, patents, and patent applications related to FG-3246 composition-of-matter and variants thereof, anti-CD46 antibodies and immunoconjugates made therefrom, and formulations, dosing regimens, and uses thereof. Composition-of-matter patents for FG-3246 are due to expire in 2035, and formulation and dosing regimen patents are due to expire in 2041, in each case exclusive of any patent term extension or adjustment that may be available.

Under the agreement, we have first right to prepare, file, prosecute, and maintain patents and patent applications in the Fortis IP at our own expense and using mutually agreed-upon counsel. We are also obligated to reimburse Fortis for all payments made by Fortis to UCSF for expenses incurred by UCSF in prosecution and maintenance of the in-licensed patent portfolio, and other payments made by Fortis to UCSF under their license agreement during the term of the Evaluation Agreement.

Unless terminated according to terms in the Evaluation Agreement, the term of the license is subject to an Option Agreement and Plan of Merger by and between the Company, Fortis Therapeutics, and Shareholder Representative Services LLC dated May 5, 2023. If we exercise the option to acquire Fortis, we will pay Fortis $80.0 million, and thereafter, Fortis would be eligible to receive from the Company up to $200.0 million in contingent payments associated with the achievement of various regulatory approvals. If we acquire Fortis, we would also be responsible to pay UCSF, an upstream licensor to Fortis, development milestone fees and a single digit royalty on net sales of therapeutic or diagnostic products arising from the collaboration. If the Company chooses not to acquire Fortis, its exclusive license to FG-3246 would expire.

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

HUMAN RESOURCES

We had 34 employees in the U.S. as of December 31, 2025. None of our U.S. employees are represented by a labor union. None of our employees have entered into a collective agreement with us.

We are highly committed to building a diverse, dedicated, and impassioned team to deliver innovative therapies to patients facing serious unmet medical needs. Our core values of excellence, respect for people, integrity, and empowerment are fundamental to how we attract, grow, engage, and retain our people.

In September 2025, we conducted a modified company-wide engagement survey to assess employee sentiment following our reduction in force. Overall, we had a 100% participation rate. Further, in an independent diversity, equity, and inclusion survey, positive employee sentiment about our progress in nurturing a culture of diversity, equity, belonging and inclusion increased to 96% in 2025 compared to 86% in 2024.

The biotechnology industry is an extremely competitive labor market and recruiting and retaining employees is critical to the continued success of our business. We focus on recruiting, retaining, and developing employees from a diverse range of backgrounds to conduct our research, development, commercialization, and administrative activities.

We consistently review and evaluate our people practices to ensure that we attract, develop and retain a diverse, engaged and talented workforce. Our offerings include competitive, innovative and equitable pay practices, comprehensive health and wellness benefits, retirement and life insurance offerings, and offer fully remote work arrangements. In addition to annual compliance training on harassment prevention, our Code of Conduct, Anti-Bribery and data privacy, our employees are offered tuition reimbursement eligibility.

Ensuring diversity in our workforce begins with role modeling and striving for diversity in senior management. On our Board of Directors, 1 of 5 members (20%) is female. Further, 1 of 5 members (20%) identifies as Asian ethnicity. Notably, our U.S. workforce is 45% female. Our U.S. employees that self-report ethnicity are 48% Asian, Hispanic or Black.

In 2023, we performed an environmental, social, and governance (“ESG”) assessment of our operations, finding that we accomplished most of our ESG goals, including adopting a policy to increase patient diversity in clinical trials. In 2024, we adopted a cybersecurity incidence response policy and committee charter, and approved a 2024 Equity Incentive Plan.

AVAILABLE INFORMATION

Our internet website address is www.kyntrabio.com. In addition to the information about us and our subsidiaries contained in this Annual Report, information about us can be found on our website. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated into, this Annual Report.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission. Additionally the Securities and Exchange Commission maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is www.sec.gov.

CORPORATE INFORMATION

Our mailing address is at 350 Bay Street, Suite 100, #6009, San Francisco, California 94133 and our telephone number is (415) 978-1200. Our website address is www.kyntrabio.com. The information contained on our website is not incorporated by reference herein.

"Kyntra Bio," the Kyntra Bio logo and other trademarks or service marks of Kyntra Bio, Inc. appearing in this Annual Report are the property of Kyntra Bio, Inc.. This Annual Report contains additional trade names, trademarks and service marks of others, which are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

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 Annual Report on Form 10-K for the year ended December 31, 2025 ("Annual Report"), including our 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.

Risks Related to the Development and Commercialization of Our Product Candidates

We are substantially dependent on the success of our lead products roxadustat and FG-3246 (in conjunction with our PET (as defined below) imaging agent FG-3180).

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

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

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

The development, manufacturing, marketing, and selling of our products and product candidates are and will continue to be subject to extensive and rigorous review and regulation by numerous government authorities in the United States of America ("U.S.") and in other countries where we intend to develop and, if approved, market any product candidates. Before obtaining regulatory approval for the commercial sale of any product candidate, we must demonstrate through extensive preclinical trials and clinical trials that the product candidate is effective and has an acceptable safety profile for use in each indication for which approval is sought.

The drug development and approval processes are expensive and require substantial resources and time, and in general, very few product candidates that enter development ultimately receive regulatory approval. In addition, our collaboration partner for roxadustat has final control over development decisions in their respective territories and they may make decisions with respect to development or regulatory authorities that delay or limit the potential approval of roxadustat or increase the cost of development or commercialization. Accordingly, we may be unable to successfully develop or commercialize any of our other product candidates in one or more indications and jurisdictions.

Moreover, for any clinical trial to support a New Drug Application / Biologics License Application submission for approval, the U.S. Food and Drug Administration ("FDA") and foreign regulatory authorities require compliance with regulations and standards (including good clinical practices ("GCP") requirements for designing, conducting, monitoring, recording, analyzing, and reporting the results of clinical trials) to ensure that (1) the data and results from trials are credible and accurate; and (2) that the rights, integrity and confidentiality of trial participants are protected. Although we rely on third parties to conduct our clinical trials, we as the sponsor remain responsible for ensuring that each of these clinical trials is conducted in accordance with its general investigational plan and protocol under legal and regulatory requirements, including GCP.

Regulatory authorities may take actions or impose requirements that delay, limit or deny approval of our product candidates for many reasons, including, among others:

- our failure to adequately demonstrate to the satisfaction of regulatory authorities or an independent advisory committee that our product candidate is effective and has an acceptable safety profile in a particular indication, or that such product candidate's clinical and other benefits outweigh its safety risks;
- failure of clinical trials to meet the level of statistical significance required for approval;
- the determination by regulatory authorities that additional information (including additional preclinical or clinical data or trials) is necessary to demonstrate the safety and efficacy of a product candidate;
- disagreement over the design or implementation of our clinical trials;
- our product candidates exhibiting an unacceptable safety signal at any stage of development;
- failure either by us or the clinical research organizations ("CROs") or investigators that conduct clinical trials on our behalf, to comply with regulations or GCPs, clinical trial protocols, or contractual agreements, which may adversely impact our clinical trials, as well as, investigator-sponsored trials;
- disagreement over whether to accept results from clinical trial sites in a country where the standard of care is potentially different from that in the U.S.;
- failure either by us or third-party contractors manufacturing our product candidates to maintain current good manufacturing practices ("cGMP"), successfully pass inspection, or meet other applicable manufacturing regulatory requirements;
- requirements by regulatory authorities to exclude the use of patient data from unreliable clinical trials, or disagreement with our interpretation of the data from our preclinical trials and clinical trials;
- failure or delay in approval of one of our clinical trial investigational new drug applications or protocol or protocol amendments (in particular, due to a government shutdown or other factor outside of our control);
- failure by collaboration partners or other third parties such as clinical investigators to perform or complete their clinical programs in a timely manner, or at all; or
- failure of data from investigator-sponsored clinical trials to meet GCP standards.

Any of these factors, many of which are beyond our control, could delay or jeopardize our or our collaboration partners' abilities to obtain regulatory approval for our product candidates in one or more indications.

Even if we believe our clinical trials, as well as, investigator-sponsored trials are successful, regulatory authorities may not agree that our completed clinical trials provide adequate data on safety or efficacy. Approval by one regulatory authority does not ensure approval by any other regulatory authority.

Even if we do obtain regulatory approval, our product candidates may be approved for fewer or more limited indications than we request, approval may be contingent on the performance of costly post-marketing clinical trials, or approval may require labeling that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. In addition, if our product candidates produce undesirable side effects or safety issues, the FDA may require the establishment of Risk Evaluation and Mitigation Strategy (or other regulatory authorities may require the establishment of a similar strategy), that may restrict distribution of our approved products, if any, and impose burdensome implementation requirements on us.

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

Preclinical, Phase 1, and Phase 2 clinical trial results may not be indicative of the results that may be obtained in larger clinical trials.

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical and early clinical trials, which are often highly variable and use small sample sizes, may not be predictive of similar results in humans or in larger, controlled clinical trials, and successful results from clinical trials in one indication may not be replicated in other indications.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we may face similar setbacks.

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

We do not know whether our ongoing or planned clinical trials will need to be redesigned based on interim results or if we will be able to achieve sufficient patient enrollment or complete planned clinical trials on schedule.

Clinical trials can be delayed, suspended, or terminated by us, by the relevant institutional review boards at the sites at which such trials are being conducted, or by the FDA or other regulatory authorities, for a variety of reasons or factors, including:

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

In particular, identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials, as well as, investigator-sponsored trials depends on the rate at which we can recruit and enroll patients in testing our product candidates. Patients may be unwilling to participate in clinical trials of our product candidates for a variety of reasons, some of which may be beyond our control, including:

- severity of the disease under investigation;
- availability of alternative treatments;
- size and nature of the patient population;
- eligibility criteria for and design of the study in question;
- perceived risks and benefits of the product candidate under study;
- ongoing clinical trials of competitive agents;
- physicians' and patients' perceptions of the potential advantages of our product candidates being studied in relation to available therapies or other products under development;
- our CRO's and our trial sites' efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients and collect patient data adequately during and after treatment.

Any delays in completing our clinical trials will increase the costs of the trial, delay the product candidate development and approval process and jeopardize our ability to commence marketing and generate revenues. Any of these occurrences may materially and adversely harm our business, operations, and prospects.

Our product candidates may cause or have attributed to them undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.

Undesirable side effects caused by our product candidates or that may be identified as related to our product candidates by physician investigators conducting our clinical trials, as well as, investigator-sponsored trials, or even competing products in development that utilize a similar mechanism of action or act through a similar biological disease pathway could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. If we determine that there is a likely causal relationship between a serious adverse event and our product candidate, and such safety event is material or significant enough, it may result in:

- our clinical trial development plan becoming longer and more expensive;
- terminating our clinical trials, as well as, investigator-sponsored trials for the product candidates or specific indications affected;
- regulatory authorities increasing the data and information required to approve our product candidates and imposing other requirements; and
- our collaboration partners terminating our existing agreements.

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

Clinical trials of our product candidates may not uncover all possible adverse effects that patients may experience.

Clinical trials are conducted in representative samples of the potential patient population, which may have significant variability. Our drug candidates are being studied in patient populations that are at high risk of death and adverse events, and even if unrelated to our drug candidate, adverse safety findings in these trials may limit its further development or commercial potential. Clinical trials are by design based on a limited number of subjects and of limited duration for exposure to the product used to determine whether, on a potentially statistically significant basis, the planned safety and efficacy of any product candidate can be achieved. As with the results of any statistical sampling, we cannot be sure that all side effects of our product candidates may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to the product candidate for a longer duration, that a more complete safety profile is identified. Further, even larger clinical trials may not identify rare serious adverse effects or the duration of such studies may not be sufficient to identify when those events may occur. Patients treated with our products, if approved, may experience adverse reactions and it is possible that the FDA or other regulatory authorities may ask for additional safety data as a condition of, or in connection with, our efforts to obtain approval of our product candidates. If safety problems occur or are identified after our product candidates reach the market, we may, or regulatory authorities may require us to amend the labeling of our products, recall our products or even withdraw approval for our products.

If our manufacturers or we cannot properly manufacture the appropriate volume of product, we may experience delays in development, regulatory approval, launch or successful commercialization.

Completion of our clinical trials, as well as, investigator-sponsored trials, and commercialization of our products require access to, or development of, facilities to manufacture and manage our product candidates at sufficient yields, quality and scale. We may need to enter into additional manufacturing agreements and may be unable to do so on satisfactory terms or in a timely manner. In addition, we may experience delays or technical problems associated with technology transfer of manufacturing processes to any new suppliers.

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

There is a general risk of delayed drug supply due to delays experienced by any third-party provider in the supply chain, including raw material and components suppliers, export and customs locations, and shipping companies. Any delay or interruption in the supply of our product candidates or products could have a material adverse effect on our business and operations.

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

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

Our commercial drug product and the product we use for clinical trials must be produced under applicable cGMP regulations. Failure to comply with these regulations by us or our third-party manufacturers may require us to recall commercial product or repeat clinical trials, which would impact sales revenue and/or delay the regulatory approval process.

We or our partners may add or change manufacturers, change our manufacturing processes, or change packaging specifications to accommodate changes in regulations, manufacturing equipment or to account for different processes at new or second source suppliers. Manufacturing changes made to one of our drugs or drug candidates, include, but are not limited to, demonstration of comparability to regulatory approved/ in approval products and processes, additional clinical trials, delays in development or commercialization, earlier expiration dates, shorter shelf life, or specification failures, and those changes may materially impact our operations and potential profitability. This includes the scenario that the change may be unsuccessful and cause delays or other negative impact.

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

- costs and challenges associated with scale-up and attaining sufficient manufacturing yields;
- contracting with additional suppliers and validation/qualification of additional facilities to meet growing demand;
- supply chain issues, including coordination of multiple contractors in our supply chain and securing necessary licenses (such as export licenses);

- the timely availability and shelf-life requirements of raw materials and supplies;
- limited stability and product shelf life;
- equipment maintenance issues or failure;
- quality control and quality assurance issues;
- shortages of qualified personnel and capital required to manufacture large quantities of product;
- compliance with regulatory requirements that vary in each country where a product might be sold;
- capacity or forecasting limitations and scheduling availability in contracted facilities;
- natural disasters, such as pandemics, floods, storms, earthquakes, tsunamis, and droughts, or accidents such as fire, that affect facilities, possibly limit or postpone production, and increase costs; and
- failure to obtain license to proprietary starting materials.

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

Regulatory authorities will do their own benefit risk analysis and may reach a different conclusion than we or our partners have, and these regulatory authorities may base their approval decision on different analyses, data, and statistical methods than ours.

Even if we believe we have achieved positive clinical results, regulatory authorities conduct their own benefit-risk analysis and may reach different conclusions. Regulatory authorities may use, among other things, different statistical methods, different endpoints or definitions thereof, and different patient populations or sub-populations. Furthermore, while we may seek regulatory advice or agreement in key commercial markets prior to and after application for marketing authorization, regulatory authorities may change their approvability criteria based on the data, their internal analyses and external factors, including discussions with expert advisors. Regulatory authorities may approve one of our product candidates for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, even if we are able to provide positive data with respect to certain analyses, regulatory authorities may not include such claims on any approved labeling. The failure to obtain regulatory approval, or any label, population or other approval limitations in any jurisdiction, may significantly limit or delay our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenue.

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

The development and commercialization of new pharmaceutical products is highly competitive. Our future success depends on our ability and/or the ability of our collaboration partners to achieve and maintain a competitive advantage with respect to the development and commercialization of our product candidates. Our objective is to develop and commercialize new products with superior efficacy, convenience, tolerability, and safety.

We expect that in many cases, the products that we commercialize will compete with existing marketed products of companies that have large, established commercial organizations.

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

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

Moreover, many of our competitors have significantly greater resources than we do. Large pharmaceutical companies have extensive experience, greater scale, and efficiency, in clinical testing, obtaining regulatory approvals, recruiting patients, manufacturing pharmaceutical products, and commercialization. If our collaboration partners and Kyntra Bio are not able to compete effectively against existing and potential competitors, our business and financial condition may be materially and adversely affected.

Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors, and others in the medical community. Demonstrating safety and efficacy of our product candidates and obtaining regulatory approvals will not guarantee future revenue. The degree of market acceptance of any of our approved product candidates will depend on several factors, including:

- the efficacy of the product candidate as demonstrated in clinical trials;
- the safety profile and perceptions of safety of our product candidates relative to competitive products;
- acceptance of the product candidate as a safe and effective treatment by healthcare providers and patients;
- the clinical indications for which the product candidate is approved;
- the potential and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments;
- the inclusion or exclusion of the product candidate from treatment guidelines established by various physician groups and the viewpoints of influential physicians with respect to the product candidate;
- the cost of the product candidate relative to alternative treatments;
- adequate pricing and reimbursement by third parties and government authorities as described below;
- the relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- any unfavorable publicity relating to the product candidate.

In addition, see the risk factor titled "*Our product candidates may cause or have attributed to them undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential*" above. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

No or limited reimbursement or insurance coverage of our approved products, by third-party payors may render our products less attractive to patients and healthcare providers.

Market acceptance and sales of any approved products will depend significantly on reimbursement or coverage of our products by government or third-party payors and may be affected by existing and future healthcare reform measures or prices of related products for which the government or third-party reimbursement applies. Coverage and reimbursement by the government or a third-party payor may depend upon a number of factors, including the payor's determination that use of a product is:

- a covered benefit under applicable health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor, which we may not be able to provide. Furthermore, the reimbursement policies of governments and third-party payors may significantly change in a manner that renders our clinical data insufficient for adequate reimbursement or otherwise limits the successful marketing of our products. Even if we obtain coverage for our product candidates, the pricing may be subject to re-negotiations or third-party payors may not establish adequate reimbursement amounts, which may reduce the demand for, or the price of, our products.

Reference pricing is used by various Europe member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, our partner or we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available products in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unacceptable levels, our partner or we may elect not to commercialize our products in such countries, and our business and financial condition could be adversely affected.

Risks Related to Our Reliance on Third Parties

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

We have entered into an Evaluation Agreement with Fortis Therapeutics, Inc. ("Fortis") under which we rely, in part, on Fortis and its development partners, including University of California, San Francisco, for the continued development of FG-3246 (in conjunction with our PET biomarker). While we control development of FG-3246 for the evaluation period, we will be doing so under our investigational new drug application that references Fortis's investigational new drug application. If Fortis were unwilling to cooperate with development efforts, our ability to develop FG-3246 (in conjunction with our PET biomarker) could be delayed.

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

Our current agreements with Astellas provide them with the right to terminate their agreements for convenience or for breach, either of which could have an adverse effect on our business and operations. Moreover, if Astellas, or any successor entity, were to determine that their collaborations with us are no longer a strategic priority, or if either of them or a successor were to reduce their level of commitment to their collaborations with us, our ability to profit from the commercialization of roxadustat could suffer.

For instance, the collaboration agreement between the Company and AstraZeneca, effective as of July 2013, for the development and commercialization of roxadustat for the treatment of anemia in the U.S. and all other countries in the world, other than China, not previously licensed to Astellas (the "AstraZeneca U.S./RoW Agreement") was terminated on February 25, 2024 as amended and restated on August 29, 2025 (except for South Korea). Our collaboration agreement with AstraZeneca for the development and commercialization of roxadustat for the treatment of anemia in China (the "AstraZeneca China Agreement") culminated as a result of the completion of the sale of FibroGen International and its subsidiaries pursuant to the share purchase agreement entered into by the Company and AstraZeneca Treasury Limited on February 20, 2025, as amended on August 29, 2025 (the "Share Purchase Agreement"). This eliminates any additional potential milestones or other payments AstraZeneca could have made under the AstraZeneca U.S./RoW Agreement or the AstraZeneca China Agreement. And while we are now investigating new licensing opportunities for roxadustat, there can be no assurance that we will find such a partner or be able to agree to a license on reasonable terms.

In addition, if our collaboration partners are unsuccessful in their commercialization efforts (particularly in Europe), our results will be negatively affected.

If we do not establish and maintain strategic collaborations related to our product candidates, we will bear all of the risk and costs related to the development and commercialization of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise at significant cost. This in turn may negatively affect the development of our other product candidates as we direct resources to our most advanced product candidates.

We may conduct proprietary research programs in specific disease areas that are not covered by our collaboration agreements. Our pursuit of such opportunities could, however, result in conflicts with our collaboration partners in the event that any of our collaboration partners take the position that our internal activities overlap with those areas that are exclusive to our collaboration agreements. Moreover, disagreements with our collaboration partners could develop over rights to our intellectual property, including the enforcement of those rights. In addition, our collaboration agreements may have provisions that give rise to disputes regarding the rights and obligations of the parties. Any conflict with our collaboration partners could lead to the termination of our collaboration agreements, delay collaborative activities, reduce our ability to renew agreements or obtain future collaboration agreements, or result in litigation or arbitration and would negatively impact our relationship with existing collaboration partners, as well as potentially impacting our commercial results.

Certain collaboration partners could also become our competitors in the future. If our collaboration partners develop competing products, fail to obtain necessary regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of our product candidates, the development and commercialization of our product candidates and products could be delayed.

If our preclinical and clinical trial contractors do not properly perform their agreed upon obligations, we may not be able to obtain or may be delayed in receiving regulatory approvals for our product candidates.

We rely heavily on university, hospital, and other institutions and third parties, including the principal investigators and their staff, to carry out our clinical trials, as well as, investigator-sponsored trials in accordance with GCP, clinical protocols, and designs. We also rely on a number of third-party CROs or other third parties to assist in undertaking, managing, monitoring, imaging and testing, and otherwise executing our ongoing clinical trials. We expect to continue to rely on CROs, clinical data management organizations, medical institutions, clinical investigators, and other third parties to conduct our development efforts in the future. We compete with many other companies for the resources of these third parties, and other companies may have significantly more extensive agreements and relationships with such third-party providers, and such third-party providers may prioritize these relationships over ours. The third parties on whom we rely may terminate their engagements with us at any time, which may cause delay in the development and commercialization of our product candidates. If any such third party terminates its engagement with us or fails to perform as agreed, we may be required to enter into alternative arrangements, which would result in significant cost and delay to our product development program. Moreover, our agreements with such third parties generally do not provide assurances regarding employee turnover and availability, which may cause interruptions in the research on our product candidates by such third parties.

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

To ensure the quality and accuracy of our data remains uncompromised and reliable, our third-party service providers and clinical investigators or clinical partners must comply with applicable GCP requirements, regulations, protocols, and agreements. Failures to do so by such third-party partners, or needing to replace such third-party service providers, may delay, suspend or terminate development of our product candidates, result in exclusion of patient data from approval applications, or require additional clinical trials before approval of marketing applications. Such events may ultimately prevent regulatory approval for our product candidates on a timely basis, at a reasonable cost, or at all.

We currently rely, and expect to continue to rely, on third parties to conduct many aspects of our product manufacturing and distribution, and these third parties may terminate these agreements or not perform satisfactorily.

We do not have our own operating manufacturing facilities at this time. We currently rely, and expect to continue to rely, on third parties to scale-up, manufacture and supply roxadustat and our other product candidates for drug product in Europe and other countries, and on our partner Astellas for drug product in Japan. We rely on third parties for distribution, including our collaboration partners and their vendors. Risks arising from our reliance on third-party manufacturers include:

- reduced control and additional burdens of oversight as a result of using third-party manufacturers and distributors for all aspects of manufacturing activities, including regulatory compliance and quality control and quality assurance;
- termination of manufacturing agreements, termination fees associated with such termination, or nonrenewal of manufacturing agreements with third parties may negatively impact our planned development and commercialization activities;

- significant financial commitments we may be required to make with third-party manufacturers for early-stage clinical or pre-clinical programs that may fail to produce scientific results that would justify further development (without the ability to mitigate the manufacturing investments);
- the possible misappropriation of our proprietary technology, including our trade secrets and know-how;
- potential regulatory actions taken against one of our contract manufacturers for failure to adhere to GMP;
- disruptions to the operations of our third-party manufacturers, distributors or suppliers unrelated to our product, including the merger, acquisition, or bankruptcy of a manufacturer or supplier or a catastrophic event, affecting our manufacturers, distributors or suppliers; and
- inability for Kyntra Bio to meet timing and volume obligations to Astellas or other partners due to insufficient resources.

Any of these events could lead to development delays or failure to obtain regulatory approval or affect our ability to successfully commercialize our product candidates. Some of these events could be the basis for action by the FDA or another regulatory authority, including injunction, recall, seizure or total or partial suspension of production.

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

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

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

Our product candidates and any products that we may develop may compete with other product candidates and products for access and prioritization to manufacture. Certain third-party manufacturers may be contractually prohibited from manufacturing our product due to non-compete agreements with our competitors or a commitment to grant another party priority relative to our products. There are a limited number of third-party manufacturers that operate under cGMP and that might be capable of manufacturing to meet our requirements. Due to the limited number of third-party manufacturers with the contractual freedom, expertise, required regulatory approvals and facilities to manufacture our products on a commercial scale, identifying and qualifying a replacement third-party manufacturer would be expensive and time-consuming and may cause delay or interruptions in the production of our product candidates or products, which in turn may delay, prevent or impair our development and commercialization efforts. We also carry the risk that we may need to pay termination fees to other manufacturers in the event that we have to manufacture lower volumes or not at all depending on the results of our clinical trials. We may be subject to payments to other third-party manufacturers to cover portions or all of the committed manufacturing campaigns even if we do not need the material for clinical or commercial usage. In addition, third-party manufacturers tend to change their upfront fees or postponement/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 candidates. We do not have direct control over the acquisition of those materials by our contract manufacturers.

The logistics of our supply chain, which include shipment of materials and intermediates from countries such as China and India add additional time and risk (including risk of loss) to the manufacture of our product candidates. While we have in the past maintained sufficient inventory of materials, active pharmaceutical ingredient ("API"), and drug product to meet our and our collaboration partners' needs to date, the lead-time and regulatory approvals required to source from and into countries outside of the U.S. increase the risk of delay and potential shortages of supply.

Risks Related to Our Intellectual Property

If our efforts to protect our proprietary and exclusively licensed technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection, and contractual arrangements to protect the intellectual property related to our technologies. We will only be able to protect our products and proprietary information and technology to the extent that our patents, trade secrets, contractual position, and governmental regulations and laws allow us to do so. Any unauthorized use or disclosure of our proprietary information or technology could compromise our competitive position.

We have in the past and may in the future be involved in initiating legal or administrative proceedings involving the product candidates and intellectual property of our competitors. Moreover, we are, have been, and may in the future be involved in legal proceedings initiated by third parties involving our intellectual property. These proceedings can result in significant costs and commitment of management time and attention, and there can be no assurance that our efforts would be successful in preventing or limiting the ability of our competitors to market competing products or defending our intellectual property.

Composition-of-matter patents are generally considered the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection not limited to any one method of use. Method-of-use patents protect the use of a product for the specified method(s), and do not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. We rely on a combination of these and other types of patents to protect our product candidates, and there can be no assurance that our intellectual property will create and sustain the competitive position of our product candidates.

Biotechnology and pharmaceutical patents involve highly complex legal and scientific questions and can be uncertain. Any patent applications we own or license may fail to result in granted or issued patents. Even if patents do successfully issue from our applications, third parties may challenge their validity or enforceability, which may result in such patents being narrowed, invalidated, or held unenforceable. Even if our patents and patent applications are not challenged by third parties, those patents and patent applications may not prevent others from designing around our claims and may not otherwise adequately protect our product candidates. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, generic manufacturers and competitors with significantly greater resources could threaten our ability to commercialize our product candidates.

Discoveries are generally published in the scientific literature well after their actual development, and patent applications in the U.S. and other countries are typically not published until 18 months after their filing, and in some cases are never published. Therefore, we cannot be certain that our licensors or we were the first to make the inventions claimed in our owned and licensed patents or patent applications, or that our licensors or we were the first to file for patent protection covering such inventions. Subject to meeting other requirements for patentability, for U.S. patent applications filed prior to March 16, 2013, the first to invent the claimed invention is entitled to receive patent protection for that invention while, outside the U.S., the first to file a patent application encompassing the invention is entitled to patent protection for the invention. The U.S. moved to a "first to file" system under the Leahy-Smith America Invents Act, effective March 16, 2013. This system also includes procedures for challenging issued patents and pending patent applications, which creates additional uncertainty. We have, are, and may again become involved in, *inter partes* review, opposition, invalidation, or interference proceedings challenging our patents and patent applications, or the patents and patent applications of others, and the outcome of any such proceedings are highly uncertain. An unfavorable outcome in any such proceedings could reduce the scope of or invalidate our patent rights, allow third parties to commercialize our technology and compete directly with us, or result in our inability to manufacture, develop or commercialize our product candidates without infringing the patent rights of others.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how, information, or technology that is not covered by our patents. Although our agreements require employees to acknowledge ownership by us of inventions conceived as a result of employment from the point of conception and, to the extent necessary, perfect such ownership by assignment, and we require employees, consultants, advisors and third parties who have access to our trade secrets, proprietary know-how and other confidential information and technology to enter into appropriate confidentiality agreements, we cannot be certain that our trade secrets, proprietary know-how and other confidential information and technology will not be subject to unauthorized disclosure, use, or misappropriation or that our competitors will not otherwise gain access to or independently develop substantially equivalent trade secrets, proprietary know-how and other information and technology. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property globally. If we cannot prevent unauthorized disclosure of our intellectual property related to our product candidates and technology to third parties, we may not establish or maintain a competitive advantage in our market, which could materially and adversely affect our business and operations.

Intellectual property disputes may be costly, time consuming, and may negatively affect our competitive position.

Our commercial success may depend on our avoiding infringement of the patents and other proprietary rights of third parties as well as on enforcing our patents and other proprietary rights against third parties.

Our collaboration partners or we may be subject to patent infringement claims from third parties. We attempt to ensure that our product candidates do not infringe third-party patents and other proprietary rights. However, the patent landscape in competitive product areas is highly complex, and there may be patents of third parties of which we are unaware that may result in claims of infringement. Accordingly, there can be no assurance that our product candidates do not infringe proprietary rights of third parties, and parties making claims against us may seek and obtain injunctive or other equitable relief, which could potentially block further efforts to develop and commercialize our product candidates, including roxadustat or FG-3246 (in conjunction with our PET imaging agent FG-3180). Any litigation involving defense against claims of infringement, regardless of the merit of such claims, would involve substantial litigation expense and would be a substantial diversion of management time.

We may consider administrative proceedings and other means for challenging third-party patents and patent applications. An unfavorable outcome in any such challenge could require us to cease using the related technology and to attempt to license rights to it from the prevailing third party, which may not be available on commercially reasonable terms, if at all, in which case our business could be harmed.

Furthermore, there is a risk that any public announcements concerning the status or outcomes of intellectual property litigation or administrative proceedings may adversely affect the price of our stock. If securities analysts or our investors interpret such status or outcomes as negative or otherwise creating uncertainty, our common stock price may be adversely affected.

Our reliance on third parties and agreements with collaboration partners requires us to share our trade secrets, which increases the possibility that a competitor may discover them or that our trade secrets will be misappropriated or disclosed.

Our reliance on third-party contractors to develop and manufacture our product candidates is based upon agreements that limit the rights of the third parties to use or disclose our confidential information, including our trade secrets and know-how. Despite the contractual provisions, the need to share trade secrets and other confidential information increases the risk that such trade secrets and information are disclosed or used, even if unintentionally, in violation of these agreements. In the highly competitive markets in which our product candidates are expected to compete, protecting our trade secrets, including our strategies for addressing competing products and generic competition, is imperative, and any unauthorized use or disclosure could impair our competitive position and may have a material adverse effect on our business and operations.

In addition, certain collaboration partners are larger, more complex organizations than ours, and the risk of inadvertent disclosure of our proprietary information may be increased despite their internal procedures and contractual obligations that we have in place with them. Despite our efforts to protect our trade secrets and other confidential information, a competitor's discovery of such trade secrets and information could impair our competitive position and have an adverse impact on our business.

The cost of maintaining our patent protection is high and requires continuous review and diligence. We may not be able to effectively maintain our intellectual property position throughout the major markets of the world.

The U.S. Patent and Trademark Office and foreign patent authorities require maintenance fees and payments as well as continued compliance with a number of procedural and documentary requirements. Noncompliance may result in abandonment or lapse of the subject patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance may result in reduced royalty payments for lack of patent coverage in a particular jurisdiction from our collaboration partners or may result in competition, either of which could have a material adverse effect on our business.

We have made, and will continue to make, certain strategic decisions in balancing costs and the potential protection afforded by the patent laws of certain countries. As a result, we may not be able to prevent third parties from practicing our inventions in all countries throughout the world, or from selling or importing products made using our inventions in and into the U.S. or other countries. Third parties may use our technologies in territories in which we have not obtained patent protection to develop their own products and, further, may infringe our patents in territories which provide inadequate enforcement mechanisms, even if we have patent protection. Such third-party products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some foreign countries do not protect proprietary rights to the same extent as do the laws of the U.S., and we may encounter significant problems in securing and defending our intellectual property rights outside the U.S.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain countries. The legal systems of certain countries do not always favor the enforcement of patents, trade secrets, and other intellectual property rights, particularly those relating to pharmaceutical and biotechnology products, which could make it difficult for us to stop infringement of our patents, misappropriation of our trade secrets, or marketing of competing products in violation of our proprietary rights. As we have experienced in multiple jurisdictions, proceedings to enforce our intellectual property rights in foreign countries could result in substantial costs and divert our efforts and attention from other aspects of our business, and could put our patents in these territories at risk of being invalidated or interpreted narrowly, or our patent applications at risk of not being granted, and could provoke third parties to assert claims against us. We may not prevail in all legal or other proceedings that we may initiate and, if we were to prevail, the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Intellectual property rights do not address all potential threats to any competitive advantage we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds or independently develop similar or alternative technologies that are the same as or similar to our current or future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- Patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product.
- Our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates.

The existence of counterfeit pharmaceutical products in pharmaceutical markets may compromise our brand and reputation and have a material adverse effect on our business, operations and prospects.

Counterfeit products, including counterfeit pharmaceutical products, can be a significant problem. Counterfeit pharmaceuticals are products sold or used for research under the same or similar names, or similar mechanism of action or product class, but which are sold without proper licenses or approvals, and are often lower cost, lower quality, different potency, or have different ingredients or formulations, and have the potential to damage the reputation for quality and effectiveness of the genuine product. Such products may be used for indications or purposes that are not recommended or approved or for which there is no data or inadequate data with regard to safety or efficacy. Such products divert sales from genuine products. If counterfeit pharmaceuticals illegally sold or used for research result in adverse events or side effects to consumers, we may be associated with any negative publicity resulting from such incidents. Consumers may buy counterfeit pharmaceuticals that are in direct competition with our pharmaceuticals, which could have an adverse impact on our revenues, business and results of operations. In addition, counterfeit products could be used in non-clinical or clinical studies, or could otherwise produce undesirable side effects or adverse events that may be attributed to our products as well, which could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. The existence of and any increase in the sales and production of counterfeit pharmaceuticals, or the technological capabilities of counterfeiters, could negatively impact our revenues, brand reputation, business and results of operations.

Risks Related to Government Regulation

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

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that our product candidates we may discover, in-license or acquire and seek to develop in the future, will not obtain regulatory approval in any particular jurisdiction or indication.

Our current and future relationships with customers, physicians, and third-party payors are subject to healthcare fraud and abuse laws, false claims laws, transparency laws, and other regulations. If we are unable to comply with such laws, we could face substantial penalties.

Our current and future relationships with customers, physicians, and third-party payors are subject to health care laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing approval. If we obtain approval in the U.S. for any of our product candidates, the regulatory requirements applicable to our operations, in particular our sales and marketing efforts, will increase significantly with respect to our operations and the potential for administrative, civil and criminal enforcement by the federal government and the states and foreign governments will increase with respect to the conduct of our business. The laws that may affect our operations in the U.S. include: the federal Anti-Kickback Statute; federal civil and criminal false claims laws and civil monetary penalty laws; the Health Insurance Portability and Accountability Act, including as amended by Health Information Technology for Economic and Clinical Health Act, and its implementing regulations; the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act; and the Trade Agreement Act. In addition, foreign and state law equivalents of each of the above federal laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, imprisonment, disgorgement, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could materially adversely affect our ability to operate our business and our financial results.

Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. Such actions could have a substantial adverse effect on the price of our common shares and could have a material adverse effect on our operations.

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

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

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

In the U.S., there are State data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and the Federal Health Insurance Portability and Accountability Act, and other similar laws (e.g., wiretapping laws). For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (collectively, "CCPA") applies to personal data of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. In addition, the California Privacy Rights Act of 2020 expands the CCPA's requirements, including by adding a new right for individuals to correct their personal data and establishing a new regulatory agency to implement and enforce the law. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. These developments further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the U.S., laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR") and the United Kingdom's GDPR impose strict requirements for processing personal data, including health-related information. Specifically, under the EU GDPR, companies may face fines of up to 20 million Euros or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

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

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

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

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

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

We are subject to laws and regulations governing corruption, which require us to maintain costly compliance programs.

We must comply with a wide range of laws and regulations to prevent corruption, bribery, and other unethical business practices, including the U.S. Foreign Corrupt Practices Act ("FCPA"), anti-bribery and anti-corruption laws in other countries. The implementation and maintenance of compliance programs can be costly and such programs may be difficult to enforce, particularly where reliance on third parties is required.

Compliance with these anti-bribery laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. Certain payments to hospitals in connection with clinical studies, procurement of pharmaceuticals and other work have been deemed to be improper payments to government officials that have led to vigorous anti-bribery law enforcement actions and heavy fines in multiple jurisdictions, particularly in the U.S.

It is not always possible to identify and deter violations, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

In the pharmaceutical industry, corrupt practices include, among others, acceptance of kickbacks, bribes or other illegal gains or benefits by the hospitals and medical practitioners from pharmaceutical manufacturers, distributors or their third-party agents in connection with the prescription of certain pharmaceuticals. If our employees, partners, affiliates, subcontractors, distributors or third-party marketing firms violate these laws or otherwise engage in illegal practices with respect to their sales or marketing of our products or other activities involving our products, we could be required to pay damages or heavy fines by multiple jurisdictions where we operate, which could materially and adversely affect our financial condition and results of operations.

Considering our current presence and potential expansion in international jurisdictions, the creation, implementation, and maintenance of anti-corruption compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required. Violation of the FCPA and other anti-corruption laws can result in significant administrative and criminal penalties for us and our employees, including substantial fines, suspension or debarment from government contracting, prison sentences, or even the death penalty in extremely serious cases in certain countries. The U.S. Securities and Exchange Commission ("SEC") also may suspend or bar us from trading securities on U.S. exchanges for violation of the FCPA's accounting provisions. Even if we are not ultimately punished by government authorities, the costs of investigation and review, distraction of our personnel, legal defense costs, and harm to our reputation could be substantial and could limit our profitability or our ability to develop or commercialize our product candidates. In addition, if any of our competitors are not subject to the FCPA, they may engage in practices that will lead to their receipt of preferential treatment from foreign hospitals and enable them to secure business from foreign hospitals in ways that are unavailable to us.

If we fail to maintain an effective system of internal control, it may result in material misstatements in our financial statements.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for evaluating and reporting on the effectiveness of our system of internal control. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external reporting purposes in accordance with generally accepted accounting principles. As a public company, we are required to comply with the Sarbanes-Oxley Act and other rules that govern public companies.

If we experience material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting, the accuracy and timing of our financial reporting and subsequently our liquidity and our access to capital markets may be adversely affected, we may be unable to maintain compliance with applicable securities laws and the Nasdaq Stock Market LLC listing requirements, we may be subject to regulatory investigations and penalties, investors may lose confidence in our financial reporting, and our stock price may decline. In addition, if our internal control over financial reporting is deemed ineffective, efforts required to remediate an ineffective system of control over financial reporting may place a significant burden on management and add increased pressure on our financial resources and processes.

The impact of U.S. healthcare reform may adversely affect our business model.

In the U.S. and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could affect our operations. In particular, the commercial potential for our approved products could be affected by changes in healthcare spending and policy in the U.S. and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations, or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

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

Further, in the U.S. there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products if approved or additional pricing pressures, or otherwise adversely affect our business.

Roxadustat is considered a Class 2 substance on the 2019 World Anti-Doping Agency Prohibited List that could limit sales and increase security and distribution costs for our partners and us.

Roxadustat is considered a Class 2 substance on the World Anti-Doping Agency Prohibited List. There are enhanced security and distribution procedures we and our collaboration partners and third-party contractors will have to take to limit the risk of loss of product in the supply chain. As a result, our distribution, manufacturing and sales costs for roxadustat, as well as for our partners, will be increased which will reduce profitability. In addition, there is a risk of reduced sales due to patient access to this drug.

Our employees may engage in misconduct or improper activities, which could result in significant liability or harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failure to:

- comply with FDA regulations or similar regulations of comparable foreign regulatory authorities;
- provide accurate information to the FDA or comparable foreign regulatory authorities;
- comply with manufacturing standards we have established;
- comply with data privacy and security laws protecting personal data;
- comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities;
- comply with the FCPA and other anti-bribery laws;
- report financial information or data accurately; or
- disclose unauthorized activities to us.

Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions, delays in clinical trials, or serious harm to our reputation. We have adopted a code of conduct for our directors, officers and employees, but it is not always possible to identify and deter employee misconduct. The precautions we take to detect and prevent this activity may not be effective in protecting us from the negative impacts of governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. An unfavorable outcome or settlement in connection with a governmental investigation or other action or lawsuit may result in a material adverse impact on our business, results of operations, financial condition, prospects, and stock price. Regardless of the outcome, litigation and governmental investigations can be costly, time-consuming, and disruptive to our business, results of operations, financial condition, reputation, and prospects.

If we fail to comply with environmental, health or safety laws and regulations, we could incur fines, penalties or other costs.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations applicable to our operations in the U.S. and foreign countries. These current or future laws and regulations may impair our research, development or manufacturing efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

International Risks

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

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

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

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

The U.S. government, including the SEC, has made statements and taken certain actions that have led to changes to U.S. and international relations, and will impact companies with connections to China, including imposing several rounds of tariffs affecting certain products manufactured in China. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with connections to China. We have business operations in the U.S., and conduct contract manufacturing in both the U.S. and China. Any unfavorable government policies on cross-border relations and/or international trade, including tariffs, may affect the import of products and product components from China. While we have thus far imported products manufactured in China under exemptions from tariffs, if we are unable to do so in the future, the Company could encounter additional costs to supply our product and product candidates.

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

Our suppliers are obligated to comply with cGMP requirements but there can be no assurance that they will maintain all of the appropriate licenses required to manufacture our product candidates for clinical and commercial use. Our product suppliers must continually spend time, money and effort in production, record-keeping and quality assurance and appropriate controls in order to ensure that any products manufactured in their facilities meet applicable specifications and other requirements for product safety, efficacy and quality but there can be no assurance that their efforts will continue to be successful in meeting these requirements.

Manufacturing facilities in China are subject to periodic unannounced inspections by the National Medical Products Administration and other regulatory authorities. We expect to depend on these facilities for our product candidates, and we do not yet have a secondary source supplier for either roxadustat API. Consequently, we carry single source supplier risk for all countries we or our partners are selling in. Natural disasters or other unanticipated catastrophic events, including power interruptions, water shortages, storms, fires, pandemics, earthquakes, terrorist attacks, government appropriation of our facilities, and wars, could significantly impair our suppliers' abilities to operate their manufacturing facilities. Certain equipment, records and other materials located in such facilities would be difficult to replace or would require substantial replacement lead-time that would impact our ability to successfully commercialize supply roxadustat API or other clinical products.

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

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

We may be subject to currency exchange rate fluctuations and currency exchange restrictions with respect to our partner's operations in Japan and Europe, which could adversely affect our financial performance.

Most of our and our partner's product sales will occur in local currency and our operating results will be subject to volatility from currency exchange rate fluctuations. To date, we have not hedged against the risks associated with fluctuations in exchange rates and, therefore, exchange rate fluctuations could have an adverse impact on our future operating results. Changes in the value of the Euro or Yen against the U.S. dollar and other currencies are affected by, among other things, changes in political and economic conditions. Any significant currency exchange rate fluctuations may have a material adverse effect on our business and financial condition.

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

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

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

On December 22, 2017, the Tax Cuts and Jobs Act was enacted which instituted various changes to the taxation of multinational corporations. Since inception, various regulations and interpretations have been issued by governing authorities and we continue to examine the impacts to our business, which could potentially have a material adverse effect on our business, results of operations or financial conditions.

Risks Related to the Operation of Our Business

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future and may never achieve or sustain profitability. We may require additional financing in order to fund our operations, which may be dilutive to our shareholders, restrict our operations or require us to relinquish rights to our intellectual property or product candidates. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce or eliminate our research and development programs and/or our commercialization efforts.

We are a biopharmaceutical company with two lead product candidates in clinical development, roxadustat for anemia in lower-risk MDS in the U.S. and elsewhere, and FG-3246 (in conjunction with our PET imaging agent FG-3180) for mCRPC. Most of our revenue generated to date has been based on our collaboration agreements. We continue to incur significant research and development and other expenses related to our ongoing operations. Our loss from continuing operations were $58.2 million and $153.1 million for the year ended December 31, 2025, and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $1.7 billion. As of December 31, 2025, we had capital resources from cash and cash equivalents of $47.9 million and short-term and long-term investments of $61.3 million. Despite the commercialization efforts of Astellas for roxadustat for the treatment of anemia caused by CKD, we anticipate we will continue to incur losses on an annual basis for the foreseeable future. Furthermore, due to the sale of FibroGen International to AstraZeneca Treasury Limited, we will not be due any royalty, development or milestone payments under the AstraZeneca China Agreement. If we do not successfully develop and continue to obtain regulatory approval for our existing or any future product candidates and effectively manufacture, market and sell the product candidates that are approved, we may never achieve or sustain profitability on a quarterly or annual basis. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity (deficit) and working capital. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

We believe that we will continue to expend substantial resources for the foreseeable future as we continue our clinical development efforts. These expenditures will include costs associated with research and development, conducting preclinical trials and clinical trials, obtaining regulatory approvals in various jurisdictions, and manufacturing and supplying products and product candidates for our partners and ourselves. The outcome of any clinical trial and/or regulatory approval process is highly uncertain and we are unable to fully estimate the actual costs necessary to successfully complete the development and regulatory approval process for our compounds in development and any future product candidates. Our operating plans or third-party collaborations may change as a result of many factors, including the success of our development and commercialization efforts, operations costs (including manufacturing and regulatory), competition, and other factors that may not currently be known to us, and we therefore may need to seek additional funds sooner than planned, through offerings of public or private securities, debt financing or other sources, such as revenue interest monetization or other structured financing. Future sales of equity or debt securities may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may adversely affect our business. We may also seek additional capital due to favorable market conditions or strategic considerations even if we currently believe that we have sufficient funds for our current or future operating plans.

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

In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. If we raise additional funds by issuing equity securities, dilution to our existing stockholders will result. In addition, as a condition to providing additional funding to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Moreover, any debt financing, if available, may involve restrictive covenants that could limit our flexibility in conducting future business activities and, in the event of insolvency, would be paid before holders of equity securities received any distribution of corporate assets. For example, in 2022 we entered into a revenue interest financing agreement (the "RIFA") with NQ Project Phoebus, L.P. ("NovaQuest"), which imposes certain performance and financial obligations on our business. Our ability to satisfy and meet any future debt service obligations will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control.

If we are unable to obtain funding, we could delay, reduce or eliminate research and development programs, product portfolio development or future commercialization efforts which could adversely affect our business prospects.

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

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

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

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

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

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

For additional details about this financing transaction, see Note 9, *Liability Related to Sale of Future Revenues*, to the consolidated financial statements.

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

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional non-dilutive financing or enter into collaboration or partnership agreements of a certain size;
- requiring the dedication of a portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business; and
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

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

To the extent we incur additional debt, the risks described above could increase. Any of the above risks would negatively impact our ability to operate our business and obtain additional debt or equity financing on favorable terms.

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

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

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

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

We cannot predict whether any particular legal matter will be resolved favorably or ultimately result in charges or material damages, fines or other penalties, government enforcement actions, bars against serving as an officer or director, or civil or criminal proceedings against us or certain members of our senior management.

Legal proceedings, regardless of their merits or their ultimate outcomes, are costly, divert management's attention and may materially adversely affect our business, results of operations, financial condition, prospects, and stock price. Such costs may include indemnification for proceedings against our current or former officers, and there is one ongoing proceeding against a former officer where costs could be material but are uncertain at this time. In addition, such legal matters could negatively impact our reputation among our customers, collaboration partners or our shareholders. Furthermore, publicity surrounding legal proceedings, including regulatory investigations, even if resolved favorably for us, could result in additional legal proceedings or regulatory investigations, as well as damage to our reputation.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may have to limit commercial operations.

We face an inherent risk of product liability as a result of the clinical testing, manufacturing and commercialization of our product candidates. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in a product, negligence, strict liability or breach of warranty. Claims could also be asserted under state consumer protection acts. If we are unable to obtain insurance coverage at levels that are appropriate to maintain our business and operations, or if we are unable to successfully defend ourselves against product liability claims, we may incur substantial liabilities or otherwise cease operations. Product liability claims may result in:

- termination of further development of unapproved product candidates or significantly reduced demand for any approved products;
- material costs and expenses to defend the related litigation;
- a diversion of time and resources across the entire organization, including our executive management;
- product recalls, product withdrawals or labeling restrictions;
- termination of our collaboration relationships or disputes with our collaboration partners; and
- reputational damage negatively impacting our other product candidates in development.

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

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

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

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

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

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

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

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

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

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

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

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

Applicable data privacy and security obligations may require us to 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 December 31, 2025, the closing price of our common stock on the Nasdaq Global Select Market has ranged from $5.16 per share to $19.30 per share. In general, pharmaceutical, biotechnology and other life sciences company stocks have been highly volatile in the current market. The volatility of pharmaceutical, biotechnology and other life sciences company stocks is sometimes unrelated to the operating performance of particular companies, and biotechnology and life science companies' stocks often respond to trends and perceptions rather than financial performance. In particular, the market price of shares of our common stock could be subject to wide fluctuations in response to the following factors:

- results of clinical trials of our product candidates;
- the timing of the release of results of and regulatory updates regarding our clinical trials, as well as, investigator-sponsored trials;
- the level of expenses related to any of our product candidates or clinical development programs;
- results of clinical trials of our competitors' products;
- safety issues with respect to our product candidates or our competitors' products;
- regulatory actions with respect to our product candidates and any approved products or our competitors' products;
- fluctuations in our financial condition and operating results, which will be significantly affected by the manner in which we recognize revenue from the achievement of milestones under our collaboration agreements;
- adverse developments concerning our collaborations and our manufacturers;
- the termination of a collaboration or the inability to establish additional collaborations;
- the inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- changes in legislation or other regulatory developments affecting our product candidates or our industry;
- fluctuations in the valuation of the biotechnology industry and particular companies perceived by investors to be comparable to us;
- speculation in the press or investment community;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- changes in market conditions for biopharmaceutical stocks; and
- the other factors described in this "*Risk Factors*" section.

As a result of fluctuations caused by these and other factors, comparisons of our operating results across different periods may not be accurate indicators of our future performance. Any fluctuations that we report in the future may differ from the expectations of market analysts and investors, which could cause the price of our common stock to fluctuate significantly. Moreover, securities class action litigation has often been initiated against companies following periods of volatility in their stock price.

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

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

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

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

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

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

- problems integrating the purchased business, products or technologies, or employees or other assets of the acquisition target;
- increases to our expenses;
- disclosed or undisclosed liabilities of the acquired asset or company;
- diversion of management's attention from their day-to-day responsibilities;
- reprioritization of our development programs and even cessation of development and commercialization of our current product candidates;
- harm to our operating results or financial condition;
- entrance into markets in which we have limited or no prior experience; and
- potential loss of key employees, particularly those of the acquired entity.

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

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

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

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

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

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

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

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

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

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

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

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

Tariffs or other trade policy changes could harm our business.

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

Our certificate of incorporation designates courts located in Delaware as the sole forum for certain proceedings, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the Court of Chancery of the State of Delaware is the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated by-laws, or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. While the Delaware courts determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than that designated in the exclusive forum provisions. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. If a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

We do not plan to pay dividends. Capital appreciation will be your sole possible source of gain, which may never occur.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future and investors seeking cash dividends should not purchase our common stock. We plan to retain any earnings to invest in our product candidates and maintain and expand our operations. Therefore, capital appreciation, or an increase in your stock price, which may never occur, may be the only way to realize any return on your investment.

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Cybersecurity Governance and Responsibilities

Our Board of Directors recognizes that cybersecurity represents an important component of the Company's overall enterprise risk management (“ERM”). Throughout the year, our Board of Directors and its Committees engage with management to discuss and mitigate a wide range of enterprise risks, including cybersecurity.

We seek to mitigate cybersecurity risks through a cross-functional approach, including our Cybersecurity Committee, focused on preserving the confidentiality, security, and availability of the information that the Company collects and stores by identifying, preventing and mitigating cybersecurity threats and effectively responding to and remediating cybersecurity incidents as and if they occur.

Our Cybersecurity Committee is comprised of information technology, finance, legal, human resources and data privacy employees. It meets regularly to review and oversee the Company’s data security programs, policies, and strategies, including with respect to cybersecurity risk mitigation, business continuity, and business resiliency. Our Cybersecurity Committee (along with the Chief Financial Officer and General Counsel) also reviews, analyzes, and responds to cybersecurity incidents and breaches.

Our Audit Committee of the Board of Directors has the responsibility to review and discuss with management the Company’s guidelines, policies, and governance with respect to financial risk exposures and ERM (including with respect to cybersecurity) and to regularly report to the full Board. Our Audit Committee also oversees our internal audit department and management’s internal controls over financial reporting, including with respect to cybersecurity. Our Audit Committee receives regular presentations and reports on cybersecurity risks, progress on continued updates to the Company’s cybersecurity procedures, as well as is made aware, on a timely basis, of any cybersecurity incidents deemed significant enough to be raised to their attention by management, as well as ongoing updates regarding any such incident until it has been remediated.

Our head of Information Technology (“IT”) oversees overall cybersecurity management and implements our cybersecurity programs with the IT group, including appropriate risk mitigation strategies, systems, processes, and controls and provides periodic reports to our Audit Committee at least semi-annually. The head of IT holds a Masters in Computer Information Systems and a Bachelor of Science degree in Microbiology, and has served in leadership roles within the pharmaceutical and biotechnology industries for over 25 years, including leading enterprise-wide cybersecurity strategies, regulatory compliance programs, and IT transformation initiatives at leading biopharmaceutical companies. The head of IT has expertise spanning cybersecurity governance, risk management, cloud security, AI-driven cybersecurity enhancements, infrastructure modernization, and enterprise-wide IT resilience. The head of IT plays a key role in aligning cybersecurity frameworks with industry regulations such as SOC compliance, SOX, GxP, and data privacy standards, ensuring a secure and compliant IT environment to support business objectives.

Risk Management and Strategy

We periodically assess and test our cybersecurity procedures. We identify and assess material risks from cybersecurity threats by engaging outside advisors and experts to identify, anticipate, and assess future threats and trends, to perform assessments on our cybersecurity risk and measures to mitigate such risk, including information security maturity assessments of our information security control environment. The results of such assessments and reviews are reported as appropriate to the Cybersecurity Committee and Audit Committee, and we adjust our cybersecurity procedures as necessary based on the information provided by these assessments and reviews.

Cybersecurity Technical Safeguards

We continually invest in information and cybersecurity services and technologies. Technical safeguards are designed to protect the Company's information systems from cybersecurity threats, including firewalls, continuous intrusion detection and response system(s), data leak prevention strategies, enhanced email protection software, antimalware functionality and access controls. These safeguards are evaluated and improved through periodic assessments and review of cybersecurity threat intelligence. We rely on third parties to support its cybersecurity program, including but not limited to email security management, security operations and vulnerability management.

Cybersecurity Incident Response and Recovery Planning

We have established and maintain incident response and data recovery plans that address our response to a cybersecurity incident. Our Cybersecurity Committee and members of the Cyber Security Incident Response Team (which contains additional information technology specialists) regularly test and evaluate the effectiveness of these incident response and data recovery plans. In addition to the incident detection safeguards described above, our cybersecurity policy requires employees and third party vendors to report any and all cybersecurity incidents to our IT department.

Third-Party Risk Management

We maintain a risk-based approach to identifying and overseeing cybersecurity risks presented by third parties, including vendors, service providers and other external users of the Company’s systems, as well as the systems of third parties that could materially impact our business in the event of a cybersecurity incident affecting those third-party systems. Depending on the nature of the services provided, we may conduct different amounts of diligence into the cybersecurity practices of the third party, monitor the third party for cybersecurity issues, and impose contractual obligations relating to privacy and cybersecurity onto the third party.

Education and Awareness

We provide regular (at least annual) training for personnel regarding cybersecurity threats to equip our personnel with effective tools to address cybersecurity threats, and to communicate the Company's evolving information security procedures.

Current Cybersecurity Risk Posture

For an additional description of the risks from cybersecurity threats that may materially affect the Company, see “Risk Factors” in this Annual Report on Form 10-K, including “ 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.”

ITEM 2. PROPERTIES

We do not own or lease any physical properties. We currently operate in a fully remote environment, which we believe, combined with contracted services, is sufficient for our operations.

ITEM 3. 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 legal proceedings in our consolidated balance sheet as of December 31, 2025, as we could not predict the ultimate outcome of these matters, or reasonably estimate any possible loss or range of loss. For a discussion of our legal proceedings, refer to Note 11, *Commitments and Contingencies*, to the consolidated financial statements.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information for Common Stock

Our common stock has been listed on the Nasdaq Global Select Market ("Nasdaq") since November 14, 2014, formerly under the symbol "FGEN." On January 8, 2026, the Company's common stock began trading under the new trading symbol "KYNB" following the name change of the Company from "FibroGen, Inc." to "Kyntra Bio, Inc." Prior to our initial public offering, there was no public market for our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Stockholders

As of February 28, 2026, there were 80 registered stockholders of record for our common stock. This number of registered stockholders does not include stockholders whose shares are held in street names by brokers and other nominees, or may be held in trust by other entities. Therefore, the actual number of stockholders is greater than this number of registered stockholders of record.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. [RESERVED]

ITEM 7. 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 together with our consolidated financial statements and related notes and other financial information included in Item 8 of this Annual Report on Form 10-K for the year ended December 31, 2025 ("Annual Report"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, international operations and product candidates, includes forward-looking statements that involve risks and uncertainties. You should review the "Forward-Looking Statements" and ""Risk Factors" sections of this Annual Report for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Unless noted otherwise, this management's discussion and analysis relates solely to our continuing operations and does not reflect the operations results of FibroGen International (defined below), which is reflected as discontinued operations in our Consolidated Financial Statements.

BUSINESS OVERVIEW

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

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

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

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

On August 29, 2025, we closed the sale of our China operations through FibroGen International (Hong Kong) Ltd. ("FibroGen International") to AstraZeneca Treasury Limited pursuant to the share purchase agreement entered into with AstraZeneca Treasury Limited on February 20, 2025, as amended (the "Share Purchase Agreement") for a total consideration of $220.4 million comprised of $85.0 million in enterprise value and $135.4 million in net cash held in China. AstraZeneca AB ("AstraZeneca") was our long-time commercialization partner for roxadustat in greater China. This sale included all of our roxadustat assets in China, including FibroGen International's subsidiary FibroGen (China) Medical Technology Development Co., Ltd. ("FibroGen Beijing") and its 51.1% interest in Beijing Falikang Pharmaceutical Co. Ltd. ("Falikang").

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

We continue to advance our development plan for roxadustat in anemia associated with lower-risk myelodysplastic syndromes ("MDS"), a high-value indication with significant unmet medical need. We had a positive Type-C meeting with the U.S. Food and Drug Administration ("FDA") in July 2025 and reached alignment on several elements of our proposed Phase 3 study design for roxadustat in anemia associated with lower-risk MDS, including the starting dose and the patient inclusion criteria. We are starting preparations for the Phase 3 trial, while evaluating internal development and potential partnership opportunities for this late-stage program. We submitted the Phase 3 trial protocol for roxadustat for the treatment of anemia in patients with lower-risk MDS and high transfusion burden to the FDA in December 2025.

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

Financial Highlights

	Years Ended December 31,	
	2025	2024
	(in thousands, except for per share data)	
Result of Operations		
Revenue	$ 6,440	$ 29,621
Operating costs and expenses	52,335	180,037
Loss from continuing operations	(58,204)	(153,098)
Loss from continuing operations per share - basic and diluted	$ (14.40)	$ (38.26)

	December 31, 2025	December 31, 2024
	(in thousands)	
Balance Sheet		
Cash and cash equivalents	$ 47,872	$ 50,482
Short-term investments	41,106	—
Accounts receivable	216	481
Long-term investments	$ 20,160	$ —

Our revenue for the year ended December 31, 2025 primarily included $5.8 million of drug product revenue from commercial-grade active pharmaceutical ingredient ("API") or bulk drug product sales to Astellas.

As comparison, our revenue for the year ended December 31, 2024 primarily included the revenues recognized related to the following:

- $25.7 million cumulative catch-up net adjustment in the drug product revenue, as a result of terminating the AstraZeneca U.S./RoW Agreement (as defined below), effective as of February 25, 2024 as amended and restated on August 29, 2025 ("AstraZeneca Termination and Transition Agreement"), with the exception of South Korea.
- $2.0 million of drug product revenue related to API deliveries to Astellas; and
- $1.8 million of development revenue recognized under our collaboration agreements with our partners Astellas and AstraZeneca.

Total operating costs and expenses decreased $127.7 million for the year ended December 31, 2025 compared to the prior year as a result of the net effect of the following:

- $25.8 million lower employee-related expenses primarily due to the impact from reduction in force actions in August 2024 and July 2023, and cost control efforts;
- $23.8 million lower facilities-related expenses due to cost control efforts and lower depreciation expense as certain property and equipment reached their useful lives in prior year period, offset by the loss on disposal of property and equipment associated with efforts to streamline operations;
- $18.9 million restructuring charge related to the reduction in force plan in August 2024 recorded in prior year, which did not recur in 2025;
- $17.1 million lower stock-based compensation primarily resulting from significantly lower stock price and cancellations of stock options and restricted stock units due to reduced headcount;
- $16.9 million lower clinical trial expenses primarily associated with the termination of pamrevlumab programs during the second half of 2024 responding to the topline clinical data results we reported in July 2024;
- $15.0 million cost of goods sold corresponding to the drug product revenue resulting from the AstraZeneca Termination and Transition Agreement in 2024 related to the AstraZeneca U.S./RoW Agreement (as defined below), which did not recur in 2025; and
- $8.0 million lower drug development expenses associated with drug substance activities and logistic expenses related to pamrevlumab programs which were completed and terminated.

Our research and development expenses were $23.5 million and $95.7 million for the years ended December 31, 2025 and 2024, respectively. Since inception and through December 31, 2025, we have incurred a total of approximately $3.3 billion in research and development expenses, a majority of which relates to the development of roxadustat, pamrevlumab, FG-3246 and other hypoxia-inducible factor prolyl hydroxylase inhibitors. We expect to incur significant expenses and operating losses over at least the next few years as we continue to make investments in research and development to advance our current product candidate portfolio. We consider the active management and development of our clinical pipeline to be particularly crucial to our long-term success. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time consuming. We implemented cost reduction efforts in 2024 in connection with our efforts to streamline operations to align with our business goals. As a result, operating expenses have decreased and may continue to decrease in certain areas over time.

During the year ended December 31, 2025, we had a loss from continuing operations of $58.2 million or loss from continuing operations per basic and diluted share of $14.40, as compared to a loss from continuing operations of $153.1 million, or loss from continuing operations per basic and diluted share of $38.26 for the prior year, primarily due to a decrease in operating costs and expenses, offset by a decrease in revenues.

Consolidated cash and cash equivalents, investments and accounts receivable totaled $109.4 million at December 31, 2025, an increase of $58.4 million from December 31, 2024. Upon the the close of our sale of FibroGen International to AstraZeneca Treasury Limited during the third quarter of 2025, we accessed the entirety of our cash and cash equivalents held in China. For additional details, refer to Note 3, *Discontinued Operations and Divestiture,* to the consolidated financial statement, and the *Liquidity and Capital Resources* section below. Comparatively, consolidated cash and cash equivalents and accounts receivable for both continuing operations and discontinued operations totaled $121.1 million at December 31, 2024.

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 consolidated financial statements for details.

Astellas

In June 2005, we entered into a collaboration agreement with Astellas for the development and commercialization (but not manufacture) of roxadustat for the treatment of anemia in Japan ("Astellas Japan Agreement"). In April 2006, we entered into the Europe Agreement with Astellas for roxadustat for the treatment of anemia in Europe, the Commonwealth of Independent States, the Middle East, and South Africa ("Astellas Europe Agreement"). Under these agreements, the aggregate amount for upfront payments and milestone payments received through December 31, 2025 totals $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 $0.8 million and $(2.9) million for the years ended December 31, 2025 and 2024, respectively.

During the first quarter of 2021, we entered into an EU Supply Agreement with Astellas under the Astellas Europe Agreement to define general forecast, order, supply and payment terms for Astellas to purchase roxadustat bulk drug product from us in support of commercial supplies (the "Astellas EU Supply Agreement"). The related drug product revenue was $5.1 million and $4.9 million for the years ended December 31, 2025 and 2024, respectively.

AstraZeneca

In July 2013, we entered into a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in the U.S. and all territories except for China and those territories previously licensed to Astellas (the "AstraZeneca U.S./RoW Agreement"). In 2020, we entered into a Master Supply Agreement with AstraZeneca under the AstraZeneca U.S./RoW Agreement (the "AstraZeneca Master Supply Agreement") to define general forecast, order, supply and payment terms for AstraZeneca to purchase roxadustat bulk drug product from Kyntra Bio 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. Pursuant to the AstraZeneca Termination and Transition Agreement, AstraZeneca returns all of their non-China roxadustat rights to us, with the exception of South Korea, and provides certain assistance during a transition period. In addition, as a part of this AstraZeneca Termination and Transition Agreement, AstraZeneca will receive tiered mid-single digit royalties on Kyntra Bio's sales of roxadustat in the terminated territories, or thirty-five percent of all revenue Kyntra Bio receives if it licenses or sells such rights to a third-party. Neither party incurred any early termination penalties. The aggregate amount of consideration for milestone and upfront payments received under the AstraZeneca U.S./RoW Agreement through the termination totaled $439.0 million. In addition, resulting from the AstraZeneca Termination and Transition Agreement, Kyntra Bio and AstraZeneca settled the outstanding balances relating to past transactions under the AstraZeneca Master Supply Agreement. Accordingly, during the first quarter of 2024, we recorded a cumulative catch-up net adjustment of $25.7 million to the drug product revenue.

In July 2013, through our China subsidiary and related affiliates, we entered into a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in China (the "AstraZeneca China Agreement"). The aggregate amount for upfront payments and milestone payments received through December 31, 2025 totals $81.2 million.

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 consolidated financial statements.

AstraZeneca China Amendment

In July 2020, FibroGen China and AstraZeneca (together with FibroGen China, the "Parties") entered into an amendment, effective July 1, 2020, to the AstraZeneca China Agreement, relating to the development and commercialization of roxadustat in China (the "AstraZeneca China Amendment"). Under the AstraZeneca China Amendment, in 2020, FibroGen Beijing and AstraZeneca completed the establishment of a jointly owned entity, Falikang, which performs roxadustat distribution, as well as conduct 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 consolidated statement of operations, and the investment in unconsolidated subsidiary is included the held for sale assets in the consolidated balance sheet as of December 31, 2024. See Note 3, *Discontinued Operations and Divestiture*, to the consolidated financial statements for details.

Product revenue, net, which was included in the discontinued operations, consisted 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, while FibroGen Beijing continues to sell roxadustat product directly in limited areas in China. FibroGen Beijing manufactures and supplies commercial product to Falikang, based on a gross transaction price, adjusted for the estimated profit share.

We recognized revenue upon the transfer of control of commercial products to Falikang in an amount that reflected the allocation of transaction price of the China manufacturing and supply obligation ("China Performance Obligation") to the performance obligation satisfied during the reporting period. For our direct sales of commercial drug product, we recognized revenue when control of the promised good was transferred to the customer in an amount that reflected the consideration that we expected to be entitled to in exchange for the product. As discussed in Note 3, *Discontinued Operations and Divestiture,* to the 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. As a result, all the previously deferred revenues were recognized as revenue during the third quarter of 2025. During the years ended December 31, 2025 and 2024, included in the discontinued operations, we recognized $218.6 million and $159.0 million of net product revenue from the sales to Falikang, and $8.1 million and $14.7 million of net product revenue from sales directly to distributors in one province in China, respectively.

Licensing Activities

Exclusive License with Eluminex

In April 2023, we entered into an Amended and Restated Exclusive License Agreement with Eluminex ("A&R Eluminex Agreement") in order to add to the license rights to recombinant human collagen Type I (in addition to the rights to collagen Type III that were already licensed).

RESULTS OF OPERATIONS

Revenue

	Years Ended December 31,		Change	
	2025	2024	$	%
	(dollars in thousands)			
Revenue:				
Development and other revenue	592	1,948	(1,356)	(70)%
Drug product revenue, net	5,848	27,673	(21,825)	(79)%
Total revenue	$ 6,440	$ 29,621	$ (23,181)	(78)%

Under our revenue recognition policy, 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 December 31, 2025, 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, which have not been material for any of the periods presented. Development and other revenues represented 9% and 7% of total revenues for the years ended December 31, 2025 and 2024, respectively.

Drug product revenue includes commercial-grade API or bulk drug product sales to AstraZeneca, under the AstraZeneca U.S./RoW Agreement, and Astellas in support of pre-commercial preparation prior to the new drug application or marketing authorization application approval, and to Astellas for ongoing commercial activities 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. Drug product revenues represented 91% and 93% of total revenues for the years ended December 31, 2025 and 2024, respectively.

The AstraZeneca U.S./RoW Agreement was terminated on February 25, 2024 (except for South Korea). 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 consolidated financial statements. 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 decreased $23.2 million or 78% for the year ended December 31, 2025 compared to the year ended December 31, 2024 for the reasons discussed in the sections below.

Development and Other Revenue

	Years Ended December 31,		Change	
	2025	2024	$	%
	(dollars in thousands)			
Development revenue:				
Astellas	$ 592	$ 1,413	$ (821)	(58)%
AstraZeneca	—	418	(418)	NM
Total development revenue	592	1,831	(1,239)	(68)%
Other revenue	—	117	(117)	NM
Total development and other revenue	$ 592	$ 1,948	$ (1,356)	(70)%

NM = Not meaningful

Development and other revenue decreased $1.4 million, or 70% for the year ended December 31, 2025 compared to the year ended December 31, 2024, mainly due to the decrease in co-development billings resulting from the closeout activities under our collaboration agreements with Astellas for roxadustat.

Drug Product Revenue

	Years Ended December 31,		Change	
	2025	2024	$	%
	(dollars in thousands)			
Drug product revenue, net:				
Astellas Japan Agreement	$ 793	$ (2,872)	$ 3,665	128 %
Astellas Europe Agreement	5,055	4,874	181	4 %
AstraZeneca U.S./RoW Agreement	—	25,671	(25,671)	NM
Total drug product revenue, net:	$ 5,848	$ 27,673	$ (21,825)	(79) %

NM = Not meaningful

Drug product revenue decreased $21.8 million, or 79% for the year ended December 31, 2025 compared to the year ended December 31, 2024.

Astellas Japan Agreement

We updated our estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment and accordingly recorded an adjustment to the drug product revenue of $0.8 million for the year ended December 31, 2025. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect the changes in the estimated bulk product strength mix intended to be manufactured by Astellas and foreign exchange impacts, among others.

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 for the year ended December 31, 2024. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect the changes in the estimated bulk product strength mix intended to be manufactured by Astellas and foreign exchange impacts, among others.

As of December 31, 2025, the balances related to the API price true-up under the Astellas Japan Agreement were $1.6 million in accrued liabilities, representing our best estimate of the timing for these amounts to be paid. As of December 31, 2024, the related balances were $2.5 million in accrued liabilities and $0.6 million in other long-term liabilities.

Astellas Europe Agreement

During the fourth quarter of 2025, 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 $0.3 million as drug product revenue, and recorded $2.2 million as deferred revenue due to a high degree of uncertainty associated with the variable consideration for revenue recognition purposes. In addition, we updated our estimate of variable consideration related to the bulk drug product transferred in prior years. Specifically, the change in estimated variable consideration was based on the bulk drug product held by Astellas at the period end, adjusted to reflect the changes in the estimated transfer price, forecast information, shelf-life estimates and other items. As a result, for the year ended December 31, 2025, we reclassified $1.8 million from the related deferred revenue to accrued liabilities. As of December 31, 2025, the related balance in accrued liabilities was $5.4 million, representing our best estimate that this amount will be paid within the next 12 months.

During the fourth quarter of 2024, 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 $0.6 million as drug product revenue, and recorded $4.4 million as deferred revenue due to a high degree of uncertainty associated with the variable consideration for revenue recognition purposes. In addition, we updated our estimate of variable consideration related to the bulk drug product transferred in prior years. Specifically, the change in estimated variable consideration was based on the bulk drug product held by Astellas at the period end, adjusted to reflect the changes in the estimated transfer price, forecast information, shelf-life estimates and other items. As a result, for the year ended December 31, 2024, we reclassified $7.2 million from the related deferred revenue to accrued liabilities. As of December 31, 2024, the related balance in accrued liabilities was $10.5 million, and we paid $7.1 million to Astellas during the year ended December 31, 2025.

In addition, we recognized royalty revenue of $4.8 million and $4.3 million as drug product revenue from the deferred revenue under the Astellas Europe Agreement for the years ended December 31, 2025 and 2024, respectively. The remainder of the deferred revenue will be recognized as and when uncertainty is resolved, based on the performance of roxadustat product sales in the Astellas territory.

AstraZeneca U.S./RoW Agreement

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

Operating Costs and Expenses

	Years Ended December 31,		Change	
	2025	2024	$	%
	(dollars in thousands)			
Operating costs and expenses				
Cost of goods sold	$ 556	$ 15,561	$ (15,005)	(96)%
Research and development	23,517	95,692	(72,175)	(75)%
Selling, general and administrative	27,709	49,330	(21,621)	(44)%
Restructuring charge	553	19,454	(18,901)	(97)%
Total operating costs and expenses	$ 52,335	$ 180,037	$ (127,702)	(71)%

Total operating expenses decreased $127.7 million, or 71% for the year ended December 31, 2025 compared to the year ended December 31, 2024, for the reasons discussed in the sections below.

Cost of goods sold

Cost of goods sold decreased $15.0 million or 96% for the year ended December 31, 2025 compared to the year ended December 31, 2024.

As described above, during the year ended December 31, 2024, we recorded a cumulative catch-up net adjustment to the drug product revenue resulting from the AstraZeneca Termination and Transition Agreement related to the AstraZeneca U.S./RoW Agreement. Correspondingly, we recorded the related cost of goods sold of $14.6 million during the year ended December 31, 2024.

Cost of goods sold associated with the roxadustat drug product revenue in the U.S. was $0.3 million and $0.8 million for the years ended December 31, 2025 and 2024, respectively, associated with the costs of API or bulk drug product delivered to Astellas and AstraZeneca in the respective periods.

Research and Development Expenses

Research and development expenses consist of independent research and development costs and the gross amount of costs associated with work performed under collaboration agreements. Research and development expenses include employee-related expenses for research and development functions, expenses incurred under agreements with clinical research organizations, other clinical and preclinical costs and allocated direct and indirect overhead costs, such as facilities costs, information technology costs and other overhead. We expense research and development costs as incurred. We recognize costs for certain development activities based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites. We have implemented a significant cost reduction plan in the U.S. in the third quarter of 2024. As a result, research and development expenses have overall decreased and may continue to decrease in certain areas over time.

The following table summarizes our research and development expenses incurred during the years ended December 31, 2025 and 2024:

Product Candidate	Phase of Development	Years Ended December 31, 2025	2024
		(in thousands)	
FG-3246	Phase 2	$ 14,087	$ 20,484
Roxadustat	Approved / Phase 3	2,837	6,527
Pamrevlumab	Phase 2/3	2,373	49,696
Other research and development expenses		4,220	18,985
Total research and development expenses		$ 23,517	$ 95,692

The program-specific expenses summarized in the table above include costs we directly attribute to our product candidates. We allocate research and development salaries, benefits, stock-based compensation and other indirect costs to our product candidates on a program-specific basis, and we include these costs in the program-specific expenses.

Research and development expenses decreased $72.2 million, or 75% for the year ended December 31, 2025 compared to the year ended December 31, 2024 as a result of the net effect of the following:

- Decrease of $19.2 million in facilities-related expenses due to cost control efforts including the lease termination in the third quarter of 2024;
- Decrease of $16.9 million in clinical trials costs primarily associated with the termination of pamrevlumab programs during the second half of 2024 responding to the topline clinical data results we reported in July 2024;
- Decrease of $16.0 million in employee-related costs primarily due to the impact from reduction in force actions in August 2024, and cost control efforts;
- Decrease of $9.7 million in stock-based compensation primarily resulting from significantly lower stock price and cancellations of stock options and restricted stock units due to reduced headcount and terminations; and
- Decrease of $8.0 million in drug development expenses associated with drug substance activities related to pamrevlumab programs which were completed and terminated.

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses consist primarily of employee-related expenses for executive, operational, finance, legal, compliance, and human resource functions. SG&A expenses also include facility-related costs, professional fees, accounting and legal services, other outside services, recruiting fees and expenses associated with obtaining and maintaining patents. We have implemented a significant cost reduction plan in the U.S. in the third quarter of 2024. As a result, SG&A expenses have overall decreased and may continue to decrease over time.

SG&A expenses decreased $21.6 million, or 44% for the year ended December 31, 2025 compared to the year ended December 31, 2024, as a result of the net effect of the following:

- Decrease of $9.8 million in employee-related costs primarily due to the impact from reduction in force action in August 2024 and cost control efforts due to reduced headcount and terminations;
- Decrease of $7.4 million in stock-based compensation primarily resulting from significantly lower stock price and cancellations of stock options and restricted stock units; and
- Decrease of $4.6 million in facilities-related expenses due to cost control efforts including the lease termination in the third quarter of 2024.

Restructuring Charge

In response to the topline clinical results for pamrevlumab in patients with pancreatic cancer we announced in July 2024, we implemented an immediate and significant cost reduction plan in the U.S., including terminating pamrevlumab research and development investment and expeditiously winding down remaining obligations, and reducing our U.S. workforce by approximately 75%. As a result, we recorded a total of $19.5 million non-recurring restructuring charge during the year

ended December 31, 2024, primarily consisting of notice period and severance payments, accrued vacation, and employee benefits contributions. The related restructuring charges for the year ended December 31, 2025 were not material.

Interest and Other, Net

	Years Ended December 31,		Change	
	2025	2024	$	%
	(dollars in thousands)			
Interest and other, net:				
Interest expense	$ (8,759)	$ (8,247)	$ (512)	6 %
Loss on debt extinguishments	(6,583)	—	(6,583)	100 %
Interest income and other income (expenses), net	2,943	5,296	(2,353)	(44) %
Total interest and other, net	$ (12,399)	$ (2,951)	$ (9,448)	320 %

Interest Expense

Interest expense represents the interest associated with the liability related to sale of future revenues and interest related to the Technology Development Center of the Republic of Finland product development obligations.

Interest expense remained relatively flat for the year ended December 31, 2025 compared to the year ended December 31, 2024, and primarily included interest expense of $8.4 million and $7.9 million, respectively, related to sale of future revenues under a revenue interest financing agreement (the "RIFA") with NQ Project Phoebus, L.P. ("NovaQuest") entered into in November 2022. See Note 9, *Liability Related to Sale of Future Revenues*, to the consolidated financial statements for details.

Loss on Debt Extinguishments

On August 29, 2025, upon the above-mentioned 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 prepayment premium and fees. Accordingly, we recorded a loss on debt extinguishments of $6.6 million for the year ended December 31, 2025. See Note 8, *Senior Secured Term Loan Facilities*, to the 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 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 $2.4 million, or 44%, for the year ended December 31, 2025 compared to the year ended December 31, 2024, primarily due to lower interest income resulting from lower investment balances.

Benefits from Income Taxes

	Years Ended December 31,	
	2025	2024
	(dollars in thousands)	
Loss from continuing operations before income taxes	$ (58,294)	$ (153,367)
Benefit from income taxes	(90)	(269)
Effective tax rate	0.2 %	0.2 %

The benefits from income taxes for each of the two years ended December 31, 2025 were due to foreign taxes.

Based upon the weight of available evidence, which includes our historical operating performance, reported cumulative net losses since inception and expected continuing net loss, we have established a full valuation allowance against our net deferred tax assets as we do not currently believe that realization of those assets is more likely than not. We intend to continue maintaining a full valuation allowance on our deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of this allowance.

Discontinued Operations

On February 20, 2025, we entered into the Share Purchase Agreement with AstraZeneca Treasury Limited pursuant to which we and our subsidiary FibroGen China Anemia Holdings, Ltd. agreed to sell all of the issued and outstanding equity interests of FibroGen International to AstraZeneca Treasury Limited. 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 Boards 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 consolidated statements of operations. See Note 3, *Discontinued Operations and Divestiture*, for details.

LIQUIDITY AND CAPITAL RESOURCES

Financial Conditions

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

Upon the close of the sale of FibroGen International and its subsidiaries to AstraZeneca Treasury Limited on August 29, 2025, we received $210.4 million in cash paid at closing, and a total of $10.0 million cash payable by AstraZeneca at the closing subject to holdbacks of: (i) a $6.0 million holdback to offset final net cash adjustments which will be released following a customary adjustment process approximately 90 days post-closing (as such time may be extended for the parties to mutually agree upon final adjustments), and (ii) a $4.0 million holdback to satisfy any indemnity claims, which will be released, net of any claims paid or unresolved, nine months after the closing. On November 6, 2025, we received a $6.4 million payment from AstraZeneca, which is in full satisfaction of the first holdback of $6.0 million, plus $0.4 million that was an additional payment following the final net cash adjustments after closing. See Note 3, *Discontinued Operations and Divestiture*, to the 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. The clinical development milestones which could have triggered Delayed Draw Term Loan 1 were not achieved, and the Lenders have not funded Delayed Draw Term Loan 2. 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. See Note 8, *Senior Secured Term Loan Facilities*, to the consolidated financial statements for details.

In November 2022, we entered into a RIFA with NovaQuest with respect to our revenues from Astellas' sales of roxadustat in Europe, Japan and the other Astellas territories. Pursuant to the RIFA, in the fourth quarter of 2022, we received $49.8 million from NovaQuest, representing the gross proceeds of $50.0 million net of initial issuance costs, in consideration for a portion of future revenues we will receive from Astellas. For additional details about this financing transaction, see Note 9, *Liability Related to Sale of Future Revenues*, to the 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 during the year ended December 31, 2025.

Cash and cash equivalents, investments and accounts receivable totaled $109.4 million as of December 31, 2025, compared to $50.5 million as of December 31, 2024. Cash is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting of available-for-sale securities, and stated at fair value, are also available as a source of liquidity. Upon the close of our sale of FibroGen International to AstraZeneca during the third quarter of 2025, we accessed the entirety of our cash and cash equivalents held in China.

Cash Sources and Uses

The following table summarizes the primary sources and uses of cash for the years ended December 31, 2025 and 2024 (in thousands), including both continuing operations and discontinued operations:

	Years Ended December 31,	
	2025	2024
Net cash provided by (used in):		
Operating activities	$ (4,774)	$ (137,999)
Investing activities	35,419	125,993
Financing activities	(86,028)	(255)
Effect of exchange rate changes on cash and cash equivalents	1,077	751
Net decrease in cash and cash equivalents	$ (54,306)	$ (11,510)

Operating Activities

Net cash used in operating activities was $4.8 million for the year ended December 31, 2025 and consisted primarily of net income of $183.5 million, adjusted for non-cash items and non-operating activities of $35.2 million and a net decrease in operating assets and liabilities of $153.0 million. The significant non-cash items included gain on divesture of FibroGen International of $52.6 million, loss on debt extinguishments of $6.6 million and stock-based compensation expense of $6.6 million. The significant items in the changes in operating assets and liabilities included the following:

- Deferred revenue decreased $136.4 million, due to the recognition of all the previously deferred balance related to our China Performance Obligation under our agreements with AstraZeneca 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. See the *China Performance Obligation* section in Note 4, *Collaboration Agreements, License Agreement and Revenues*, to the consolidated financial statements for details;
- Accrued and other liabilities decreased $53.5 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 payment of the transaction costs related to the divestiture, $7.3 million total payments of bonus and severance payouts, and $7.1 million payment to Astellas related to accrued API and bulk drug product price true-up. The accrued and other liabilities were also impacted by cost control efforts and the timing of invoicing and payment.
- Accounts payable decreased $27.7 million, primarily driven by the payments made during the current year 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 $54.1 million, primarily due to the $28.5 million distribution of the above-mentioned litigation settlement during the year, 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 $8.0 million due to the interest expense of $8.4 million accrued, offset by the interest paid of $0.5 million during the period. See Note 9, *Liability Related to Sale of Future Revenues*, to the consolidated financial statements for details; and
- Inventory decreased $5.4 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 as discussed in Note 3, *Discontinued Operations and Divestiture,* to the consolidated financial statements.

Net cash used in operating activities was $138.0 million for the year ended December 31, 2024 and consisted primarily of net loss of $47.6 million adjusted for non-cash items and non-operating activities of $27.0 million and a net decrease in operating assets and liabilities of $117.5 million. The significant non-cash items included stock-based compensation expense of $25.2 million. The significant items in the changes in operating assets and liabilities included the following:

- Accrued and other liabilities decreased $93.8 million, driven by payment of $35.3 million to Astellas and $11.5 million to AstraZeneca related to accrued API and bulk drug product price true-up, bonus and severance payouts totaling $35.6 million, and settlement of historical co-promotion balances under the settlement agreements entered in September 2024 between FibroGen China and AstraZeneca. The accrued and other liabilities were also impacted by cost control efforts and the timing of invoicing and payment.
- Operating lease right-of-use assets decreased $66.3 million, operating lease liabilities, non-current decreased $66.2 million and operating lease liabilities, current decreased $12.8 million related to the operating lease termination of our corporate headquarters;
- Deferred revenue decreased $28.3 million, primarily related to the $46.7 million product revenue recognized, which is included in the discontinued operations, from the previously deferred revenue of the China Performance Obligation during the year. In addition, the decrease in deferred revenue was also related to the reclassification of $7.2 million to accrued liabilities, resulting from changes in estimated variable consideration associated with the bulk drug product transferred to Astellas under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement during the year. The decreases were offset by the impact that deferred revenue was no longer netted against any contract assets as of December 31, 2024, as the $22.5 million of unbilled co-development revenue under the AstraZeneca China Amendment and the $4.0 million unbilled regulatory milestone payment under the AstraZeneca China Agreement as of December 31, 2023 were billed during the third quarter of 2024 under the above-mentioned settlement agreements;
- Prepaid expenses and other current assets increased $15.6 million, primarily due to the unbilled receivables from Falikang based on the arrangements under the above-mentioned settlement agreements between FibroGen China and AstraZeneca to settle certain historical items, offset by the reimbursements from the insurance for the legal fees associated with the class action lawsuit, which is recoverable under our insurance policies.
- Accounts receivable increased $6.7 million, primarily driven by the billings to Falikang based on the arrangements under the above-mentioned settlement agreements and related to the increase product sales, as well as the timing of receipt of the billings under our collaboration and license agreements. Accounts receivable from Falikang is part of the held-for-sale assets resulting from the Share Purchase Agreement with AstraZeneca Treasury Limited;
- Inventory decreased $22.3 million primarily driven by the $12.6 million of work-in-progress inventory that was reimbursed as part of the above-mentioned termination of the AstraZeneca U.S./RoW Agreement, and lower inventory production in China as we have decommissioned our API manufacturing facility in Cangzhou, China, and intend to manufacture API for China at Shanghai SynTheAll Pharmaceutical Co., Ltd. (“WuXi STA”). Inventory in China is part of the held-for-sale assets resulting from the Share Purchase Agreement with AstraZeneca Treasury Limited; and
- Accounts payable increased $14.5 million, primarily driven by the payments to be made for the historical co-promotion expenses to AstraZeneca during the current year, which is part of the held-for-sale liabilities resulting from the Share Purchase Agreement with AstraZeneca Treasury Limited. The increase was offset by timing of invoicing and payments and cost control efforts.

Investing Activities

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

Net cash provided by investing activities was $35.4 million for the year ended December 31, 2025 and consisted primarily of $96.6 million net proceeds from the divestiture of FibroGen International, 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, and the $6.4 million cash received from AstraZeneca as 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; partially offset by $61.2 million of cash used in purchases of available-for-sale securities.

Net cash provided by investing activities was $126.0 million for the year ended December 31, 2024 and consisted primarily of $133.8 million of proceeds from maturities of investments, partially offset by $8.6 million of cash used in purchases of available-for-sale securities.

Financing Activities

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

Net cash used in financing activities was $86.0 million for the year ended December 31, 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 8, *Senior Secured Term Loan Facilities*, to the 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. See the *Subsidiary Stock and Non-Controlling Interests - FibroGen Cayman* section in Note 12, *Equity and Stock-based Compensation,* to the consolidated financial statements for details.

Net cash used in financing activities was not material for the year ended December 31, 2024.

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 Item 1A "*Risk Factors*" in this Annual Report on Form 10-K, 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

At December 31, 2025, our material cash requirements from known contractual and other obligations primarily relate to our lease liabilities, non-cancelable purchase obligations and liability related to sale of future revenues. Expected timing of those payments are as follows (in thousands):

			Payments Due In	
	Total		Next 12 Months	Beyond 12 Months
Purchase obligations	$	5,618	$ 5,618	$ —
Liability related to sale of future revenues		118,897	1,334	117,563
Total payments	$	124,515	$ 6,952	$ 117,563

Our outstanding non-cancelable purchase obligations primarily related to manufacturing and supply for FG-3246 and roxadustat, and other purchases and programs. See Note 11, *Commitments and Contingencies*, to the consolidated financial statements for details.

Under the RIFA with NovaQuest, as of December 31, 2025, we had $67.3 million of liability related to sale of future revenues on the consolidated balance sheets, $1.3 million of which we expect to pay within the next 12 months. Based on our current estimates of drug product revenue and revenue from milestone payments under the Astellas Agreements, and taking into the consideration of the terms under the RIFA, we anticipate to reach a payment cap up to $125.0 million by 2031. See Note 9, *Liability Related to Sale of Future Revenues*, to the consolidated financial statements for details.

The table above excludes uncertain tax benefits of approximately $74.5 million that are disclosed in Note 14, *Income Taxes*, to the consolidated financial statements because these uncertain tax positions, if recognized, would be an adjustment to the gross deferred tax assets and the corresponding valuation allowance, if warranted.

As of December 31, 2025, we have several on-going clinical studies in various stages. Under agreements with various contract research organizations ("CROs"), and clinical study sites, we incur expenses related to clinical studies of our product candidates and potential other clinical candidates. The timing and amounts of these disbursements are contingent upon the achievement of certain milestones, patient enrollment and services rendered or as expenses are incurred by the CROs or clinical trial sites. Therefore, we cannot estimate the potential timing and amount of these payments and they have been excluded from the table above. Although our material contracts with CROs are cancelable, we have historically not canceled such contracts.

As of December 31, 2025, our FibroGen Europe Oy ("FibroGen Europe") subsidiary had $11.1 million of principal outstanding and $8.5 million of interest accrued related to loans from the Finnish government ("TEKES" loans), respectively, which have been included as product development obligations on our consolidated balance sheet. See Note 10, *Product Development Obligations*, to the consolidated financial statements for details. There is no stated maturity date related to these loans and each loan may be forgiven if the research work funded by TEKES does not result in an economically profitable business or does not meet its technological objectives. In addition, we are not a guarantor of the TEKES loans, and the principal or the accrued interest of these loans are not repayable by FibroGen Europe until it has distributable funds. We do not expect FibroGen Europe to have such funds in the foreseeable future. For the foregoing reasons, we cannot estimate the potential timing and the amounts of repayments (if required) or forgiveness. As a result, the TEKES loans have been excluded from the table above.

Off-Balance Sheet Arrangements

During the year ended December 31, 2025, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements.

Indemnification Agreements

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

Recently Issued Accounting Guidance

For recently issued accounting guidance, see Note 2, *Significant Accounting Policies,* to the consolidated financial statements.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated 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.

While our significant accounting policies and critical estimates are described in more detail in the notes to our financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Drug product revenue

Drug product revenue includes commercial-grade API or bulk drug product sales to Astellas for ongoing commercial activities 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 we include it 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. Estimating variable consideration and the related constraint requires the use of significant management judgment. We review new information that may affect its variable consideration estimate at every reporting period and records revenue adjustment, if certain and material. 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.

As each of our collaboration agreements provide for annual true up to the considerations paid for our commercial supplies, we will re-evaluate the transaction price in each reporting period and record adjustment to revenue as uncertain events are resolved or other changes in circumstances occur.

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 for a total consideration of $220.4 million comprised of $85.0 million in cash for the enterprise value of FibroGen International and $135.4 million in net cash held in China. The total consideration included a $210.4 million in cash paid at closing, and a total of $10.0 million cash payable by AstraZeneca at the closing subject to two holdbacks. On November 6, 2025, we received a $6.4 million payment from AstraZeneca, which is in full satisfaction of the first holdback of $6.0 million, plus $0.4 million that was an additional payment following the final net cash adjustments after closing. We analyzed the quantitative and qualitative factors and concluded that the sale of FibroGen International represents a strategic shift in our business and qualified as a discontinued operation. As a result, we determined that FibroGen International met the "held for sale" criteria and the "discontinued operations" criteria in accordance with Financial Accounting Standard Boards Accounting Standards Codification 205, *Presentation of Financial Statements* ("ASC 205"), 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 consolidated statements of operations, while the related assets and liabilities were classified within the consolidated balance sheets as held for sale for all periods presented. See Note 3, *Discontinued Operations and Divestiture*, to our consolidated financial statements for related disclosures.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

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 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Kyntra Bio, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Kyntra Bio, Inc. and its subsidiaries (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations, of comprehensive income (loss), of changes in redeemable non-controlling interests and stockholders' deficit and of cash flows for the years then ended, including the related notes and financial statement schedule listed in the accompanying index for each of the years then ended (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Discontinued Operations – FibroGen International

As described in Notes 2 and 3 to the consolidated financial statements, 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 includes all of the Company's roxadustat assets in China, including FibroGen International's subsidiary FibroGen (China) Medical Technology Development Co., Ltd ("FibroGen Beijing") and its 51.1% interest in Beijing Falikang Pharmaceutical Co., Ltd. ("Falikang"). The Transaction was closed on August 29, 2025. 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. The operating results of FibroGen International have been reflected as discontinued operations in the consolidated financial statements for all periods presented. The Company recorded income from discontinued operations, net of tax, of $241.7 million, which included gain on divestiture of $52.6 million, for the year ended December 31, 2025.

The principal consideration for our determination that performing procedures relating to the discontinued operations of FibroGen International is a critical audit matter is a high degree of auditor effort in performing procedures related to the disposal transaction.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, (i) reading the purchase and close agreements; (ii) evaluating the sufficiency of the disclosures in the consolidated financial statements; (iii) testing the gain recorded upon disposal, including obtaining and inspecting source documents, such as contracts, bank statements, and historical accounting records, and agreeing the corresponding inputs in the gain calculation and testing the mathematical accuracy of the gain calculation, and (iv) testing the completeness, accuracy and classification of certain classes of transactions included in income from discontinued operations, net, on a sample basis, by obtaining and inspecting source documents, such as contracts, purchase orders, invoices, and shipping documents.

/s/ PricewaterhouseCoopers LLP
Irvine, California
March 16, 2026

We have served as the Company's auditor since 2000.

KYNTRA BIO, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except per share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 47,872	$ 50,482
Short-term investments	41,106	—
Accounts receivable, net	216	481
Inventories	3,743	3,155
Prepaid expenses and other current assets	6,136	31,542
Current assets held for sale	—	110,849
Total current assets	99,073	196,509
Long-term investments	20,160	—
Other assets	361	1,405
Long-term assets held for sale	—	16,611
Total assets	$ 119,594	$ 214,525
Liabilities, redeemable non-controlling interests and deficit		
Current liabilities:		
Accounts payable	$ 3,745	$ 5,064
Accrued and other current liabilities	20,183	62,035
Deferred revenue	5,314	27,290
Current liabilities held for sale	—	38,917
Total current liabilities	29,242	133,306
Product development obligations	19,560	17,012
Deferred revenue, net of current	255	114,708
Senior secured term loan facilities, non-current	—	73,092
Liability related to sale of future revenues, non-current	65,980	58,864
Other long-term liabilities	82	822
Long-term liabilities held for sale	—	356
Total liabilities	115,119	398,160
Commitments and Contingencies (Note 11)		
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 December 31, 2025 and 2024	—	—
Common stock, $0.01 par value; 225,000 shares authorized at December 31, 2025 and 2024; 4,047 and 4,037 shares issued and outstanding at December 31, 2025 and 2024	1,012	1,009
Additional paid-in capital	1,677,179	1,668,620
Accumulated other comprehensive loss	(2,182)	(5,732)
Accumulated deficit	(1,706,047)	(1,889,499)
Total stockholders' deficit attributable to Kyntra Bio	(30,038)	(225,602)
Nonredeemable non-controlling interests	13,033	20,487
Total deficit	(17,005)	(205,115)
Total liabilities, redeemable non-controlling interests and deficit	$ 119,594	$ 214,525

The accompanying notes are an integral part of these Consolidated Financial Statements.

KYNTRA BIO, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Years Ended December 31,	
	2025	**2024**
Revenue:		
Development and other revenue	$ 592	$ 1,948
Drug product revenue, net	5,848	27,673
Total revenue	6,440	29,621
Operating costs and expenses:		
Cost of goods sold	556	15,561
Research and development	23,517	95,692
Selling, general and administrative	27,709	49,330
Restructuring charge	553	19,454
Total operating costs and expenses	52,335	180,037
Loss from operations	(45,895)	(150,416)
Interest and other, net		
Interest expense	(8,759)	(8,247)
Loss on debt extinguishments	(6,583)	—
Interest income and other income (expenses), net	2,943	5,296
Total interest and other, net	(12,399)	(2,951)
Loss from continuing operations before income taxes	(58,294)	(153,367)
Benefit from income taxes	(90)	(269)
Loss from continuing operations	(58,204)	(153,098)
Income from discontinued operations, net of tax	241,656	105,519
Net income (loss)	$ 183,452	$ (47,579)
Loss from continuing operations per share - basic and diluted	$ (14.40)	$ (38.26)
Income from discontinued operations per share - basic and diluted	59.77	26.37
Net income (loss) per share - basic and diluted	$ 45.37	$ (11.89)
Weighted average number of common shares used to calculate net income (loss) per share - basic and diluted	4,043	4,002

The accompanying notes are an integral part of these Consolidated Financial Statements.

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

	Years Ended December 31,	
	2025	2024
Net income (loss)	$ 183,452	$ (47,579)
Other comprehensive income (loss):		
Foreign currency translation adjustments	(1,966)	1,166
Cumulative currency translation adjustment attributable to divestiture	5,479	—
Unrealized gain (loss) on investments, net of tax effect	37	(23)
Other comprehensive income, net of taxes	3,550	1,143
Comprehensive income (loss)	187,002	(46,436)

The accompanying notes are an integral part of these Consolidated Financial Statements.

KYNTRA BIO, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE NON-CONTROLLING INTERESTS AND STOCKHOLDERS' DEFICIT
(In thousands, except share data)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Non Controlling	Total	Redeemable Non-Controlling
	Shares	Amount	Capital	Loss	Deficit	Interests	Deficit	Interests (Note 5)
Balance at December 31, 2023	3,950,809	$ 988	$ 1,643,641	$ (6,875)	$ (1,841,920)	$ 20,487	$ (183,679)	$ 21,480
Net loss	—	—	—	—	(47,579)	—	(47,579)	—
Change in unrealized gain or loss on investments	—	—	—	(23)	—	—	(23)	—
Foreign currency translation adjustments	—	—	—	1,166	—	—	1,166	—
Shares issued from stock plans, net of payroll taxes paid	85,869	21	(236)	—	—	—	(215)	—
Stock-based compensation	—	—	25,215	—	—	—	25,215	—
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	—	—	—	—	183,452	—	183,452	—
Change in unrealized gain or loss on investments	—	—	—	37	—	—	37	—
Foreign currency translation adjustments	—	—	—	(1,966)	—	—	(1,966)	—
Cumulative currency translation adjustment attributable to divestiture (Note 3)	—	—	—	5,479	—	—	5,479	—
Distribution to non-controlling interest (Note 12)	—	—	2,101	—	—	(7,454)	(5,353)	—
Shares issued from stock plans, net of payroll taxes paid	10,204	3	(72)	—	—	—	(69)	—
Issuance cost under ATM Program	—	—	(46)	—	—	—	(46)	—
Redemption of fractional shares due to reverse stock split	(55)	—	—	—	—	—	—	—
Stock-based compensation	—	—	6,576	—	—	—	6,576	—
Balance at December 31, 2025	4,046,827	$ 1,012	$ 1,677,179	$ (2,182)	$ (1,706,047)	$ 13,033	$ (17,005)	$ 21,480

The accompanying notes are an integral part of these Consolidated Financial Statements.

KYNTRA BIO, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,	
	2025	**2024**
Operating activities		
Net income (loss)	$ 183,452	$ (47,579)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	713	2,654
Amortization of finance lease right-of-use assets	35	38
Net accretion of premium and discount on investments	(72)	(1,680)
Investment income in unconsolidated variable interest entity	(2,485)	(3,969)
Gain on divestiture	(52,553)	—
Loss on debt extinguishments	6,583	—
Impairment of property and equipment	2,062	—
Loss on disposal of property and equipment	—	2,551
Stock-based compensation	6,576	25,215
Dividend received from unconsolidated variable interest entity	3,947	2,230
Changes in operating assets and liabilities:		
Accounts receivable, net	(2,543)	(6,737)
Inventories	5,362	22,284
Prepaid expenses and other current assets	54,102	(15,550)
Operating lease right-of-use assets	808	66,306
Other assets	(902)	1,010
Accounts payable	(27,654)	14,512
Accrued and other liabilities	(53,497)	(93,790)
Operating lease liabilities, current	(568)	(12,774)
Deferred revenues	(136,429)	(28,297)
Accrued interest expense related to sale of future revenues	7,990	2,257
Accrued interest for finance lease liabilities	6	14
Operating lease liabilities, non-current	(202)	(66,154)
Other long-term liabilities	495	(540)
Net cash used in operating activities	(4,774)	(137,999)
Investing activities		
Purchases of property and equipment	(38)	(266)
Proceeds from divestiture, net of cash transferred	96,615	—
Proceeds from sale of property and equipment	—	1,046
Purchases of available-for-sale securities	(61,158)	(8,628)
Proceeds from maturities of investments	—	133,841
Net cash provided by investing activities	35,419	125,993
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)	—
Repayments of finance lease liabilities	(10)	(40)
Cash paid for payroll taxes on restricted stock unit releases	(69)	(354)
Cash paid to non-controlling interest	(5,353)	—
Payment of issuance cost under ATM Program	(46)	—
Proceeds from issuance of common stock under employee stock plans	—	139
Net cash used in financing activities	(86,028)	(255)
Effect of exchange rate change on cash and cash equivalents	1,077	751
Net decrease in cash and cash equivalents	(54,306)	(11,510)
Total cash and cash equivalents at beginning of period	102,178	113,688
Total cash and cash equivalents at end of period	$ 47,872	$ 102,178
Supplemental cash flow information:		
Holdback consideration receivable related to divestiture in prepaid expenses and other current assets	$ 4,000	$ —
Interest payments	$ 7,830	$ 16,207

Reconciliation of cash and cash equivalents to the consolidated balance sheets:	**December 31, 2025**	**December 31, 2024**
Cash and cash equivalents of continuing operations	$ 47,872	$ 50,482
Cash and cash equivalents included in assets held for sale	—	51,696
Total cash and cash equivalents in the consolidated statements of cash flows	$ 47,872	$ 102,178

The accompanying notes are an integral part of these Consolidated Financial Statements.

1. The Company

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

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

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

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

On August 29, 2025, the Company closed the sale of its China operations through FibroGen International (Hong Kong) Ltd. ("FibroGen International") to AstraZeneca Treasury Limited pursuant to the share purchase agreement entered into by the Company and AstraZeneca Treasury Limited on February 20, 2025, as amended (the "Share Purchase Agreement") for a total consideration of $220.4 million comprised of $85.0 million in enterprise value and $135.4 million in net cash held in China. AstraZeneca AB ("AstraZeneca") was the Company's long-time commercialization partner for roxadustat in greater China. This sale included all of its roxadustat assets in China, including FibroGen International's subsidiary FibroGen (China) Medical Technology Development Co., Ltd ("FibroGen Beijing") and its 51.1% interest in Beijing Falikang Pharmaceutical Co. Ltd. ("Falikang"). For additional details, refer to Note 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.

The Company continues to advance its development plan for roxadustat in anemia associated with lower-risk myelodysplastic syndromes ("MDS"), a high-value indication with significant unmet medical need. The Company had a positive Type-C meeting with the U.S. Food and Drug Administration ("FDA") in July 2025 and reached alignment on several elements of its proposed Phase 3 study design for roxadustat in anemia associated with lower-risk MDS, including the starting dose and the patient inclusion criteria. The Company is starting preparations for the Phase 3 trial, while evaluating internal development and potential partnership opportunities for this late-stage program. The Company submitted the Phase 3 trial protocol for roxadustat for the treatment of anemia in patients with lower-risk MDS and high transfusion burden to the FDA in December 2025.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP"). The consolidated financial statements include the accounts of the Company, its wholly owned subsidiaries and its majority-owned subsidiaries, as well as any variable interest entity ("VIE") for which Kyntra Bio is the primary beneficiary. All inter-company transactions and balances have been eliminated in consolidation.

The Company operates in 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 includes all of the Company's roxadustat assets in China, including FibroGen International's subsidiary FibroGen Beijing and its 51.1% interest in Falikang. The Transaction was closed on August 29, 2025 for a total consideration of $220.4 million, subject to certain customary adjustments as set forth in the purchase agreement, comprised of $85.0 million in enterprise value and $135.4 million in net cash held in China.

The Company analyzed the quantitative and qualitative factors and concluded that the sale of FibroGen International represents a strategic shift in the Company's business and qualified as a discontinued operation since December 31, 2024. As a result, the Company determined that FibroGen International met the "held for sale" criteria and the "discontinued operations" criteria in accordance with Financial Accounting Standard Board ("FASB") Accounting Standards Codification ("ASC") 205, *Presentation of Financial Statements.* Accordingly, the operating results related to FibroGen International are classified as discontinued operations, and have been reflected as discontinued operations in the consolidated statements of operations for all periods presented, and therefore, the consolidated statements of operations and the notes to the consolidated financial statements were recasted for all comparative periods presented to classify FibroGen International as discontinued operations. In addition, the related assets and liabilities were classified within the consolidated balance sheets as held for sale for each balance sheet date before the Transaction closed since December 31, 2024. See Note 3, *Discontinued Operations and Divestiture*, for related disclosures. Unless otherwise noted, discussion in the notes to the consolidated financial statements, relates to solely to the Company's continuing operations.

Reverse Stock Split

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

Liquidity and Going Concern

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

As disclosed in previous filings (including the September 30, 2024 Form 10-Q and subsequent December 31, 2024 Form 10-K, March 31, 2025 Form 10-Q and June 30, 2025 Form 10-Q), if the Company was unable to complete the above mentioned sale of FibroGen International, access additional cash from its China operations, or raise additional capital in the U.S., the Company would not have sufficient liquidity to continue operations in the U.S. for the 12 months from the date that the financial statements were issued and would not be able to comply with its financial covenant that required a minimum balance of unrestricted cash and cash equivalents to be held in accounts in the U.S. Upon an event of default, the Company's senior secured term loan facilities with Morgan Stanley Tactical Value ("MSTV") would become immediately due and payable. These factors had raised substantial doubt about the Company's ability to continue as a going concern.

On August 29, 2025, upon the Transaction close, the Company received cash for the sale of $210.4 million and repaid its senior secured term loan facilities with MSTV, outstanding interest and related premium and fees for approximately $80.9 million. With the cash proceeds from the Transaction close, 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 December 31, 2025 and concluded that the conditions and events that initially raised substantial doubt have been alleviated and that substantial doubt does not exist as of issuance.

Foreign Currency Translation

The reporting currency of the Company and its subsidiaries is the U.S. dollar.

The functional currency of FibroGen Europe is the Euro. The functional currency of FibroGen Beijing, a part of the above-mentioned discontinued operations, is CNY. As such, monetary assets and liabilities of FibroGen Europe and FibroGen Beijing in currencies other than their functional currencies are remeasured using exchange rates in effect at the end of the period. The assets and liabilities of FibroGen Europe and FibroGen Beijing are translated to U.S. dollars at exchange rates in effect at the balance sheet date. All income statement accounts are translated at monthly average exchange rates. Resulting foreign currency translation adjustments are recorded directly in accumulated other comprehensive income (loss) as a separate component of stockholders' equity (deficit).

The functional currency of Kyntra Bio, Inc. and all other subsidiaries is the U.S. dollar. Accordingly, monetary assets and liabilities in the non-functional currency of these subsidiaries are remeasured using exchange rates in effect at the end of the period. Revenues and costs in local currency are remeasured using average exchange rates for the period, except for costs related to those balance sheet items that are remeasured using historical exchange rates. The resulting remeasurement gains and losses are included within interest income and other, net in the consolidated statements of operations as incurred and have not been material for all periods presented.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. The more significant areas requiring the use of management estimates and assumptions include valuation and recognition of revenue and deferred revenue, specifically, estimates in variable consideration for drug product sales, and estimates in transaction price per unit for the China Performance Obligation (as defined and discussed under *Revenue Recognition* below), which was completed during the third quarter of 2025 upon the above-mentioned Transaction close. 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.

Concentration of Credit Risk

The Company is subject to risks associated with concentration of credit for cash and cash equivalents. Outside of short-term operating needs, cash on hand is invested in commercial paper, money market funds and U.S. government securities. Any remaining cash is deposited with major financial institutions primarily in the U.S. At times, such deposits may be in excess of insured limits. The Company has not experienced any loss on its deposits of cash and cash equivalents. As of December 31, 2025 and 2024, the accounts receivable was not material.

Other 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.

Cash, Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents also include certain money market accounts, commercial paper and U.S. government securities.

Investments

As of December 31, 2025, the Company's short-term investments consist of diversified bonds, commercial paper, and money market funds with original maturities of greater than three months and remaining maturities of less than 12 months (365 days) are considered. Any investments with maturities greater than 12 months (365 days) from the balance sheet date are considered long-term investments. When such investments are held, the Company's investments classified as available-for-sale are recorded at fair value based upon quoted market prices at period end. Unrealized gains and losses for available-for-sale debt investments that are deemed temporary in nature are recorded in accumulated other comprehensive income (loss) as a separate component of stockholder' equity. Realized and unrealized gains or losses resulting from changes in value and sale of the Company's marketable equity investments are recorded in other income (expenses) in the consolidated statement of operations.

A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the corresponding establishment of a new cost basis for the security. Premiums and discounts are amortized (accreted) over the life of the related security as an adjustment to its yield. Dividend and interest income are recognized when earned. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of investments sold.

Trade accounts receivable

The allowance for credit losses is based on the Company's assessment of the collectability of customer accounts. The Company makes estimates of expected credit losses for the allowance for doubtful accounts by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, current economic and regulatory conditions that may affect a customer's ability to pay, and estimates of expected future losses. The Company's bad debt expense for the years ended December 31, 2025 and 2024 and the allowance for credit losses as of December 31, 2025 and 2024 were immaterial.

Credit losses – Available-for-sale debt securities

The Company periodically assesses its available-for-sale investments for other-than-temporary impairment. For debt securities in an unrealized loss position, the Company first considers its intent to sell, or whether it is more likely than not that the Company will be required to sell the debt securities before recovery of their amortized cost basis. If either of these criteria are met, the amortized cost basis of such debt securities is written down to fair value through interest and other, net.

For debt securities in an unrealized loss position that do not meet the aforementioned criteria, the Company assesses whether the decline in the fair value of such debt securities has resulted from credit losses or other factors. The Company considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and any adverse conditions specifically related to the securities, among other factors. If this assessment indicates that a credit loss may exist, the Company then compares the present value of cash flows expected to be collected from such securities to their amortized cost basis. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded through interest and other, net, limited by the amount that the fair value is less than the amortized cost basis. Any additional impairment not recorded through an allowance for credit losses is recognized in other comprehensive income.

Changes in the allowance for credit losses are recorded as provision for, or reversal of, credit loss expense. Losses are charged against the allowance when the Company believes that an available-for-sale security is confirmed uncollectable or when either of the criteria regarding intent or requirement to sell is met.

Inventories

Inventories are stated at the lower of cost or net realizable value, on a first-in, first-out, or FIFO, basis. The Company's inventories uses actual costs to determine its cost basis. The cost of inventories includes direct material cost, direct labor and manufacturing overhead.

When the technical feasibility of the Company's future commercialization is considered probable and the future economic benefit is expected to be realized, based on management's judgment, the Company capitalizes pre-launch inventory costs prior to regulatory approval. A number of factors are considered, including the status in the validation process in significant jurisdictions, regulatory application and approval process, and terms and condition for future sale of such inventory or future alternative use. The pre-launch inventory cost includes purchase cost of raw materials, cost paid to contract manufacturers for inventory manufacturing, freight and custom charges, and certain direct internal labor and overhead expenses.

The Company periodically reviews its inventories to identify obsolete, slow-moving, excess or otherwise unsaleable items. If obsolete, excess or unsaleable items are observed and there are no alternate uses for the inventory, an inventory valuation adjustment is recorded through a charge to cost of goods sold on the Company's consolidated statements of operations. Inventory valuation adjustments require judgment including consideration of many factors, such as estimates of future product demand and product expiration period, among others.

Variable Interest Entity

Under the Accounting Standards Codification ("ASC") 810, *Consolidation* ("ASC 810"), when the Company obtains an economic interest in an entity, it evaluates the entity to determine if it should be deemed a VIE, and, if so, whether the Company is the primary beneficiary and is therefore required to consolidate the VIE, based on significant judgment whether the Company (i) has the power to direct the activities that most significantly impact the economic performance of the VIE and (ii) has the obligation to absorb losses or the right to receive benefits of the VIE that could potentially be significant to the VIE.

On an ongoing basis, the Company re-evaluates the VIE assessment based on potential changes in facts and circumstances, including but not limited to, the shareholder loans to the entity and the execution of any future significant agreements between the entity and its shareholders and/or other third parties.

Liability Related to Sale of Future Revenues

The Company accounts for the sale of future revenue as a debt, because the risks and rewards to the investor are limited by the terms of the transaction as discussed further in Note 9, *Liability Related to Sale of Future Revenues*. The difference between the carrying amount of the initial liability and the gross proceeds received is accounted for as a discount. The Company recognizes interest expense based on an estimated effective annual interest rate, which is affected by the amount and timing of revenues recognized and changes in the timing of forecasted revenues. Quarterly, the Company reassesses the expected revenues and the timing of such revenues, recalculates the amortization and effective interest rate and adjusts the accounting prospectively as needed.

Revenue Recognition

Revenues under collaboration agreements

The Company's collaboration agreements include multiple performance obligations comprised of promised services, or bundles of services, that are distinct. Services that are not distinct are combined with other services in the agreement until they form a distinct bundle of services. The Company's process for identifying performance obligations and an enumeration of each obligation for each agreement is outlined in Note 4, *Collaboration Agreements, License Agreement and Revenues*. Determining the performance obligations within a collaboration agreement often involves significant judgment and is specific to the facts and circumstances contained in each agreement.

The Company has identified the following material promises under its collaboration agreements: (1) license of the Company's technology, (2) the performance of co-development services, including manufacturing of clinical supplies and other services during the development period, and (3) manufacture of commercial supply. The evaluation as to whether these promises are distinct, and therefore represent separate performance obligations, is described in more detail in Note 4, *Collaboration Agreements, License Agreement and Revenues*.

For revenue recognition purposes, the Company determines that the terms of its collaboration agreements begin on the effective date and end upon the completion of all performance obligations contained in the agreements. In each agreement, the contract term is defined as the period in which parties to the contract have present and enforceable rights and obligations. The Company believes that the existence of what it considers to be substantive termination penalties on the part of the counterparty create sufficient incentive for the counterparty to avoid exercising its right to terminate the agreement.

The transaction price for each collaboration agreement is determined based on the amount of consideration the Company expects to be entitled for satisfying all performance obligations within the agreement. The Company's collaboration agreements include payments to the Company of one or more of the following: non-refundable upfront license fees; co-development billings; development, regulatory, and commercial milestone payments; payments from sales of active pharmaceutical ingredient ("API"); payments from sales of bulk drug product and royalties on net sales of licensed products.

Upfront license fees are non-contingent and non-refundable in nature and are included in the transaction price at the point when the license fees become due to the Company. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Co-development billings resulting from the Company's research and development efforts, which are reimbursable under its collaboration agreements, are considered variable consideration. Determining the reimbursable amount of research and development efforts requires detailed analysis of the terms of the collaboration agreements and the nature of the research and development efforts incurred. Prior to CKD approval in the third quarter of 2021, determining the amount of variable consideration from co-development billings required the Company to make estimates of future research and development efforts, which involved significant judgment. Co-development billings are allocated entirely to the co-development services performance obligation when amounts are related specifically to research and development efforts necessary to satisfy the performance obligation, and such an allocation is consistent with the allocation objective.

Milestone payments are also considered variable consideration, which requires the Company to make estimates of when achievement of a particular milestone becomes probable. Similar to other forms of variable consideration, milestone payments are included in the transaction price when it becomes probable that such inclusion would not result in a significant revenue reversal. Milestones are therefore included in the transaction price when achievement of the milestone becomes probable.

For arrangements that include sales-based royalties and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

The transaction price is allocated to performance obligations based on their relative standalone selling price ("SSP"), with the exception of co-development billings allocated entirely to co-development services performance obligations. The SSP is determined based on observable prices at which the Company separately sells the products and services. If an SSP is not directly observable, then the Company will estimate the SSP considering marketing conditions, entity-specific factors, and information about the customer or class of customer that is reasonably available. The process for determining SSP involves significant judgment and includes consideration of multiple factors, including assumptions related to the market opportunity and the time needed to commercialize a product candidate pursuant to the relevant license, estimated direct expenses and other costs, which include the rates normally charged by contract research and contract manufacturing organizations for development and manufacturing obligations, and rates that would be charged by qualified outsiders for committee services.

Significant judgment may be required in determining whether a performance obligation is distinct, determining the amount of variable consideration to be included in the transaction price, and estimating the SSP of each performance obligation. An enumeration of the Company's significant judgments is outlined in Note 4, *Collaboration Agreements, License Agreement and Revenues*.

For each performance obligation identified within an arrangement, the Company determines the period over which the promised services are transferred and the performance obligation is satisfied. Service revenue that was recognized over time was based on progress toward complete satisfaction of the performance obligation. For each performance obligation satisfied over time, the Company assesses the proper method to be used for revenue recognition, either an input method to measure progress toward the satisfaction of services or an output method of determining the progress of completion of performance obligation.

Drug product revenue

Drug product revenue includes commercial-grade API or bulk drug product sales to AstraZeneca and Astellas in support of pre-commercial preparation prior to the New Drug Application ("NDA") or Marketing Authorization Application approval, and to Astellas for ongoing commercial activities in Japan and Europe. Drug product revenue is recognized when the Company fulfills 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. Estimating variable consideration and the related constraint requires the use of significant management judgment. The Company reviews new information that may affect its variable consideration estimate at every reporting period and records revenue adjustment, if certain and material. Actual amounts of consideration ultimately received in the future may differ from the Company's estimates, for which the Company will adjust these estimates and affect the drug product revenue in the period such variances become known.

As each of the Company's collaboration agreements provide for annual true up to the considerations paid for its commercial supplies, the Company will re-evaluate the transaction price in each reporting period and record adjustment to revenue as uncertain events are resolved or other changes in circumstances occur.

China Performance Obligation

Product revenue, net, which is included in the discontinued operations, consists primarily of revenues from sales of roxadustat commercial product to Falikang. Falikang is jointly owned by AstraZeneca and FibroGen Beijing.

Falikang is FibroGen Beijing's primary customer in China and substantially all roxadustat product sales to distributors in China are made by Falikang. Falikang bears inventory risk once it receives and accepts the product from FibroGen Beijing, and is responsible for delivering product to its distributors.

The promises identified under the AstraZeneca China Agreement (as defined in Note 4, *Collaboration Agreements, License Agreement and Revenues*), including the license, co-development services and manufacturing of commercial supplies have been bundled into a single performance obligation ("China Performance Obligation"). Amounts of the transaction price allocable to this performance obligation under the Company's agreements with AstraZeneca as outlined in Note 4, *Collaboration Agreements, License Agreement and Revenues,* are deferred until control of the manufactured commercial product is transferred to AstraZeneca.

The initiation of roxadustat sales to Falikang marks the beginning of the China Performance Obligation. Revenue is recognized at a point in time when control of roxadustat commercial product is transferred to Falikang. Revenue is recognized based on the estimated transaction price per unit and actual quantity of product delivered during the reporting period. Specifically, the transaction price per unit is determined based on the overall transaction price over the total estimated sales quantity for the estimated performance period in which the Company determined it is likely those sales would occur. The price per unit is subject to reassessment on a quarterly basis, which may result in cumulative catch up adjustments due to changes in estimates.

The overall transaction price for FibroGen Beijing's product sales to Falikang includes the following elements of consideration:

- Non-refundable upfront license fees; development, regulatory, and commercial milestone payments based on the AstraZeneca China Agreement allocated to the China Performance Obligation;
- Co-development billings resulting from the Company's research and development efforts, which are reimbursable under the AstraZeneca China Agreement;
- Interim profit/loss share between FibroGen Beijing and AstraZeneca from April 1, 2020 through December 31, 2020; and
- Net transaction price from product sales to Falikang from January 1, 2021 onwards. The net transaction price includes the following elements:
    - Gross transaction price: The gross transaction price is based on a percentage of Falikang's net sales to its distributors, which takes into account Falikang's operating expenses and its payments to AstraZeneca for roxadustat sales and marketing efforts, capped at a percentage of Falikang's net roxadustat sales.
    - Profit share: The gross transaction price is then adjusted for an estimated amount to achieve the 50/50 profit share from current period roxadustat net sales in China. The adjustments to date have been a reduction to the transaction price and the related accounts receivable from Falikang.

The non-refundable upfront license fees constitute a fixed consideration. The remainder of the above are variable consideration components, which may be constrained, and included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period when the uncertainty associated with the variable consideration is subsequently resolved. The calculation of the above variable consideration includes significant assumptions such as total sales quantity, performance period, gross transaction price and profit share, which require significant judgment.

Any net transaction price in excess of the revenue recognized is deferred, and will be recognized over future periods as the performance obligations are satisfied. As of December 31, 2024, the related deferred revenues were not included in the disposal group held for sale as the related obligation to AstraZeneca would be satisfied upon the closing of the divestiture FibroGen International. 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. As a result, all the previously deferred revenues were recognized as revenue during the year ended December 31, 2025. The product revenue recognized under the China Performance Obligation is included in discontinued operations for all periods presented. See Note 3, *Discontinued Operations and Divestiture,* for more details.

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 costs include employee-related expenses, expenses incurred under agreements with clinical research organizations, other clinical and preclinical costs and allocated direct and indirect overhead costs, such as facilities costs, information technology costs and other overhead. All research and development costs are expensed as incurred.

Clinical Trial Accruals

Clinical trial costs are a component of research and development expenses. The Company accrues and expenses clinical trial activities performed by third parties based upon actual work completed in accordance with agreements established with clinical research organizations and clinical sites. The Company determines the costs to be recorded based upon validation with the external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services.

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses consist primarily of employee-related expenses for executive, operational, finance, legal, compliance and human resource functions. SG&A expenses also include facility-related costs, professional fees, accounting and legal services, other outside services, recruiting fees and expenses associated with obtaining and maintaining patents.

Restructuring Charge

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

Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes, which requires the recognition of deferred tax assets and liabilities for expected future consequences of temporary differences between the financial reporting and income tax bases of assets and liabilities using enacted tax rates. Management makes estimates, assumptions and judgments to determine the Company's provision for income taxes and for deferred tax assets and liabilities, and any valuation allowances recorded against the Company's deferred tax assets. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent the Company believes that recovery is not likely, the Company must establish a valuation allowance.

The calculation of the Company's current provision for income taxes involves the use of estimates, assumptions and judgments while taking into account current tax laws, interpretation of current tax laws and possible outcomes of future tax audits. The Company has established reserves to address potential exposures related to tax positions that could be challenged by tax authorities. Although the Company believes its estimates, assumptions and judgments to be reasonable, any changes in tax law or its interpretation of tax laws and the resolutions of potential tax audits could significantly impact the amounts provided for income taxes in the Company's consolidated financial statements.

The calculation of the Company's deferred tax asset balance involves the use of estimates, assumptions and judgments while taking into account estimates of the amounts and type of future taxable income. Actual future operating results and the underlying amount and type of income could differ materially from the Company's estimates, assumptions and judgments thereby impacting the Company's financial position and results of operations.

The Company has adopted ASC 740-10, *Accounting for Uncertainty in Income Taxes*, that prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in the Company's income tax return, and also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The Company includes interest and penalties related to unrecognized tax benefits within income tax expense in the Consolidated Statements of Operations.

Stock-Based Compensation

The Company maintains equity incentive plans under which equity awards are granted to employees, which are comprised of stock options, service-based restricted stock units ("RSUs"), performance-based RSUs ("PRSUs"), and total shareholder return ("TSR") awards.

The Company measures and recognizes compensation expense for all stock options, RSUs and PRSUs granted to its employees and directors based on the estimated fair value of the award on the grant date. The Company uses the Black-Scholes valuation model to estimate the fair value of stock option awards. The determination of the grant date fair value of options using the Black-Scholes valuation model is affected by the Company's estimated common stock fair value and requires management to make a number of assumptions including the expected life of the option, the volatility of the underlying stock, the risk-free interest rate and expected dividends. The Company determines the fair value of RSUs and PRSUs using the fair value of its common stock on the date of grant. To estimate the fair value of the TSR awards, the Company uses the Monte Carlo valuation model to simulate the probabilities of achievement, which requires management to make a number of assumptions including 30-day average price, volatility of the underlying stock and the Company's peers, and the risk-free interest rate.

The compensation cost of service-based stock options and restricted stock units is recognized net of any estimated forfeitures on a straight-line basis over the employee requisite service period. Compensation cost for PRSUs is expensed over the respective vesting periods when the achievement of performance criteria is probable. Compensation cost for the TSR awards is recognized over the requisite service period, regardless of when, if ever, the market condition is satisfied.

The Company believes that the fair value of stock options granted to non-employees is more reliably measured than the fair value of the services received.

Comprehensive Income (Loss)

The Company is required to report all components of comprehensive income (loss), including net income (loss), in the consolidated financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on investments and foreign currency translation adjustments. Comprehensive gains (losses) have been reflected in the consolidated statements of comprehensive income (loss) for all periods presented.

Recently Adopted Accounting Guidance

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires enhanced income tax disclosures, including specific categories and disaggregation of information in the effective tax rate reconciliation, disaggregated information related to income taxes paid, income or loss from continuing operations before income tax expense or benefit, and income tax expense or benefit from continuing operations. This guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company adopted this guidance in 2025 using a prospective transition method. The adoption resulted in expanded disclosures and did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Guidance Not Yet Adopted

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40),* which 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.

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 Limited. This sale includes 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 consolidated statements of operations, while the related assets and liabilities were classified within the consolidated balance sheets as held for sale for all periods presented.

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

The financial results of the discontinued operations with respect to FibroGen International reflected in the consolidated statements of operations for the years ended December 31, 2025 and 2024 were as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Revenue:		
Product revenue, net	$ 226,651	$ 173,664
Operating costs and expenses:		
Cost of goods sold	13,454	21,036
Research and development	1,739	7,375
Selling, general and administrative	14,849	32,304
Total operating costs and expenses	30,042	60,715
Income from operations	196,609	112,949
Interest and other, net		
Interest expense	(7,816)	(11,683)
Gain on divestiture	52,553	—
Interest income and other income (expenses), net	(2,173)	423
Total interest and other, net	42,564	(11,260)
Income before income taxes	239,173	101,689
Provision for income taxes	—	139
Investment income in unconsolidated variable interest entity	2,483	3,969
Income from discontinued operations, net of tax	$ 241,656	$ 105,519

The product revenue, net, consists primarily of revenues from sales of roxadustat commercial product to Falikang, a distribution entity jointly owned by AstraZeneca and FibroGen Beijing, and is discussed in the *China Performance Obligation* section in Note 4, *Collaboration Agreements, License Agreement and Revenues*.

The gain on divestiture of $52.6 million resulted from the above-mentioned total consideration of $220.4 million and additional payment of $0.4 million related to the first holdback, 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.

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

	December 31, 2024
Assets	
Cash and cash equivalents	$ 51,696
Accounts receivable, net	18,443
Inventories	15,547
Prepaid expenses and other current assets	25,163
Total current assets held for sale	110,849
Property and equipment, net	7,041
Equity method investment in unconsolidated variable interest entity	6,864
Operating lease right-of-use assets	1,716
Other assets	990
Total long-term assets held for sale	16,611
Liabilities	
Accounts payable	$ 26,974
Accrued and other current liabilities	10,679
Operating lease liabilities, current	1,264
Total current liabilities held for sale	38,917
Operating lease liabilities, non-current	356
Total long-term liabilities held for sale	356

The significant non-cash items and capital expenditures for the discontinued operations with respect to FibroGen International included in the consolidated statements of cash flows for the years ended December 31, 2025 and 2024 were as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Depreciation	$ 713	$ 1,458
Investment income in unconsolidated variable interest entity	(2,486)	(3,969)
Gain on divestiture	(52,553)	—
Impairment of property and equipment	2,062	—
Dividend received from unconsolidated variable interest entity	3,947	2,230
Stock-based compensation	$ 231	$ 1,770

Included in the discontinued operations, Falikang, an entity jointly owned by FibroGen Beijing and AstraZeneca is an unconsolidated VIE accounted for as an equity method investment, and considered as a related party to the Company. FibroGen Beijing owns 51.1% of Falikang's equity.

For the years ended December 31, 2025 and 2024, the net product revenue from sales to Falikang were $218.6 million and $159.0 million, respectively. The other income from Falikang were immaterial for the years ended December 31, 2025 and 2024.

For the years ended December 31, 2025 and 2024, the investment income in Falikang was $2.5 million and $4.0 million, respectively. As of December 31, 2024, the Company's equity method investment in Falikang were $6.9 million which was included in the long-term assets held for sale on the consolidated balance sheets. As of December 31, 2024 accounts receivable, net, from Falikang were $13.9 million which were included in the current assets held for sale on the consolidated balance sheets.

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

The aggregate amount of the considerations received under the Astellas Japan Agreement, through December 31, 2025 totals $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 years ended December 31, 2025 and 2024.

The transaction price related to consideration received through December 31, 2025 and accounts receivable has been allocated to each of the performance obligations under the Astellas Japan Agreement, including $100.3 million for license and $17.1 million for co-development.

There was no license revenue or development revenue resulting from changes to estimated variable consideration in the current period relating to performance obligations satisfied or partially satisfied in previous periods for the year ended December 31, 2025 under the Astellas Japan Agreement. The Company does not expect material variable consideration from estimated future co-development billing beyond the development period in the transaction price related to the Astellas Japan Agreement.

In 2018, 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"). Under this amendment, the Company would continue to manufacture and supply roxadustat API to Astellas for the roxadustat commercial activities in Japan. The commercial terms of the Astellas Japan Agreement relating to the transfer price for roxadustat for commercial use remain substantially the same, reflecting an adjustment for the manufacture of drug product by Astellas rather than the Company. The related drug product revenue is described under the *Drug Product Revenue, Net* section below.

Astellas Europe Agreement

In April 2006, the Company entered into a separate collaboration agreement with Astellas for the development and commercialization of roxadustat for the treatment of anemia in Europe, the Middle East, the Commonwealth of Independent States and South Africa ("Astellas Europe Agreement"). Under the terms of the Astellas Europe Agreement, Astellas agreed to pay license fees, other upfront consideration and various milestone payments, totaling $745.0 million. Under the Astellas Europe Agreement, Astellas committed to fund 50% of joint development costs for Europe and North America, and all territory-specific costs. The Astellas Europe Agreement also provides for tiered payments based on net sales of product (as defined) in the low 20% range.

The aggregate amount of the considerations received under the Astellas Europe Agreement through December 31, 2025 totals $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 years ended December 31, 2025 and 2024.

The transaction price related to consideration received through December 31, 2025 and accounts receivable has been allocated to each of the performance obligations under the Astellas Europe Agreement, including $619.0 million for license and $288.7 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 year ended December 31, 2025 under the Astellas Europe Agreement. The Company does not expect material variable consideration from estimated future co-development billing beyond the development period in the transaction price related to the Astellas Europe Agreement.

During the first quarter of 2021, the Company entered into an EU Supply Agreement with Astellas ("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.

Accounting for the Astellas Agreements

For each of the Astellas agreements, the Company has evaluated the promised services within the respective arrangements and has identified performance obligations representing those services and bundles of services that are distinct.

Promised services that were not distinct have been combined with other promised services to form a distinct bundle of promised services, with revenue being recognized on the bundle of services rather than the individual services. There are no right-of-return provisions for the delivered items in the Astellas agreements.

As of December 31, 2025, the transaction price for the Astellas Japan Agreement, excluding manufacturing services that is discussed separately below, included $40.1 million of non-contingent upfront payments, $65.0 million of variable consideration related to payments for milestones achieved, and $12.4 million of variable consideration related to co-development billings. The transaction price for the Astellas Europe Agreement, excluding manufacturing services that is discussed separately below, included $320.0 million of non-contingent upfront payments, $365.0 million of variable consideration related to payments for milestones achieved, and $222.5 million of variable consideration related to co-development billings.

For the technology license under the Astellas Japan Agreement and the Astellas Europe Agreement, SSP was determined primarily by using the discounted cash flow ("DCF") method, which aggregates the present value of future cash flows to determine the valuation as of the effective date of each of the agreements. The DCF method involves the following key steps: 1) the determination of cash flow forecasts and 2) the selection of a range of comparative risk-adjusted discount rates to apply against the cash flow forecasts. The discount rates selected were based on expectations of the total rate of return, the rate at which capital would be attracted to the Company and the level of risk inherent within the Company. The discounts applied in the DCF analysis ranged from 17.5% to 20.0%. The Company's cash flow forecasts were derived from probability-adjusted revenue and expense projections by territory. Such projections included consideration of taxes and cash flow adjustments. The probability adjustments were made after considering the likelihood of technical success at various stages of clinical trials and regulatory approval phases. SSP also considered certain future royalty payments associated with commercial performance of the Company's compounds, transfer prices and expected gross margins.

The promised services that were analyzed, along with their general timing of satisfaction and recognition as revenue, are as follows:

(1) *License to the Company's technology existing at the effective date of the agreements.* For both of the Astellas agreements, the license was delivered at the beginning of the agreement term. In both cases, the Company concluded at the time of the agreement that its collaboration partner, Astellas, would have the knowledge and capabilities to fully exploit the licenses without the Company's further involvement. However, the Astellas Japan Agreement has contractual limitations that might affect Astellas' ability to fully exploit the license and therefore, potentially, the conclusion as to whether the license is capable of being distinct. The Company considered the fact that at the time of delivery of the license, the development services were beyond the preclinical development phase and any remaining development work in either agreement would not be expected to result in any significant modification or customization to the licensed technology. As such, the development services are separately identifiable from the licensed technology, indicating that the license is a distinct performance obligation. The portion of the transaction price allocated to this performance obligation based on a relative SSP basis was recognized as revenue in its entirety at the point in time the license transfers to Astellas.

(2) *Co-development services (Astellas Europe Agreement).* This promise relates to co-development services that were reasonably expected to be performed by the Company at the time the collaboration agreement was signed and is considered distinct. Co-development billings are allocated entirely to the co-development services performance obligation as amounts are related specifically to research and development efforts necessary to satisfy the performance obligation related to CKD approval, and such an allocation is consistent with the allocation objective. Subsequent to the approval of CKD in 2021, the Company accounts for the development services for the indications related to chemotherapy-induced anemia and MDS separately as services are provided. There was no provision for co-development services in the Astellas Japan Agreement.

(3) *License to the Company's technology developed during the term of the agreement and development (referred to as "when and if available") and information sharing services.* These promises are generally satisfied throughout the term of the agreements.

(4) *Manufacturing of clinical supplies of products.* This promise is satisfied as supplies for clinical product are delivered for use in the Company's clinical trial programs during the development period, or pre-commercialization period.

(5) *Committee service*. This promise is satisfied throughout the course of the agreements as meetings are attended.

Items (2)-(5) are bundled into a single performance obligation that is distinct given the fact that all are highly interrelated during the development period (pre-commercial phase of development) such that satisfying them independently is not practicable. For the revenue recognized over time based on progress toward complete satisfaction of the performance obligation, the Company uses an input method to measure progress toward the satisfaction of the performance obligation, which is based on costs of labor hours or full time equivalents and out-of-pocket expenses incurred relative to total expected costs to be incurred, and updates the measure of progress in each reporting period.

(6) *Manufacturing commercial supplies of products.* This promised service is distinct as services are not interrelated with any of the other performance obligations. Payments received for commercial supplies of products represent sales-based payments related predominately to the license of intellectual property under both Astellas agreements. Revenue is recognized as supplies are shipped for commercial use during the commercialization period. See the *Drug Product Revenue, Net* section below.

Under the Astellas Japan Amendment, the drug product revenue represents variable consideration and is estimated based on the quantity of product shipped, actual listed price for roxadustat issued by the Japanese Ministry of Health, Labour and Welfare and possible future changes to the listed price, adjusted for the timing of and estimated bulk product strength mix intended to be manufactured by Astellas, estimated cost to convert the API to bulk drug product tablets, and estimated yield from the manufacture of bulk product tablets, among others.

Under the Astellas Europe Agreement, the drug product revenue amount represents variable consideration and is estimated based on the quantity of product transferred and an estimated price. The estimated price is based on the contractual transfer price percentage applied on the estimated weighted average net sales price per strength, which is estimated to be realized by Astellas from the end sale of roxadustat in its approved territories.

AstraZeneca Agreements

AstraZeneca U.S./Rest of World Agreement

Effective July 30, 2013, the Company entered into a collaboration agreement with AstraZeneca for the development and commercialization of roxadustat for the treatment of anemia in the U.S. and all other countries in the world, other than China, not previously licensed under the Astellas Europe and Astellas Japan Agreements ("AstraZeneca U.S./RoW Agreement").

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. Pursuant to the AstraZeneca Termination and Transition Agreement, AstraZeneca returns all of their non-China roxadustat rights to the Company, with the exception of South Korea, and provides certain assistance during a transition period. In addition, as a part of this AstraZeneca Termination and Transition Agreement, AstraZeneca will receive tiered mid-single digit royalties on the Company's sales of roxadustat in the terminated territories, or thirty-five percent of all revenue the Company receives if it licenses or sells such rights to a third-party. Neither party incurred any early termination penalties.

The aggregate amount of the considerations received under the AstraZeneca U.S./RoW Agreement through December 31, 2025 totals $439.0 million, excluding drug product revenue under the Master Supply Agreement with AstraZeneca under the AstraZeneca U.S./RoW Agreement ("AstraZeneca Master Supply Agreement"), entered in 2020, which is described under the *Drug Product Revenue, Net* section below. In addition, resulting from the AstraZeneca Termination and Transition Agreement, the Company and AstraZeneca settled the outstanding balances relating to past transactions under the AstraZeneca Master Supply Agreement. Accordingly, during the first quarter of 2024, the Company accounted for the termination of the AstraZeneca U.S./RoW Agreement as a contract modification under the Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("ASC 606") and recorded a cumulative catch-up adjustment as described under the *Drug Product Revenue, Net* section below.

AstraZeneca China Agreement

AstraZeneca was the Company's long-time commercialization partner for roxadustat in greater China. 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"). Under the terms of the AstraZeneca China Agreement, AstraZeneca agreed to pay upfront consideration and potential milestone payments, totaling $376.7 million. The aggregate amount of such considerations received for milestone and upfront payments through the third quarter of 2025 totals $81.2 million. As discussed in Note 3, *Discontinued Operations and Divestiture,* on August 29, 2025, the Transaction was completed to sell the Company's China operations to AstraZeneca pursuant to the Share Purchase Agreement.

AstraZeneca China Amendment

In July 2020, FibroGen China Anemia Holdings, Ltd., FibroGen Beijing, and FibroGen International (Hong Kong) Limited and AstraZeneca entered into an amendment, relating to the development and commercialization of roxadustat in China (the "AstraZeneca China Amendment"). Under the AstraZeneca China Amendment, in 2020, FibroGen Beijing and AstraZeneca completed the establishment of a jointly owned entity, Falikang, which performs roxadustat distribution, as well as conducts sales and marketing through AstraZeneca.

Substantially all direct roxadustat product sales to distributors in China are made by Falikang, while FibroGen Beijing continues to sell roxadustat product directly in limited areas in China. FibroGen Beijing manufactures and supplies commercial product to Falikang based on a gross transfer price, which is adjusted for the estimated profit share. Further discussion related to the sales to Falikang is discussed under the *China Performance Obligation* section below.

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

The related net product revenue recognized from the sales to Falikang is discussed under the *China Performance Obligation* section below. The related net product revenue recognized from the sales to Falikang was $218.6 million and $159.0 million for the years ended December 31, 2025 and 2024, respectively, and were included in the discontinued operations in the consolidated statements of operations together with the sales directly to distributors, resulting from the Share Purchase Agreement with AstraZeneca Treasury Limited as discussed in Note 3, *Discontinued Operations and Divestiture*.

Accounting for the AstraZeneca Agreements

The Company evaluated whether the AstraZeneca U.S./RoW Agreement and the AstraZeneca China Agreement should be accounted for as a single or separate arrangements and concluded that the agreements should be accounted for 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, and therefore upfront and other non-contingent consideration received and to be received has been pooled together and allocated to each of the performance obligations in both the AstraZeneca U.S./RoW Agreement and the AstraZeneca China Agreement based on their relative SSPs.

For each of the AstraZeneca agreements, the Company has evaluated the promised services within the respective arrangements and has identified performance obligations representing those services and bundled services that are distinct.Promised services that were not distinct have been combined with other promised services to form a distinct bundle of promised services, with revenue being recognized on the bundle of services rather than the individual promised services. There are no right-of-return provisions for the delivered items in the AstraZeneca agreements.

The transaction price related to consideration received and accounts receivable through the termination of the AstraZeneca U.S./RoW Agreement has been allocated to each of the performance obligations under the AstraZeneca U.S./RoW Agreement and AstraZeneca China Agreement, including $344.5 million for license, $625.5 million for co-development, information sharing and committee services, and $573.4 million for China Performance Obligation (cumulative revenue through the third quarter of 2025) that is recognized as product revenue, net, included in discontinued operations as described under *China Performance Obligation* section below.

For the AstraZeneca agreements, the Company allocated the transaction price to the various performance obligations based on the relative SSP of each performance obligation, with the exception of co-development billings and commercial sale of product. Co-development billings under the AstraZeneca U.S./RoW Agreement were allocated entirely to the U.S./RoW co-development services performance obligation, and co-development billings under the AstraZeneca China Agreement were allocated entirely to the combined performance obligation under the AstraZeneca China Agreement. Commercial sale of product under the AstraZeneca U.S./RoW Agreement is entirely allocated to the manufacturing commercial supply of products performance obligation, and commercial sale of product under the AstraZeneca China Agreement is allocated entirely to the combined China Performance Obligation.

In accordance with the AstraZeneca China Amendment, substantially all product sales will be made by Falikang directly to the distributors in China, while the Company continues to sell directly in one province in China. Revenue is recognized at a point in time when control of roxadustat commercial product is transferred to Falikang. See the *China Performance Obligation* section below. The related net product revenue is included in the discontinued operations in the consolidated statements of operations, resulting from the Share Purchase Agreement with AstraZeneca Treasury Limited as discussed in Note 3, *Discontinued Operations and Divestiture*.

China Performance Obligation

Product revenue, net, which is included in the discontinued operations, consists primarily of revenues from sales of roxadustat commercial product to Falikang. Substantially all direct roxadustat product sales to distributors in China are made by Falikang. FibroGen Beijing manufactures and supplies commercial product to Falikang. The net transaction price for FibroGen Beijing's product sales to Falikang is based on a gross transaction price, adjusted for the estimated profit share.

The roxadustat sales to Falikang marked the beginning of the Company's China Performance Obligation under the Company's agreements with AstraZeneca. Product revenue is based on the transaction price of the China Performance Obligation. Revenue is recognized when control of the product is transferred to Falikang, in an amount that reflects the allocation of the transaction price to the performance obligation satisfied during the reporting period. Periodically, the Company updates its assumptions such as total sales quantity, 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 is added to the deferred balance, and recognized in future periods as the performance obligation is satisfied.

As discussed in Note 3, *Discontinued Operations and Divestiture,* 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. As a result, all the previously deferred revenues were recognized as revenue during the third quarter of 2025. The following table includes a roll-forward of the related deferred revenue that was considered as a contract liability that was not included in the disposal group held for sale as of December 31, 2024 (in thousands):

	Balance at December 31, 2024	Additions	Recognized as Revenue (Discontinued Operations)	Currency Translation and Other	Balance at December 31, 2025
AstraZeneca China performance obligation - deferred revenue	$ (132,097)	$ (82,494)	$ 218,575	$ (3,984)	$ —

The related net product revenue recognized from the sales to Falikang was $218.6 million and $159.0 million for year ended December 31, 2025 and 2024, respectively, which were included in the discontinued operations in the consolidated statements of operations together with the sales directly to distributors.

Drug Product Revenue, Net

Drug product revenue from commercial-grade API or bulk drug product sales to Astellas and AstraZeneca was as follows for the years ended December 31, 2025 and 2024 (in thousands):

	Years Ended December 31,	
	2025	2024
Astellas Japan Agreement	$ 793	$ (2,872)
Astellas Europe Agreement	5,055	4,874
AstraZeneca U.S./RoW Agreement	—	25,671
Drug product revenue, net	$ 5,848	$ 27,673

Astellas Japan Agreement

For the year ended December 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 $0.8 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 bulk product strength mix intended to be manufactured by Astellas and foreign exchange impacts, among others.

For the year ended December 31, 2024, the Company updated its estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment, and accordingly recorded a reduction to the drug product revenue of $2.9 million. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect the changes in the estimated bulk product strength mix intended to be manufactured by Astellas and foreign exchange impacts, among others.

As of December 31, 2025, the balances related to the API price true-up under the Astellas Japan Agreement were $1.6 million in accrued liabilities, representing the Company's best estimate of the timing for these amounts to be paid. As of December 31, 2024, the balances related to the API price true-up under the Astellas Japan Agreement were $2.5 million in accrued liabilities and $0.6 million in other long-term liabilities.

Astellas Europe Agreement

During the fourth quarter of 2025, 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 $0.3 million as drug product revenue, and recorded $2.2 million as deferred revenue due to a high degree of uncertainty associated with the variable consideration for revenue recognition purposes. In addition, the Company updated its estimate of variable consideration related to the bulk drug product transferred in prior years. Specifically, the change in estimated variable consideration was based on the bulk drug product held by Astellas at the period end, adjusted to reflect the changes in the estimated transfer price, forecast information, shelf-life estimates and other items. As a result, for the year ended December 31, 2025, the Company reclassified $1.8 million from the related deferred revenue to accrued liabilities. As of December 31, 2025, the related balance in accrued liabilities was $5.4 million, representing the Company's best estimate that this amount will be paid within the next 12 months.

During the fourth quarter of 2024, the Company transferred bulk drug product for commercial purposes under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement, and recognized the related fully-burdened manufacturing costs of $0.6 million as drug product revenue, and recorded $4.4 million as deferred revenue due to a high degree of uncertainty associated with the variable consideration for revenue recognition purposes. In addition, the Company updated its estimate of variable consideration related to the bulk drug product transferred in prior years. Specifically, the change in estimated variable consideration was based on the bulk drug product held by Astellas at the period end, adjusted to reflect the changes in the estimated transfer price, forecast information, shelf-life estimates and other items. As a result, for the year ended December 31, 2024, the Company reclassified $7.2 million from the related deferred revenue to accrued liabilities. As of December 31, 2024, the related balance in accrued liabilities was $10.5 million, and the Company paid $7.1 million to Astellas during the year ended December 31, 2025.

The Company recognized royalty revenue of $4.8 million and $4.3 million as drug product revenue from the deferred revenue under the Astellas Europe Agreement during the years ended December 31, 2025 and 2024, respectively. The remainder of the deferred revenue will be recognized as and when uncertainty is resolved, based on the performance of roxadustat product sales in the Astellas territory.

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

	Balance at December 31, 2024	Additions	Recognized as Revenue	Reclassified to Accrued Liability / Accounts Payable	Balance at December 31, 2025
Drug product revenue - deferred revenue:					
Astellas Europe Agreement	$ (9,901)	$ (2,210)	$ 4,778	$ 1,764	$ (5,569)

AstraZeneca U.S./RoW Agreement

As described under *AstraZeneca Agreements* section above, pursuant to the AstraZeneca Termination and Transition Agreement related to the AstraZeneca U.S./RoW Agreement, the Company and AstraZeneca settled the outstanding balances relating to past transactions under the AstraZeneca Master Supply Agreement. Accordingly, during the year ended December 31, 2024, the Company accounted for the termination of the AstraZeneca U.S./RoW Agreement as a contract modification under the ASC 606 and recorded a cumulative catch-up net adjustment of $25.7 million to the drug product revenue and correspondingly recorded the related cost of goods sold of $14.6 million.

5. Consolidated Variable Interest Entity - Fortis

In May 2023 (the "Option Acquisition Date"), the Company entered into an exclusive option agreement to acquire Fortis Therapeutics ("Fortis") with its novel Phase 1 ADC, FOR46 (now referred to as "FG-3246"), that targets a novel epitope on CD46 preferentially expressed on certain cancer cells. FG-3246 is in development for the treatment of mCRPC with potential applicability in other solid tumors and hematologic malignancies. If the Company exercises the option to acquire Fortis, it will pay Fortis an option exercise payment of $80.0 million, and thereafter, legacy Fortis shareholders would be eligible to receive from the Company up to $200.0 million in contingent payments associated with the achievement of various regulatory approvals. If the Company acquires Fortis, it would also be responsible to pay University of California, San Francisco ("UCSF"), an upstream licensor to Fortis, development milestone fees and a single digit royalty on net sales of therapeutic or diagnostic products arising from the licensing arrangement between Fortis and UCSF. If the Company chooses not to acquire Fortis, its exclusive license to FG-3246 would expire.

Pursuant to an evaluation agreement entered into with Fortis concurrent with the option agreement (together the "Fortis Agreements"), the Company has exclusively licensed FG-3246 and will control and fund future research, development, including a Phase 2 clinical study sponsored by the Company, and manufacturing of FG-3246 option period (which ends on December 31, 2027). As part of the clinical development strategy, the Company will continue the work to develop a PET-based biomarker utilizing a radiolabeled version of the targeting antibody for patient selection. Additionally, the Company is obligated to pay Fortis in support of its continued development activities, and the Company fulfilled such obligation with a last payment of $1.7 million in the first quarter of 2024.

Pursuant to the guidance under ASC 810, the Company determined that Fortis is a VIE and that the Company is the primary beneficiary of Fortis, as through the Fortis Agreements the Company has the power to direct activities that most significantly impact the economic performance of Fortis. Therefore, the Company consolidated Fortis starting from the Option Acquisition Date, and continues to consolidate as of December 31, 2025.

The transaction was accounted for as an asset acquisition under ASC 805, *Business Combinations*, as substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable in-process research and development ("IPR&D") asset. The fair value of the consideration transferred was zero. The Company determined that the above mentioned quarterly payments to support Fortis' continued development obligations should not be included in the purchase consideration, as those payments are payable to Fortis rather than to its shareholders.

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

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

The Company expensed fair value of the acquired IPR&D assets as research and development expense in 2023. The fair value of Fortis (enterprise value) and the fair value of nonredeemable NCI and redeemable NCI were determined based on the above-mentioned option exercise payment of $80.0 million and contingent payments up to $200.0 million, weighted with probability and expected timing of the underlying events, and discounted by the Company's estimated market level cost of debt.

As of December 31, 2025 and 2024, total assets and liabilities of Fortis were immaterial. For the years ended December 31, 2025 and 2024, Fortis' net income (losses) was immaterial.

6. Fair Value Measurements

In accordance with the authoritative guidance on fair value measurements and disclosures under U.S. GAAP, the Company presents all financial assets and liabilities and any other assets and liabilities that are recognized or disclosed at fair value on a nonrecurring basis. The guidance defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair-value measurements. The guidance also requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than quoted prices in active markets for identical assets or liabilities.

Level 3: Unobservable inputs.

The Company values certain assets and liabilities, focusing on the inputs used to measure fair value, particularly in instances where the measurement uses significant unobservable (Level 3) inputs. The Company's financial instruments are valued using quoted prices in active markets (Level 1) or based upon other observable inputs (Level 2). The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and considers factors specific to the asset or liability. In addition, the categories presented do not suggest how prices may be affected by the size of the purchases or sales, particularly with the largest highly liquid financial issuers who are in markets continuously with non-equity instruments, or how any such financial assets may be impacted by other factors such as U.S. government guarantees. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The availability of observable data is monitored to assess appropriate classification of financial instruments within the fair value hierarchy. Depending upon the availability of such inputs, specific securities may transfer between levels. In such instances, the transfer is reported at the end of the reporting period.

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

	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

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

The Company's Level 2 investments are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar investments, issuer credit spreads, benchmark investments, prepayment/default projections based on historical data and other observable inputs. During the years ended December 31, 2025 and 2024, the transfers of assets between levels was a total of $22.8 million and $26.3 million transfer from Level 1 to Level 2, respectively, as such US treasury notes and bills were changed to off-the-run when they were issued before the most recent issue and were still outstanding at measurement day.

7. Balance Sheet Components

Cash and Cash Equivalents

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

	December 31, 2025	December 31, 2024
Cash	$ 2,309	$ 2,004
Commercial paper	11,272	14,269
Money market funds	24,302	28,241
U.S. government bonds	9,989	5,968
Total cash and cash equivalents	$ 47,872	$ 50,482

Investments

As of December 31, 2025, The Company's investments consist primarily of available-for-sale debt investments and the amortized cost, gross unrealized holding gains or losses, and fair value of the Company's investments by major investments type are summarized in the tables below (in thousands):

	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

As of December 31, 2025, the available-for-sale investments had remaining contractual maturities within two years.

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

The Company did not have any short-term or long-term investments as of December 31, 2024.

Prepaid Expenses and Other Current Assets

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

	December 31, 2025	December 31, 2024
Insurance proceeds receivable for litigation settlement	$ —	$ 28,500
Holdback consideration receivable related to divestiture	4,000	—
Prepaid assets	1,015	1,903
Other current assets	1,121	1,139
Total prepaid expenses and other current assets	$ 6,136	$ 31,542

As of December 31, 2025, the Company recorded a $4.0 million receivable in prepaid expenses and other current assets for the second holdback related to the closing of the divestiture of FibroGen International. See Note 3, *Discontinued Operations and Divestiture,* for details.

As of December 31, 2024, the Company recorded a $28.5 million receivable in prepaid expenses and other current assets, corresponding to the accrued litigation settlement of the same amount related to the Company's agreement in principle with plaintiffs to settle the class action lawsuit. As the Company maintains insurance that covers exposure related to the class action lawsuit, this amount is fully recoverable under the Company's insurance policies. The determination that the recorded receivables are probable of collection is based on the terms of the applicable insurance policies and communications with the insurers. Such amount was fully distributed during the first quarter of 2025. As a result, the related accrued liability and the corresponding receivable were fully settled in the same period. See the *Accrued and Other Current Liabilities* section below, and the *Legal Proceedings and Other Matters* section in Note 11, *Commitments and Contingencies*, for details.

Accrued and Other Current Liabilities

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

	December 31, 2025	December 31, 2024
Preclinical and clinical trial accruals	$ 3,066	$ 6,327
API and bulk drug product price true-up	6,977	13,071
Litigation settlement	—	28,500
Payroll and related accruals	3,983	4,640
Accrued restructuring charge	537	4,572
Professional services	2,465	2,049
Current portion of liability related to sale of future revenues	1,334	460
Other	1,821	2,416
Total accrued and other current liabilities	$ 20,183	$ 62,035

The accrued liabilities of $7.0 million and $13.1 million for API and bulk drug product price true-up as of December 31, 2025 and 2024, respectively, resulted from changes in estimated variable consideration associated with the API shipments fulfilled under the terms of the Astellas Japan Amendment, the bulk drug product transferred under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement. During the fourth quarter of 2025, the Company paid $7.1 million to Astellas related to accrued amounts. See the *Drug Product Revenue, Net* section in Note 4, *Collaboration Agreements, License Agreement and Revenues,* for details.

As of December 31, 2024, the accrued litigation settlement of $28.5 million was related to the Company's agreement in principle with plaintiffs to settle the class action lawsuit, which was fully distributed during the first quarter of 2025 as mentioned above. See the *Prepaid Expenses and Other Current Assets* section above, and the *Legal Proceedings and Other Matters* section in Note 11, *Commitments and Contingencies*, for details.

Responding to the reported results for pamrevlumab in July 2024, the Company implemented an immediate and significant cost reduction plan in the U.S., including terminating pamrevlumab research and development investment and expeditiously wind down remaining obligations, and reducing U.S. workforce by approximately 75%. As a result, the Company recorded a total of $19.5 million non-recurring restructuring charge during the year ended December 31, 2024, primarily consisting of notice period and severance payments, accrued vacation, and employee benefits contributions. Total cash payments under the reduction in force were $3.5 million and $16.5 million for the years ended December 31, 2025 and 2024, respectively. The remaining accrued restructuring charge of $0.5 million as of December 31, 2025 will be paid out in 2026.

8. Senior Secured Term Loan Facilities

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

The initial issuance costs and the related transaction costs, totaling $3.7 million were amortized as interest expense using the effective interest method over the term of the Initial Term Loan and were reported on the balance sheet as a direct deduction from the amount of the Initial Term Loan. The effective annual interest rate of the Initial Term Loan was 16.13% for the year ended December 31, 2025. The Company recorded interest expense of $7.8 million and $11.7 million for the year ended December 31, 2025 and 2024, respectively, which were included in discontinued operations as the Company was required to repay the loan upon the closing of the divestiture FibroGen International.

On August 29, 2025, upon the above-mentioned Transaction close, 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, the Company recorded a loss on debt extinguishments of $6.6 million, including the $5.5 million of prepayment premium and fees and a $1.1 million amortization of issuance costs, for the year ended December 31, 2025.

The Company's senior secured term loan facilities as of December 31, 2024 were as follows (in thousands):

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

9. 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 ("Investment Amount") before advisory fees.

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

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

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

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

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

Over the course of the RIFA, the effective interest rate is affected by the amount and timing of drug product revenue and revenue from milestone payments recognized, the changes in the timing of forecasted drug product revenue and revenue from milestone payments, and the timing of the Company's payments to NovaQuest. On a quarterly basis, the Company reassesses the expected total revenue and the timing of such revenue, recalculates the amortization of debt discount and transactions costs and effective interest rate, and adjusts the accounting prospectively as needed. The Company's estimated effective annual interest rate was 15.21% as of December 31, 2025.

The table below shows the activity of the liability related to sale of future revenues for the year ended December 31, 2025 and 2024:

	For the Year Ended December 31,	
	2025	2024
Liability related to sale of future revenues - beginning balance	$ 59,324	$ 57,067
Interest paid	(450)	(5,653)
Interest expense recognized	8,440	7,910
Liability related to sale of future revenues - ending balance	67,314	59,324
Less: Current portion classified to accrued and other current liabilities	(1,334)	(460)
Liability related to sale of future revenues, non-current	$ 65,980	$ 58,864

During the years ended December 31, 2025 and 2024, the Company recognized, under Astellas Agreements, development revenue of $0.6 million and $1.4 million, respectively, and drug product revenue of $5.8 million and $2.0 million, respectively. See Note 4, *Collaboration Agreements, License Agreement and Revenue*, for details.

During the years ended December 31, 2025 and 2024, the Company recognized the related interest expense of $8.4 million and $7.9 million, respectively. During the years ended December 31, 2025 and 2024, the Company paid $0.5 million and $5.7 million accrued interest, respectively.

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

10. Product Development Obligations

The Technology Development Center of the Republic of Finland ("TEKES") product development obligations consist of 11 separate advances (each in the form of a note agreement) received by FibroGen Europe between 1996 and 2008 from TEKES. These advances are granted on a project-by-project basis to fund various product development efforts undertaken by FibroGen Europe only. Each separate note is denominated in EUR and bears interest (not compounded) calculated as one percentage point less than the Bank of Finland rate in effect at the time of the note, but no less than 3.0%.

If the research work funded by TEKES does not result in an economically profitable business or does not meet its technological objectives, TEKES may, on application from FibroGen Europe, forgive each of these loans, including accrued interest, either in full or in part. As of December 31, 2025 and 2024, the Company had U.S. Dollar equivalent of $11.1 million and $9.8 million of principal outstanding, respectively, and $8.5 million and $7.2 million of interest accrued, respectively, which were presented in the product development obligations line on the consolidated balance sheets.

The Company is not a guarantor of these loans, and the principal or the accrued interest of these loans are not repayable by FibroGen Europe until it has distributable funds.

11. Commitments and Contingencies

Contract Obligations

As of December 31, 2025, the Company had outstanding total non-cancelable purchase obligations of $3.3 million for general purchases and other programs and $2.3 million for manufacture and supply of roxadustat, expected to pay within the next twelve months. The Company expects to fulfill its commitments under these agreements in the normal course of business, and as such, no liability has been recorded.

See Note 9, *Liability Related to Sale of Future Revenues* and Note 10, *Product Development Obligations* for details of the respective obligations.

Legal Proceedings and Other Matters

From time to time, the Company is a party to various legal actions, both inside and outside the U.S., arising in the ordinary course of its business or otherwise. The Company accrues amounts, to the extent they can be reasonably estimated, that the Company believes will result in a probable loss (including, among other things, probable settlement value) to adequately address any liabilities related to legal proceedings and other loss contingencies. A loss or a range of loss is disclosed when it is reasonably possible that a material loss will incur and can be estimated, or when it is reasonably possible that the amount of a loss, when material, will exceed the recorded provision. The Company did not have any material accruals for any active legal action, in its consolidated balance sheet as of December 31, 2025.

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

In the fourth quarter of 2021, the Company received a subpoena from the U.S. Securities and Exchange Commission ("SEC") requesting documents related to roxadustat's pooled cardiovascular safety data. The SEC followed up with a subpoena for additional documents in the second quarter of 2024. In May 2025, the Company entered into a settlement with the SEC. As part of the settlement, and without admitting or denying the findings in the settlement offer or administrative order to be issued by the SEC, the Company agreed to pay a $1.25 million civil penalty. In September 2025, the agreement was approved by the Commission and the Company has been making payments to the agreed upon payment schedule.

Between 2022 and 2024, the Company's Board of Directors received seven litigation demands from purported shareholders of the Company, asking the Board of Directors to investigate and take action against certain current and former officers and directors of the Company for alleged wrongdoing based on the same allegations in the derivative and securities class action lawsuits. The litigation demands have been withdrawn.

Indemnification Agreements

The Company enters into standard indemnification arrangements in the ordinary course of business, including for example, service, manufacturing and collaboration agreements. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, including in connection with intellectual property infringement claims by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual after the execution of the agreement. The Company has entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the extent permissible under applicable law.

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

As of December 31, 2025, the Company's accrued liabilities related to these obligations were not material. The Company is unable to reasonably estimate the total amount of future indemnification costs beyond amounts currently accrued due to the early stage of the litigation and significant uncertainties regarding the duration, scope, and outcome of the proceedings.

12. Equity and Stock-based Compensation

Common Stock

On June 16, 2025, the Company effected the Reverse Stock Split. Proportionate adjustments have been made to the number of shares available for issuance under the Company's equity incentive plans as well as outstanding equity awards, in accordance with their respective terms. Each share of Common Stock is entitled to one vote. The holders of Common Stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding.

Shares of Common Stock outstanding, shares of stock plans outstanding and shares reserved for future issuance related to stock options and RSU grants and the Company's Employee Stock Purchase Plan ("ESPP") purchases are as follows (in thousands):

	December 31,	
	2025	2024
Common stock outstanding	4,047	4,037
Stock options outstanding	373	389
RSUs outstanding	16	53
Shares reserved for future stock options and RSUs grant	818	776
Shares reserved for future ESPP offering	265	265
Total shares of common stock reserved	5,519	5,520

At-the-Market Program

On February 24, 2025, the Company entered into an Equity Distribution Agreement with BofA Securities, Inc. ("BofA"), under which it may offer and sell its common stock having aggregate sales proceeds of up to $30.0 million from time to time through BofA as its sales agent. The Company did not sell any shares of common stock under this ATM program during the years ended December 31, 2025.

Stock Plans

Stock Option and RSU Plans

In September 2014, the Company adopted a 2014 Equity Incentive Plan (the "2014 Plan") which became effective in November 2014. The 2014 Plan is the successor equity compensation plan to the 2005 Plan. The 2014 Plan provided for the grant of incentive stock options, nonqualified stock options, restricted stock awards, stock appreciation rights, performance stock awards, performance cash awards, restricted stock units and other stock awards to employees, directors and consultants. Stock options granted must be at prices not less than 100% of the fair market value at date of grant. Option vesting schedules were determined by the Company at the time of issuance and generally have a four year vesting schedule. Options generally expire ten years from the date of grant . Unvested options exercised are subject to the Company's repurchase right.

In June 2024, the Company's 2024 Equity Incentive Plan (the "2024 Plan"), the successor to and continuation of the 2014 Plan, became effective. The 2024 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance stock awards to employees, directors and consultants. Stock options granted must be at prices not less than 100% of the fair market value at date of grant. Option vesting schedules are determined by the Company at the time of issuance and generally have a four year vesting schedule. Options generally expire ten years from the date of grant. Unvested options exercised are subject to the Company's repurchase right. As of December 31, 2025, the Company has reserved 823,929 shares of its common stock that remains unissued for issuance under the 2024 Plan.

Issuance of shares upon share option exercise or share unit conversion is made through issuance of new shares authorized under the plan.

Certain Common Stock option holders have the right to exercise unvested options, subject to a right held by the Company to repurchase the stock, at the original exercise price, in the event of voluntary or involuntary termination of employment of the stockholder. The shares are generally released from repurchase provisions ratably over four years. The Company accounts for the cash received in consideration for the early exercised options as a liability. At December 31, 2025 and 2024, no shares of Common Stock were subject to repurchase by the Company.

In February 2023, the Company granted 6,366 total shares of PRSUs to certain executives for the performance period beginning January 1, 2023 and ending December 31, 2026. In February 2022, the Company granted 11,218 total shares of PRSUs to certain executives for the performance period beginning January 1, 2022 and ending December 31, 2025. The ultimate number of shares eligible to vest for PRSUs range from 0% to 200% of the target number of shares depending on achievement relative to the predefined clinical performance metrics and continued employment with the Company. During the year ended December 31, 2025, 93 shares of the PRSUs have vested and been released.

In February 2023, the Company granted 6,366 total shares of TSR awards to certain executives for the performance period beginning January 1, 2023 and ending December 31, 2026. In February 2022, the Company granted 11,218 total shares of TSR awards to certain executives for the performance period beginning January 1, 2022 and ending December 31, 2025. The ultimate number of shares eligible to vest for the TSR awards range from 0% to 200% of the target number of shares depending on the TSR of the Company's common stock as compared to companies in the NBI index, and continued employment with the Company. During the year ended December 31, 2025, no TSR awards shares have vested and been released.

Stock option transactions, including forfeited options granted under the 2024 Plan as well as prior plans, are summarized below:

	Shares (In thousands)	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life (In Years)	Aggregate Intrinsic Value (In thousands)
Outstanding at December 31, 2024	389	$ 400.52		
Granted	263	15.14		
Forfeited	(82)	59.65		
Expired	(197)	577.45		
Outstanding at December 31, 2025	373	110.26	8.23	$ 30
Vested and expected to vest, December 31, 2025	329	122.04	8.15	28
Exercisable at December 31, 2025	146	$ 240.24	7.33	$ 12

The estimated weighted-average fair value of the stock options granted during the years ended December 31, 2025 and 2024 was $15.14 and $43.43, respectively. There was no option exercised during the years ended December 31, 2025 and 2024.

The following table summarizes the activities of RSUs, PRSUs and TSR awards:

	Shares (In thousands)	Weighted Average Fair Value at Grant
Unvested at December 31, 2024	53	$ 235.21
Granted	—	—
Vested	(18)	205.80
Forfeited	(19)	289.51
Unvested at December 31, 2025	16	$ 201.50

Among the vested RSUs during the year ended December 31, 2025, 10,204 shares were released and issued, while the remaining was withheld for the related payroll taxes. There was no awards granted during the year ended December 31, 2025. The estimated weighted-average fair value of the awards granted during the years ended December 31, 2024 was $44.47.

ESPP

In September 2014, the Company adopted a 2014 ESPP that became effective in November 2014. The 2014 ESPP is designed to enable eligible employees to periodically purchase shares of the Company's common stock at a discount through payroll deductions of up to 15% of their eligible compensation, subject to any plan or IRS limitations. At the end of each offering period, employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the last day of the offering period. Purchases are accomplished through participation in discrete offering periods. The 2014 ESPP is intended to qualify as an ESPP under Section 423 of the Internal Revenue Code. The Company has reserved 64,000 shares of its common stock for issuance under the 2014 ESPP. There were 14,163 shares purchased by employees under the 2014 ESPP during the years ended December 31, 2024. The 2014 ESPP was suspended as of December 31, 2024.

Stock-Based Compensation

Stock-based compensation expense was recorded directly to research and development and selling, general and administrative expense for the years the years ended December 31, 2025 and 2024 was as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Research and development	$ 2,322	$ 12,064
Selling, general and administrative	4,023	11,381
Total stock-based compensation expense	$ 6,345	$ 23,445

The Company estimates the fair value of stock options using the Black-Scholes option valuation model. The fair value of employee stock options and RSUs is being amortized on a straight-line basis over the requisite service period of the awards. Compensation cost for PRSUs is expensed over the respective vesting periods when the achievement of performance criteria is probable. The Company estimates the fair value of the TSR awards using the Monte Carlo valuation model to simulate the probabilities of achievement. Compensation cost for the TSR awards is recognized over the requisite service period, regardless of when, if ever, the market condition is satisfied. The fair market value of common stock is based on the closing price of the Company's common stock as reported on the Nasdaq Global Select Market on the date of the grant.

The fair value of employee stock-based compensation is estimated using the following assumptions:

- Expected Term. Expressed as a weighted-average, the expected life of the options is based on the average period the stock options are expected to be outstanding and was based on the Company's historical information of the option exercise patterns and post-vesting termination behavior as well as contractual terms of the instruments. The expected term of 2014 ESPP shares is the average of the remaining purchase periods under each offering period. The expected term of TSR awards is determined based on the grant date to the end of the performance period.
- Expected Volatility. The Company considers its historical volatility data for volatility considerations for all of its stock-based compensation types except for its TSR awards, which is based on a blend of the Company's and comparable public entities' historical volatility.
- Risk-Free Interest Rate. Expressed as a weighted-average, the risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company's respective stock-based compensation types.
- Expected Dividend Yield. The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future.

The assumptions used to estimate the fair value of stock options granted and ESPPs using the Black-Scholes option valuation model were as follows:

	Years Ended December 31,	
	2025	2024
Stock Options		
Expected term (in years)	5.4	6.1
Expected volatility	123.8 %	113.7 %
Risk-free interest rate	4.3 %	4.2 %
Expected dividend yield	—	—
Weighted average estimated fair value	$ 13.23	$ 1.49
ESPPs		
Expected term (in years)	—	0.5 - 2.0
Expected volatility	— %	61.5 - 271.2 %
Risk-free interest rate	— %	2.6 - 5.3 %
Expected dividend yield	—	—
Weighted average estimated fair value	$ —	$ 1.67

The assumptions used to estimate the fair value of the TSR awards using the Monte Carlo valuation model were as follows:

	Year Ended December 31,	
	2025	2024
TSR awards		
Expected term (in years)	3.9	3.9
Expected volatility	69.0 - 73.3 %	69.0 - 73.3 %
Risk-free interest rate	1.8 - 4.2 %	1.8 - 4.2 %
Expected dividend yield	—	—
Weighted average estimated fair value	$ 759.23	$ 737.88

As of December 31, 2025, there was $3.6 million of total unrecognized compensation costs, net of estimated forfeitures, related to non-vested stock option awards granted that will be recognized on a straight-line basis over the weighted-average period of 2.50 years. As of December 31, 2025, there was $1.7 million of total unrecognized compensation costs, net of estimated forfeitures, related to non-vested RSUs, PRSUs and TSR awards granted that will be recognized on a straight-line basis over the weighted-average period of 1.73 years.

Subsidiary Stock and Non-Controlling Interests

FibroGen Europe

FibroGen Europe has a total of 42,619,022 shares of Preferred Stock outstanding, of which there are 1,700,845 shares of Series A Preferred Stock, 1,875,000 shares of Series B Preferred Stock, 1,599,503 shares of Series C Preferred Stock, 1,520,141 shares of Series D Preferred Stock, 459,565 shares of Series E Preferred Stock, 5,714,332 shares of Series F Preferred Stock, 9,927,500 shares of Series G Preferred Stock and 19,822,136 shares of Series H Preferred Stock, all of which shares no longer have any right to be exchanged for the Company's Common Stock. Of all the Preferred Stock outstanding, a total of 37,184,807 shares are owned by Kyntra Bio and 5,434,215 shares are owned by minority shareholders. In addition, FibroGen Europe has 7,800,000 common shares outstanding owned by Kyntra Bio. The holders of FibroGen Europe's shares of Preferred Stock ("Preferred Shares") have the following rights, preferences and privileges:

Dividend Rights — When the assets of FibroGen Europe are distributed (except for distribution in a liquidation), Preferred Shares shall have the same rights to dividend or other forms of distribution as shares of Common Stock of FibroGen Europe. In the event of a merger, holders of Preferred Shares do not have the right to demand FibroGen Europe to redeem all or part of their Preferred Shares. FibroGen Europe may repurchase shares of Common Stock or Preferred Shares for consideration.

Pre-emptive Right — Preferred Shares shall have pre-emptive subscription right in accordance with the Finnish Limited Liability Companies Act if additional shares are issued, option rights are given, or convertible loan is taken, *provided*, *however*, that the foregoing pre-emptive right does not apply to a directed share issue, for which two thirds (2/3) of the voting shares represented at a general meeting of shareholders approve for an important legitimate cause.

Redemption Right — If a Preferred Share can be redeemed by a majority shareholder owning more than ninety percent (90%) of the shares of FibroGen Europe in accordance with the provisions of the Finnish Limited Liability Companies Act, the minority holders of Preferred Shares have the right to request redemption of their shares.

Voting Right — Each share has one vote. Preferred Shares have voting rights only in situations that are specifically provided in the Articles of Association, which include a merger transaction and directed share issue. In addition, Preferred Shares have right to vote in a general shareholder meeting for amending the Articles of Association if the amendment will affect the rights of Preferred Shares.

Conversion Right (1-for-1 basis into Common Stock of FibroGen Europe):

- Voluntary conversion right: Preferred Shares can be converted into common shares upon the written request of a shareholder provided that the conversion is feasible within the maximum and minimum amounts of shares of classes of FibroGen Europe as set forth in its Articles of Association. Such request can be withdrawn before the notification of conversion is filed with the Finnish Trade Register.
- Compulsory conversion right: Preferred Shares will be converted into common shares if (i) FibroGen Europe's shares are listed in a stock exchange or other trading system in the European Economic Area, or (ii) FibroGen Europe's recombinant collagen and gelatin production technology is being put into commercial use in the area of Europe and certain other European states. Commercial use means there is income generated from the first commercial sale of the products incorporating the above-mentioned technology and does not include license fees, development financing, milestone payments or income from test products or equipment used in research. The board of directors of FibroGen Europe shall notify the shareholders of the compulsory conversion in writing, and the shareholders shall request to convert their shares within the timeframe provided in the notification. Should the shareholders fail to make the conversion request within the time limit, FibroGen Europe may redeem the shares of such shareholders.

Liquidation Right — In the event of a dissolution of FibroGen Europe, holders of Preferred Shares are entitled to be paid in an amount equal to the subscription price of the shares before any distribution is made to holders of common shares. Among holders of Preferred Shares, holders of shares of Series F Preferred Stock are entitled to be paid in an amount equal to the subscription price of Series F Preferred Stock before any distribution is made to holders of other Preferred Shares.

Non-controlling interest positions related to the issuance of FibroGen Europe's stock are reported as a separate component of consolidated equity from the equity attributable to the Company's stockholders. In addition, the Company does not allocate losses to the non-controlling interests as the outstanding shares representing the non-controlling interest do not represent a residual equity interest in FibroGen Europe.

FibroGen Cayman

FibroGen Cayman has 15,836,966 Series A Preference Shares outstanding, including 10,484,260 shares owned by Kyntra Bio. and 5,352,706 shares owned by minority shareholders, and 78,000,000 common shares outstanding owned by Kyntra Bio. The holders of the FibroGen Cayman Series A Preference Shares have the following rights, preferences and privileges:

Liquidation — In the event of liquidation, dissolution, or winding up of the entity, either voluntary or involuntary, including by means of a merger, the holders of FibroGen Cayman Series A Preference Shares are entitled to be paid an amount equal to their liquidation preference as set forth in the FibroGen Cayman Amended and Restated Memorandum and Articles of Association (the "Articles"), i.e. the product of the number of shares held by a holder of shares of FibroGen Cayman Series A Preference Shares and the original issue price of $1.00 (subject to equitable adjustment for any stock dividend, combination, split, reclassification, recapitalization) plus all declared and unpaid dividends thereon.

Conversion — Each share of FibroGen Cayman Series A Preference Shares is convertible into the number of fully paid and non-assessable shares of Common Stock of FibroGen Cayman that results from dividing the original issue price by the conversion price in effect at the time of the conversion, subject to adjustments for stock splits, stock dividends, reclassifications and like events. The FibroGen Cayman Series A Preference Shares have a conversion price that is equal to the original issuance price such that the conversion ratio to FibroGen Cayman Common Stock is 1:1 as of all periods presented.

Voting — The holders of FibroGen Cayman Series A Preference Shares are entitled to vote together with the FibroGen Cayman Common Stockholders on all matters submitted for a vote of the stockholders. The holder of each share of FibroGen Cayman Series A Preference Shares has the number of votes equal to the number of shares of FibroGen Cayman Common Stock into which it is convertible.

Dividends — The holders of FibroGen Cayman Series A Preference Shares are entitled to receive cash dividends when and if declared, at a rate of 6%.

The discontinued operations sold under the Transaction discussed in the above Note 3, *Discontinued Operations and Divestiture*, consisted substantially all the assets owned by FibroGen Cayman, and therefore triggered liquidation distribution process of FibroGen Cayman based on its Articles.

Accordingly, during the year ended December 31, 2025, the Company distributed a total of $5.4 million to FibroGen Cayman's minority shareholders ($1.00 for each of the FibroGen Cayman Series A Preference Shares held by the 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, for such distribution.

Any further distribution, if applicable, will be paid out on a pro-rata basis to the holders of all common and Series A Preference shares of FibroGen Cayman, and is subject to future adjustments, if any, including additional proceeds received from the holdbacks related to the Transaction, and future costs of FibroGen Cayman.

13. Net Loss Per Share

Potential common shares that would have the effect of increasing diluted earnings per share are considered to be anti-dilutive and as such, these shares are not included in the calculation of diluted earnings per share. The Company reported a loss from continuing operations for each of the years ended December 31, 2025 and 2024. Therefore, dilutive common shares are not assumed to have been issued since their effect is anti-dilutive for these periods.

Diluted weighted average shares excluded the following potential common shares related to stock options, RSUs, PRSUs, 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):

	Years Ended December 31,	
	2025	2024
Employee stock options	465	538
RSUs, PRSUs and TSR awards	33	125
ESPP	—	18
	498	681

14. Income Taxes

The components of loss before income taxes are as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Domestic	$ (47,917)	$ (142,819)
Foreign	(10,377)	(10,548)
Loss before benefit for income taxes	$ (58,294)	$ (153,367)

The benefit for income taxes consists of the following (in thousands):

	Years Ended December 31,	
	2025	2024
Current:		
Federal	$ —	$ —
State	—	—
Foreign	(90)	(269)
Total current	(90)	(269)
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
Total deferred	—	—
Benefit from income taxes	$ (90)	$ (269)

A reconciliation of the benefit for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to income before income taxes for the year ended December 31, 2025, after the adoption of ASU 2023-09, is as follows:

	Years Ended December 31, 2025	
	Amount	%
Tax at statutory federal rate	$ (12,242)	21.0 %
State tax, net of federal benefit	—	—%
Foreign Tax Effects		
Foreign Rate Differential – Cayman Islands	2,110	(3.6)%
Foreign Rate Differential – Finland	76	(0.1)%
Effect of cross-border tax laws		
Global intangible low-taxed income	62,730	(107.6)%
Other	(90)	0.2 %
Tax credits	578	(1.0)%
Change in valuation allowance	(59,391)	101.9 %
Worldwide changes in unrecognized tax benefits	(180)	0.3 %
Nondeductible items		
Stock based compensation	5,591	(9.6)%
Disallowed interest	448	(0.8)%
Other	9	—%
Other	271	(0.5)%
Total	$ (90)	0.2 %

The following is the reconciliation between the statutory federal income tax rate and the Company's effective tax rate for year ended in December 31, 2024, prior to the adoption of ASU 2023-09, is as follows:

	Years Ended December 31, 2024
Tax at statutory federal rate	21.0 %
State tax	—%
Stock-based compensation expense	(3.2)%
Net operating losses not benefitted	(13.9)%
Foreign net operating losses not benefitted	(1.4)%
Deduction limitation on executive compensation	—%
Global intangible low-taxed income	(2.1)%
Other	(0.2)%
Total	0.2 %

Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31,	
	2025	2024
Federal and state net operating loss carryforwards	$ 173,195	$ 206,365
Tax credit carryforwards	128,924	129,320
Foreign net operating loss carryforwards	112	120
Capitalized research and development expenses	64,293	83,329
Stock-based compensation	2,128	6,365
Lease obligations	12	22
Reserves and accruals	4,760	4,418
Deferred revenue	—	7,785
Intangible assets	14,135	15,036
Other	6	—
Subtotal	387,565	452,760
Less: Valuation allowance	(387,555)	(452,740)
Net deferred tax assets	10	20
Fixed assets	(10)	(20)
Non-deductible accrued expenses	—	—
Net deferred tax liabilities	(10)	(20)
Total net deferred tax assets	$ —	$ —

A valuation allowance has been provided to reduce the deferred tax assets to an amount management believes is more likely than not to be realized. Expected realization of the deferred tax assets for which a valuation allowance has not been recognized is based on upon the reversal of existing temporary differences and future taxable income.

The valuation allowance decreased by $65.2 million for the year ended December 31, 2025 and increased by $26.4 million for the years ended December 31, 2024. Due to uncertainty surrounding the realization of the favorable tax attributes in the future tax returns, the Company has established a valuation allowance against its otherwise recognizable net deferred tax assets.

The Company intends to continue maintaining a full valuation allowance on its deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of this allowance.

At December 31, 2025, the Company had net operating loss carryforwards available to offset future taxable income of approximately $787.4 million and $145.4 million for federal and state tax purposes, respectively. $140.5 million of the federal net operating loss carryforwards will begin to expire in 2035 if not utilized, while the remainder can be carried forward indefinitely. The state net operating loss carryforward will begin to expire in 2031 if not utilized. The Company also had foreign net operating loss carryforwards of approximately $0.6 million, which expire between 2026 and 2034 if not utilized.

At December 31, 2025, the Company had approximately $153.8 million of federal and $53.7 million of California research and development tax credit and other tax credit carryforwards available to offset future taxable income. The federal credits begin to expire in 2026 and the California research credits have no expiration dates.

Federal and state tax laws impose substantial restrictions on the utilization of net operating loss and credit carryforwards in the event of an "ownership change" for tax purposes, as defined in Internal Revenue Code ("IRC") Section 382. The Company performed an IRC Section 382 analysis and has determined that there were no ownership changes as of December 31, 2024. Thus, IRC Section 382 will not limit the use of the Company's net operating loss and tax credit carryforwards. The Company will continue to monitor trading activities in its shares which could cause ownership change in future years.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law. The OBBBA makes permanent key elements of the Tax Cuts and Jobs Act, including restoring 100% bonus depreciation, eliminating the capitalization requirement for domestic research and experimentation, and changing the business interest expense limitation. ASC 740 requires the effects of changes in tax rates and laws on deferred tax balances to be recognized in the period in which the legislation was enacted in the third quarter of 2025. The provisions do not have a material impact on the Company's financial statements.

Uncertain Tax Positions

The Company had unrecognized tax benefits of approximately $74.5 million as of December 31, 2025. Approximately $0.4 million of unrecognized tax benefits, if recognized, would affect the effective tax rate. The interest accrued as of December 31, 2025 and 2024 was immaterial.

A reconciliation of the beginning and ending amounts of unrecognized income tax benefits during the two years ended December 31, 2025 is as follows (in thousands):

	Federal and State
Balance as of December 31, 2023	$ 70,710
Decrease due to prior positions	(156)
Increase due to current year position	3,920
Foreign exchange rate differential	(153)
Balance as of December 31, 2024	74,321
Decrease due to prior positions	(229)
Increase due to current year position	372
Foreign exchange rate differential	—
Balance as of December 31, 2025	$ 74,464

Unrecognized tax benefits may change during the next twelve months for items that arise in the ordinary course of business.

The Company classifies interest and penalties as a component of tax expense, if any.

The Company files income tax returns in the U.S. federal jurisdiction, U.S. state and other foreign jurisdictions. The U.S. federal and U.S. state taxing authorities may choose to audit tax returns for tax years beyond the statute of limitation period due to significant tax attribute carryforwards from prior years, making adjustments only to carryforward attributes. The foreign statute of limitation generally remains open from 2015 to 2025. The Company is not currently under audit in any tax jurisdiction. The Company did not have any cash payment for income taxes for the years ended December 31, 2025 and 2024.

15. Segment and Geographic Information

The Company has one operating and reporting segment which primarily focuses on the development and commercialization of novel therapeutics to treat serious unmet medical needs. The Company has determined that the chief executive officer is the chief operating decision maker ("CODM"). The CODM assesses performance of the business, monitors budget versus actual results and manages and allocates resources to the Company's operations using consolidated net income (loss) as the primary measurement. The CODM is regularly provided with entity-wide expense categories that are consistent with those found on the Company's 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 consolidated statements of operations include interest expense, loss on debt extinguishments, 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.

Supplemental enterprise-wide information is presented below.

Geographic Revenues

Geographic revenues, which are based on the region that revenue is generated, are as follows (in thousands):

	Years Ended December 31,	
	2025	2024
United States	$ —	$ 26,114
Europe	5,643	6,270
Japan	797	(2,854)
China	—	91
Total revenue	$ 6,440	$ 29,621

Customer Concentration

The Company's revenues have been generated from the following collaboration partners that individually accounted for 10% or more of the Company's total revenue:

	Percentage of Revenue	
	Years Ended December 31,	
	2025	2024
AstraZeneca	—%	88%
Astellas	100%	12%

Schedule II: Valuation and Qualifying Accounts
(in thousands)

	Balance at Beginning of Year	Charged (Credited) to Statement of Operation	Charged to Other Accounts - Liabilities and Equity	Deductions, Net	Balance at End of Year
Valuation allowances for deferred tax assets					
Year ended December 31, 2025	$ 452,740	$ (65,185)	$ —	$ —	$ 387,555
Year ended December 31, 2024	$ 426,355	$ 26,385	$ —	$ —	$ 452,740

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Attached as Exhibits 31.1 and 31.2 to this Annual Report on Form 10-K for the year ended December 31, 2025 ("Annual Report") are certifications of our Chief Executive Officer and our Chief Financial Officer required by Rule 13a-14(a) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Rule 13a-14(a) and 15d-15(e) Certifications"). This Controls and Procedures section of the Annual Report includes the information concerning the controls evaluation referred to in the Rule 13a-14(a) and 15d-15(e) Certifications.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025, the end of the period covered by this Annual Report. Disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to the company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2025.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Our internal control over financial reporting is a process established under the supervision of and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer. Internal control over financial reporting is a process designed 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. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management, with the participation and under the supervision of our Chief Executive Officer and our Chief Financial Officer, evaluated our internal control over financial reporting as of December 31, 2025, the end of our fiscal year, using the criteria established in *Internal Control - Integrated Framework* (2013) set forth by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on our evaluation, our management has concluded that our internal control over financial reporting was effective as of December 31, 2025 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.

This report does not include an attestation report of our registered public accounting firm as we are a non-accelerated filer and a smaller reporting company.

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.

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 fiscal quarter ended December 31, 2025 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

We are implementing an enterprise resource planning ("ERP") system, which will replace our existing operating and financial systems in the U.S. in the first quarter of 2026. While we expect the ERP implementation to improve the efficiency of certain financial and transactional processes, the related changes will materially affect our internal control over financial reporting beginning in the first quarter of 2026, and we have been monitoring such changes during the implementation process.

ITEM 9B. OTHER INFORMATION

Trading Arrangements

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item relating to our directors and nominees, including information with respect to our audit committee, audit committee financial experts and procedures by which stockholders may recommend nominees to our Board of Directors, is incorporated by reference to the sections titled "Proposal 1 – Election of Directors" and "Directors and Corporate Governance" in our Proxy Statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2025 (the "2026 Proxy Statement"). The information required by this item regarding our executive officers is incorporated by reference to the section titled "Executive Officers" appearing in our 2026 Proxy Statement. The information, if any, required by this item regarding compliance with Section 16(a) of the Securities Exchange Act of 1934, as amended, is incorporated by reference to the section titled "Delinquent Section 16(a) Reports" appearing in our 2026 Proxy Statement.

Insider Trading Policy

We have adopted an Insider Trading Policy governing the purchase, sale and/or other dispositions of our securities by our directors, officers and employees. A copy of the Insider Trading Policy is filed as an exhibit to this Annual Report on Form 10-K. In addition, it is our practice to comply with the applicable laws and regulations relating to insider trading.

Code of Conduct

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees. A copy of our Code of Business Conduct and Ethics can be found on our website (www.kyntrabio.com) under "Corporate Governance." The contents of our website are not a part of this Annual Report.

In addition, we intend to promptly disclose the nature of any amendment to, or waiver from, our Code of Business Conduct that applies to our principal executive officer, principal financial officer, principal accounting officer or persons performing similar functions on our website in the future.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to the sections titled "Executive Compensation," "Director Compensation," and "Compensation Committee Interlocks and Insider Participation" appearing in our 2026 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to the sections titled "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" appearing in our 2026 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to the sections titled "Transactions with Related Persons" and "Directors and Corporate Governance" appearing in our 2026 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to the proposal titled "Proposal 3 - Ratification of Selection of Independent Registered Public Accounting Firm" appearing in our 2026 Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) We have filed the following documents as part of this Annual Report:

1. Consolidated Financial Statements

Information in response to this Item is included in Part II, Item 8 of this Annual Report.

2. Financial Statement Schedules

Schedule II is included on page 112. All other schedules are omitted because they are not required or the required information is included in the consolidated financial statements or notes thereto.

3. Exhibits

See Item 15(b) below.

(b) ***Exhibits***—We have filed, or incorporated into this Annual Report by reference, the exhibits listed below. Where an exhibit is incorporated by reference, the number in parentheses indicates the document to which cross-reference is made. Refer to the end of this table for a listing of cross-reference documents.

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
4.2	Shareholders' Agreement by and among FibroGen International (Cayman) Limited and certain of its shareholders, dated as of September 8, 2017.	10-Q	001-36740	4.6	11/8/2017
4.4	Description of Capital Stock.	10-K	001-36740	4.4	3/2/2020
10.1+*	2024 Equity Incentive Plan.	—	—	—	—
10.1(ii)+*	Form of Restricted Stock Unit Grant Notice and Award Agreement (2024 Equity Incentive Plan).	—	—	—	—

10.1(iii)+*	Form of Stock Option Grant Notice and Option Agreement (2024 Equity Incentive Plan).	—	—	—	—
10.2+*	2014 Equity Incentive Plan and forms of agreement thereunder.	—	—	—	—
10.3+*	2014 Employee Stock Purchase Plan.	—	—	—	—
10.4+	Non-Employee Director Compensation Policy, as amended, dated April 22, 2024.	10-Q	001-36740	10.3	5/6/2024
10.5+*	Bonus Plan.	—	—	—	—
10.6+*	Form of Employment Offer Letter.	—	—	—	—
10.7†	Collaboration Agreement, by and between FibroGen, Inc. and Astellas Pharma Inc., effective as of June 1, 2005.	10-Q	001-36740	10.1	11/5/2020
10.8†	Amendment No. 1 to Collaboration Agreement, by and between FibroGen, Inc. and Astellas Pharma Inc., effective as of January 1, 2013.	10-K	001-36740	10.9(i)	2/27/2019
10.9†	Amendment No.2 to Collaboration Agreement, by and between Astellas Pharma, Inc. and FibroGen, Inc., dated June 6, 2025.	10-Q	001-36740	10.1	8/11/2025
10.10†	Anemia License and Collaboration Agreement, by and between FibroGen, Inc. and Astellas Pharma Inc., effective as of April 28, 2006.	S-1	333-199069	10.12	10/1/2014
10.11†	Amendment to Anemia License and Collaboration Agreement, by and between FibroGen, Inc. and Astellas Pharma Inc., effective as of August 31, 2006.	S-1	333-199069	10.13	10/1/2014
10.12	Amendment No. 2 to Anemia License and Collaboration Agreement, by and between FibroGen, Inc. and Astellas Pharma Inc., effective as of December 1, 2006.	S-1	333-199069	10.14	10/1/2014
10.13†	Supplement to Anemia License and Collaboration Agreement, by and between FibroGen, Inc. and Astellas Pharma Inc., effective as of April 28, 2006.	S-1	333-199069	10.15	10/1/2014

10.14†	Amendment No. 3 to Anemia License and Collaboration Agreement, by and between FibroGen, Inc. and Astellas Pharma Inc., dated as of May 10, 2012.	S-1	333-199069	10.16	10/1/2014
10.15+*	Form of Indemnity Agreement by and between Kyntra Bio, Inc. and its directors and officers.	—	—	—	—
10.16†	Commercial Supply Agreement by and between FibroGen, Inc. and Catalent Pharma Solutions, LLC, effective as of January 1, 2020.	10-K	001-36740	10.28	3/2/2020
10.17†	Master Supply Agreement by and among FibroGen, Inc., Shanghai SynTheAll Pharmaceutical Co., Ltd. and STA Pharmaceutical Hong Kong Limited, effective March 2, 2020.	8-K	001-36740	99.1	3/24/2020
10.18†	Amendment No.1 to Master Supply Agreement by and among FibroGen, Inc., Shanghai SynTheAll Pharmaceutical Co., Ltd. and STA Pharmaceutical Hong Kong Limited, effective May 11, 2020.	10-Q	001-36740	10.2	8/6/2020
10.19†	Amendment No. 2 to Master Supply Agreement by and among FibroGen, Inc., Shanghai SynTheAll Pharmaceutical Co., Ltd. and STA Pharmaceutical Hong Kong Limited, effective July 24, 2020.	10-Q	001-36740	10.8	11/5/2020
10.20†	Astellas EU Supply Agreement by and between FibroGen, Inc. and Astellas Pharma Europe Ltd, effective as of January 1, 2021.	10-Q	001-36740	10.2	5/10/2021
10.21†	Amendment No. 3 to Master Supply Agreement by and among FibroGen, Inc., Shanghai SynTheAll Pharmaceutical Co., Ltd., and STA Pharmaceutical Hong Kong Limited, dated as of January 12, 2021.	10-Q	001-36740	10.3	5/10/2021
10.22†	Amendment No. 4 to Master Supply Agreement by and among FibroGen, Inc., Shanghai SynTheAll Pharmaceutical Co., Ltd., and STA Pharmaceutical Hong Kong Limited, dated as of October 29, 2021.	10-K	001-36740	10.36	2/28/2022
10.23+*	Form of Executive Officer Change in Control and Severance Agreement.	—	—	—	—

10.24	ATM Equity Offering Sales Agreement, by and between FibroGen, Inc. and BofA Securities, Inc., dated as of February 24, 2025.	8-K	001-36740	1.1	2/24/2025
10.25†	Revenue Interest Financing Agreement by and between FibroGen, Inc. and NQ Project Phoebus, L.P., dated as of November 4, 2022.	10-K	001-36740	10.46	2/27/2023
10.26†	Letter Agreement by and among Astellas Pharma Inc., Astellas Pharma Europe Ltd., and FibroGen, Inc., effective as of November 4, 2022.	10-K	001-36740	10.47	2/27/2023
10.27†	Amendment No.1 to Commercial Supply Agreement (Roxadustat) by and between FibroGen, Inc. and its Affiliates and Catalent Pharma Solutions, LLC, effective as of January 1, 2023.	10-Q	001-36740	10.2	5/8/2023
10.28+	Offer Letter, dated July 23, 2023, between FibroGen, Inc. and Thane Wettig.	8-K	001-36740	10.1	7/25/2023
10.29†	First Amended and Restated Evaluation Agreement by and between FibroGen, Inc. and Fortis Therapeutics, Inc., dated June 6, 2024.	10-Q	001-36740	10.2	8/6/2024
10.30†	First Amended and Restated Option Agreement and Plan of Merger by and among FibroGen, Inc., Fortis Therapeutics, Inc., and Shareholder Representative Services LLC, dated June 6, 2024.	10-Q	001-36740	10.3	8/6/2024
10.31†	Amendment No.1 to the First Amended and Restated Evaluation Agreement, by and between Fortis Therapeutics and FibroGen, Inc., dated as of March 28, 2025.	10-Q	001-36740	10.2	5/12/2025
10.32†	Amendment No.1 to the First Amended and Restated Option Agreement and Plan of Merger, by and between Fortis Therapeutics and FibroGen, Inc., dated as of March 28, 2025.	10-Q	001-36740	10.3	5/12/2025

10.33†	Termination Agreement by and between FibroGen, Inc. and AstraZeneca AB, effective as of February 25, 2024, as amended and restated on August 29, 2025.	10-Q	001-36740	10.2	11/10/2025
10.34†	Share Purchase Agreement by and among AstraZeneca Treasury Limited, FibroGen China Anemia Holdings, Ltd., and FibroGen, Inc., dated as of February 20, 2025.	10-Q	001-36740	10.1	5/12/2025
10.35†	Amendment to Share Purchase Agreement, by and among AstraZeneca Treasury Limited, FibroGen China Anemia Holdings, Ltd., and FibroGen, Inc., dated as of August 29, 2025.	10-Q	001-36740	10.3	11/10/2025
19*	Insider Trading and Trading Window Policy.	—	—	—	—
21.1*	Subsidiaries of Kyntra Bio, Inc.	—	—	—	—
23.1*	Consent of PricewaterhouseCoopers LLP.	—	—	—	—
24.1*	Power of Attorney (included in signature pages).	—	—	—	—
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).	—	—	—	—
97.1*	Policy for Recoupment of Incentive Compensation.	—	—	—	—
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 Schema Linkbase Document	—	—	—	—
104	Cover Page Interactive Data File (embedded within the inline XBRL document)	—	—	—	—

* Filed herewith.
** Furnished herewith.
† Portions of this exhibit (indicated by asterisks) have been omitted as the Company has determined that (i) the omitted information is not material and (ii) the omitted information would likely cause competitive harm if publicly disclosed or is the type of information the Company treats as confidential.
+ Indicates a management contract or compensatory plan.
(1) This certification accompanies the Form 10-K 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-K), irrespective of any general incorporation language contained in such filing.

(c) ***Financial Statement Schedules***—See (a) 2 above. All other financial statement schedules are omitted because they are not applicable because the requested information is included in the consolidated financial statements or notes thereto.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Francisco, State of California.

KYNTRA BIO, INC.

Date: March 16, 2026

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

Date: March 16, 2026

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Thane Wettig and David DeLucia, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Thane Wettig **Thane Wettig**	Chief Executive Officer *(Principal Executive Officer)*	March 16, 2026
/s/ David DeLucia **David DeLucia**	Senior Vice President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 16, 2026
/s/ James A. Schoeneck **James A. Schoeneck**	Chairman of the Board and Director	March 16, 2026
/s/ Jeffrey L. Edwards **Jeffrey L. Edwards**	Director	March 16, 2026
/s/ Maykin Ho **Maykin Ho, Ph.D.**	Director	March 16, 2026
/s/ Michael Kauffman **Michael Kauffman, M.D., Ph.D.**	Director	March 16, 2026

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