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 , 2023

OR

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

For the transition period from _ to _.

Commission file number: 001-36740

FIBROGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0357827**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
409 Illinois Street	
San Francisco , CA	**94158**
(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	FGEN	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, 2023, was approximately $

261.5

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 January 31, 2024 was

98,771,247

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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, 2023 (the “Annual Report”) incorporate information by reference from the definitive proxy statement for the registrant’s 2024 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, 2023 ("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 roxadustat, pamrevlumab and our other 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, our ability to operate in the People's Republic of China ("China"), 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 FibroGen will depend on a number of factors, many of which are beyond our control and involve risks, including but not limited to the following:

Risks Related to the Development and Commercialization of Our Product Candidates

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

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

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

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

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

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

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

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

Risks Related to Our Reliance on Third Parties

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

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

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

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

• Certain components of our products are acquired from single-source suppliers or without long-term supply agreements. The loss of these suppliers, or their failure to supply, would materially and adversely affect our business.

Risks Related to Our Intellectual Property

• If our efforts to protect our proprietary 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.

Risks Related to Our International Operations

• We have established operations in China and are seeking approval to commercialize our product candidates outside of the U.S., and a number of risks associated with international operations could materially and adversely affect our business.

• The pharmaceutical industry in China is highly regulated and such regulations are subject to change.

• We use our own manufacturing facilities in China to produce roxadustat API and drug product for the market in China. There are risks inherent to operating commercial manufacturing facilities, and with these being our single source suppliers, we may not be able to continually meet market demand.

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

• The retail prices of any product candidates that we develop will be subject to pricing control in China and elsewhere.

• FibroGen Beijing would be subject to restrictions on paying dividends or making other payments to us, which may restrict our ability to satisfy our liquidity requirements.

• Our foreign operations, particularly those in China, are subject to significant risks involving the protection of intellectual property.

• Uncertainties with respect to the China legal system and regulations could have a material adverse effect on us.

• Changes in China's economic, governmental, or social conditions could have a material adverse effect on our business.

CHINA OPERATIONS AND RELATED RISKS

We are incorporated in the state of Delaware. We operate within the Chinese market through FibroGen (China) Medical Technology Development Co., Ltd. ("FibroGen Beijing"), a wholly-owned subsidiary established in Beijing. FibroGen Beijing consists of development and commercialization operations as well as a drug product manufacturing facility. FibroGen Beijing holds the regulatory licenses issued by the Chinese regulatory authorities in respect of roxadustat. FibroGen Beijing has two branch offices located in Shanghai and Cangzhou, China. The branch office in Cangzhou operates a drug substance manufacturing facility. FibroGen Beijing also owns 51.1% of Beijing Falikang Pharmaceutical Co. Ltd. ("Falikang"), a joint venture established by FibroGen and operated in conjunction with AstraZeneca Investment (China) Co., Ltd. for the purpose of distributing our sole drug product approved for sale in China, roxadustat. Falikang conducts distribution activities for roxadustat within China while AstraZeneca Investment (China) Co., Ltd., AstraZeneca AB ("AstraZeneca") and AstraZeneca (Wuxi) Trading Co., Ltd. provide sales and marketing services in support of roxadustat. Thus, stockholders of FibroGen, Inc. have an ownership interest in the joint venture, Falikang, through the FibroGen, Inc. equity ownership in our subsidiaries, including FibroGen Beijing.

For a full discussion of our business in China, please see the section below titled "China - Roxadustat Commercial Program" as well as the sections titled "ANEMIA ASSOCIATED WITH MYELODYSPLASTIC SYNDROMES" and "CHEMOTHERAPY-INDUCED ANEMIA." We summarize certain risks associated with our operations in China in this section, however, please refer also to the section of this Annual Report captioned "Item 1A. Risk Factors" for additional risks related to our international operations.

To operate our business in China, each of our Chinese subsidiaries (and our joint venture with AstraZeneca, Falikang) is required to and does obtain a business license from the local counterpart of the State Administration for Market Regulation. Such business licenses list the business activities we are authorized to carry out and we would be noncompliant if we act outside of the scope of business activities set forth under the relevant business license. Due to China's regulatory framework in general and for the pharmaceutical industry specifically, we are required to apply for and maintain many approvals or permits specific to many of our business activities, including but not limited to manufacturing, distribution, environmental protection, workplace safety and cybersecurity, from both national and local government agencies. For certain of our clinical trials conducted in China, we need to obtain, through the clinical sites, permits from the Human Genetic Resource Administrative Commission to collect samples that include human genetic resources, such as blood samples. We may also be required to obtain certain approvals from Chinese authorities before transferring certain scientific data abroad or to foreign parties or entities established or actually controlled by them. If we are unable to obtain the necessary approvals or permissions in order to operate our business in China, or if we inadvertently conclude that such approvals or permissions are not required, or if we are subject to additional requirements, approvals, or permissions, it could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our common stock.

Due to our operations in China and the United States ("U.S."), any unfavorable government policies on cross-border relations and/or international trade (including increased scrutiny on companies with significant China-based operations, capital controls or tariffs) may affect the competitive position of our drug products, the hiring of personnel, the demand for our drug products, the import or export of products and product components, our ability to raise capital, the market price of our common stock, or prevent us from selling our drug products in certain countries. While we do not operate in an industry that is currently subject to foreign ownership limitations in China, China could decide to limit foreign ownership in our industry, in which case there could be a risk that we would be unable to do business in China as we are currently structured.

Our long-term plans for distributing cash flows from FibroGen Beijing may involve any number of scenarios including keeping the money onshore to fund future expansion of our China operations or paying down additional debt obligations. Our capital contributions to FibroGen Beijing and the liquidity position of FibroGen Beijing depend on many factors, including those set forth under Part I, Item 1A "*Risk Factors*" in this Annual Report.

Our independent registered public accounting firm, PricewaterhouseCoopers LLP, is headquartered in the U.S. and was not identified in the Public Company Accounting Oversight Board ("PCAOB") report dated December 16, 2021 as a firm that the PCAOB was unable to inspect. Therefore, the Holding Foreign Companies Accountable Act does not apply to us.

PART I

ITEM 1. BUSINESS

OVERVIEW

FibroGen, Inc. is developing and commercializing a diversified pipeline of novel therapeutics that work at the frontiers of cancer biology and anemia.

In 2023, we reported results from multiple Phase 3 trials, advanced our pancreatic cancer Phase 3 trials of pamrevlumab and our preclinical work on our product candidates FG-3165 and FG-3175, in-licensed a new product candidate (FG-3246), and we continued to see robust sales growth of roxadustat in China for anemia associated with chronic kidney disease ("CKD").

In 2024, we look forward to an approval decision in China for roxadustat in chemotherapy-induced anemia ("CIA") and presenting data from two pivotal pancreatic cancer trials of pamrevlumab, our first-in-class antibody targeting connective tissue growth factor ("CTGF").

Through our new partnership with Fortis Therapeutics ("Fortis"), we are also developing FG-3246 in metastatic castrate resistant prostate cancer ("mCRPC") and potentially other cancers, and we also look forward to advancing our late-stage pre-clinical programs: our anti-Gal9 antibody FG-3165 and our anti-CCR8 antibody FG-3175.

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

PAMREVLUMAB FOR THE TREATMENT OF PANCREATIC CANCER

Pamrevlumab is our first-in-class antibody developed to inhibit the activity of CTGF, a protein that has been shown to promote growth, survival, and spread of pancreatic tumors. To date, we have retained exclusive worldwide rights for pamrevlumab.

In clinical studies involving more than 1,000 pamrevlumab-treated patients (approximately half of whom were dosed for more than six months), pamrevlumab has been well-tolerated across the range of doses studied, and there have been no dose-limiting toxicities seen thus far.

The U.S. Food and Drug Administration ("FDA") has granted Fast Track designation to pamrevlumab for the treatment of patients with locally advanced pancreatic cancer ("LAPC"). The FDA has granted orphan drug designation to pamrevlumab for the treatment of pancreatic cancer.

In 2024, we expect to report topline results from our two ongoing pivotal studies of pamrevlumab, in LAPC and in metastatic pancreatic cancer.

PANCREATIC CANCER

Understanding Pancreatic Cancer and Current Therapies

Certain malignant solid tumors have a prominent fibrosis component consisting mostly of extracellular matrix ("ECM") that contributes to metastasis and progressive disease. Fibrosis is an aberrant response of the body to tissue injury that may be caused by trauma, inflammation, infection, cell injury, or cancer. ECM is the connective tissue framework of an organ or tissue.

Pancreatic ductal adenocarcinoma, or pancreatic cancer, is the second leading cause of cancer deaths in the U.S. Pancreatic cancer is typically not diagnosed until it is largely incurable; most patients are diagnosed after the age of 45. Approximately 64,000 people were diagnosed with pancreatic cancer in the U.S. in 2023, and approximately 50,000 people died of pancreatic cancer. Of all people diagnosed with pancreatic cancer in the U.S. between 2012 and 2018, the 5-year survival rate was 12%. Globally, an estimated 495,000 people were diagnosed with pancreatic cancer in 2020 and an estimated 466,000 people worldwide died from the disease. Because pancreatic cancer is difficult to diagnose, over 50% of new cases are metastatic, with a five-year survival rate of approximately 3%. An additional 15-20% of new pancreatic cancer patients are diagnosed with localized resectable tumors, with the remaining 30-35% of newly diagnosed patients having localized, unresectable tumors. On average, patients with resectable tumors live for 2.5 years post-diagnosis and have a five-year survival rate of 20-30%. In its report of December 2017, Decision Resources Group estimated that the major market sales (U.S., Europe and Japan) of pancreatic cancer drugs would grow from $1.3 billion in 2016 to approximately $3.7 billion in 2026.

The majority of patients are treated with chemotherapy, but pancreatic cancer is highly resistant to chemotherapy. Approximately 15% to 20% of patients are treated with surgery; however, even for those with successful surgical resection, the median survival is approximately two years, with a five-year survival rate of 15% to 20% (Neesse et al. Gut (2011)). Radiation treatment may be used for locally advanced diseases, but it is not curative.

The duration of effect of approved anti-cancer agents to treat pancreatic cancer is limited. Gemcitabine demonstrated improvement in median overall survival from approximately four to six months, and erlotinib in combination with gemcitabine demonstrated an additional ten days of survival. Nab-paclitaxel in combination with gemcitabine was approved by the FDA in 2013 for the treatment of pancreatic cancer, having demonstrated median survival of 8.5 months. The combination of folinic acid, 5-fluorouracil, irinotecan and oxaliplatin (FOLFIRINOX) was reported to increase survival to 11.1 months. These drugs illustrate that progress in treatment for pancreatic cancer has been modest, and there remains a need for substantial improvement in patient survival and quality of life.

The approved chemotherapeutic treatments for pancreatic cancer target the cancer cells themselves. Tumors are composed of cancer cells and associated non-cancer tissue, or stroma, of which ECM is a major component. In certain cancers such as pancreatic cancer, both the stroma and tumor cells produce CTGF which in turn promotes the proliferation and survival of stromal and tumor cells. CTGF also induces ECM deposition that provides advantageous conditions for tumor cell adherence and proliferation, promotes blood vessel formation, or angiogenesis, and promotes metastasis, or tumor cell migration, to other parts of the body.

Pancreatic cancers are generally resistant to powerful chemotherapeutic agents, and there is now growing interest in the use of an anti-fibrotic agent to diminish the supportive role of stroma in tumor cell growth and metastasis. The anti-tumor effects observed with pamrevlumab in preclinical models indicate that it has the potential to inhibit tumor expansion through effects on tumor cell proliferation and apoptosis as well as reduce metastasis.

Phase 3 Clinical Trial in Locally Advanced Unresectable Pancreatic Cancer

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

Phase 2/3 Clinical Trial in Metastatic Pancreatic Cancer

In June 2021, the Pancreatic Cancer Action Network's (PanCAN) Precision Promise℠ adaptive trial platform included pamrevlumab in combination with standard-of-care chemotherapy treatments for pancreatic cancer (gemcitabine and Abraxane®), for patients with metastatic pancreatic cancer. Drug candidates in the Precision Promise study will progress from Stage 1 to Stage 2 of this seamless Phase 2/3 study, unless stopped sooner for safety or futility. The objective of Precision Promise is to expedite the study and approval of promising therapies for pancreatic cancer by bringing multiple stakeholders together, including academic, industry, and regulatory entities.

In the third quarter of 2022, pamrevlumab graduated from Stage 1 to Stage 2, achieving a protocol pre-specified ≥ 35% predictive probability of success for the primary endpoint of overall survival at the completion of the trial. Pamrevlumab was the first experimental treatment arm to graduate to Stage 2 of the trial. The pamrevlumab combination therapy was offered to patients as either a first- or second-line treatment option.

In the first quarter of 2024, the pamrevlumab portion of the trial was completed, and we expect topline results in the second quarter of 2024. Precision Promise is a registration study, and the statistical design has been discussed by PanCAN with the FDA.

Completed Clinical Trials for Pancreatic Cancer

In addition to the aforementioned ongoing clinical trials, we have completed two other trials of pamrevlumab in pancreatic cancer.

Completed Phase 1/2 Clinical Trial in Locally Advanced Unresectable Pancreatic Cancer

We completed an open-label, randomized (2:1) Phase 1/2 trial (FGC004C-3019-069) of pamrevlumab combined with gemcitabine plus nab-paclitaxel chemotherapy vs. the chemotherapy regimen alone in patients with inoperable LAPC that had not been previously treated. We enrolled 37 patients in this study and completed the six-month treatment period and surgical assessment at the end of 2017. The overall goal of the trial was to determine whether pamrevlumab in combination with chemotherapy can convert inoperable pancreatic cancer to operable, or resectable, cancer. Tumor removal is the best chance for cure of pancreatic cancer, but only approximately 15% to 20% of patients are eligible for surgery.

We reported updated results from this study at the American Society of Clinical Oncology Annual Meeting in June 2018. A higher proportion (70.8%) of pamrevlumab-treated patients whose tumors were previously considered unresectable became eligible for surgical exploration than patients who received chemotherapy alone (15.4%), based on pre-specified eligibility criteria at the end of six months of treatment. Furthermore, a higher proportion of pamrevlumab-treated patients (33.3%) achieved surgical resection than those who received chemotherapy alone (7.7%).

In addition, this data showed improved overall survival among patients whose tumors were resected vs. not resected (NE vs. 18.56 months, p-value=0.0141) and a trend toward improved overall survival in patients eligible for surgery vs. patients who were not (27.73 vs. 18.40 months, p-value=0.0766). No increase in serious adverse events was observed in the pamrevlumab arm and no delay in wound healing was observed post-surgery.

If pamrevlumab in combination with chemotherapy continues to demonstrate an enhanced rate of conversion from unresectable cancer to resectable cancer, it may support the possibility that pamrevlumab could provide a substantial survival benefit for LAPC patients.

Completed Phase 1/2 Clinical Trial in Pancreatic Cancer

We completed an open-label Phase 1/2 (FGCL-MC3019-028) dose finding trial of pamrevlumab combined with gemcitabine plus erlotinib in patients with previously untreated locally advanced (Stage 3) or metastatic (Stage 4) pancreatic cancer. These study results were published in the *Journal of Cancer Clinical Trials* (Picozzi et al., J Cancer Clin Trials 2017, 2:123). Treatment continued until progression of the cancer, or the patient withdrew for other reasons. Patients were then followed until death.

Seventy-five patients were enrolled in this study with 66 (88%) having Stage 4 metastatic cancer. The study demonstrated a drug exposure-related increase in survival. At the lowest doses, no patients survived for even one year while at the highest doses up to 31% of patients survived one year.

A post-hoc analysis found that there was a significant relationship between survival and trough levels of plasma pamrevlumab measured immediately before the second dose (Cmin). Cmin greater than or equal to 150 µg/mL was associated with significantly improved progression-free survival (p=0.01) and overall survival (p=0.03) vs. those patients with Cmin less than 150 µg/mL. For patients with Cmin >150 µg/mL median survival was 9.0 months compared to median survival of 4.4 months for patients with Cmin <150 µg/mL. Similarly, 34.2% of patients with Cmin >150 µg/mL survived for longer than one year compared to 10.8% for patients with Cmin <150 µg/mL. These data suggest that sufficient blockade of CTGF requires pamrevlumab threshold blood levels of approximately 150 µg/mL in order to improve survival in patients with advanced pancreatic cancer.

In the study, the majority of adverse events were mild to moderate, and were consistent with those observed for erlotinib plus gemcitabine treatment without pamrevlumab. There were 99 treatment-emergent serious adverse events, six of which were assessed as possibly related to the investigational drug by the principal investigator, and 93 as not related to study treatment. After investigation, it was our determination that there was no causal relationship between pamrevlumab and the treatment-emergent serious adverse events deemed possibly related by the principal investigator. We did not identify any evolving dose-dependent pattern, and higher doses of pamrevlumab were not associated with higher numbers of serious adverse events or greater severity of the serious adverse events observed.

IDIOPATHIC PULMONARY FIBROSIS AND DUCHENNE MUSCULAR DYSTROPHY

In June 2023, we announced topline results from ZEPHYRUS-1, our first Phase 3 trial of pamrevlumab in 356 IPF patients. The study did not meet the primary endpoint of change from baseline in forced vital capacity (“FVC”) at week 48. Preliminary safety data showed that pamrevlumab was generally safe and well tolerated, with the majority of treatment-emergent adverse events being mild or moderate.

Given the results from ZEPHYRUS-1, we discontinued ZEPHYRUS-2, our second Phase 3 trial of pamrevlumab in approximately 340 IPF patients.

In 2023, we also announced topline results from LELANTOS-1 and LELANTOS-2, our double-blind, placebo-controlled Phase 3 trials evaluating pamrevlumab in non-ambulatory and ambulatory DMD, respectively. The studies did not meet their primary endpoints. Preliminary safety data showed that pamrevlumab was generally safe and well tolerated with the majority of treatment-emergent adverse events being mild or moderate.

ROXADUSTAT FOR THE TREATMENT OF ANEMIA

CHRONIC KIDNEY DISEASE

In collaboration with our partners Astellas Pharma Inc. (“Astellas”) and AstraZeneca, we have completed 16 Phase 3 studies worldwide in over 11,000 patients to support our marketing approvals of roxadustat (爱瑞卓®, EVRENZO™) to treat anemia in chronic kidney disease in China, Europe, Japan, and numerous other countries.

Background of Anemia in Chronic Kidney Disease

CKD is a progressive disease characterized by gradual loss of kidney function that may eventually lead to kidney failure or end-stage renal disease requiring dialysis or a kidney transplant to survive. CKD affects approximately 15% of the global adult population. CKD is more prevalent in developed countries but is also growing rapidly in emerging markets such as China.

Anemia is a complication of CKD and can be a serious medical condition in which patients have insufficient red blood cells and low levels of hemoglobin, a protein in red blood cells that carries oxygen to cells throughout the body. Anemia becomes increasingly common as kidney function declines and is associated with increased risk of hospitalization, cardiovascular complications and death, and frequently causes significant fatigue, cognitive dysfunction, and considerable reduction of quality of life.

China – Roxadustat Commercial Program

Since the launch of roxadustat (tradename: 爱瑞卓®) in 2019, the anemia of CKD market has expanded significantly. Roxadustat has captured the majority of this growth, benefiting from inclusion in the 2019, 2021, and 2023 National Reimbursement Drug Lists.

In 2023, roxadustat sales in China continued to see significant volume growth in the treatment of anemia caused by CKD in non-dialysis and dialysis patients. As of December 2023, roxadustat was the top CKD anemia brand in China with approximately 42% value share within the segment of erythropoiesis-stimulating agents ("ESAs") and HIF-PH inhibitors (roxadustat is currently the only HIF-PH inhibitor on the market in China). Roxadustat has seen broad adoption across the three segments of hemodialysis, peritoneal dialysis, and non-dialysis.

In 2024, we expect continued growth of roxadustat sales in China due to continued adoption by patients and doctors and the recent two-year renewal on the 2023 National Reimbursement Drug List with a limited price reduction of 7%.

We have established significant clinical experience and market leadership in treating CKD anemia in China, and we believe roxadustat has become the standard of care for the treatment of anemia in CKD in China. In 2024, we will focus on expanding the population treated with roxadustat, as well as the duration of treatment, which we believe is important in effective management of anemia in CKD.

Europe - Roxadustat Commercial Program

In Europe, our partner Astellas continues the commercialization of EVRENZO® (roxadustat). EVRENZO is approved for the treatment of anemia associated with CKD in both non-dialysis and dialysis patients. In 2024, we expect sales of roxadustat for CKD anemia in Europe to accelerate as reimbursement has been achieved in most European countries.

Japan - Roxadustat Commercial Program

In Japan, our partner Astellas continues the commercialization of EVRENZO (roxadustat), targeting healthcare providers that care for approximately 330,000 dialysis patients across Japan. EVRENZO is approved for the treatment of anemia associated with CKD in both non-dialysis and dialysis patients. EVRENZO is one of five HIF-PH inhibitors currently on the market in Japan.

CHEMOTHERAPY-INDUCED ANEMIA

As blood cell production in bone marrow is highly prolific, it is particularly vulnerable to the cytotoxic effects of chemotherapy used to treat cancer patients. Many chemotherapy agents directly impair hematopoiesis in bone marrow, including disruption of red blood cell production. The nephrotoxic effects of some cytotoxic agents, such as platinum-containing agents, can also result in decreased production of erythropoietin by the kidneys, further contributing to reduced red blood cell production. Radiation therapy has also been associated with hematologic toxicity.

There are approximately 10 million new cancer cases each year globally, 4.5 million in China. Of those, approximately half receive chemotheraphy, and half of those are anemic. The incidence and severity of CIA depend on a variety of factors, including the tumor type or the level of toxicity of the therapy, and further increases with each successive chemotherapy round. We believe the addressable population is approximately 500,000 in China.

ESAs have been recommended for patients who develop CIA with the desirable goals of improvement in anemia-related symptoms and the avoidance of blood transfusions, which increase risk of infections and the risk of complications such as heart failure and allergic reactions. However, not all CIA patients respond to ESA therapy, which may be due to the etiology of their CIA or inflammatory comorbidity. ESA use also has associated toxicities, including increased thrombotic events, possible decreased survival and accelerated tumor progression, as cited in randomized clinical trials and meta-analyses, that led to label restrictions and boxed warnings in the U.S. for ESAs in cancer populations in 2007, followed by the ESA Risk Evaluation and Mitigation Strategy program.

Phase 3 Clinical Trial in Chemotherapy-Induced Anemia

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

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

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

Our supplemental New Drug Application for roxadustat in CIA was accepted by the China Health Authority in August 2023, and we expect an approval decision mid-2024.

Although CIA is one of the most common side effects of chemotherapy, it is frequently undertreated. CIA can adversely affect long-term patient outcomes, as anemia limits both quality of life and the ability of patients to continue chemotherapy treatment. The incidence and severity of CIA depends on a variety of factors. This includes the type of cancer and the treatment, including the type of chemotherapy, schedule, and intensity of therapy. It also depends on whether the patient has received prior myelosuppressive chemotherapy, radiation therapy, or both.

Phase 2 Clinical Trial in Chemotherapy-Induced Anemia

The results of WHITNEY, the Phase 2 clinical trial of roxadustat in CIA in the U.S., was published by the American Journal of Hematology in January 2023. This study provided the basis for the study design for the China Phase 3 study.

ANEMIA ASSOCIATED WITH MYELODYSPLASTIC SYNDROMES

Myelodysplastic syndromes (“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., and 1.51/100,000 adults in China.

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

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

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

Lower-risk MDS patients represent approximately 77% of the total diagnosed MDS population. Most national and international guidelines recommend use of ESAs for anemia only in lower-risk MDS patients presenting with symptomatic anemia with serum EPO levels at or below 500 mU/mL.

The effectiveness of ESAs in treating anemia in lower-risk categories of MDS remains limited, with the best clinical study results showing 40% to 60% erythroid response rates, where significantly high doses of ESAs were used and enrolled patients had low serum EPO levels. New strategies to broaden the eligible population, improve anemia, and maintain adequate iron balance, as well as avoidance of transfusions, are highly desired in managing patients with MDS.

Market Opportunity for Roxadustat in Myelodysplastic Syndromes

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

Phase 3 Clinical Trial in Myelodysplastic Syndromes

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

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

However, in a post-hoc analysis of patients with higher transfusion burden (2 or more units of packed red blood cells every 4 weeks), 36.1% of the 36 roxadustat patients achieved transfusion independence, versus 11.5% of the 26 patients in the placebo arm (p=0.047).

PROSTATE CANCER

FG-3246 for the Treatment of Metastatic Castration-Resistant Prostate Cancer

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

FG-3246 showed monotherapy efficacy in a Phase 1 clinical study in patients with mCRPC. Interim efficacy results presented at ASCO 2022 showed a PSA50 response rate of 45% and an objective response rate of 19%. We expect additional data from this study by the first quarter of 2024.

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

We anticipate the initiation of a PET biomarker-driven Phase 2 trial of FG-3246 for mCRPC in the second half of 2024. This trial is expected to have a dose-ranging lead-in portion prior to the biomarker-driven portion of the study. Development of the CD46-targeted PET biomarker is continuing with UCSF. We are also exploring additional potential tumor indications in which CD46 is commonly expressed.

PRECLINICAL PIPELINE

Our preclinical pipeline consists of two antibodies for immuno-oncology that are in investigational New Drug Application-enabling studies.

FG-3165: Anti-Gal9 Antibody

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

FG-3175: Anti-CCR8 Antibody

FG-3175 is a c-c motif chemokine receptor 8 (“CCR8”) targeted antibody under development for treatment of solid tumors that are highly infiltrated by CCR8-positive T regulatory cells. T regulatory cells contribute to an immune suppressed tumor microenvironment, and multiple preclinical studies have demonstrated immune activation and tumor regression following depletion of this cell type from the tumor microenvironment. FG-3175 is a variant of our previous lead anti-CCR8 antibody, FG-3163, and was deemed to be a superior clinical candidate following extended characterization of both antibodies. FG-3175 has enhanced antibody dependent cellular cytotoxicity activity and induces potent killing of CCR8 expressing cells by natural killer cells in in vitro assay systems. We plan to submit an investigational new drug application (IND) in 2025.

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. In addition, we started roxadustat commercial sales in China in 2019. For the fiscal year ended December 31, 2023, 25% of our revenue was related to our collaboration agreements, and 68% of our revenue was from roxadustat commercial sales in China. For the fiscal year ended December 31, 2022, 40% of our revenue was related to our collaboration agreements, and 59% of our revenue was from roxadustat commercial sales in China. For the fiscal year ended December 31, 2021, 76% of our revenue was related to our collaboration agreements, and 20% of our revenue was from roxadustat commercial sales in China.

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

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 23, 2024.

However, our ongoing collaboration agreement with AstraZeneca for the development and commercialization of roxadustat for the treatment of anemia in China (the “AstraZeneca China Agreement”) continues in full force and is unaffected.

Under the AstraZeneca China Agreement, which is conducted through FibroGen China Anemia Holdings, Ltd., FibroGen Beijing, and FibroGen International (Hong Kong) Limited (collectively, "FibroGen China"), the commercial collaboration was structured as a 50/50 profit share, which was amended by the AstraZeneca China Amendment in the third quarter of 2020, as discussed and defined below.

In 2020, we entered into a Master Supply Agreement under the AstraZeneca U.S./RoW Agreement to define general forecast, order, supply, and payment terms for AstraZeneca to purchase roxadustat bulk drug product from FibroGen in support of commercial supplies.

In July 2020, FibroGen China and AstraZeneca entered into an amendment, effective July 1, 2020, to the AstraZeneca China Agreement, relating to the development and commercialization of roxadustat in China (the "AstraZeneca China Amendment").

Under the AstraZeneca China Amendment, in September 2020, FibroGen Beijing and AstraZeneca completed the establishment of a jointly owned entity, Beijing Falikang Pharmaceutical Co. Ltd. ("Falikang"), which performs roxadustat distribution, as well as conduct sales and marketing through AstraZeneca.

FibroGen Beijing manufactures and supplies commercial product to Falikang based on a gross transaction price, adjusted for the estimated profit share. Revenue is recognized upon the transfer of control of commercial products to Falikang in an amount that reflects the allocation of transaction price of the China manufacturing and supply obligation to the performance obligation satisfied during the reporting period.

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 3, *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 or accounts receivable for the last three fiscal years is set forth in Note 17, *Segment and Geographic Information*, to our consolidated financial statements under Item 8 of this Annual Report.

Exclusive License from HiFiBiO

In June 2021, we entered into an exclusive license and option agreement with HiFiBiO (HK) Ltd. (d.b.a. HiFiBiO Therapeutics) ("HiFiBiO"), pursuant to which we exclusively licensed from HiFiBiO all product candidates in HiFiBiO's Galectin-9 program and subsequently exclusively licensed all product candidates in HiFiBiO's CCR8 program. In addition to the upfront payments we previously paid, HiFiBiO may receive up to a total of $345 million in future clinical, regulatory, and commercial milestone payments for each program. HiFiBiO will also be eligible to receive tiered royalties based upon worldwide net sales.

Exclusive License and Option to Acquire Fortis Therapeutics

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

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

FibroGen is obligated to make four quarterly payments totaling $5.0 million to Fortis in support of its continued development obligations.

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

Exclusive License with Eluminex

In July 2021, we exclusively licensed to Eluminex Biosciences (Suzhou) Limited ("Eluminex") global rights to our investigational biosynthetic cornea derived from recombinant human collagen type III. FibroGen may receive up to a total of $64.0 million in future manufacturing, clinical, regulatory, and commercial milestone payments for the biosynthetic cornea program, as well as $36.0 million in commercial milestones for the first recombinant collagen III product that is not the biosynthetic cornea. FibroGen will be eligible to receive mid-single-digit to low double-digit royalties based upon worldwide net sales of cornea products, and low single-digit to mid-single-digit royalties based on worldwide net sales of other recombinant human collagen type III products that are not cornea products.

We received an $8.0 million upfront payment from Eluminex in 2022 and thereafter recognized a $3.0 million milestone payment based on Eluminex implanting a biosynthetic cornea in the first patient of its clinical trial in China, a $3.0 million manufacturing related milestone payment and a $1.0 million upfront payment. Additional information related to the Eluminex license revenue is set forth in Note 3, *Collaboration Agreements, License Agreement and Revenues*, to our consolidated financial statements under Item 8 of this Annual Report.

STRATEGIC FINANCING AGREEMENT

On November 4, 2022, we entered into a revenue interest financing agreement ("RIFA") with an affiliate of NovaQuest Capital Management ("NovaQuest") with respect to our revenues from Astellas' sales of roxadustat in Europe, Japan and the other Astellas territories.

Pursuant to the RIFA, 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 10, *Liability Related to Sale of Future Revenues*, to the consolidated financial statements.

On April 29, 2023, we entered into a financing agreement (the "Financing Agreement") with a $75.0 million senior secured term loan with investment funds managed by Morgan Stanley Tactical Value, as lenders, and Wilmington Trust, National Association, as the administrative agent. For additional details about this financing transaction, see Note 9, *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, including pancreatic cancer and anemia in CKD. 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.

We also face competition from generics that could enter the market after expiry of our composition of matter patent. As of the end of 2023, the Chinese health authority has accepted abbreviated New Drug Applications ("NDAs") for nineteen (19) generic roxadustat applicants. As these generic manufacturers would offer unpatented versions of roxadustat at a significantly reduced price, this competition could materially and adversely affect our business and financial condition.

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, such as in China. 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 or "API") and roxadustat drug product, respectively. WuXi STA is located in China and currently supplies our API globally except for China, for which it manufactures an intermediate to be further manufactured by FibroGen Beijing. 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, and China, where they are manufactured by FibroGen Beijing. Catalent has passed several regulatory inspections, including by the FDA, and manufactures commercial products for other clients.

In China, our Beijing facility received the Good Manufacturing Practice license for API and drug product. We are manufacturing drug product at our FibroGen Beijing manufacturing facility for commercial supply, but we are not currently manufacturing API at this facility. We are manufacturing API at our Cangzhou manufacturing facility, which is fully qualified and licensed. We may also qualify a third-party manufacturer to produce commercial API under the Marketing Authorization Holder System program.

Pamrevlumab

We have entered into a clinical and commercial supply agreement for the manufacture of pamrevlumab with Samsung Biologics Co., Ltd., which passed several regulatory inspections, including by the FDA, and manufactures commercial products for other clients. We are transitioning our manufacturing of pamrevlumab from Boehringer Ingelheim to Samsung Biologics Co., Ltd.

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 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 United States 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 and EU 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

In the U.S. and foreign jurisdictions, we expect there will continue to be a number of legislative and regulatory changes to the healthcare system that could affect the future results of our operations as we directly commercialize our products. In particular, there continues to be a number of initiatives at the U.S. federal and state level that seek to reduce healthcare costs.

For example, as a cost containment measure, PPACA established: an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents; revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; and extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations. There have been executive, judicial and Congressional challenges to certain aspects of the PPACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (“IRA”) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in PPACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the PPACA will be subject to future judicial or Congressional challenges, other litigation, and healthcare reform measures of the Biden administration that may impact the PPACA and our business.

Further, in the U.S. there was heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which 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. The IRA also, among other things, (1) directs the U.S. Department of Health and Human Services (“HHS") to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. It is unclear whether these or similar policy initiatives will be implemented in the future.

Some states implemented, and other states are considering, price controls or patient access constraints under the Medicaid program, and some states are considering price-control regimes that would apply to broader segments of their populations that are not Medicaid-eligible. Due to the volatility in the current economic and market dynamics, we are unable to predict the impact of any unforeseen or unknown legislative, regulatory, payor or policy actions, which may include cost containment and healthcare reform measures. Such policy actions could impact on our business.

Approval Process and Other Regulation in China

The pharmaceutical industry in China is highly regulated. The primary regulatory authority is the NMPA, including its provincial and local branches. As a developer, manufacturer and supplier of drugs, we are subject to regulation and oversight by the NMPA and its provincial and local branches. The Drug Administration Law of China provides the basic legal framework for the administration of the production and sale of pharmaceuticals in China and covers the manufacturing, distributing, packaging, pricing and advertising of pharmaceutical products. Its implementing regulations set forth detailed rules with respect to the administration of pharmaceuticals in China. In addition, we are, and we will be, subject to other Chinese laws and regulations that are applicable to business operators, manufacturers and distributors in general.

Pharmaceutical Clinical Development

A new drug must be approved by the NMPA before it can be manufactured and marketed for sale. To obtain NMPA approval, the applicant must conduct clinical trials, which must be approved by the NMPA and are subject to the NMPA's supervision and inspection. There are four phases of clinical trials. Application for registration of new drugs requires completion of Phase 1, 2 and 3 of clinical trials, similar to the U.S. In addition, the NMPA may require the conduct of Phase 4 studies as a condition to approval.

Phase 4 studies are post-marketing studies to assess the therapeutic effectiveness of and adverse reactions to the new drug, including an evaluation of the benefits and risks, when used among the general population or specific groups, with findings used to inform adjustments to dosage, among other things.

NDA and Approval to Market

China requires approval of the NDA as well as the manufacturing facility before a drug can be marketed in China. Approval and oversight are performed at national and provincial levels of the NMPA, involve multiple agencies and consist of various stages of approval.

Under the applicable drug registration regulations, drug registration applications are divided into three different types, namely Domestic NDA, Domestic Generic Drug Application, and Imported Drug Application. Drugs fall into one of three categories, namely chemical medicine, biological product, or traditional Chinese or natural medicine.

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

Pamrevlumab has received orphan drug designation in pancreatic cancer in the U.S. 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.

In China, there may also be an opportunity for data exclusivity for a period of six years for data included in an NDA applicable to a NCE. According to the Implementing Regulations of the China Drug Administration Law, the Chinese government would protect undisclosed data from drug studies and prevent the approval of an application made by another company that uses the undisclosed data for the approved drug. However, even though the NMPA issued a draft regulation on regulatory data protection on April 25, 2018 for public comment, the regulation has yet to be finalized and implemented. As such, data exclusivity is currently not enforced.

In addition, if an approved drug manufactured in China qualified as an innovative drug or an improved new drug before December 1, 2019, such drugs were eligible for a monitoring surveillance period for up to five years for the purpose of protecting public health. Under the regulations, during this post-marketing surveillance period, the NMPA would not accept marketing authorization applications filed by another company for the same product, nor approve marketing authorization applications filed by another company to produce, change dosage form of, or import the drug. The approved manufacturer was required to provide an annual report to the regulatory department of the province, autonomous region or municipality directly under the central government where it is located during the surveillance period. Although this procedure was reportedly still active for drugs that had qualified prior to changes in the law ending the monitoring surveillance provisions, the CDE started accepting marketing authorization applications for generic forms of roxadustat, starting in May 2023.

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 expire 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. 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.

In China, no photostable formulation patent has yet been granted (applications are pending). Our roxadustat China patent portfolio additionally includes a granted patent and pending patent applications directed to roxadustat particle size distribution (PSD) in commercial formulations and use of roxadustat to treat select CIA patient populations. These patents and patent applications, upon grant, could extend the exclusivity of the roxadustat franchise with respect to the claimed subject matter to 2043.

Several patents in our roxadustat patent portfolio have been challenged in Europe and China. In particular, patent challenges have been filed against our crystal form patents in Europe and China, and against our photostable formulations patent in Europe. While European Patent No. 2872488 (the "`488 Patent"), which claims the commercial crystalline form of roxadustat, was originally revoked in opposition, the decision is currently under appeal. While both the `397 Patent and our European Patent No. 3003284 (the "`284 Patent"), which claims photostable formulations of roxadustat, were upheld in opposition, the opponents have appealed the decision in the `284 Patent and we anticipate the opponents will appeal the decision in the `397 Patent. In China, three roxadustat crystal form patents were revoked in first-round proceedings and two revocations were upheld on first appeal; however, all decisions currently remain on appeal. Final resolution of these proceedings in Europe and China will take time and we cannot be assured that these patents will survive these proceedings as originally granted or at all.

Pamrevlumab Patent Portfolio

Our pamrevlumab patent portfolio includes U.S. and foreign patents providing composition-of-matter protection for pamrevlumab. Exclusive of any patent term extension, the last of the U.S. patents relating to pamrevlumab composition-of-matter is due to expire in 2025 and corresponding foreign patents are due to expire, exclusive of any patent term extension, in 2024. Therefore, in most jurisdictions, exclusivity for pamrevlumab will rely primarily on regulatory exclusivities, including a 12-year reference product exclusivity period from approval in the U.S. and a 10-year marketing protection period from approval in Europe. Similar regulatory exclusivities exist in other jurisdictions. Refer to *"Government Regulation — Regulatory Exclusivity for Approved Products — Biologic Price Competition and Innovation Act"* and *"Government Regulation — Regulatory Exclusivity for Approved Products — Foreign Country Data Exclusivity."*

We also hold additional granted U.S. and foreign patents and pending patent applications directed to the use of pamrevlumab to treat pancreatic cancer. Upon marketing approval of pamrevlumab in most jurisdictions, we can request patent term extension on a non-expired patent in that jurisdiction that is relevant to the approved label. For example, we believe that if pamrevlumab is approved in the U.S. prior to expiration of the composition-of-matter patent, a full five-year patent term extension under the Hatch-Waxman Act will be available, extending the term of that patent to 2030.

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.

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

Bristol-Myers Squibb Company (Medarex, Inc.)

Effective July 9, 1998, and as amended on June 30, 2001 and January 28, 2002, we entered into a research and commercialization agreement with Medarex, Inc. and its wholly-owned subsidiary GenPharm International, Inc. (now, collectively, part of Bristol-Myers Squibb Company ("Medarex")) to develop fully human monoclonal antibodies for potential anti-fibrotic therapies. Under the agreement, Medarex was responsible for using its proprietary immunizable transgenic mice ("HuMAb-Mouse technology") during a specified research period (the "Research Period"), to produce fully human antibodies against our proprietary antigen targets, including CTGF, for our exclusive use.

The agreement granted us an option to obtain an exclusive worldwide, royalty-bearing, commercial license to develop antibodies derived from Medarex's HuMAb-Mouse technology, for use in the development and commercialization of diagnostic and therapeutic products. In December 2002, we exercised that option with respect to twelve antibodies inclusive of the antibody from which pamrevlumab is derived. We granted back to Medarex an exclusive, worldwide, royalty-free, perpetual, irrevocable license, with the right to sublicense, to certain inventions created during the parties' research collaboration, with such license limited to use by Medarex outside the scope of our licensed antibodies.

As a result of the exercise of our option to obtain the commercial license, Medarex is precluded from:

(i) knowingly using any technology involving immunizable transgenic mice containing unrearranged human immunoglobulin genes with any of our antigen targets that were the subject of the agreement,

(ii) granting to a third party a commercial license that covers such antigen targets or those antibodies derived by Medarex during the Research Period, and

(iii) using any antibodies derived by Medarex during the Research Period, except as permitted under the agreement for our benefit or to prosecute patent applications in accordance with the agreement.

Medarex retained ownership of the patent rights relating to certain mice, mice materials, antibodies and hybridoma cell lines used by Medarex in connection with its activities under the agreement, and Medarex also owns certain claims in patents covering inventions that arise during the Research Period, which claims are directed to (i) compositions of matter (e.g., an antibody) except formulations of antibodies for therapeutic or diagnostic use, or (ii) methods of production. We own the patent rights to any inventions that arise during the Research Period that relate to antigens, as well as claims in patents covering inventions directed to (a) methods of use of an antibody, or (b) formulations of antibodies for therapeutic or diagnostic use. Upon exercise of our option to obtain the commercial license, we obtained the sole right but not obligation to control prosecution of patents relating solely to the licensed antibodies or products. Medarex has back-up patent prosecution rights in the event we decline to further prosecute or maintain such patents.

In addition to research support payments by us to Medarex during the Research Period, and an upfront commercial license fee in the form of 181,819 shares of FibroGen Series D Convertible Preferred Stock paid upon exercise of our option, we committed development-related milestone payments of up to $11 million per therapeutic product containing a licensed antibody, and we have paid a $1 million development-related milestone, in the form of 133,333 shares of FibroGen Series G Convertible Preferred Stock, and a cash payment of $2 million, for pamrevlumab to date. At our election, the remaining milestone payments may be paid in common stock of FibroGen, Inc., or cash.

With respect to our sales and sales by our affiliates, the agreement also requires us to pay Medarex low single-digit royalties for licensed therapeutic products and low double-digit royalties plus certain capped sales-based bonus royalties for licensed diagnostic products. With respect to sales of licensed products by a sublicensee, we may elect to pay the foregoing royalties based on our sublicensee's sales, or a percentage (in the high-teens) of all payments received by us from such sublicensee. We are also required to reimburse Medarex any pass-through royalties, if any, payable under Medarex's upstream license agreements with Medical Research Council and DNX. Royalties payable by us under the agreement are on a licensed product-by-licensed product and country-by-country basis and subject to reductions in specified circumstances, and royalties are payable for a period until either expiration of patents covering the applicable licensed product or a specified number of years following the first commercial sale of such product in the applicable country.

Unless earlier terminated, the agreement will continue in effect for as long as there are royalty payment obligations by us or our sublicensees. Either party may terminate the agreement for certain material breaches by the other party, or for bankruptcy, insolvency or similar circumstances. In addition, we may also terminate the agreement for convenience upon written notice.

Fortis Therapeutics / University of California, San Francisco (UCSF)

Effective May 5, 2023, we entered into an Evaluation Agreement with Fortis Therapeutics, Inc., under which FibroGen 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 metastatic castration-resistant prostate cancer (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 FibroGen, Fortis Therapeutics, and Shareholder Representative Services LLC dated May 5, 2023. If we exercise our merger option on or before the option exercise deadline, we will acquire Fortis Therapeutics and all benefits and obligations associated with the Fortis IP and license with UCSF, subject to contingent payments of up to $200 million based on certain milestones. If we do not exercise our merger option, the license will terminate at the option exercise deadline which is the earlier of 90 days from the receipt of end of phase 2 meeting minutes from FDA regarding FG-3246 or May 5, 2027 absent extension.

HiFiBiO Therapeutics

Effective June 16, 2021, we entered into an Exclusive License and Option Agreement with HiFiBiO (HK) Ltd. (d.b.a. HiFiBiO Therapeutics), under which FibroGen was granted an exclusive, worldwide license to HiFiBiO know-how and patent rights to all galectin-9 (Gal-9)-directed products for all uses, and a sublicense from HiFiBiO to in-licensed anti-Gal-9 antibodies from Société d'Accélération du Transfert de Technologie ("SATT-NORD"). The patent rights include U.S. and foreign patents and patent applications directed to specific anti-Gal-9 antibodies, fragments, and uses, and are due to expire in 2041 exclusive of any patent term extension or adjustment that may be available. The licensed patents relate to FG-3165 and related products.

We were also granted an option under the agreement to license a second program from HiFiBiO which we exercised on December 10, 2021, with respect to HiFiBiO know-how and patent rights to all CCR8-directed products for all uses. The patent rights include U.S. and foreign patents and patent applications directed to specific anti-CCR8 antibodies, fragments, and uses, and are due to expire in 2042 exclusive of any patent term extension or adjustment that may be available. The licensed patents relate to FG-3175 and related products.

Under the agreement, we have first right to prepare, file, prosecute, and maintain patents and patent applications in the HiFiBiO patent rights at our own expense and using mutually agreed-upon counsel. We are also obligated to pay an upfront licensing and option fee totaling $35 million and a subsequent option exercise payment of $35 million for the CCR8 program, all of which have been paid, and R&D and regulatory milestone payments of up to $175 million, as well as sales milestones of up to $170 million, and an escalating royalty based on calendar year aggregate net sales of licensed product capped at 10%, subject to certain reductions.

Unless earlier terminated, the agreement will continue in effect, on a country-by-country basis, until the expiration of all licensed patents in a country, after which the license will become perpetual, irrevocable, fully-paid up, and royalty free. HiFiBiO may terminate the agreement for our uncured material breach or bankruptcy. We may terminate the agreement for HiFiBiO's uncured material breach, bankruptcy, or at any time on prior written notice to HiFiBiO.

HUMAN RESOURCES

We had a total of 486 employees at FibroGen as of December 31, 2023. None of our U.S. employees are represented by a labor union. The employees of FibroGen Beijing are represented by a labor union under the China Labor Union Law. 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 2023, we conducted a company-wide employee engagement survey. We had an overall participation rate of 96% with an 89% overall engagement score (China 96%. U.S. 79%). Just as in 2022, we exceeded our corporate goal of an 85% overall engagement score. Further, in 2022, an independent firm established a diversity, equity, and inclusion index based upon 10 employee questions within the survey to measure the effectiveness of, and employee sentiment about, our progress in nurturing a culture of diversity, equity, belonging and inclusion; our diversity index score was 89% (China 90%, U.S. 88%), an increase compared to 88% in 2022. These scores significantly exceed normative industry participation and engagement benchmarks.

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. As in 2022, we have been able to contain regrettable turnover to less than 6%, and we closed 2023 with only 3.1% regrettable losses. We also believe that to be an employer of choice, we must support the communities in which we live and operate. In 2023, we doubled the size of our high school and college internship program (after re-launching the program in 2022), which provides opportunities for people of color and/or economically disadvantaged youth to contribute and learn for eight to twelve weeks at our U.S. operations.

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, learning and giving programs, and flexible work arrangements. In addition to our employee and manager fundamentals programs, we offer personal coaching and resiliency sessions, as well as access to an on-demand global learning management system. In addition to annual compliance training on harassment prevention, our Code of Conduct, Anti-Bribery and data privacy, our employees are offered internal career development programs each year in addition to tuition reimbursement eligibility.

Our state-of-art, human capital management system, implemented in 2020, has significantly expanded our capabilities to develop and assess our employees. We build comprehensive development and succession plans at all levels in the organization to ensure that we have a strong pipeline of ready talent to meet our business outcomes.

Ensuring diversity in our workforce begins with role modeling and striving for diversity in senior management. On our Board of Directors, 3 of 9 members (33%) are female. Further, 2 of 9 members (22%) identify as Asian or Hispanic ethnicity. Notably, our U.S. workforce is 50% female. Our U.S. employees that self-report ethnicity are 58% Asian, Hispanic or Black. Of our U.S. Executive population (Vice President and above), 37.5% are female and of our U.S. executives that self-report ethnicity, 25% identify as Asian or Hispanic. Our China workforce is 57% female (largely unchanged), and of our China Executives (Vice President and above) 67% are female, an increase from 50% in 2022. Across our workforce and our leadership, we have increased our female and ethnicity representation year over year and continue to expand our efforts and corporate objectives accordingly. One of our goals in 2024 is to increase female diversity at the executive director level and above, which was 49% in the U.S. and 67% in China at the end of 2023.

In addition to furthering our investments in our human resources, we plan to continue our efforts in 2024 in critical environmental, social, and governance (“ESG”) areas. In 2023, we performed an ESG assessment of our operations, finding that we accomplished most of our yearly goals, including high-impact goals such as providing disclosure on investor outreach and feedback on Say-on-Pay proposals and resulting changes, improving Compensation Discussion and Analysis (CD&A) disclosure, and adopting a policy to increase patient diversity in clinical trials. In 2023, we also determined a number of goals for 2024, including adopting a cybersecurity incidence response policy and committee charter, drafting a 2024 Equity Incentive Plan, and performing a climate impact analysis once the SEC adopts final climate disclosure regulations.

FACILITIES

Our corporate and research and development operations are located in San Francisco, California, where we lease approximately 234,000 square feet of office and laboratory space with approximately 12,000 square feet subleased. We are currently under contract to stay at our San Francisco headquarters until the end of 2028. We also lease approximately 67,000 square feet of office and manufacturing space in Beijing, China, and multiple office spaces in Beijing and Shanghai, China. Our leases in China expire in 2026. We have constructed a commercial manufacturing facility of approximately 5,500 square meters in Cangzhou, China, on approximately 33,000 square meters of land. Our right to use such land expires in 2068. We believe our facilities are adequate for our current needs and that suitable additional or substitute space would be available if needed.

AVAILABLE INFORMATION

Our internet website address is www.fibrogen.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 headquarters are located at 409 Illinois Street, San Francisco, California 94158 and our telephone number is (415) 978-1200. Our website address is www.FibroGen.com.

Our subsidiaries consist of the following: 1) FibroGen Europe Oy, a majority-owned entity incorporated in Finland in 1996; 2) Skin Sciences, Inc., a majority-owned entity incorporated in the State of Delaware in 1995; 3) FibroGen International (Cayman) Limited, a majority-owned entity incorporated in the Cayman Islands in 2011; 4) FibroGen China Anemia Holdings Ltd., a majority-owned entity incorporated in the Cayman Islands in 2012; 5) FibroGen International (Hong Kong) Limited, a majority-owned entity incorporated in Hong Kong in 2011; 6) FibroGen INTL LLC, a majority-owned entity incorporated in the State of Delaware in 2021; 7) FibroGen (China) Medical Technology Development Co., Ltd., a majority-owned entity incorporated in China in 2011; and 8) Beijing Falikang Pharmaceutical Co. Ltd., an unconsolidated variable interest entity incorporated in China in 2020.

"FibroGen," the FibroGen logo and other trademarks or service marks of FibroGen, Inc. appearing in this Annual Report are the property of FibroGen, 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, 2023 ("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 pamrevlumab and roxadustat.

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

The near-term value drivers for the Company depend in large part on pamrevlumab, which is in clinical development for locally advanced unresectable pancreatic cancer ("LAPC") and metastatic pancreatic cancer. Even if one or both of the Phase 3 clinical trials are successful, pamrevlumab will require substantial further investment. At this time, we do not have a collaboration partner to support the development and commercialization of pamrevlumab. Additionally, as a monoclonal antibody, it will cost significantly more to manufacture pamrevlumab than it would for a typical small molecule drug.

Our near-term value drivers also include continued development and commercialization of roxadustat in the People's Republic of China ("China"), Japan, Europe, and elsewhere. We continue to co-commercialize roxadustat in China with AstraZeneca AB ("AstraZeneca") and develop roxadustat in China in chemotherapy-induced anemia ("CIA").

After terminating (except for South Korea) 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 Pharma Inc. ("Astellas") (the "AstraZeneca U.S./RoW Agreement") on February 23, 2024, we are currently investigating new licensing opportunities for roxadustat; however, there can be no assurance that we will find such a partner or be able to agree to a license on reasonable terms.

As we continue to fulfill our mission to develop novel therapeutics, we are investing in new drug programs to expand our early oncology pipeline. While we see great potential value in our early development oncology pipeline, these programs are years away from commercialization, and the success of any development program is not guaranteed. Our biggest value drivers in the near term rely on the success of pamrevlumab Phase 3 trials and roxadustat commercialization.

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

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

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

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

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

• our failure to adequately demonstrate to the satisfaction of regulatory authorities or an independent advisory committee that our product candidate is safe and effective in a particular indication, or that such product candidate's clinical and other benefits outweigh its safety risks;

• our failure of clinical trials to meet the level of statistical significance required for approval;

• the determination by regulatory authorities that additional information (including additional preclinical or clinical data or trials) 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;

• 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; or

• failure by collaboration partners to perform or complete their clinical programs in a timely manner, or at all.

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

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

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.

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;

• 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 or military conflicts around the world;

• delay or failure to maintain clinical sites in compliance with clinical trial protocols or to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

• delay or failure to initiate or add a sufficient number of clinical trial sites;

• delay or failure to manufacture sufficient quantities of product candidate for use in clinical trials;

• difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned;

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

• changes in laws or regulations.

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

• severity of the disease under investigation;

• availability of alternative treatments;

• size and nature of the patient population;

• eligibility criteria for and design of the study in question;

• perceived risks and benefits of the product candidate under study;

• ongoing clinical trials of competitive agents;

• physicians' and patients' perceptions of the potential advantages of our product candidates being studied in relation to available therapies or other products under development;

• our CRO's and our trial sites' efforts to facilitate timely enrollment in clinical trials;

• patient referral practices of physicians; and

• ability to monitor patients and collect patient data adequately during and after treatment.

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

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

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

• our clinical trial development plan becoming longer and more expensive;

• terminating some of our clinical trials for the product candidates or specific indications affected;

• regulatory authorities increasing the data and information required to approve our product candidates and imposing other requirements; and

• our collaboration partners terminating our existing agreements.

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

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

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

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

Completion of our clinical trials and commercialization of our products require access to, or development of, facilities to manufacture and manage our product candidates at sufficient yields, quality and at commercial scale. Although we have entered into commercial supply agreements for roxadustat and pamrevlumab, we will need to enter into additional commercial supply agreements, including for backup or second source third-party manufacturers. We may not be able to enter into these agreements with satisfactory terms or on a timely manner. In addition, we may experience delays or technical problems associated with technology transfer of manufacturing processes to any new suppliers.

We have relatively limited experience manufacturing or managing third parties in manufacturing any of our product candidates in the volumes that are expected to be necessary to support large-scale clinical trials and sales. In addition, we have limited experience forecasting supply requirements or coordinating supply chain (including export and customs management) for launch or commercialization, which is a complex process involving our third-party manufacturers and logistics providers, and for roxadustat, our collaboration partners. We may not be able to accurately forecast supplies for commercial launch or do so in a timely manner and our efforts to establish these manufacturing and supply chain management capabilities may not meet our requirements as to quantities, scale-up, yield, cost, potency or quality in compliance with cGMP, particularly if the marketing authorization or market uptake is more rapid than anticipated or we have an unanticipated surge in demand.

We have a limited amount of roxadustat and pamrevlumab in storage, limited capacity reserved at our third-party manufacturers, and, even if we have or are able to put sufficient supply agreements in place for our development and commercialization plan, there are long lead times required to manufacture and scale-up the manufacture of additional supply, as well as for raw materials and components for manufacture of our products, as required for both late-stage clinical trials, post-approval trials, and commercial supply. There is a general risk of delayed drug supply due to delays experienced by any third-party provider in the supply chain, including raw material and components suppliers, export and customs locations, and shipping companies. In addition, if we or a partner are not able to obtain regulatory approval of roxadustat in the U.S. in anemia associated with MDS, we may have excess supply manufactured in anticipation of commercialization. Such roxadustat excess supply could be wasted, for example, if it expires prior to being used in other clinical trials or prior to being used in other territories where such roxadustat formulation is approved. If we are unable to forecast, order or manufacture sufficient quantities of roxadustat or pamrevlumab on a timely basis, it may delay our development, launch or commercialization in some or all indications we are currently pursuing. Insufficient supply could be a particular risk if we were to obtain regulatory approval of pamrevlumab in the indications being studied (LAPC and metastatic pancreatic cancer). Any delay or interruption in the supply of our product candidates or products could have a material adverse effect on our business and operations.

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

We or our partners may add or change manufacturers, change our manufacturing processes, or change packaging specifications to accommodate changes in regulations, manufacturing equipment or to account for different processes at new or second source suppliers. Changes made to roxadustat or pamrevlumab including, but not limited to, demonstration of comparability to regulatory approved/ in approval products and processes, additional clinical trials, delays in development or commercialization, earlier expiration dates, shorter shelf life, or specification failures, may materially impact our operations and potential profitability.

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

• costs and challenges associated with scale-up and attaining sufficient manufacturing yields, in particular for biologic products such as pamrevlumab, which is a monoclonal antibody;

• contracting with additional suppliers and validation/qualification of additional facilities to meet growing demand;

• supply chain issues, including coordination of multiple contractors in our supply chain and securing necessary licenses (such as export licenses);

• the timely availability and shelf-life requirements of raw materials and supplies;

• limited stability and product shelf life;

• equipment maintenance issues or failure;

• quality control and quality assurance issues;

• shortages of qualified personnel and capital required to manufacture large quantities of product;

• compliance with regulatory requirements that vary in each country where a product might be sold;

• capacity or forecasting limitations and scheduling availability in contracted facilities;

• natural disasters, such as pandemics, floods, storms, earthquakes, tsunamis, and droughts, or accidents such as fire, that affect facilities, possibly limit or postpone production, and increase costs; and

• failure to obtain license to proprietary starting materials.

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

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

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

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

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

We expect that in many cases, the products that we commercialize will compete with existing marketed products of companies that have large, established commercial organizations. We face competition from generics that could enter the market after expiry of our composition of matter patent. As of the end of 2023, the Chinese health authority has accepted abbreviated New Drug Applications for 19 generic roxadustat applicants.

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

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

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

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

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

• the efficacy of the product candidate as demonstrated in clinical trials;

• the safety profile and perceptions of safety of our product candidates relative to competitive products;

• acceptance of the product candidate as a safe and effective treatment by healthcare providers and patients;

• the clinical indications for which the product candidate is approved;

• the potential and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments;

• the inclusion or exclusion of the product candidate from treatment guidelines established by various physician groups and the viewpoints of influential physicians with respect to the product candidate;

• the cost of the product candidate relative to alternative treatments;

• adequate pricing and reimbursement by third parties and government authorities as described below;

• the relative convenience and ease of administration;

• the frequency and severity of adverse events;

• the effectiveness of sales and marketing efforts; and

• any unfavorable publicity relating to the product candidate.

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

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

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

• a covered benefit under applicable health plan;

• safe, effective and medically necessary;

• appropriate for the specific patient;

• cost-effective; and

• neither experimental nor investigational.

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

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

Risks Related to Our Reliance on Third Parties

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

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

We rely on the Pancreatic Cancer Action Network (“PanCAN”) to run its Precision Promise[SM] Phase 2/3 registration study in metastatic pancreatic cancer. While this study includes pamrevlumab in combination with standard of care chemotherapy, PanCAN is the sponsor of the study and we do not run or control its conduct. Therefore, pamrevlumab’s success in this indication is highly dependent on PanCAN’s ability and willingness to run the Precision Promise study. Similarly, we depend on PanCAN to perform certain analyses of the study data and provide these to us to support the submission of a market authorization application to applicable regulatory authorities, if appropriate.

While we have recently terminated the AstraZeneca U.S./RoW Agreement (except for South Korea), we have active collaboration agreements with respect to the development and commercialization of roxadustat with Astellas and with AstraZeneca in China and South Korea. These agreements provide for reimbursement of our development costs by our collaboration partners and also provide for the commercialization of roxadustat throughout the major territories of the world.

Our current agreements with Astellas and AstraZeneca provide them with the right to terminate their agreements with us upon the occurrence of negative clinical results, delays in the development and commercialization of our product candidates or adverse regulatory requirements or guidance. In addition, each of those agreements provides our partners the right to terminate any of those agreements upon written notice for convenience. The termination of any of our collaboration agreements would require us to fund and perform the further development and commercialization of roxadustat in the affected territory or pursue another collaboration, which we may be unable to do, either of which could have an adverse effect on our business and operations. Moreover, if Astellas or AstraZeneca, or any successor entity, were to determine that their collaborations with us are no longer a strategic priority, or if either of them or a successor were to reduce their level of commitment to their collaborations with us, our ability to commercialize roxadustat could suffer.

For instance, the AstraZeneca U.S./RoW Agreement was terminated on February 23, 2024 (except for South Korea). , Although our ongoing collaboration agreement with AstraZeneca for the development and commercialization of roxadustat for the treatment of anemia in China (the “AstraZeneca China Agreement”) continues in full force and is unaffected, this eliminates any additional potential milestones or other payments AstraZeneca would have made under the AstraZeneca U.S./RoW Agreement except for potentially in South Korea. Such payments were remote due to our withdrawal of the U.S. NDA for CKD anemia. And while we are now investigating new licensing opportunities for roxadustat, there can be no assurance that we will find such a partner or be able to agree to a license on reasonable terms.

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

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

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

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

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

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

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

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

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

We do not have operating manufacturing facilities at this time other than our roxadustat manufacturing facilities in China. We currently rely, and expect to continue to rely, on third parties to scale-up, manufacture and supply roxadustat and our other product candidates for drug product in Europe and other countries, and on our partner Astellas for drug product in Japan. We rely on third parties for distribution, including our collaboration partners and their vendors, except in China where we have established a jointly owned entity with AstraZeneca to manage most of the distribution in China. Risks arising from our reliance on third-party manufacturers include:

• reduced control and additional burdens of oversight as a result of using third-party manufacturers and distributors for all aspects of manufacturing activities, including regulatory compliance and quality control and quality assurance;

• termination of manufacturing agreements, termination fees associated with such termination, or nonrenewal of manufacturing agreements with third parties may negatively impact our planned development and commercialization activities;

• significant financial commitments we may be required to make with third-party manufacturers for early-stage clinical or pre-clinical programs that may fail to produce scientific results that would justify further development (without the ability to mitigate the manufacturing investments);

• the possible misappropriation of our proprietary technology, including our trade secrets and know-how;

• disruptions to the operations of our third-party manufacturers, distributors or suppliers unrelated to our product, including the merger, acquisition, or bankruptcy of a manufacturer or supplier or a catastrophic event, affecting our manufacturers, distributors or suppliers; and

• inability for FibroGen to meet timing and volume obligations to Astellas 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.

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

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

We have made certain manufacturing commitments to Samsung, and there is a contractual risk we will not require the quantities of pamrevlumab we have committed to, particularly if we do not submit a Biologics License Application (“BLA”) for pamrevlumab. In addition, our product candidates and any products that we may develop may compete with other product candidates and products for access and prioritization to manufacture. Certain third-party manufacturers may be contractually prohibited from manufacturing our product due to non-compete agreements with our competitors or a commitment to grant another party priority relative to our products. There are a limited number of third-party manufacturers that operate under cGMP and that might be capable of manufacturing to meet our requirements. Due to the limited number of third-party manufacturers with the contractual freedom, expertise, required regulatory approvals and facilities to manufacture our products on a commercial scale, identifying and qualifying a replacement third-party manufacturer would be expensive and time-consuming and may cause delay or interruptions in the production of our product candidates or products, which in turn may delay, prevent or impair our development and commercialization efforts. We also carry the risk that we may need to pay termination fees to Samsung or other manufacturers in the event that we have to manufacture lower volumes or not at all depending on the results of our clinical trials. We may be subject to payments to Samsung to cover portions or all of the committed manufacturing campaigns even if we do not need the material for clinical or commercial usage. In addition, third-party manufacturers tend to change their upfront fees or postponement/cancelation fees over time or upon initiation of additional contracts, and this may lead to unanticipated financial loss for FibroGen.

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

Certain components of our products are acquired from single-source suppliers or without long-term supply agreements. The loss of these suppliers, or their failure to supply, would materially and adversely affect our business.

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

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

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

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trade secret protection, and contractual arrangements to protect the intellectual property related to our technologies. We will only be able to protect our products and proprietary information and technology to the extent that our patents, trade secrets, contractual position, and governmental regulations and laws allow us to do so. Any unauthorized use or disclosure of our proprietary information or technology could compromise our competitive position. Moreover, we are, have been, and may in the future be involved in legal proceedings initiated by third parties involving our intellectual property, which proceedings can be associated with significant costs and commitment of management time and attention.

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

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

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

Intellectual property protecting our roxadustat product is either being challenged or will expire at various times in the coming years, raising the possibility of generic competition. The introduction of generic competition for a patented branded medicine typically results in a significant and rapid reduction in net sales and operating income for the branded product because generic manufacturers typically offer their unpatented versions at sharply lower prices. Such competition can occur after successful challenges to intellectual property rights or the regular expiration of the term of the patent or other intellectual property rights. Such competition can also result from a Declaration of Public Interest or the compulsory licensing of our drugs by governments, or from a general weakening of intellectual property laws in certain countries around the world. In addition, generic manufacturers sometimes take an aggressive approach to challenging intellectual property rights, including conducting so-called "launches at risk" of products that are still under legal challenge for infringement before final resolution of legal proceedings. In China, numerous generic manufacturers have filed abbreviated new drug applications (ANDAs) seeking marketing approval for generic versions of our EVRENZOTM product (爱瑞卓®, roxadustat). While we are taking steps to both defend our roxadustat patents and challenge these ANDA filers, the outcome is uncertain.

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

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how, information, or technology that is not covered by our patents. Although our agreements require employees to acknowledge ownership by us of inventions conceived as a result of employment from the point of conception and, to the extent necessary, perfect such ownership by assignment, and we require employees, consultants, advisors and third parties who have access to our trade secrets, proprietary know-how and other confidential information and technology to enter into appropriate confidentiality agreements, we cannot be certain that our trade secrets, proprietary know-how and other confidential information and technology will not be subject to unauthorized disclosure, use, or misappropriation or that our competitors will not otherwise gain access to or independently develop substantially equivalent trade secrets, proprietary know-how and other information and technology. Furthermore, the laws of some foreign countries, in particular, China, where we have operations, 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, pamrevlumab or FG-3246. Any litigation involving defense against claims of infringement, regardless of the merit of such claims, would involve substantial litigation expense and would be a substantial diversion of management time.

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

Third parties have challenged and may again challenge our patents and patent applications. In particular, patent challenges have been filed against our crystal form patents in Europe and China, and against our photostable formulations patent in Europe. While European Patent No. 2872488 (the "`488 Patent"), which claims the commercial crystalline form of roxadustat, was originally revoked in opposition, the decision is currently under appeal. While both the `397 Patent and our European Patent No. 3003284 (the "`284 Patent"), which claims photostable formulations of roxadustat, were upheld in opposition, the opponents have appealed the decision in the `284 Patent and we anticipate the opponents will appeal the decision in the `397 Patent. In China, three roxadustat crystal form patents were revoked in first-round proceedings and two revocations were upheld on first appeal; however, all decisions currently remain on appeal. Final resolution of these proceedings in Europe and China will take time and we cannot be assured that these patents will survive these proceedings as originally granted or at all.

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

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

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

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

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

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

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

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

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

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

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

• Others may be able to make compounds or independently develop similar or alternative technologies that are the same as or similar to our current or future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.

• Patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product.

• Our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates.

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

Counterfeit products, including counterfeit pharmaceutical products, are a significant problem, particularly in China. Counterfeit pharmaceuticals are products sold or used for research under the same or similar names, or similar mechanism of action or product class, but which are sold without proper licenses or approvals, and are often lower cost, lower quality, different potency, or have different ingredients or formulations, and have the potential to damage the reputation for quality and effectiveness of the genuine product. Such products may be used for indications or purposes that are not recommended or approved or for which there is no data or inadequate data with regard to safety or efficacy. Such products divert sales from genuine products. If counterfeit pharmaceuticals illegally sold or used for research result in adverse events or side effects to consumers, we may be associated with any negative publicity resulting from such incidents. Consumers may buy counterfeit pharmaceuticals that are in direct competition with our pharmaceuticals, which could have an adverse impact on our revenues, business and results of operations. In addition, the use of counterfeit products could be used in non-clinical or clinical studies, or could otherwise produce undesirable side effects or adverse events that may be attributed to our products as well, which could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. With respect to China, although the government has recently been increasingly active in policing counterfeit pharmaceuticals, there is not yet an effective counterfeit pharmaceutical regulation control and enforcement system in China. As a result, we may not be able to prevent third parties from selling or purporting to sell our products in China. The 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 roxadustat will not obtain regulatory approval in additional countries or indications. It is possible that our other product candidates we may discover, in-license or acquire and seek to develop in the future, will not obtain regulatory approval in any particular jurisdiction.

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

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

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, 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 ("GDPR"), the United Kingdom ("UK's) GDPR, Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais) (Law No. 13,709/2018), and China's Personal Information Protection Law ("PIPL") impose strict requirements for processing personal data, including health-related information. For example, under the European Union GDPR, companies may face fines of up to 20 million Euros or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. We also target customers in Asia and have operations in China and are subject to new and emerging data privacy regimes in Asia, including China's PIPL, Japan's Act on the Protection of Personal Information, and Singapore's Personal Data Protection Act.

Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the U.S. in compliance with law, such as the EEA and UK's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto, these mechanisms are subject to legal challenges and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions are subject to scrutiny from regulators, individual litigants, and activities groups.

Our employees and personnel could use generative artificial intelligence ("AI") technologies to perform certain work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. 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; and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations including clinical trials; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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

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

Compliance with these anti-bribery laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the anti-bribery laws present particular challenges in the pharmaceutical industry because in many countries including China, hospitals are state-owned or operated by the government, and doctors and other hospital employees are considered foreign government officials. Furthermore, in certain countries (China in particular), hospitals and clinics are permitted to sell pharmaceuticals to their patients and are primary or significant distributors of pharmaceuticals. Certain payments to hospitals in connection with clinical studies, procurement of pharmaceuticals and other work have been deemed to be improper payments to government officials that have led to vigorous anti-bribery law enforcement actions and heavy fines in multiple jurisdictions, particularly in the U.S. and China.

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

In the pharmaceutical industry, corrupt practices include, among others, acceptance of kickbacks, bribes or other illegal gains or benefits by the hospitals and medical practitioners from pharmaceutical manufacturers, distributors or their third-party agents in connection with the prescription of certain pharmaceuticals. If our employees, partners, affiliates, subcontractors, distributors or third-party marketing firms violate these laws or otherwise engage in illegal practices with respect to their sales or marketing of our products or other activities involving our products, we could be required to pay damages or heavy fines by multiple jurisdictions where we operate, which could materially and adversely affect our financial condition and results of operations. The Chinese government has also sponsored anti-corruption campaigns from time to time, which could have a chilling effect on any future marketing efforts by us to new hospital customers. There have been recent occurrences in which certain hospitals have denied access to sales representatives from pharmaceutical companies because the hospitals wanted to avoid the perception of corruption. If this attitude becomes widespread among our potential customers, our ability to promote our products to hospitals may be adversely affected.

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

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

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

Efforts required to remediate an ineffective system of control over financial reporting may place a significant burden on management and add increased pressure on our financial resources and processes. Moreover, we implemented an enterprise resource planning ("ERP") system in the first quarter of 2023, which replaced our existing operating and financial systems, to improve the efficiency of certain financial and transactional processes. However, there is an increased risk that changing controls may be ineffective during the implementation and this ERP system may place additional burdens on employees to learn and adapt our processes to effectively operate under the ERP system. If the ERP system does not operate as intended, the effectiveness of our internal control over financial reporting could be negatively impacted. If we experience material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting, the accuracy and timing of our financial reporting and subsequently our liquidity and our access to capital markets may be adversely affected, we may be unable to maintain or regain compliance with applicable securities laws and the Nasdaq Stock Market LLC listing requirements, we may be subject to regulatory investigations and penalties, investors may lose confidence in our financial reporting, and our stock price may decline.

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

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

Further, in the U.S. there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. For example, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. Further, the IRA (1) directs HHS to negotiate the price of certain single-source drugs or biologics covered under Medicare, and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid ("CMS") Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

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

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

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

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

- comply with FDA regulations or similar regulations of comparable foreign regulatory authorities;
- provide accurate information to the FDA or comparable foreign regulatory authorities;
- comply with manufacturing standards we have established;
- comply with data privacy and security laws protecting personal data;

• comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities;

• comply with the FCPA and other anti-bribery laws;

• report financial information or data accurately; or

• disclose unauthorized activities to us.

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

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

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

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

Risks Related to Our International Operations

We have established operations in China and are seeking approval to commercialize our product candidates outside of the U.S., and a number of risks associated with international operations could materially and adversely affect our business.

A number of risks related to our international operations, many of which may be beyond our control, include: different regulatory requirements in different countries, including for drug approvals, manufacturing, and distribution; potential liability resulting from development work conducted by foreign distributors; economic weakness, including inflation, or foreign currency fluctuations, which could result in increased operating costs and expenses and reduced revenues, and other obligations incident to doing business in another country; workforce uncertainty in countries where labor unrest is more common than in the U.S.; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; political instability in particular foreign economies and markets; and business interruptions resulting from geopolitical actions specific to an international region, including war and terrorism, or natural disasters, including pandemics.

The pharmaceutical industry in China is highly regulated and such regulations are subject to change.

The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, many aspects of pharmaceutical industry regulation have undergone significant reform, and reform may continue. For example, the Chinese government implemented regulations that impact distribution of pharmaceutical products in China, where at most two invoices may be issued throughout the distribution chain, a change that required us to change our distribution paradigm. Any regulatory changes or amendments may result in increased compliance costs to our business or cause delays in or prevent the successful development or commercialization of our product candidates in China. Any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China.

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

The majority of audit work incurred for the audit report included in the 2023 Form 10-K was performed by the U.S.-based independent registered public accounting firm we have retained, PricewaterhouseCoopers LLP, which is headquartered in the U.S. and was not identified in the report issued by the PCAOB on December 16, 2021.

However, we estimate that between 20% and 30% of the total audit hours for our December 31, 2023 audit were provided by PricewaterhouseCoopers Zhong Tian LLP located in China.

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

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

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

Even though we currently view the likelihood to be remote, if our operations fundamentally change in a way that requires our independent registered public accounting firm be located in China or Hong Kong in order to comply with the standards of the PCAOB regarding principal auditor, then the HFCAA would apply to us, which consequences could include the potential delisting of our stock from the Nasdaq Global Select Market and prohibition from trading in the over-the counter market in the U.S. Such a restriction would negatively impact our ability to raise capital. Additionally, we cannot rule out the possibility that in the future Congress could amend the HFCAA or the SEC could modify its regulations to apply the restrictions, including trading prohibitions and delisting, under the HFCAA in situations in which an independent registered public accounting firm in China or Hong Kong performs part of the audit such as in our current situation.

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

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

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

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

We use our own manufacturing facilities in China to produce roxadustat API and drug product for the market in China. There are risks inherent to operating commercial manufacturing facilities, and with these being our single source suppliers, we may not be able to continually meet market demand.

We have two manufacturing facilities in China, with one located in Beijing and the other in Cangzhou, Hebei.

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

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

Further, 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”) and companies that do business with WuXi Biologics. While the current legislation does not affect our roxadustat supplier Shanghai SynTheAll Pharmaceutical Co., Ltd. (“WuXi STA”), there is a risk that FibroGen could face consequences from contracting with WuXi Biologics, could be forced to find an alternative supplier for FG-3246, and there is a risk that such legislation could expand to include WuXi STA. The occurrence of any such event could materially and adversely affect our business, financial condition, results of operations, cash flows and prospects.

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

AstraZeneca and we have a profit-sharing arrangement with respect to roxadustat in China and any difficulties we may experience in growing and sustaining sales will affect our bottom line. Difficulties may be related to competition and our ability to maintain reasonable pricing and reimbursement, obtain and maintain hospital listing, or other difficulties related to distribution, marketing, and sales efforts in China. Roxadustat's recent inclusion in the 2023 National Reimbursement Drug List came with a limited 7% price reduction. Such reimbursement pricing for China is effective for a standard two-year period (between January 1, 2024, and December 31, 2025). However, after four generics are approved in China, there is a substantial risk of being subject to the country's volume-based purchasing program whereby a national tender could be called for roxadustat. If a tender is called for roxadustat, our access to the market as the originator drug would be significantly constrained and our price would be further reduced.

Sales of roxadustat in China may also be limited due to the complex nature of the healthcare system, low average personal income, pricing controls, still developing infrastructure, and potentially rapid competition from other products.

The retail prices of any product candidates that we develop will be subject to pricing control in China and elsewhere.

The price of pharmaceutical products is highly regulated in China, both at the national and provincial level. Price controls may reduce prices to levels significantly below those that would prevail in less regulated markets or limit the volume of products that may be sold, either of which may have a material and adverse effect on potential revenues from sales of roxadustat in China. Moreover, the process and timing for the implementation of price restrictions are unpredictable, which may cause potential revenues from the sales of roxadustat to fluctuate from period to period.

FibroGen (China) Medical Technology Development Co., Ltd. ("FibroGen Beijing") would be subject to restrictions on paying dividends or making other payments to us, which may restrict our ability to satisfy our liquidity requirements.

We plan to conduct all of our business in China through FibroGen China Anemia Holdings, Ltd., FibroGen Beijing and its branch offices, and our joint venture distribution entity, Beijing Falikang Pharmaceutical Co., Ltd. ("Falikang"). We may in the future rely on dividends and royalties paid by FibroGen Beijing for a portion of our cash needs, including the funds necessary to service any debt we may incur and to pay our operating costs and expenses. The payment of dividends by FibroGen Beijing is subject to limitations. Regulations in China currently permit payment of dividends only out of accumulated profits as determined in accordance with applicable accounting standards and regulations in China. FibroGen Beijing is not permitted to distribute any profits until losses from prior fiscal years have been recouped and in any event must maintain certain minimum capital requirements. FibroGen Beijing is also required to set aside at least 10.0% of its after-tax profit based on Chinese accounting standards each year to its statutory reserve fund until the cumulative amount of such reserves reaches 50.0% of its registered capital. Statutory reserves are not distributable as cash dividends. In addition, if FibroGen Beijing incurs debt on its own behalf in the future, the agreements governing such debt may restrict its ability to pay dividends or make other distributions to us. As of December 31, 2023, approximately $32.1 million of our cash and cash equivalents is held in China.

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

The Ministry of Commerce in China or its local counterpart must approve the amount and use of any capital contributions from us to FibroGen Beijing, and there can be no assurance that we will be able to complete the necessary government registrations and obtain the necessary government approvals on a timely basis, or at all. If we fail to do so, we may not be able to contribute additional capital or find suitable financing alternatives within China to fund our Chinese operations, and the liquidity and financial position of FibroGen Beijing may be materially and adversely affected.

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

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

In addition, the Chinese government imposes controls on the convertibility of the Renminbi into foreign currencies and the remittance of foreign currency out of China for certain transactions. Shortages in the availability of foreign currency may restrict the ability of FibroGen Beijing to remit sufficient foreign currency to pay dividends or other payments to us, or otherwise satisfy their foreign currency-denominated obligations. Under existing Chinese foreign exchange regulations, payments of current account items, including profit distributions, interest payments and balance of trade, can be made in foreign currencies without prior approval from the State Administration of Foreign Exchange by complying with certain procedural requirements. However, approval from the State Administration of Foreign Exchange or its local branch is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. The Chinese government may also at its discretion restrict access in the future to foreign currencies for current account transactions. If the foreign exchange control system prevents us from obtaining sufficient foreign currency to satisfy our operational requirements, our liquidity and financial position may be materially and adversely affected.

Because FibroGen Beijing's funds are held in banks that do not provide insurance, the failure of any bank in which FibroGen Beijing deposits its funds could adversely affect our business.

Banks and other financial institutions in China do not provide insurance for funds held on deposit. As a result, in the event of a bank failure, FibroGen Beijing may not have access to funds on deposit. Depending upon the amount of money FibroGen Beijing maintains in a bank that fails, its inability to have access to cash could materially impair its operations.

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

The tax regulations of the U.S. and other jurisdictions in which we operate are extremely complex and subject to change. New laws, new interpretations of existing laws, such as the Base Erosion Profit Shifting project initiated by the Organization for Economic Co-operation and Development, and any legislation proposed by the relevant taxing authorities, or limitations on our ability to structure our operations and intercompany transactions may lead to inefficient tax treatment of our revenue, profits, royalties, and distributions, if any are achieved. For example, the Biden administration has proposed to increase the U.S. corporate income tax rate from 21%, increase the U.S. taxation of our international business operations and impose a global minimum tax, although the recently enacted Inflation Reduction Act of 2022 omitted to include any of these proposals but included only a minimum tax on certain large corporations and a tax on certain repurchases of stock on the corporations doing those repurchases. Such proposed changes, as well as regulations and legal decisions interpreting and applying these changes, may adversely impact our effective tax rate.

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

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

Our foreign operations, particularly those in China, are subject to significant risks involving the protection of intellectual property.

We seek to protect the products and technology that we consider important to our business by pursuing patent applications in China and other countries, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. We note that the filing of a patent application does not mean that we will be granted a patent, or that any patent eventually granted will be as broad as requested in the patent application or will be sufficient to protect our technology. There are a number of factors that could cause our patents, if granted, to become invalid or unenforceable or that could cause our patent applications not to be granted, including known or unknown prior art, deficiencies in the patent application, or lack of originality of the technology. Furthermore, the terms of our patents are limited. The patents we hold and the patents that may be granted from our currently pending patent applications have, absent any patent term adjustment or extension, a twenty-year protection period starting from the date of application.

Intellectual property rights and confidentiality protections in China may not be as effective as those in the U.S. or other countries for many reasons, including lack of procedural rules for discovery and evidence, low damage awards, and lack of judicial independence. Implementation and enforcement of China intellectual property laws have historically been deficient and ineffective and may be hampered by corruption and local protectionism. Policing unauthorized use of proprietary technology is difficult and expensive, and we may need to resort to litigation to enforce or defend patents issued to us or to determine the enforceability and validity of our proprietary rights or those of others. The experience and capabilities of China courts in handling intellectual property litigation varies and outcomes are unpredictable. An adverse determination in any such litigation could materially impair our intellectual property rights and may harm our business.

Uncertainties with respect to the China legal system and regulations could have a material adverse effect on us.

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

Unlike in a common law system, prior court decisions may be cited for reference but are not binding. Because the China legal system continues to rapidly evolve, the interpretations of many laws, regulations and rules are not always uniform and enforcement of these laws, regulations and rules involve uncertainties, which may limit legal protections available to us. Moreover, decision makers in the China judicial system have significant discretion in interpreting and implementing statutory and contractual terms, which may render it difficult for FibroGen Beijing to enforce the contracts it has entered into with our business partners, customers and suppliers. Different government departments may have different interpretations of certain laws and regulations, and licenses and permits issued or granted by one government authority may be revoked by a higher government authority at a later time. Furthermore, new laws or regulations may be passed, in some cases with little advance notice, that affect the way we or our collaboration partner do business in China (including the manufacture, sale, or distribution of roxadustat in China). Our business may be affected if we rely on laws and regulations that are subsequently adopted or interpreted in a manner different from our understanding of these laws and regulations. Navigating the uncertainty and change in the China legal and regulatory systems will require the devotion of significant resources and time, and there can be no assurance that our contractual and other rights will ultimately be maintained or enforced.

Changes in China's economic, governmental, or social conditions could have a material adverse effect on our business.

Chinese society and the Chinese economy continue to undergo significant change. Changes in the regulatory structure, regulations, and economic policies of the Chinese government could have a material adverse effect on the overall economic growth of China, which could adversely affect our ability to conduct business in China. The Chinese government continues to adjust economic policies to promote economic growth. Some of these measures benefit the overall Chinese economy, but may also have a negative effect on us. For example, our financial condition and results of operations in China may be adversely affected by government control over capital investments or changes in tax regulations. Recently, Chinese regulators announced regulatory actions aimed at providing China's government with greater oversight over certain sectors of China's economy, including the for-profit education sector and technology platforms that have a quantitatively significant number of users located in China. Although the biotech industry is already highly regulated in China and while there has been no indication to date that such actions or oversight would apply to companies that are similarly situated as us and that are pursuing similar portfolios of drug products and therapies as us, China's government may in the future take regulatory actions that may materially adversely affect the business environment and financial markets in China as they relate to us. As the Chinese pharmaceutical industry grows and evolves, the Chinese government may also implement measures to change the regulatory structure and structure of foreign investment in this industry. We are unable to predict the frequency and scope of such policy changes and structural changes, any of which could materially and adversely affect FibroGen Beijing's development and commercialization timelines, liquidity, access to capital, and its ability to conduct business in China. Any failure on our part to comply with changing government regulations and policies could result in the loss of our ability to develop and commercialize our product candidates in China. In addition, the changing government regulations and policies could result in delays and cost increases to our development, manufacturing, approval, and commercialization timelines in China.

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

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

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

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

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

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

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

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

Our operations in China subject us to various Chinese labor and social insurance laws, and our failure to comply with such laws may materially and adversely affect our business, financial condition and results of operations.

We are subject to China Labor Contract Law, which provides strong protections for employees and imposes many obligations on employers. The Labor Contract Law places certain restrictions on the circumstances under which employers may terminate labor contracts and require economic compensation to employees upon termination of employment, among other things. In addition, companies operating in China are generally required to contribute to labor union funds and the mandatory social insurance and housing funds. Any failure by us to comply with Chinese labor and social insurance laws may subject us to late fees, fines and penalties, or cause the suspension or termination of our ability to conduct business in China, any of which could have a material and adverse effect on business, results of operations and prospects.

Risks Related to the Operation of Our Business

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

We are a biopharmaceutical company with two lead product candidates in clinical development, roxadustat for CIA in China, and pamrevlumab for pancreatic cancer. Most of our revenue generated to date has been based on our collaboration agreements and we have limited commercial drug product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. Our net loss for the years ended December 31, 2023, 2022 and 2021 were $284.2 million, $293.7 million and $290.0 million, respectively. As of December 31, 2023, we had an accumulated deficit of $1.8 billion. As of December 31, 2023, we had capital resources consisting of cash, cash equivalents and short-term investments of $235.6 million. In addition, as of December 31, 2023, we had $12.6 million of accounts receivable in our current assets. Despite contractual development and cost coverage commitments from our collaboration partners, AstraZeneca and Astellas, and the potential to receive milestone and other payments from these partners, and despite commercialization efforts for roxadustat for the treatment of anemia caused by CKD, we anticipate we will continue to incur losses on an annual basis for the foreseeable future. If we do not successfully develop and continue to obtain regulatory approval for our existing or any future product candidates and effectively manufacture, market and sell the product candidates that are approved, we may never achieve or sustain profitability on a quarterly or annual basis. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity (deficit) and working capital. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

We believe that we will continue to expend substantial resources for the foreseeable future as we continue to grow our operations in China, continue our clinical development efforts on pamrevlumab, continue to seek regulatory approval, establish commercialization capabilities of our product candidates, and pursue additional indications. These expenditures will include costs associated with research and development, conducting preclinical trials and clinical trials, obtaining regulatory approvals in various jurisdictions, and manufacturing and supplying products and product candidates for our partners and ourselves. The outcome of any clinical trial and/or regulatory approval process is highly uncertain and we are unable to fully estimate the actual costs necessary to successfully complete the development and regulatory approval process for our compounds in development and any future product candidates. We believe that our existing cash and cash equivalents, short-term and long-term investments and accounts receivable, cash flows from commercial sales and sales of drug product, and expected third-party collaboration revenues will allow us to fund our operating plans through at least 12 months from the date of issuance of these consolidated financial statements. Our operating plans or third-party collaborations may change as a result of many factors, including the success of our development and commercialization efforts, operations costs (including manufacturing and regulatory), competition, and other factors that may not currently be known to us, and we therefore may need to seek additional funds sooner than planned, through offerings of public or private securities, debt financing or other sources, such as revenue interest monetization or other structured financing. Future sales of equity or debt securities may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may adversely affect our business. We may also seek additional capital due to favorable market conditions or strategic considerations even if we currently believe that we have sufficient funds for our current or future operating plans.

Accordingly, we may seek additional funds sooner than planned. We may also seek additional capital due to favorable market conditions or strategic considerations even if we currently believe that we have sufficient funds for our current or future operating plans.

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

In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. If we raise additional funds by issuing equity securities, dilution to our existing stockholders will result. In addition, as a condition to providing additional funding to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Moreover, any debt financing, if available, may involve restrictive covenants that could limit our flexibility in conducting future business activities and, in the event of insolvency, would be paid before holders of equity securities received any distribution of corporate assets. For example, in 2022 we entered into a Revenue Interest Financing Agreement ("RIFA") with an affiliate of NovaQuest Capital Management ("NovaQuest") and in 2023 we entered into a debt financing agreement with investment funds managed by Morgan Stanley Tactical Value, each of which 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 adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate our research and development efforts or other operations or activities that may be necessary to commercialize our product candidates.

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

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

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

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

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

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

On April 29, 2023, we entered into a financing agreement ("Financing Agreement") with a $75 million senior secured term loan with investment funds managed by Morgan Stanley Tactical Value, as lenders, and Wilmington Trust, National Association, as the administrative agent.

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

For additional details about these financing transactions, see Note 9, *Senior Secured Term Loan Facilities* and Note 10, *Liability Related to Sale of Future Revenues*, to the consolidated financial statements.

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

• increasing our vulnerability to adverse economic and industry conditions;

• limiting our ability to obtain additional non-dilutive financing or enter into collaboration or partnership agreements of a certain size;

• requiring the dedication of a portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;

• limiting our flexibility to plan for, or react to, changes in our business; and

• placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

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

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

Most of our recent revenue has been earned through our roxadustat collaborations.

If either our Astellas collaboration or our AstraZeneca China collaboration were to be terminated, we could have a sudden decrease of revenue and require significant additional capital in order to help fund our operations. If adequate funds or partners are not available to us on a timely basis or on favorable terms, we may be required to delay, limit, reduce or terminate development or commercialization efforts.

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

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

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

We are highly dependent on members of our senior management team. The loss of the services of any of our senior management could significantly impact the development and commercialization of our products and product candidates and our ability to successfully implement our business strategy.

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

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

On July 14, 2023 and December 11, 2023, FibroGen approved a reduction to its U.S. workforce of approximately 32% and 7.4% to lower its operating expenses, causing the loss of valuable skills, experience, and productivity. Furthermore, employee turnover and other risks described above may be exacerbated by the restructuring as well as recent stock performance.

If we are unable to continue to attract and retain personnel with the quality and experience applicable to our product candidates, our ability to pursue our strategy will be limited and our business and operations would be adversely affected.

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

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

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

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

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

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

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

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

- termination of further development of unapproved product candidates or significantly reduced demand for any approved products;
- material costs and expenses to defend the related litigation;

• a diversion of time and resources across the entire organization, including our executive management;

• product recalls, product withdrawals or labeling restrictions;

• termination of our collaboration relationships or disputes with our collaboration partners; and

• reputational damage negatively impacting our other product candidates in development.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our headquarters are located near known earthquake fault zones.

We and some of the third-party service providers on which we depend for various support functions are vulnerable to damage from catastrophic events, such as power loss, natural disasters, terrorism and similar unforeseen events beyond our control. Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes and fires.

After a comprehensive earthquake risk analysis conducted by Marsh Risk, we decided not to purchase earthquake or flood insurance. Based upon (among other factors) the Marsh Risk analysis, the design and construction of our building, the expected potential loss, and the costs and deductibles associated with earthquake and flood insurance, we chose to self-insure. However, earthquakes or other natural disasters could severely disrupt our operations, or have a larger cost than expected, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, or otherwise disrupted operations, all critical systems and services can be accessible from the disaster recovery site, but it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans are in draft and are unlikely to provide adequate protection in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

Risks Related to Our Common Stock

The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above your purchase price.

The market price of our common stock has at times experienced price volatility and may continue to be volatile. For example, during 2023, the closing price of our common stock on The Nasdaq Global Select Market has ranged from $0.38 per share to $25.18 per share. In general, pharmaceutical, biotechnology and other life sciences company stocks have been highly volatile in the current market. The volatility of pharmaceutical, biotechnology and other life sciences company stocks is sometimes unrelated to the operating performance of particular companies and biotechnology and life science companies stocks often respond to trends and perceptions rather than financial performance. In particular, the market price of shares of our common stock could be subject to wide fluctuations in response to the following factors:

• results of clinical trials of our product candidates, including roxadustat and pamrevlumab;

• the timing of the release of results of and regulatory updates regarding our clinical trials;

• the level of expenses related to any of our product candidates or clinical development programs;

• results of clinical trials of our competitors' products;

• safety issues with respect to our product candidates or our competitors' products;

• regulatory actions with respect to our product candidates and any approved products or our competitors' products;

• fluctuations in our financial condition and operating results, which will be significantly affected by the manner in which we recognize revenue from the achievement of milestones under our collaboration agreements;

• adverse developments concerning our collaborations and our manufacturers;

• the termination of a collaboration or the inability to establish additional collaborations;

• the inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices;

• disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

• changes in legislation or other regulatory developments affecting our product candidates or our industry;

• fluctuations in the valuation of the biotechnology industry and particular companies perceived by investors to be comparable to us;

• speculation in the press or investment community;

• announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;

• activities of the government of China, including those related to the pharmaceutical industry as well as industrial policy generally;

• performance of other U.S. publicly traded companies with significant operations in China;

• changes in market conditions for biopharmaceutical stocks; and

• the other factors described in this "*Risk Factors*" section.

As a result of fluctuations caused by these and other factors, comparisons of our operating results across different periods may not be accurate indicators of our future performance. Any fluctuations that we report in the future may differ from the expectations of market analysts and investors, which could cause the price of our common stock to fluctuate significantly. Moreover, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. We are currently subject to such litigation and it has diverted, and could continue to result in diversions of, our management's attention and resources and it could result in significant expense, monetary damages, penalties or injunctive relief against us. For a description of our pending litigation and SEC investigation, see Note 12, *Commitments and Contingencies*, to the consolidated financial statements.

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

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

• issue stock that would dilute our existing stockholders' percentage of ownership;

• incur debt and assume liabilities; and

• incur amortization expenses related to intangible assets or incur large and immediate write-offs.

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

• problems integrating the purchased business, products or technologies, or employees or other assets of the acquisition target;

• increases to our expenses;

• disclosed or undisclosed liabilities of the acquired asset or company;

• diversion of management's attention from their day-to-day responsibilities;

• reprioritization of our development programs and even cessation of development and commercialization of our current product candidates;

• harm to our operating results or financial condition;

• entrance into markets in which we have limited or no prior experience; and

• potential loss of key employees, particularly those of the acquired entity.

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

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

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

• authorize "blank check" preferred stock, which could be issued by our Board of Directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;

• create a classified Board of Directors whose members serve staggered three-year terms;

• specify that special meetings of our stockholders can be called only by our Board of Directors pursuant to a resolution adopted by a majority of the total number of directors;

• prohibit stockholder action by written consent;

• establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our Board of Directors;

• provide that our directors may be removed prior to the end of their term only for cause;

• provide that vacancies on our Board of Directors may be filled only by a majority of directors then in office, even though less than a quorum;

• require a supermajority vote of the holders of our common stock or the majority vote of our Board of Directors to amend our bylaws; and

• require a supermajority vote of the holders of our common stock to amend the classification of our Board of Directors into three classes and to amend certain other provisions of our certificate of incorporation.

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

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

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

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

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

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

The tax regulations in the U.S. and other jurisdictions in which we operate are extremely complex and subject to change. Changes in tax regulations could have an adverse effect on our results of operations and financial condition.

Tariffs imposed by the U.S. and those imposed in response by other countries could have a material adverse effect on our business.

Changes in U.S. and foreign governments' trade policies have resulted in, and may continue to result in, tariffs on imports into and exports from the U.S. Throughout 2018 and 2019, the U.S. imposed tariffs on imports from several countries, including China. In response, China has proposed and implemented their own tariffs on certain products, which may impact our supply chain and our costs of doing business. If we are impacted by the changing trade relations between the U.S. and China, our business and results of operations may be negatively impacted. Continued diminished trade relations between the U.S. and other countries, including potential reductions in trade with China and others, as well as the continued escalation of tariffs, could have a material adverse effect on our financial performance and results of operations.

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

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

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

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

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

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

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

ITEM 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 Chief Legal Officer) 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 enterprise risk management (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 Vice President 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 Vice President of IT holds an undergraduate degree in Computer Engineering and has served in Information Technology & Security roles dedicated to the Pharma & Biotechnology sector for the last 15+ years, including serving as the Chief Information Officer of another public biopharmaceutical company.

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

Our corporate and research and development operations are located in San Francisco, California, where we lease approximately 234,000 square feet of office and laboratory space with approximately 30,000 square feet subleased. The lease for our San Francisco headquarters was originally scheduled to expire in 2023, and in June 2021, we amended the lease to extend it through 2028. We also lease approximately 67,000 square feet of office and manufacturing space in Beijing, China, and multiple office spaces in Beijing and Shanghai, China. Our leases in China expire in 2026. We have constructed a commercial manufacturing facility of approximately 5,500 square meters in Cangzhou, China, on approximately 33,000 square meters of land. Our right to use such land expires in 2068. We believe our facilities are adequate for our current needs and that suitable additional or substitute space would be available if needed.

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 active legal action in our consolidated balance sheet as of December 31, 2023, as we could not predict the ultimate outcome of these matters, or reasonably estimate the potential exposure. For a discussion of our legal proceedings, refer to Note 12, *Commitments and Contingencies*, to the consolidated financial statements.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

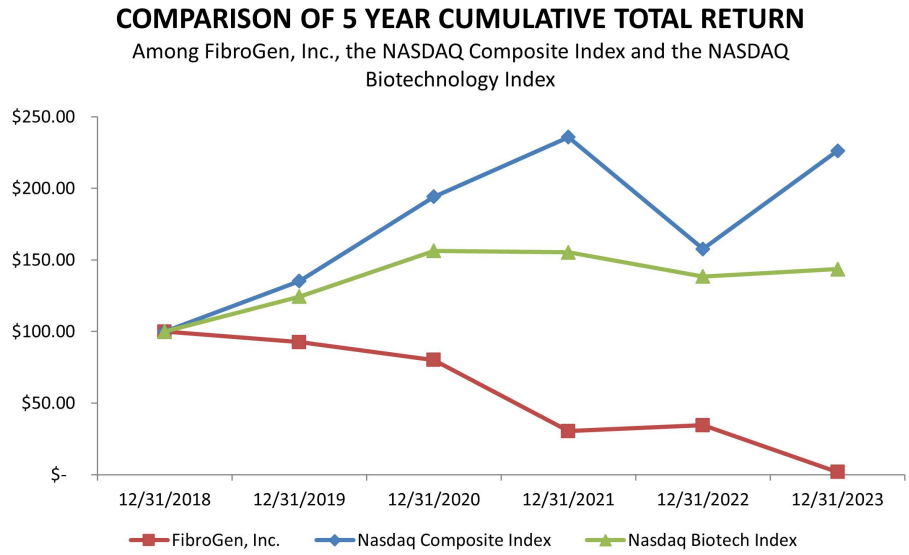
ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information for Common Stock

Our common stock has been listed on the Nasdaq Global Select Market ("Nasdaq") since November 14, 2014, under the symbol "FGEN." Prior to our initial public offering, there was no public market for our common stock.

Stock Price Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return for our common stock since December 31, 2018 to two indices: the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The graph assumes an initial investment of $100 on December 31, 2018, in our common stock, the stocks comprising the Nasdaq Composite Index, and the stocks comprising the Nasdaq Biotechnology Index. The stockholder return shown in the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.



The above Stock Price Performance Graph and related information shall not be deemed "soliciting material" or to be "filed" with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act or Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

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 January 31, 2024, there were 105 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, 2023 ("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.

This discussion and analysis generally addresses 2023 and 2022 items and year-over-year comparisons between 2023 and 2022. Discussions of 2021 items and year-over-year comparisons between 2022 and 2021 that are not included in this Annual Report can be found in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on February 27, 2023.

BUSINESS OVERVIEW

We are headquartered in San Francisco, California, with subsidiary offices in Beijing and Shanghai, People's Republic of China ("China"). We are developing and commercializing a diversified pipeline of novel therapeutics that work at the frontier of cancer biology and anemia.

We and Astellas Pharma Inc. ("Astellas") are collaborating on the development and commercialization of roxadustat in territories including Japan, Europe, Turkey, Russia and the Commonwealth of Independent States, the Middle East, and South Africa. We and AstraZeneca AB ("AstraZeneca") are collaborating on the development and commercialization of roxadustat in the United States ("U.S."), China, and other markets in the Americas, Australia/New Zealand, and Southeast Asia.

Our collaboration agreement with AstraZeneca AB ("AstraZeneca") for roxadustat for the treatment of anemia in the U.S. and all territories except for China and those territories previously licensed to Astellas (the "AstraZeneca U.S./RoW Agreement") was terminated (except for South Korea) on February 23, 2024.

However, our ongoing collaboration agreement with AstraZeneca for the development and commercialization of roxadustat for the treatment of anemia in China (the "AstraZeneca China Agreement") continues in full force and is unaffected.

We are also developing earlier stage clinical and preclinical product candidates, FG-3246, FG-3165 and FG-3175, to address unmet patient needs in oncology.

Financial Highlights

	Years Ended December 31,		
	2023	2022	2021
	(in thousands, except for per share data)		
Result of Operations			
Revenue	$ 147,752	$ 140,734	$ 235,309
Operating costs and expenses	429,567	441,759	523,839
Net loss	(284,232)	(293,654)	(290,023)
Net loss per share - basic and diluted	$ (2.92)	$ (3.14)	$ (3.14)

	December 31, 2023	December 31, 2022
	(in thousands)	
Balance Sheet		
Cash and cash equivalents	$ 113,688	$ 155,700
Short-term and long-term investments	121,898	270,656
Accounts receivable	$ 12,553	$ 16,299

Our revenue for the year ended December 31, 2023 included the revenues recognized related to the following:

• $100.9 million from roxadustat commercial sales in China, mostly from sales to Beijing Falikang Pharmaceutical Co. Ltd. (“Falikang”);

• $18.8 million of drug product revenue related to active pharmaceutical ingredient (“API”) deliveries to Astellas;

• $16.1 million of development revenue recognized under our collaboration agreements with our partners Astellas and AstraZeneca;

• $1.0 million upfront payment, $3.0 million milestone payment based on Eluminex Biosciences (Suzhou) Limited (“Eluminex”) implanting a biosynthetic cornea in the first patient of its clinical trial in China and $3.0 million manufacturing related milestone payment, recognized under our license agreement and amendments with Eluminex; and

• $4.0 million regulatory milestone recognized under AstraZeneca China Agreement (defined further below) associated with the renewal of our right to continue to market roxadustat in China. Of this amount, $2.7 million was recognized as license revenue, $0.8 million was recognized as development revenue and the remainder was included in deferred revenue.

As comparison, our revenue for the year ended December 31, 2022 included the revenues recognized related to the following:

• $25.0 million regulatory milestone recognized in the first quarter of 2022 under our collaboration agreements with our partner Astellas associated with the approval of EVRENZO® (roxadustat) in Russia. Of this amount, $22.6 million was recognized as license revenue and the remainder was included as development revenue;

• $22.4 million of development revenue recognized under our collaboration agreements with our partners Astellas and AstraZeneca;

• $82.9 million from roxadustat commercial sales in China, mostly from sales to Falikang; and

• $11.1 million of drug product revenue related to active pharmaceutical ingredient (“API”) deliveries to Astellas.

Total operating costs and expenses decreased $12.2 million for the year ended December 31, 2023 compared to the prior year as a result of the net effect of the following:

• $37.8 million lower drug development expenses associated with drug substance and drug product manufacturing activities related to roxadustat post-approval safety studies in China and pamrevlumab which were largely completed in the prior periods;

• $14.8 million lower stock-based compensation primarily resulting from significantly lower stock price and cancellations of stock options and restricted stock units;

• $3.8 million lower legal expenses primarily due to lower corporate legal activities;

• $24.6 million one-time, non-cash charge of acquired in-process research and development (“IPR&D”) expenses associated with the recent exclusive license for FG-3246 from Fortis Therapeutics (“Fortis”) and the acquisition of Fortis;

• $12.6 million of restructuring charge recorded in the third quarter of 2023 related to reduction in force actions in July 2023;

• $4.8 million higher employee-related expenses primarily due to the impact from payroll tax refunds received during 2022 that did not recur in the current year, as well as more business travel activities and higher severance during the current year period, offset by the impact from reduction in force actions in July 2023; and

• $3.7 million higher outside services expenses due to higher consulting activities in roxadustat post-approval safety studies and efforts to prepare for commercialization in the first half of the year.

Our research and development expenses were $282.9 million, $296.8 million and $387.0 million for the years ended December 31, 2023, 2022 and 2021, respectively. Since inception and through December 31, 2023, we have incurred a total of approximately $3.2 billion in research and development expenses, a majority of which relates to the development of roxadustat, pamrevlumab and other HIF-PH inhibitors. We expect to continue 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 product candidate portfolio. In addition, we expect to incur significant expenses relating to seeking regulatory approval for our product candidates and commercializing those products in various markets, including China. 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 started to implement a cost reduction effort in the second half of 2021, following the complete response letter ("CRL") for roxadustat in the U.S., and in the second half of 2023 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, 2023, we had a net loss of $284.2 million, or net loss per basic and diluted share of $2.92, as compared to a net loss of $293.7 million, or net loss per basic and diluted share of $3.14 for the prior year, primarily due to an increase in revenues and a decrease in operating costs and expenses.

Cash and cash equivalents, investments and accounts receivable totaled $248.1 million at December 31, 2023, a decrease of $194.5 million from December 31, 2022, primarily due to cash used in operations, partially offset by the net proceeds received under our senior secured term loan facilities and at-the-market program, discussed under the *Liquidity and Capital Resources* section below.

Collaboration Partnerships for Roxadustat

Our current and future research, development, manufacturing and commercialization efforts with respect to roxadustat depend on funds from our collaboration agreements with Astellas and AstraZeneca. See Note 3, *Collaboration Agreements, License Agreement and Revenues*, to the 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, 2023 totals $790.1 million.

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

In 2018, we and Astellas entered into an amendment to the Astellas Japan Agreement that allows Astellas to manufacture roxadustat drug product for commercialization in Japan (the "Astellas Japan Amendment"). The related drug product revenue was $15.7 million and $9.5 million for the years ended December 31, 2023 and 2022, respectively.

During the first quarter of 2021, we entered into an EU Supply Agreement with Astellas under the Astellas Europe Agreement to define general forecast, order, supply and payment terms for Astellas to purchase roxadustat bulk drug product from FibroGen in support of commercial supplies (the "Astellas EU Supply Agreement"). The related drug product revenue was $3.1 million and $1.6 million for the years ended December 31, 2023 and 2022, respectively.

In addition, Astellas has been an equity investor in FibroGen and considered a related party.

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 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, 2023 totals $516.2 million.

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

Under the AstraZeneca China Agreement, which is conducted through FibroGen China Anemia Holdings, Ltd., FibroGen (China) Medical Technology Development Co., Ltd. ("FibroGen Beijing"), and FibroGen International (Hong Kong) Limited (collectively, "FibroGen China"), the commercial collaboration was structured as a 50/50 profit share, which was amended by the AstraZeneca China Amendment in the third quarter of 2020, as discussed and defined below in *AstraZeneca China Amendment*.

In 2020, we entered into a Master Supply Agreement with AstraZeneca under the AstraZeneca U.S./RoW Agreement (the "AstraZeneca Master Supply Agreement") to define general forecast, order, supply and payment terms for AstraZeneca to purchase roxadustat bulk drug product from FibroGen in support of commercial supplies. There was no related drug product revenue for the years ended December 31, 2023 and 2022.

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

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 account for our investment in Falikang under the equity method, and Falikang is not consolidated into our consolidated financial statements. In addition, we recognized our proportionate share of the reported profits or losses of Falikang, as other income (loss) in the consolidated statement of operations, and as an adjustment to investment in unconsolidated subsidiary in the consolidated balance sheet. See Note 5, *Equity method investment - Variable Interest Entity*, to the consolidated financial statements for details.

Substantially all direct roxadustat product sales to distributors in China are made by Falikang, while FibroGen Beijing continues to sell roxadustat product directly in one province in China. FibroGen Beijing manufactures and supplies commercial product to Falikang based on a gross transaction price, adjusted for the estimated profit share. In addition, AstraZeneca bills the co-promotion expenses to Falikang and to FibroGen Beijing, respectively, for its services provided to the respective entity. AstraZeneca is entitled to reimbursement of its sales and marketing expenses up to a cumulative capped amount of a percentage of net sales. Once such amount is reached, AstraZeneca will bill the co-promotion expenses based on actual costs as incurred plus a markup on a prospective basis, which is currently expected to continue through 2033. In addition, Development costs continue to be shared 50/50 between the Parties.

We recognize revenue upon the transfer of control of commercial products to Falikang in an amount that reflects the allocation of transaction price of the China manufacturing and supply obligation ("China performance obligation") to the performance obligation satisfied during the reporting period. For our direct sales of commercial drug product, we recognize revenue when control of the promised good is transferred to the customer in an amount that reflects the consideration that we expect to be entitled to in exchange for the product. During the years ended December 31, 2023 and 2022, we recognized $89.1 million and $71.2 million of net product revenue from the sales to Falikang, respectively, and $11.9 million and $11.7 million of net product revenue from sales directly to distributors in one province in China, as described in details under *Product Revenue, Net* section below.

Additional Information Related to Collaboration Agreements

For more detailed discussions on the accounting for these agreements, See Note 3, *Collaboration Agreements, License Agreement and Revenues,* to the consolidated financial statements.

Total cash consideration received through December 31, 2023 and potential cash consideration for upfront payments and milestone payments under our collaboration agreements are as follows:

	Cash Received for Upfront Payments and Milestone Payments Through December 31, 2023	Additional Potential Cash Payment for Milestones	Total Potential Cash Payments for Upfront Payments and Milestones
		(in thousands)	
Astellas--related-party:			
Astellas Japan Agreement	$ 105,093	$ 67,500	$ 172,593
Astellas Europe Agreement	685,000	60,000	745,000
Total Astellas	790,093	127,500	917,593
AstraZeneca:			
AstraZeneca U.S./RoW Agreement	439,000	810,000	1,249,000
AstraZeneca China Agreement	77,200	299,500	376,700
Total AstraZeneca	516,200	1,109,500	1,625,700
Total	$ 1,306,293	$ 1,237,000	$ 2,543,293

The above table does not include development cost reimbursement, transfer price payments, and royalties and profit share under our existing collaboration agreements. Based on our current development plans for roxadustat, we do not expect to receive most or all of these additional potential milestones. The AstraZeneca U.S./RoW Agreement was terminated on February 23, 2024 (except for South Korea), while the AstraZeneca China Agreement and relationship continue unaffected.

Licensing Activities

Exclusive License with Eluminex

In July 2021, we exclusively licensed to Eluminex global rights to our investigational biosynthetic cornea derived from recombinant human collagen type III.

Under the terms of the agreement with Eluminex, Eluminex made an $8.0 million upfront payment to FibroGen during the first quarter of 2022. In addition, FibroGen may receive up to a total of $64.0 million in future manufacturing, clinical, regulatory, and commercial milestone payments for the biosynthetic cornea program, as well as $36.0 million in commercial milestones for the first recombinant collagen III product that is not the biosynthetic cornea. FibroGen will also be eligible to receive mid single-digit to low double-digit royalties based upon worldwide net sales of cornea products, and low single-digit to mid single-digit royalties based on worldwide net sales of other recombinant human collagen type III products that are not cornea products.

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

For the year ended December 31, 2023, FibroGen recognized a $3.0 million milestone payment based on Eluminex implanting a biosynthetic cornea in the first patient of its clinical trial in China, a $3.0 million manufacturing related milestone payment, a $1.0 million upfront payment, and a $0.5 million upfront payment related to patent transfer. See the *Eluminex Agreements* section in Note 3, *Collaboration Agreements, License Agreement and Revenues*, to the consolidated financial statements for details.

RESULTS OF OPERATIONS

Revenue

	Years Ended December 31,			Change 2023 vs. 2022	
	2023	2022	2021	$	%
	(dollars in thousands)				
Revenue:					
License revenue	$ 9,649	$ 22,590	$ 116,434	$ (12,941)	(57) %
Development and other revenue	18,401	24,189	70,275	(5,788)	(24) %
Product revenue, net	100,949	82,869	47,638	18,080	22 %
Drug product revenue, net	18,753	11,086	962	7,667	69 %
Total revenue	$ 147,752	$ 140,734	$ 235,309	$ 7,018	5 %

Under our revenue recognition policy, license revenue includes amounts from upfront, non-refundable license payments and amounts allocated pursuant to the standalone selling price method from other consideration received during the respective periods. This revenue is generally recognized as deliverables are met and services are performed. License revenues represented 7%, 16% and 50% of total revenues for the years ended December 31, 2023, 2022 and 2021, respectively.

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, 2023, we do not expect to incur significant future co-development services. For China co-development services, we defer revenue until we begin to transfer control of the manufactured commercial product to AstraZeneca, which commenced in the first quarter of 2021 and we expect to continue through 2033, which reflects our best estimates, taking into account our estimated loss of exclusivity upon expiry of our composition of matter patent in 2024, our existing patent portfolio, and competition from generics. 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 12%, 17% and 30% of total revenues for the years ended December 31, 2023, 2022 and 2021, respectively.

We recognize product revenue when our customer obtains control of promised goods or services in an amount that reflects the consideration we expect to receive in exchange for those goods or services. Product revenue represented 68%, 59% and 20% of total revenue for the years ended December 31, 2023, 2022 and 2021, 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 13%, 8%, and 0% of total revenues for the years ended December 31, 2023, 2022 and 2021, respectively.

In the future, we will continue generating revenue from collaboration agreements in the form of license fees, milestone payments, reimbursements for collaboration services and royalties on drug product sales, and from product sales. The AstraZeneca U.S./RoW Agreement was terminated on February 23, 2024 (except for South Korea), while the AstraZeneca China Agreement and relationship continue unaffected. We expect that any revenues we generate will fluctuate from quarter to quarter due to the uncertain timing and amount of such payments and sales.

Total revenue increased $7.0 million, or 5.0% for the year ended December 31, 2023 compared to the year ended December 31, 2022 for the reasons discussed in the sections below.

License Revenue

	Years Ended December 31,			Change 2023 vs. 2022	
	2023	2022	2021	$	%
	(dollars in thousands)				
License revenue:					
Astellas	$ —	$ 22,590	$ 108,434	$ (22,590)	100 %
AstraZeneca	2,649	—	—	2,649	NM
Eluminex	7,000	—	8,000	7,000	NM
Total license revenue	$ 9,649	$ 22,590	$ 116,434	$ (12,941)	(57) %

NM = Not meaningful

License revenue decreased $12.9 million, or 57% for the year ended December 31, 2023 compared to the year ended December 31, 2022.

License revenue recognized under our collaboration agreements with AstraZeneca for the year ended December 31, 2023 represented the allocated revenue related to $4.0 million regulatory milestone associated with the renewal of our right to continue to market roxadustat in China that was included in the transaction price during the third quarter of 2023 when such milestone was achieved. License revenue recognized for the year ended December 31, 2023 also included a $1.0 million upfront payment under the A&R Eluminex Agreement, a $3.0 million milestone payment based on Eluminex implanting a biosynthetic cornea in the first patient of its clinical trial in China, and a $3.0 million manufacturing related milestone payment when such milestones were achieved.

License revenue recognized under our collaboration agreements with Astellas for the year ended December 31, 2022 represented the allocated revenue related to $25.0 million regulatory milestone associated with the approval of EVRENZO® (roxadustat) in Russia that was included in the transaction price during the first quarter of 2022 when such milestone was achieved.

Development and Other Revenue

	Years Ended December 31,			Change 2023 vs. 2022	
	2023	2022	2021	$	%
	(dollars in thousands)				
Development revenue:					
Astellas	$ 6,662	$ 9,908	$ 21,927	$ (3,246)	(33) %
AstraZeneca	9,473	12,519	48,345	(3,046)	(24) %
Total development revenue	16,135	22,427	70,272	(6,292)	(28) %
Other revenue	2,266	1,762	3	504	29 %
Total development and other revenue	$ 18,401	$ 24,189	$ 70,275	$ (5,788)	(24) %

Development and other revenue decreased $5.8 million, or 24% for the year ended December 31, 2023 compared to the year ended December 31, 2022.

Development revenue recognized under our collaboration agreements with Astellas for the year ended December 31, 2023 was impacted by the decrease in co-development billings due to substantial completion of Phase 3 trials for roxadustat under our collaboration agreements with Astellas for roxadustat. Development revenue recognized under our collaboration agreements with Astellas for the year ended December 31, 2022 included the allocated revenue of $2.4 million related to the above-mentioned $25.0 million regulatory milestone associated with the approval in Russia during the first quarter of 2022, which did not recur in 2023.

Development revenue recognized under our collaboration agreements with AstraZeneca for the year ended December 31, 2023 was impacted by the decrease in co-development billings due to the closeout activities under our collaboration agreements with AstraZeneca for roxadustat, which was partially offset by the allocated revenue of $0.8 million related to the above-mentioned $4.0 million regulatory milestone associated with the renewal of our right to continue to market roxadustat in China.

Other revenue recognized for the year ended December 31, 2023 included an upfront payment related to patent transfer under from Eluminex, revenue from sales of certain research and development material, as well as revenue related to our contract manufacturing agreement with Eluminex, under which we were responsible for supplying the cornea product at 110% of our product manufacturing costs until our manufacturing technology is fully transferred to Eluminex, which occurred by the end of 2023.

Product Revenue, Net

	Years Ended December 31,			Change 2023 vs. 2022	
	2023	2022	2021	$	%
	(dollars in thousands)				
Direct Sales:					
Gross revenue	$ 13,190	$ 12,366	$ 13,727	$ 824	7 %
Discounts and rebates	(1,298)	(665)	(1,740)	(633)	95 %
Sales returns	2	1	83	1	100 %
Direct sales revenue, net	11,894	11,702	12,070	192	2 %
Sales to Falikang:					
Gross transaction price	154,817	112,544	97,531	42,273	38 %
Profit share	(66,254)	(43,716)	(34,759)	(22,538)	52 %
Net transaction price	88,563	68,828	62,772	19,735	29 %
Decrease (increase) in deferred revenue	492	2,339	(27,204)	(1,847)	(79) %
Sales to Falikang revenue, net	89,055	71,167	35,568	17,888	25 %
Total product revenue, net	$ 100,949	$ 82,869	$ 47,638	$ 18,080	22 %

Substantially all direct product sales to distributors in China have been made by Falikang, while FibroGen Beijing continues to sell product directly in one province in China. Total product revenue, net increased $18.1 million, or 22% for the year ended December 31, 2023 compared to the year ended December 31, 2022.

We recognize product revenue from direct sales to distributors in an amount that reflects the consideration that we expect to be entitled to in exchange for those products, net of various sales rebates and discounts. Product revenue from direct sales, net increased $0.2 million, or 2% for the year ended December 31, 2023 compared to the year ended December 31, 2022. The gross product revenue from direct sales to distributors increased $0.8 million, or 7% for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily due to an increase in sales volume. The discounts and rebates primarily consisted of the price adjustments recorded based on government-listed price guidance and estimated channel inventory levels, the contractual sales rebate calculated based on the stated percentage of gross sales by each distributor in the distribution agreement entered between FibroGen and each distributor, and other rebates and discounts, as well as sales return allowance. The total discounts and rebates were immaterial for the years ended December 31, 2023 and 2022.

FibroGen Beijing manufactures and supplies commercial product to Falikang based on a gross transaction price, adjusted for the estimated profit share. We recognize revenue upon the transfer of control of commercial products to Falikang in an amount that reflects the allocation of the China performance obligation transaction price to the performance obligation satisfied during the reporting period. The variable consideration components that are included in the transaction price may be constrained, and are included in the product revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period when the uncertainty associated with the variable consideration is subsequently resolved.

Sales to Falikang revenue, net increased $17.9 million, or 25% for the year ended December 31, 2023 compared to the year ended December 31, 2022. The gross transaction price increased $42.3 million and the calculated profit share increased $22.5 million for the year ended December 31, 2023 compared to the year ended December 31, 2022, respectively, primarily due to the increase in sales volume.

Periodically, we update our assumptions such as total sales quantity, performance period, gross transaction price, profit share and other inputs including foreign currency translation impact, among others. Following updates to our estimates, we recognized $0.5 million and $2.3 million from the previously deferred revenue of the China performance obligation during the years ended December 31, 2023 and 2022, respectively.

Drug Product Revenue

	Years Ended December 31,			Change 2023 vs. 2022	
	2023	2022	2021	$	%
	(dollars in thousands)				
Drug product revenue, net:					
Astellas Japan Agreement	$ 15,656	$ 9,480	$ 2,056	$ 6,176	65 %
Astellas Europe Agreement	3,097	1,606	1,130	1,491	93 %
AstraZeneca U.S./RoW Agreement	—	—	(2,224)	—	—
Total drug product revenue, net:	$ 18,753	$ 11,086	$ 962	$ 7,667	69 %

Drug product revenue increased $7.7 million, or 69% for the year ended December 31, 2023 compared to the year ended December 31, 2022.

Astellas Japan Agreement

During the second quarter of 2023, we fulfilled two shipment obligations under the terms of Astellas Japan Amendment, and recognized related drug product revenue of $14.4 million in the same period. In addition,we updated our estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment and accordingly recorded an adjustment to the drug product revenue of $1.3 million for the year ended December 31, 2023. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect the changes in the estimated bulk product strength mix intended to be manufactured by Astellas, foreign exchange impacts and estimated yield from the manufacture of bulk product tablets, among others.

During the first quarter of 2022, we fulfilled a shipment obligation under the terms of Astellas Japan Amendment and recognized related drug product revenue of $9.8 million in the same period. During the fourth quarter of 2022, we fulfilled a shipment obligation under the terms of Astellas Japan Amendment, and recognized related drug product revenue of $8.4 million in the same period. In addition, we updated our estimate of variable consideration related to the API shipments fulfilled under the terms of Japan Amendment with Astellas, and recorded a reduction to the drug product revenue of $8.7 million during the year ended December 31, 2022. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect foreign currency translation impact, the changes in the estimated bulk product strength mix intended to be manufactured by Astellas, estimated cost to convert the API to bulk product tablets, and estimated yield from the manufacture of bulk product tablets, among others.

As of December 31, 2023, the balances related to the API price true-up under the Astellas Japan Agreement were $1.2 million in accrued liabilities and $0.7 million in other long-term liabilities, representing the Company's best estimate of the timing for these amounts to be paid. As of December 31, 2022, the related balance in accrued liabilities was $6.5 million.

Astellas Europe Agreement

During the fourth quarter of 2023, 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 $0.8 million as drug product revenue, and recorded $17.7 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, 2023, we reclassified $38.7 million from the related deferred revenue to accrued liabilities. As of December 31, 2023, the related balance in accrued liabilities was $38.6 million, representing our best estimate that this amount will be paid within the next 12 months.

During the second quarter of 2022, 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 $1.0 million as drug product revenue, and recorded $23.2 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, during the year ended December 31, 2022, we reclassified a total of $57.4 million from the related deferred revenue to accrued liabilities. As of December 31, 2022, the related balance in accrued liabilities was $57.4 million.

In addition, we recognized royalty revenue of $2.3 million and $0.6 million as drug product revenue from the deferred revenue under the Astellas Europe Agreement for the years ended December 31, 2023 and 2022, 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

There was no shipment of bulk drug product to AstraZeneca as commercial supply under the terms of the AstraZeneca Master Supply Agreement during the years ended December 31, 2023 and 2022.

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

Operating Costs and Expenses

	Years Ended December 31,			Change 2023 vs. 2022	
	2023	2022	2021	$	%
	(dollars in thousands)				
Operating costs and expenses					
Cost of goods sold	$ 18,848	$ 20,280	$ 12,871	$ (1,432)	(7) %
Research and development	282,861	296,791	387,043	(13,930)	(5) %
Selling, general and administrative	115,252	124,688	123,925	(9,436)	(8) %
Restructuring charge	12,606	—	—	12,606	NM
Total operating costs and expenses	$ 429,567	$ 441,759	$ 523,839	$ (12,192)	(3) %

NM = Not meaningful

Total operating expenses decreased $12.2 million, or 3% for the year ended December 31, 2023 compared to the year ended December 31, 2022, for the reasons discussed in the sections below.

Cost of goods sold

Cost of goods sold decreased ($1.4) million, or (7)% for the year ended December 31, 2023 compared to the year ended December 31, 2022.

Cost of goods sold, associated with the roxadustat commercial sales in China, consists of direct costs to manufacture commercial product, as well as indirect costs including factory overhead, storage, shipping, quality assurance, idle capacity charges, and inventory valuation adjustments. Cost of goods sold associated with the roxadustat commercial sales in China was $14.9 million for the year ended December 31, 2023, as compared to $15.1 million for the year ended December 31, 2022, a decrease of $0.2 million, resulting from improved unit cost efficiency primarily due to higher production volume, partially offset by the increase in the sales volume.

Cost of goods sold associated with the roxadustat drug product revenue in the U.S. was $3.1 million and $3.8 million for the years ended December 31, 2023 and 2022, respectively, associated with the costs of API or bulk drug product delivered to Astellas and AstraZeneca in the respective periods.

Cost of goods sold for the years ended December 31, 2023 and 2022 also included manufacturing costs $0.8 million and $1.4 million, respectively, related to our contract manufacturing revenue from Eluminex.

Research and Development Expenses

Research and development expenses consist of third-party research and development costs and the fully-burdened amount of costs associated with work performed under collaboration agreements. Research and development expenses include employee-related expenses for research and development functions, expenses incurred under agreements with clinical research organizations, other clinical and preclinical costs and allocated direct and indirect overhead costs, such as facilities costs, information technology costs and other overhead. We expense research and development costs as incurred. We recognize costs for certain development activities based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites. Research and development expenses also include in-process research and development assets that have no alternative future use other than in a particular research and development project. We have implemented a cost reduction effort since 2021 and efforts to streamline operations to align with our business goals in the second half of 2023, as a result, research and development expenses have 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, 2023, 2022 and 2021:

Product Candidate	Phase of Development	Years Ended December 31, 2023	2022	2021	
		(in thousands)			
Pamrevlumab	Phase 2/3	$ 145,730	$ 198,764	$ 188,534	
Roxadustat	Approved / Phase 3	31,116	46,469	97,245	
FG-3246	Preclinical	30,362	* —	—	
Other research and development expenses		75,653	51,558	101,264	**
Total research and development expenses		$ 282,861	$ 296,791	$ 387,043	

* Included $24.6 million one-time, non-cash acquired IPR&D expenses associated with the recent exclusive license for FG-3246 from Fortis and the acquisition of Fortis. See Note 4, *Exclusive License and Option to Acquire Fortis Therapeutics*, to the consolidated financial statements.

** Other research and development expenses included $60.0 million of acquired in-process research and development assets related to upfront payments to HiFiBiO during the year ended December 31, 2021.

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 $13.9 million, or 5% for the year ended December 31, 2023 compared to the year ended December 31, 2022 as a result of the net effect of the following:

• Decrease of $37.8 million in drug development expenses associated with drug substance, drug product manufacturing activities and logistic activities related to pamrevlumab which were largely completed in the prior periods;

• Decrease of $9.4 million in stock-based compensation primarily resulting from significantly lower stock price and cancellations of stock options and restricted stock units;

• $24.6 million one-time, non-cash acquired IPR&D expenses associated with the recent exclusive license for FG-3246 from Fortis and the acquisition of Fortis;

• Increase of $3.7 million in employee-related costs primarily due to the impact from payroll tax refunds received during 2022 that did not recur in the current year, as well as more business travel activities and higher severance, offset by the impact from reduction in force actions in July 2023; and

• Increase of $3.1 million information technology, facilities and allocated costs primarily associated with software costs and maintenance 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 including co-promotional expenses associated with our commercialization efforts in China, recruiting fees and expenses associated with obtaining and maintaining patents. We have implemented a cost reduction effort since 2021 and efforts to streamline operations to align with our business goals in the second half of 2023, as a result, SG&A expenses have decreased in certain areas and may continue to decrease over time.

SG&A expenses decreased $9.4 million, or (8)% for the year ended December 31, 2023 compared to the year ended December 31, 2022, as a result of the net effect of the following:

• Decrease of $5.4 million in stock-based compensation primarily resulting from significantly lower stock price and cancellations of stock options and restricted stock units;

• Decrease of $3.8 million in legal expenses primarily due to lower corporate legal activities;

• Decrease of $3.3 million due to higher expenses in information technology, facilities and equipment costs primarily associated with software costs and maintenance services, which were allocated to research and development expenses;

• Increase of $1.7 million in outside services expenses due to higher consulting activities in general administrative function and efforts to prepare for commercialization in the first half of the year; and

• Increase of $1.1 million in employee-related costs primarily due to the impact from payroll tax refunds received during 2022 that did not recur in the current year, as well as higher severance during the current year period, offset by the impact from reduction in force actions in July 2023 and lower recruiting and relocation costs.

Restructuring Charge

On July 14, 2023, we approved a restructuring plan (the "Plan") to lower our operating expenses. The Plan included a reduction to our U.S. workforce of approximately 32% (or 104 employees). As a result, we recorded a total of $12.6 million non-recurring restructuring charge during the third quarter of 2023, primarily consisting of notice period and severance payments, accrued vacation and employee benefits contributions. The Plan is in connection with the Company's efforts to streamline operations to align with the Company's business goals.

Interest and Other, Net

	Years Ended December 31,			Change 2023 vs. 2022	
	2023	2022	2021	$	%
	(dollars in thousands)				
Interest and other, net:					
Interest expense	$ (15,532)	$ (1,440)	$ (1,075)	$ (14,092)	979 %
Interest income and other income (expenses), net	10,480	7,596	(1,078)	2,884	38 %
Total interest and other, net	$ (5,052)	$ 6,156	$ (2,153)	$ (11,208)	(182) %

Interest Expense

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

Interest expense increased $14.1 million, or 979% for the year ended December 31, 2023 compared to the year ended December 31, 2022. Interest expense for the year ended December 31, 2023 included $7.4 million related to the senior secured term loan facilities entered into in April 2023. See Note 9, *Senior Secured Term Loan Facilities,* to the consolidated financial statements for details.

Interest expense for the years ended December 31, 2023 and 2022 also included interest expense of $7.7 million and $1.0 million, respectively, related to sale of future revenues under the Revenue Interest Financing Agreement ("RIFA") with an affiliate of NovaQuest Capital Management ("NovaQuest") entered into in November 2022. See Note 10, *Liability Related to Sale of Future Revenues*, 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 of our subsidiaries into the functional currency, realized gains (losses) on sales of investments, and other non-operating income and expenses.

Interest income and other income (expenses), net increased $2.9 million, or 38% for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily due to $5.8 million higher interest income from our investments with higher interest rate during the current year period, and $2.3 million of favorable foreign exchange impact, partially offset by an impact of $5.0 million recorded during the second quarter of 2022, which did not recur in the current year period, resulting from a reduction to other expenses to release the previously estimated late payment fees related to value added tax in China.

Provision for Income Taxes

	Years Ended December 31,		
	2023	2022	2021
	(dollars in thousands)		
Loss before income taxes	$ (286,867)	$ (294,869)	$ (290,683)
Provision for income taxes	3	358	347
Effective tax rate	— %	(0.1) %	(0.1) %

The provisions for income taxes for each of the three years ended December 31, 2023 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.

Investment Income (Loss) in Unconsolidated Variable Interest Entity

Investment income (loss) in unconsolidated variable interest entity represented our proportionate share of the reported profits or losses of Falikang, an unconsolidated variable interest entity accounted for under the equity method. See Note 5, *Equity method investment - Variable Interest Entity*, to the consolidated financial statements 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.

On November 4, 2022, we entered into a RIFA with NovaQuest with respect to our revenues from Astellas' sales of roxadustat in Europe, Japan and the other Astellas territories. Pursuant to the RIFA, in the fourth quarter of 2022, we received $49.8 million from NovaQuest, representing the gross proceeds of $50.0 million net of initial issuance costs, in consideration for a portion of future revenues we will receive from Astellas. For additional details about this financing transaction, see Note 10, *Liability Related to Sale of Future Revenues*, to the consolidated financial statements.

On February 27, 2023, we entered into an Amended and Restated Equity Distribution Agreement (the "at-the-market agreement") with Goldman Sachs & Co., LLC and BofA Securities, Inc. (each a "Sales Agent"), which amended and restated its Equity Distribution Agreement with Goldman Sachs & Co., LLC, dated August 8, 2022, to add BofA Securities, Inc. as an additional Sales Agent under that agreement. Under the at-the-market agreement, we may issue and sell, from time to time and through the Sales Agents, shares of our common stock having an aggregate offering price of up to $200.0 million (the "ATM Program"). Under the ATM Program, we sold 2,472,090 shares of our common stock and received net proceeds of approximately $48.4 million during the year ended December 31, 2023. See the *At-the-Market Program* section, in Note 13, *Equity and Stock-based Compensation,* to the consolidated financial statements for details.

On April 29, 2023, we entered into the Financing Agreement with investment funds managed by Morgan Stanley Tactical Value, ("Lenders"), and Wilmington Trust, National Association, as the administrative agent, providing for senior secured term loan facilities consisting of a $75.0 million initial term loan. The clinical development milestones which could have triggered Delayed Draw Term Loan 1 were not achieved, and the Lenders have not funded Delayed Draw Term Loan 2. For additional details about this financing transaction, see Note 9, *Senior Secured Revolving Line of Credit*, to the consolidated financial statements.

As of December 31, 2023, we had cash and cash equivalents of $113.7 million, compared to $155.7 million as of December 31, 2022. Cash is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting of available-for-sale securities, and stated at fair value, are also available as a source of liquidity. As of December 31, 2023, we had short-term investments of $121.9 million, compared to short-term investments of $266.3 million and long-term investments of $4.3 million as of December 31, 2022. As of December 31, 2023, a total of $32.2 million of our cash and cash equivalents was held outside of the U.S. in our foreign subsidiaries, including $32.1 million held in China, to be used primarily for our China operations.

Our long-term plans for distributing cash flows from FibroGen Beijing may involve any number of scenarios including keeping the money onshore to fund future expansion of our China operations or paying down certain debt obligations. During the year ended December 31, 2023, FibroGen Beijing made a total of $55.5 million repayments of intercompany loans. Our capital contributions to FibroGen Beijing and the liquidity position of FibroGen Beijing depend on many factors, including those set forth under Part I, Item 1A "Risk Factors" in this Annual Report.

Cash Sources and Uses

The following table summarizes the primary sources and uses of cash for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Net cash provided by (used in):			
Operating activities	$ (315,021)	$ (145,933)	$ (82,232)
Investing activities	153,657	89,116	(426,972)
Financing activities	122,749	46,776	(563)
Effect of exchange rate changes on cash and cash equivalents	(3,397)	(5,482)	2,597
Net decrease in cash and cash equivalents	$ (42,012)	$ (15,523)	$ (507,170)

Operating Activities

Net cash used in operating activities was $315.0 million for the year ended December 31, 2023 and consisted primarily of net loss of $284.2 million adjusted for non-cash items and non-operating activities of $88.9 million and a net decrease in operating assets and liabilities of $119.7 million. The significant non-cash items included stock-based compensation expense of $50.8 million, acquired IPR&D expenses associated with the acquisition of Fortis of $24.6 million, depreciation expense of $9.5 million, non-cash interest expense related to sale of future revenues of $7.7 million, and net accretion of premium and discount on investments of $5.1 million. The significant items in the changes in operating assets and liabilities included the following:

• Accrued and other liabilities decreased $49.8 million, primarily due to the movements related to API and bulk drug product price true-up resulting from changes in estimated variable consideration associated with the API shipments fulfilled under the terms of the Astellas Japan Amendment, the bulk drug product transferred under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement, including the payment of $57.4 million previously accrued balance made during the current year period. See the *Drug Product Revenue, Net* section in Note 3, *Collaboration Agreements, License Agreement and Revenues*, to the consolidated financial statements for details. The decrease was partially offset by the accrued liabilities of $28.5 million for the litigation settlement as of December 31, 2023, which is fully recoverable under our insurance policies. See Note 12, *Commitments and Contingencies,* to the consolidated financial statements for details. The accrued and other liabilities were also impacted by the timing of invoicing and payment;

• Deferred revenue decreased $28.2 million, primarily related to related to the reclassification of $38.7 million to accrued liabilities, resulting from changes in estimated variable consideration associated with the bulk drug product transferred to Astellas under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement during the current year. See the *Drug Product Revenue, Net* section in Note 3, *Collaboration Agreements, License Agreement and Revenues*, to the consolidated financial statements for details;

• Accounts payable decreased $15.5 million, primarily driven by the payments made for the historical co-promotion expenses to AstraZeneca during the current year, as well as the timing of invoicing and payments; and

• Prepaid expenses and other current assets increased $28.2 million, primarily due to the $28.5 million receivable as of December 31, 2023 for the insurance recovery for the above-mentioned litigation settlement.

Net cash used in operating activities was $145.9 million for the year ended December 31, 2022 and consisted primarily of net loss of $293.7 million adjusted for non-cash items and non-operating activities of $77.3 million and a net increase in operating assets and liabilities of $70.4 million. The significant non-cash items included stock-based compensation expense of $65.6 million, and depreciation expense of $10.0 million. The significant items in the changes in operating assets and liabilities included the following:

• Accrued and other liabilities increased $90.6 million, primarily related to the total of $75.1 million for API and bulk drug product price true-up as of December 31, 2022, resulting from changes in estimated variable consideration associated with the API shipments fulfilled under the terms of the Astellas Japan Amendment, the bulk drug product transferred under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement, and the bulk drug product shipments to AstraZeneca under the terms of the AstraZeneca Master Supply Agreement. The accrued and other liabilities were also impacted by the classification of a portion of accrued co-promotion expenses from other long-term liabilities to current liabilities based on the updated estimate of timing for payment, and by the timing of invoicing and payment;

• Accounts payable increased $5.9 million, primarily driven by the timing of invoicing and payments;

• Prepaid expenses and other current assets decreased $4.9 million, primarily due to the collection of $8.0 million from Eluminex for upfront license payment during the first quarter of 2022, and less prepayments made for roxadustat API manufacturing activities, partially offset by a payroll tax refund recorded as other receivables as of December 31, 2022 and received in the first quarter of 2023;

• Other long-term liabilities decreased $18.3 million primarily driven by the above-mentioned classification of a portion of accrued co-promotion expenses from other long-term liabilities to current liabilities based on the updated estimate of timing for payment;

• Inventories increased $11.0 million, driven by the increased inventory level primarily related to inventory cost capitalized related to Europe and other territories, and FibroGen Beijing's productions of roxadustat for commercial sales purposes; and

• Deferred revenue decreased $4.1 million, primarily related to revenue recognized from the previously deferred revenue of the China performance obligation during the year ended December 31, 2022, and the above-mentioned reclassification to accrued liabilities, resulting from changes in estimated variable consideration associated with the API or bulk drug product deliveries fulfilled with Astellas and AstraZeneca.

Investing Activities

Investing activities primarily consist of purchases of property and equipment, purchases of investments, purchase of acquired in-process research and development asset and proceeds from the maturity and sale of investments.

Net cash provided by investing activities was $153.7 million for the year ended December 31, 2023 and consisted primarily of $400.6 million of proceeds from maturities of investments and $6.7 million of proceeds from sales of available-for-sale securities, partially offset by $251.8 million of cash used in purchases of available-for-sale securities.

Net cash provided by investing activities was $89.1 million for the year ended December 31, 2022 and consisted primarily of $284.5 million of proceeds from maturities of investments and $7.4 million of proceeds from sales of available-for-sale securities, partially offset by $164.0 million of cash used in purchases of available-for-sale securities, $35.0 million of cash paid for the acquired in-process research and development asset and $3.7 million of cash used in purchases of property and equipment.

Financing Activities

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

Net cash provided by financing activities was $122.7 million for the year ended December 31, 2023 and consisted primarily of $74.1 million net proceeds from senior secured term loan facilities, $48.4 million net proceeds received under the ATM Program and $3.7 million of proceeds from the issuance of common stock upon exercise of stock options and purchases under our Employee Share Purchase Plan ("ESPP").

Net cash provided by financing activities was $46.8 million for the year ended December 31, 2022 and consisted primarily of $49.8 million of net proceeds from sale of future revenues from NovaQuest, $4.2 million of proceeds from the issuance of common stock upon exercise of stock options and purchases under our ESPP, partially offset by $5.2 million of cash paid for payroll taxes on restricted stock unit releases, and $1.5 million of cash paid for transaction costs related to sale of future revenues.

Material Cash Requirements

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

We believe that our existing cash and cash equivalents, short-term investments and accounts receivable, together with the proceeds from senior secured term loan facilities in the second quarter of 2023, the financing amount under the RIFA received in fourth quarter of 2022, and the net proceeds received under our ATM program in the first half of 2023, as well as the cost savings we have recently implemented (including from the reduction in workforce that we announced on July 19, 2023), will be sufficient to meet our anticipated cash requirements for at least the next 12 months from the date of issuance of the financial statements included in this Annual Report. However, we may need additional capital thereafter and our liquidity assumptions may materially differ and we could utilize our available financial resources sooner than we currently expect. We may incur additional expenses not currently contemplated due to events associated with the recently announced reduction in workforce. In addition, we may elect to raise additional funds at any time through equity, equity-linked, debt financing arrangements or from other sources. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. Our future capital requirements and the adequacy of available funds will depend on many factors, including those set forth under Part I, Item 1A "*Risk Factors*" in this Annual Report. We may not be able to secure additional financing to meet our operating requirements on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, the ownership of our existing stockholders will be diluted. If we raise additional financing by the incurrence of indebtedness, we will be subject to increased fixed payment obligations and could also be subject to restrictive covenants, such as limitations on our ability to incur additional debt, and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to obtain needed additional funds, we will have to reduce our operating costs and expenses, which would impair our growth prospects and could otherwise negatively impact our business.

Commitments and Contingencies

Contractual Obligations

At December 31, 2023, 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
Lease liabilities	$ 90,511	$	17,601	$ 72,910
Purchase obligations	36,291		30,318	5,973
Liability related to sale of future revenues	125,000		5,654	119,346
Total payments	$ 251,802	$	53,573	$ 198,229

Our lease liabilities are primarily related to our real estate leases for office spaces in the U.S. and China. See Note 7, *Leases*, to the consolidated financial statements for details.

Our outstanding non-cancelable purchase obligations primarily related to manufacturing and supply for pamrevlumab and roxadustat, and other purchases and programs. See Note 12, *Commitments and Contingencies*, to the consolidated financial statements for details.

Under the Financing Agreement with Morgan Stanley Tactical Value, as of December 31, 2023, we had $71.9 million of senior secured term loan facilities balance on the consolidated balance sheets, which are not subject for repayment until May 2026. Meanwhile, we are obliged to pay interest on a monthly basis, for which we expect to pay a total of $10.5 million within the next 12 months. See Note 9, *Senior Secured Term Loan Facilities*, to the consolidated financial statements for details.

Under the RIFA with NovaQuest, as of December 31, 2023, we had $57.1 million of liability related to sale of future revenues on the consolidated balance sheets, $5.7 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 10, *Liability Related to Sale of Future Revenues*, to the consolidated financial statements for details.

Some of our license agreements provide for periodic maintenance fees over specified time periods, as well as payments by us upon the achievement of development, regulatory and commercial milestones. As of December 31, 2023, future milestone payments for research and preclinical stage development programs consisted of up to approximately $697.9 million in total potential future milestone payments under our license agreements with HiFiBiO (for Gal-9 and CCR8), Medarex, Inc. and others. These milestone payments generally become due and payable only upon the achievement of certain developmental, clinical, regulatory and/or commercial milestones. The event triggering such payment or obligation has not yet occurred and therefore these amounts have been excluded from the table above.

The table above excludes uncertain tax benefits of approximately $81.0 million that are disclosed in Note 15, *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, 2023, we have several on-going clinical studies in various stages. Under agreements with various 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, 2023, our FibroGen Europe Oy (“FibroGen Europe”) subsidiary had $10.4 million of principal outstanding and $7.3 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 11, *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 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, 2023, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements.

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 Not Yet Adopted

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 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

Revenues under collaboration agreements

Our 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. Our process for identifying performance obligations and an enumeration of each obligation for each agreement is outlined in Note 3, *Collaboration Agreements, License Agreement and Revenues*, to our consolidated financial statements. Determining the performance obligations within a collaboration agreement often involves significant judgment and is specific to the facts and circumstances contained in each agreement.

We have identified the following material promises under its collaboration agreements: (1) license of FibroGen 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 3, *Collaboration Agreements, License Agreement and Revenues*, to our consolidated financial statements.

For revenue recognition purposes, we determine that the terms of our 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. We believe that the existence of what we consider 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 we expect to be entitled for satisfying all performance obligations within the agreement. Our collaboration agreements include payments to us 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 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 us. We do 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 our 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 us to make estimates of future research and development efforts, which involves 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 us 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, we recognize 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). To date, royalty revenue resulting from collaboration arrangements has been immaterial.

We allocate the transaction price 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 we separately sell the products and services. If an SSP is not directly observable, then we 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 our significant judgments is outlined in Note 3, *Collaboration Agreements, License Agreement and Revenues,* to our consolidated financial statements.

For each performance obligation identified within an arrangement, we determine 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, we assess 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.

Revenue under license agreements

Under a license agreement, if the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from upfront license fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, we use judgment in determining the appropriate method of measuring progress for purposes of recognizing revenue from the up-front license fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Product revenue, net

Product revenue, net consists of revenues from sales of roxadustat commercial product to Falikang, and directly to pharmaceutical distributors located in one province in China that are not covered by Falikang. Falikang is jointly owned by AstraZeneca and FibroGen Beijing. We are not the primary beneficiary of Falikang for accounting purposes, as AstraZeneca is the final decision maker for all the roxadustat commercialization activities, and we lack the power criterion to direct the activities of Falikang (see Note 5, *Equity method investment - Variable Interest Entity,* to our consolidated financial statements).

Sales to Falikang

Falikang became fully operational in January 2021, at which time FibroGen Beijing began selling roxadustat commercial product to Falikang. 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 3, *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 our agreements with AstraZeneca as outlined in Note 3, *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 marked 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 we determined it is likely those sales would occur. The price per unit is subject to reassessment on a quarterly basis, which may result in 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 our 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:
    - o 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.
    - o 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.

We defer any net transaction price in excess of the revenue recognized, and recognize it over future periods as the performance obligations are satisfied.

Direct Sales to Distributors

We sell roxadustat in China directly to a number of pharmaceutical distributors located in one province in China that are not covered by Falikang. These pharmaceutical distributors are our customers. Hospitals order roxadustat through a distributor and we ship the product directly to the distributors. The delivery of roxadustat to a distributor represents a single performance obligation. Distributors are responsible for delivering product to end users, primarily hospitals. Distributors bear inventory risk once they receive and accept the product. We recognize product revenue when control of the promised good is transferred to the customer in an amount that reflects the consideration that we expect to be entitled to in exchange for the product.

The period between the transfer of control of the promised goods and when we receive payment is based on 60-day payment terms. As such, we do not adjust product revenue for the effects of a significant financing component.

We record product revenue at the net sales prices that includes certain estimates of variable consideration. These estimates include price adjustment calculated based on estimated channel inventory levels when China's National Healthcare Security Administration releases price guidance for roxadustat under the National Reimbursement Drug List, various fixed-amount or percentage-based rebates and discounts recorded as a reduction to revenue at the point of sale to the distributor or when distributor meets eligibility requirements, and estimated sales return as distributors can request to return product to us only due to quality issues or for product purchased within one year prior to the product's expiration date.

We calculate the variable consideration based on gross sales to the distributor, or estimate it utilizing best available information from the distributor, maximum known exposures and other available information including estimated channel inventory levels and estimated sales made by the distributor to hospitals, which involves significant judgment.

The rebates and discounts all together are eligible to be applied against the distributor's future sales order, limited to certain maximums until such rebates and discounts are exhausted. We record these rebates and discounts as contract liabilities at the time they become eligible and in the same period that the related revenue is recorded. Due to our legal right to offset, at each balance sheet date, we present the rebates and discounts as reductions to gross accounts receivable from the distributor, or as a current liability to the distributor to the extent that the total amount exceeds the gross accounts receivable or when we expect to settle the discount in cash. We calculate the distributor's legal right of offset at the individual distributor level.

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 NDA 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 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates.

Our market risk exposure is primarily a result of fluctuations in foreign currency exchange rates. Currently, the functional currency of our subsidiaries, FibroGen Europe Oy and FibroGen Beijing, is the local currency. Our consolidated results of operations are reported in U.S. Dollars. Our revenues and operating costs and expenses are denominated in the currencies of the countries in which our operations are located, which are primarily in the U.S. and China. Therefore, our consolidated results of operations and cash flows are subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates.

As of December 31, 2023, we did not have material financial assets and liabilities denominated in foreign currencies that are subject to fluctuation in the exchange rate with the U.S. dollar. Therefore, our financial assets and liabilities are not currently subject to significant foreign currency risk.

The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to maximize income from our cash and cash equivalents without assuming significant risk. To achieve our objectives, we invest our non-operating cash and cash equivalents primarily in commercial paper and money market funds as of December 31, 2023. Given the nature of our investments as of December 31, 2023, we believe that our exposure to interest rate risk is not significant. We actively monitor changes in interest rates.

To date, we have not entered into any hedging arrangements with respect to foreign currency risk or other derivative financial instruments.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of FibroGen, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of FibroGen, Inc. and its subsidiaries (the “Company”) as of December 31, 2023 and 2022, and the related consolidated statements of operations, of comprehensive loss, of changes in stockholders' equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2023, including the related notes and financial statement schedule listed in the accompanying index (collectively referred to as the “consolidated financial statements”). We also have audited the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management’s Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company’s consolidated financial statements and on the Company's internal control over financial reporting 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 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, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company’s 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. A company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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.

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.

Determining the Transaction Price for Product Revenue Recognition for Sales to Beijing Falikang Pharmaceutical Co., Ltd. ("Falikang")

As described in Notes 2 and 3 to the consolidated financial statements, with respect to the roxadustat commercial product, revenue is recognized at a point in time when control of the product is transferred to Falikang. Total product revenue, net recognized related to sales to Falikang was $89.1 million for the year ended December 31, 2023. Revenue is recognized based on the estimated transaction price per unit and the actual quantity of product delivered to Falikang during the reporting period. The estimated 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 management determined it is likely those sales would occur. Management applied significant judgment in determining the transaction price per unit, which involved the use of significant assumptions such as (i) the estimated total gross transaction price and profit share, (ii) the estimated total sales quantity, and (iii) the estimated performance period in which the Company determined it is likely those sales would occur.

The principal considerations for our determination that performing procedures relating to determining the transaction price for product revenue recognition for sales to Falikang is a critical audit matter are the significant judgment by management when determining the transaction price per unit, which in turn led to a high degree of auditor judgment, subjectivity, and effort in performing procedures and in evaluating management's significant assumptions related to the estimated total gross transaction price, estimated total sales quantity, and estimated performance period over which the Company determined it is likely those sales would occur.

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 testing the effectiveness of controls relating to revenue recognition, including controls over the determination of the transaction price per unit for sales to Falikang. These procedures also included, among others, testing management's process for determining the transaction price per unit, which included evaluating the appropriateness of the method, testing the completeness and accuracy of the data used in the method, and evaluating the reasonableness of significant assumptions related to the estimated total gross transaction price, estimated total sales quantity, and estimated performance period over which the Company determined it is likely those sales would occur. Evaluating the reasonableness of the significant assumptions used by management involved evaluating whether the assumptions were reasonable considering (i) the current and historical transaction price and quantity, (ii) the consistency with external market, industry and regulatory data, (iii) whether these assumptions were consistent with evidence obtained in other areas of the audit, and (iv) patent expiration and market exclusivity.

/s/ PricewaterhouseCoopers LLP
San Jose, California
February 26, 2024

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

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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 113,688	$ 155,700
Short-term investments	121,898	266,308
Accounts receivable, net ($ 6,079 and $ 12,088 from related parties)	12,553	16,299
Inventories	41,565	40,436
Prepaid expenses and other current assets	41,855	14,083
Total current assets	331,559	492,826
Restricted time deposits	1,658	2,072
Long-term investments	—	4,348
Property and equipment, net	13,126	20,605
Equity method investment in unconsolidated variable interest entity	5,290	5,061
Operating lease right-of-use assets	68,093	79,893
Other assets	3,803	5,282
Total assets	$ 423,529	$ 610,087
Liabilities, redeemable non-controlling interests and deficit		
Current liabilities:		
Accounts payable	$ 17,960	$ 30,758
Accrued and other current liabilities ($ 39,814 and $ 63,886 to a related party)	172,891	219,773

Deferred revenue ($ 7,220 and $ 9,259 to related parties)	12,740	12,739
Operating lease liabilities, current	14,077	10,292
Total current liabilities	217,668	273,562
Product development obligations	17,763	16,917
Deferred revenue, net of current ($ 9,705 and $ 31,044 to a related party)	157,555	185,722
Operating lease liabilities, non-current	66,537	79,593
Senior secured term loan facilities, non-current	71,934	—
Liability related to sale of future revenues, non-current	51,413	49,333
Other long-term liabilities ($ 656 and $ 0 to a related party)	2,858	6,440
Total liabilities	585,728	611,567
Commitments and Contingencies (Note 12)		
Redeemable non-controlling interests	21,480	—
Stockholders' deficit:		
Preferred stock, $ 0.01 par value; 125,000 shares authorized; no shares issued and outstanding at December 31, 2023 and 2022	—	—

Common stock, $ 0.01 par value; 225,000 shares authorized at December 31, 2023 and 2022; 98,770 and 94,166 shares issued and outstanding at December 31, 2023 and 2022	988	942
Additional paid-in capital	1,643,641	1,541,019
Accumulated other comprehensive loss	(6,875)	(5,720)
Accumulated deficit	(1,841,920)	(1,557,688)
Total stockholders' deficit attributable to FibroGen	(204,166)	(21,447)
Nonredeemable non-controlling interests	20,487	19,967
Total deficit	(183,679)	(1,480)
Total liabilities, redeemable non-controlling interests and deficit	$ 423,529	$ 610,087

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

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

	Years Ended December 31,		
	2023	2022	2021
Revenue:			
License revenue (includes $ 0 , $ 22,590 and $ 108,434 from a related party)	$ 9,649	$ 22,590	$ 116,434
Development and other revenue (includes $ 6,662 , $ 9,908 and $ 21,928 from a related party)	18,401	24,189	70,275
Product revenue, net (includes $ 89,055 , $ 71,167 and $ 35,568 from a related party)	100,949	82,869	47,638
Drug product revenue, net (includes $ 18,753 , $ 11,086 and $ 3,186 from a related party)	18,753	11,086	962
Total revenue	147,752	140,734	235,309
Operating costs and expenses:			
Cost of goods sold	18,848	20,280	12,871
Research and development	282,861	296,791	387,043
Selling, general and administrative	115,252	124,688	123,925
Restructuring charge	12,606	—	—
Total operating costs and expenses	429,567	441,759	523,839
Loss from operations	(281,815)	(301,025)	(288,530)

Interest and other, net			
Interest expense	(15,532)	(1,440)	(1,075)
Interest income and other income (expenses), net	10,480	7,596	(1,078)
Total interest and other, net	(5,052)	6,156	(2,153)
Loss before income taxes	(286,867)	(294,869)	(290,683)
Provision for income taxes	3	358	347
Investment income in unconsolidated variable interest entity	2,638	1,573	1,007
Net loss	(284,232)	(293,654)	(290,023)
	$	$	$
Net loss per share - basic and diluted	(2.92)	(3.14)	(3.14)
	$	$	$
Weighted average number of common shares used to calculate net loss per share - basic and diluted	97,303	93,582	92,349

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

FIBROGEN, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Years Ended December 31,		
	2023	2022	2021
Net loss	$ (284,232)	$ (293,654)	$ (290,023)
Other comprehensive income (loss):			
Foreign currency translation adjustments	(3,712)	75	1,235
Available-for-sale investments:			
Unrealized gain (loss) on investments, net of tax effect	2,557	(1,632)	(899)
Other comprehensive gain (loss), net of taxes	(1,155)	(1,557)	336
Comprehensive loss	(285,387)	(295,211)	(289,687)

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

FIBROGEN, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (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	Equity (Deficit)	Interests (Note 4)
Balance at December 31, 2020	91,440,633	$ 914	$ 1,399,774	$ (4,499)	$ (974,011)	$ 19,271	$ 441,449	$ —
Net loss	—	—	—	—	(290,023)	—	(290,023)	—
Change in unrealized gain or loss on investments	—	—	—	(899)	—	—	(899)	—
Foreign currency translation adjustments	—	—	—	1,235	—	—	1,235	—
Shares issued from stock plans, net of payroll taxes paid	1,439,900	15	5,479	—	—	—	5,494	—
Stock-based compensation	—	—	71,161	—	—	—	71,161	—
Conversion of subsidiary's convertible note payable (Note 13)	—	—	—	—	—	696	696	—
Balance at December 31, 2021	92,880,533	$ 929	$ 1,476,414	$ (4,163)	$ (1,264,034)	$ 19,967	$ 229,113	$ —
Net loss	—	—	—	—	(293,654)	—	(293,654)	—
Change in unrealized gain or loss on investments	—	—	—	(1,632)	—	—	(1,632)	—
Foreign currency translation adjustments	—	—	—	75	—	—	75	—
Shares issued from stock plans, net of payroll taxes paid	1,285,553	13	(996)	—	—	—	(983)	—
Stock-based compensation	—	—	65,601	—	—	—	65,601	—
Balance at December 31, 2022	94,166,086	$ 942	$ 1,541,019	$ (5,720)	$ (1,557,688)	$ 19,967	$ (1,480)	$ —
Net loss	—	—	—	—	(284,232)	—	(284,232)	—

Consolidation of Fortis (Note 4)	—	—	—	—	—	520	520	21,480
Change in unrealized gain or loss on investments	—	—	—	2,557	—	—	2,557	—
Foreign currency translation adjustments	—	—	—	(3,712)	—	—	(3,712)	—
Issuance of common stock under ATM Program	2,472,090	24	48,383	—	—	—	48,407	—
Shares issued from stock plans, net of payroll taxes paid	2,132,071	22	3,472	—	—	—	3,494	—
Stock-based compensation	—	—	50,767	—	—	—	50,767	—
Balance at December 31, 2023	98,770,247	$ 988	$ 1,643,641	$ (6,875)	$ (1,841,920)	$ 20,487	$ (183,679)	$ 21,480

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

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

	Years Ended December 31,		
	2023	2022	2021
Operating activities			
Net loss	$ (284,232)	$ (293,654)	$ (290,023)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	9,518	10,017	10,170
Amortization of finance lease right-of-use assets	412	587	4,639
Net accretion of premium and discount on investments	(5,061)	1,619	2,482
Unrealized loss on equity investments	—	—	30
Investment income in unconsolidated variable interest entity	(2,638)	(1,573)	(1,007)
Loss (gain) on disposal of property and equipment	4	(1)	233
Stock-based compensation	50,767	65,601	71,161
Acquired in-process research and development expenses	24,636	—	60,000
Non-cash interest expense related to sale of future revenues	7,734	1,036	—
Dividend received from unconsolidated variable interest entity	2,255	—	—
Impairment of investment	1,000	—	—
Realized loss on sales of available-for-sale securities	271	5	—
Changes in operating assets and liabilities:			
Accounts receivable, net ($6,009, $(1,158) and $(6,803) from related parties)	3,433	765	25,180
Inventories	(1,695)	(10,999)	(14,158)

Prepaid expenses and other current assets ($ 0 , $ 0 and $ 889 from a related party)	28,165	4,916	9,854
Operating lease right-of-use assets	11,704	10,908	4,209
Other assets	256	263	4,412
Accounts payable ($ 0 , $ 0 and $(1,118) from a related party)	15,514	5,909	805
Accrued and other liabilities ($(24,072), $ 63,882 and $(20) from a related party)	49,778	90,556	16,380
Operating lease liabilities, current	3,820	547	503
Deferred revenue ($(23,378), $ 11,211 and $ 21,549 from related parties)	28,166	4,130	57,637
Accrued interest for finance lease liabilities	11	33	75
Operating lease liabilities, non-current	12,998	8,994	4,043
Other long-term liabilities	2,573	18,250	12,089
Net cash used in operating activities	315,021	145,933	82,232
Investing activities			
Purchases of property and equipment	2,519	3,741	5,186
Payment made for acquired in-process research and development asset	—	35,000	25,000
Proceeds from sale of property and equipment	—	6	—

Purchases of available-for-sale securities	(251,830)	(164,023)	(484,144)
Cash acquired from consolidation of Fortis	656	—	—
Proceeds from sales of available-for-sale securities	6,729	7,382	4,214
Proceeds from maturities of investments	400,621	284,492	83,144
Net cash provided by (used in) investing activities	153,657	89,116	(426,972)
Financing activities			
Proceeds from senior secured term loan facilities, net of issuance costs	74,078	—	—
Cash paid for transaction costs for senior secured term loan facilities	(2,746)	—	—
Repayments of finance lease liabilities	(148)	(135)	(5,489)
Repayments of lease obligations	(336)	(403)	(403)
Cash paid for payroll taxes on restricted stock unit releases	(237)	(5,167)	(7,372)
Proceeds from sale of future revenues, net of issuance costs	—	49,750	—
Cash paid for transaction costs related to sale of future revenues	—	(1,453)	—
Proceeds from issuance of common stock under ATM Program, net of commissions	48,407	—	—
Proceeds from issuance of common stock under employee stock plans	3,731	4,184	12,701
Net cash provided by (used in) financing activities	122,749	46,776	(563)
Effect of exchange rate change on cash and cash equivalents	(3,397)	(5,482)	2,597
Net decrease in cash and cash equivalents	(42,012)	(15,523)	(507,170)
Total cash and cash equivalents at beginning of period	155,700	171,223	678,393
Total cash and cash equivalents at end of period	113,688	155,700	171,223
	$	$	$
Supplemental cash flow information:			

Non cash acquisition in Fortis	$ (22,000)	$ —	$ —
Interest payments	54	104	94
Balance in accounts payable and accrued liabilities related to purchases of property and equipment	103	428	1,009
Balance in accrued liabilities related to issuance costs of secured term loan facilities	—	—	35,000
Balance in other receivables related to stock option exercise	—	—	165
Conversion of subsidiary's convertible note payable to non-controlling interests	$ —	$ —	$ 696

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

1. Th e Company

FibroGen, Inc. (“FibroGen” or the “Company”) is headquartered in San Francisco, California, with subsidiary offices in Beijing and Shanghai, People’s Republic of China (“China”). FibroGen is developing and commercializing a diversified pipeline of novel therapeutics that work at the frontier of cancer biology and anemia.

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

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

FibroGen is also developing earlier stage clinical and preclinical product candidates, FG-3246, FG-3165 and FG-3175, to address unmet patient needs in oncology.

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 FibroGen is the primary beneficiary. All inter-company transactions and balances have been eliminated in consolidation. For any VIE for which FibroGen is not the primary beneficiary, the Company uses the equity method of accounting.

The Company operates in

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

The Company believes that its existing cash and cash equivalents, short-term investments and accounts receivable will be sufficient to meet its anticipated cash requirements for at least the next 12 months from the date of issuance of the financial statements. However, the Company may need additional capital thereafter and its liquidity assumptions may materially differ. The Company may utilize its available financial resources sooner than it currently expects and may incur additional expenses not currently contemplated. In addition, the Company may elect to raise additional funds at any time through equity, equity-linked, debt financing arrangements or from other sources.

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 (China) Medical Technology Development Co., Ltd. (“FibroGen Beijing”) 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 FibroGen, 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). 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, the majority of cash on hand is invested in U.S. treasuries, corporate bonds, commercial paper and money market funds. Any remaining cash is deposited with major financial institutions primarily in the U.S., China and the Cayman Islands. 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. Included in current assets are significant balances of accounts receivable as follows:

	December 31,	
	2023	2022
Falikang — Related party	42 %	65 %
AstraZeneca	33 %	16 %

As of December 31, 2023 and 2022, the aggregate accounts receivable related to roxadustat sales in China from distributors represented

17
% and

10
%, respectively, of the consolidated accounts receivable, with no material balance from any individual distributor.

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 and Restricted Time Deposits

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 money market accounts and various deposit accounts. As of December 31, 2023 and 2022, a total of $

32.2
million and $

92.5
million, respectively, of the Company's cash and cash equivalents was held outside of the U.S. in the Company's foreign subsidiaries to be used primarily for the Company's China operations. Restricted time deposits include an irrevocable standby letter of credit as security deposit for a long-term property lease with the Company's landlord. Restricted time deposits were $

1.7
million and $

2.1
million as of December 31, 2023 and 2022, respectively.

Investments

As of December 31, 2023, the Company's investments consist primarily of diversified bonds, commercial paper, and money market funds. Those investments with original maturities of greater than three months and remaining maturities of less than 12 months (365 days) are considered short-term investments. Those 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, 2023, 2022 and 2021 and the allowance for credit losses as of December 31, 2023 and 2022 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 cost of the Company's inventories in China is determined using full absorption and standard costing method. The Company reviews the standard cost of raw materials, work-in-process and finished goods annually and more often as appropriate to ensure that its inventories approximate current actual cost. The cost of the Company's inventories in the U.S. 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.

Property and Equipment

Property and equipment are recorded at cost and depreciated over their estimated useful lives using the straight-line method. Computer equipment, laboratory equipment, machinery and furniture and fixtures are depreciated over three to five years . Leasehold improvements are recorded at cost and amortized over the term of the lease or their useful life, whichever is shorter.

Equity method investment - 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.

Leases

The Company determines if an arrangement is or contains a lease at inception date when it is given control of the underlying assets. The Company elected the practical expedient not to apply the lease recognition and measurement requirements to short-term leases, which is any lease with a term of 12 months or less as of the commencement date that does not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise.

Lease right-of-use ("ROU") assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As its leases do not typically provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The Company reassesses the incremental borrowing rate periodically for application to any new leases or lease modifications, which approximates the rate at which the Company would borrow, on a secured basis, in the country where the lease was executed. For any lease modification, the Company reassesses the lease classification, remeasures the related lease liability using an updated discount rate, and adjusts the related ROU asset under the lease modification guidance under the ASC 842, *Leases*, ("ASC 842").

Lease ROU assets include any lease payments made and initial direct costs incurred. The Company has lease agreements with lease and non-lease components. The Company generally accounts for each lease component separately from the non-lease components, and excludes all non-lease components from the calculation of minimum lease payments in measuring the ROU asset and lease liability.

The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease terms.

Regarding leases denominated in a foreign currency, the related ROU assets and the corresponding ROU asset amortization costs are remeasured using the exchange rate in effect at the date of initial recognition; the related lease liabilities are remeasured using the exchange rate in effect at the end of the reporting period; the lease costs and interest expenses related to lease liability accretion are remeasured using average exchange rates for the reporting period.

Finance leases are included in finance lease ROU assets, finance lease liabilities, current and non-current on the Company's consolidated balance sheets. Operating leases are included in operating lease ROU assets, operating lease liabilities, current and non-current on the Company's consolidated balance sheets.

Impairment of Long-Lived Assets

The Company continually evaluates whether events or circumstances have occurred that indicate that the estimated remaining useful life of its long-lived assets may warrant revision or that the carrying value of these assets may be impaired. If the Company determines that an impairment trigger has been met, the Company evaluates the realizability of its long-lived assets (asset group) based on a comparison of projected undiscounted cash flows from use and eventual disposition with the carrying value of the related asset. Any write-downs (which are measured based on the difference between the fair value and the carrying value of the asset) are treated as permanent reductions in the carrying amount of the assets (asset group). Based on this evaluation, the Company believes that, as of each of the balance sheet dates presented,

no

ne of the Company's long-lived assets were impaired. The Company had

no

impairment of long-lived assets for the years ended December 31, 2023, 2022 and 2021.

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 10, *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 .

Asset Acquisition

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

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

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

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 3, *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 FibroGen 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 3, *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). To date, royalty revenue resulting from its collaboration arrangements was immaterial.

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 3, *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.

Revenue under license agreements

Under a license agreement, if the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from upfront license fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company determines whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, the Company uses judgment in determining the appropriate method of measuring progress for purposes of recognizing revenue from the up-front license fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Product revenue, net

Product revenue, net consists of revenues from sales of roxadustat commercial product to Falikang, and directly to pharmaceutical distributors located in one province in China that are not covered by Falikang. Falikang is jointly owned by AstraZeneca AB ("AstraZeneca") and FibroGen Beijing. The Company is not the primary beneficiary of Falikang for accounting purposes, as AstraZeneca is the final decision maker for all the roxadustat commercialization activities, and the Company lacks the power criterion to direct the activities of Falikang (see Note 5, *Equity method investment - Variable Interest Entity*).

Sales to Falikang

Falikang became fully operational in January 2021, at which time FibroGen Beijing began selling roxadustat commercial product to Falikang. 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 3, *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 3, *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 marked 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:
    - o 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.
    - o 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.

Direct Sales to Distributors

The Company sells roxadustat in China directly to a number of pharmaceutical distributors located in one province in China that are not covered by Falikang. These pharmaceutical distributors are the Company's customers. Hospitals order roxadustat through a distributor and the Company ships the product directly to the distributors. The delivery of roxadustat to a distributor represents a single performance obligation. Distributors are responsible for delivering product to end users, primarily hospitals. Distributors bear inventory risk once they receive and accept the product. Product revenue is recognized when control of the promised good is transferred to the customer in an amount that reflects the consideration that the Company expects to be entitled to in exchange for the product.

The period between the transfer of control of the promised goods and when the Company receives payment is based on 60-day payment terms. As such, product revenue is not adjusted for the effects of a significant financing component.

Product revenue is recorded at the net sales prices that includes certain estimates of variable consideration. These estimates include price adjustment calculated based on estimated channel inventory levels when China's National Healthcare Security Administration releases price guidance for roxadustat under the National Reimbursement Drug List, various fixed-amount or percentage-based rebates and discounts recorded as a reduction to revenue at the point of sale to the distributor or when distributor meets eligibility requirements, and estimated sales return as d i stributors can request to return product to the Company only due to quality issues or for product purchased within one year prior to the product's expiration date.

The calculation of the variable consideration is based on gross sales to the distributor, or estimated utilizing best available information from the distributor, maximum known exposures and other available information including estimated channel inventory levels and estimated sales made by the distributor to hospitals, which involve a significant judgment.

The rebates and discounts all together are eligible to be applied against the distributor's future sales order, limited to certain maximums until such rebates and discounts are exhausted. These rebates and discounts are recorded as contract liabilities at the time they become eligible and in the same period that the related revenue is recorded. Due to the Company's legal right to offset, at each balance sheet date, the rebates and discounts are presented as reductions to gross accounts receivable from the distributor, or as a current liability to the distributor to the extent that the total amount exceeds the gross accounts receivable or when the Company expects to settle the discount in cash. The Company's legal right to offset is determined at the individual distributor level. The contract liabilities were included in accrued and other current liabilities in the consolidated balance sheet. The rebates and discounts reflected as reductions to gross accounts receivable for direct sales.

Drug product revenue

Drug product revenue includes commercial-grade API or bulk drug product sales to AstraZeneca and Astellas Pharma Inc. ("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.

License Acquisition Agreement

In June 2021, the Company entered into an exclusive license and option agreement (the "HiFiBiO Agreement") with HiFiBiO Therapeutics ("HiFiBiO"), pursuant to which the Company exclusively licensed all product candidates in HiFiBiO's Galectin-9 program and subsequently exclusively licensed all product candidates in HiFiBiO's CCR8 program in December 2021. Under the terms of the HiFiBiO Agreement, the Company has paid a $

25.0

million upfront payment to HiFiBiO during the year ended December 31, 2021, and recorded a $

35.0

million upfront payment for the CCR8 option exercise in accrued liabilities as of December 31, 2021, which was paid during the first quarter of 2022. HiFiBiO may receive R&D and regulatory milestone payments of up to $

175

million, as well as sales milestones of up to $

170

million. HiFiBiO will also be eligible to receive tiered royalties based upon worldwide net sales capped at

10

%, subject to certain reductions. We expect to file INDs on product candidates for both the CCR8 and Galectin-9 programs in the first half of 2024.

The acquisition of these licenses was accounted for as an asset acquisition. The above-mentioned upfront payments of $

60.0

million related to the license and options acquisition meets the definition of an in-process research and development asset ("IPR&D asset") under the ASC 730, *Research and Development*. They relate to particular research and development projects and are determined to have no alternative future uses and thus have no separate economic value. Therefore, these upfront payments were recorded as research and development expenses during the year ended December 31, 2021, and the cash payments were reflected as investing activities in the consolidated statement of cash flows during the years ended December 31, 2022 and 2021, respectively.

Contingent consideration payments will be evaluated and recognized when they become probable and reasonably estimable. The related IPR&D asset will only be capitalized if it has an alternative future use other than in a particular research and development project. Otherwise, amounts allocated to IPR&D asset that have no alternative use will be expensed. As of December 31, 2023, the contingencies related to the milestone payments had not been resolved, therefore no contingent consideration was recognized. The Company will reassess the probability of future option payments and contingent payments on a quarterly basis.

Research and Development Expenses

Research and development expenses consist of above-mentioned expense for acquired IPR&D asset, 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 including co-promotional expenses associated with our commercialization efforts in China, 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 our 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 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 Issued Accounting Guidance Not Yet Adopted

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures,* which requires all public entities, including public entities with a single reportable segment, to provide in interim and annual periods one or more measures of segment profit or loss used by the chief operating decision maker to allocate resources and assess performance. In addition, this guidance requires disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. This guidance is effective for fiscal years beginning after December 15, 2023, and interim periods after December 15, 2024, with retrospective application required, and early adoption permitted. The Company is currently in the process of evaluating the effects of this guidance on its related disclosures.

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

3. Collaboration Agreements, License Agreement and Revenues

Astellas Agreements

Astellas Japan Agreement

In June 2005, the Company entered into a collaboration agreement with Astellas for the development and commercialization (but not manufacture) of roxadustat for the treatment of anemia in Japan ("Astellas Japan Agreement"). Under this agreement, Astellas paid license fees and other consideration totaling $

40.1

million (such amounts were fully received as of February 2009). Under the Astellas Japan Agreement, the Company is also eligible to receive from Astellas an aggregate of approximately $

132.5

million in potential milestone payments, comprised of (i) up to $

22.5

million in milestone payments upon achievement of specified clinical and development milestone events (such amounts were fully received as of July 2016), (ii) up to $

95.0

million in milestone payments upon achievement of specified regulatory milestone events, and (iii) up to approximately $

15.0

million in milestone payments upon the achievement of specified commercial sales milestone. 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, 2023 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.

In 2018, FibroGen and Astellas entered into an amendment to the Astellas Japan Agreement that allows Astellas to manufacture roxadustat drug product for commercialization in Japan (the "Astellas Japan Amendment"). Under this amendment, FibroGen 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 FibroGen. 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 paid license fees and other upfront consideration totaling $

320.0

million (such amounts were fully received as of February 2009). The Astellas Europe Agreement also provides for additional development and regulatory approval milestone payments up to $

425.0

million, comprised of (i) up to $

90.0

million in milestone payments upon achievement of specified clinical and development milestone events (such amounts were fully received as of 2012), and (ii) up to $

335.0

million in milestone payments upon achievement of specified regulatory milestone events. Under the Astellas Europe Agreement, Astellas committed to fund

50

% of joint development costs for Europe and North America, and all territory-specific costs. The Astellas Europe Agreement also provides for tiered payments based on net sales of product (as defined) in the low 20% range .

On March 21, 2022, EVRENZO® (roxadustat) was registered with the Russian Ministry of Health. The Company evaluated the regulatory milestone payment associated with the approval in Russia under the Astellas Europe Agreement and concluded that this milestone was achieved in the first quarter of 2022. Accordingly, the consideration of $

25.0

million associated with this milestone was included in the transaction price and allocated to performance obligations under the Astellas Europe Agreement, all of which was recognized as revenue during the year ended December 31, 2022 from performance obligations satisfied.

During the third quarter of 2021, the European Commission approved EVRENZO® (roxadustat) for the treatment of adult patients with symptomatic anemia associated with CKD. Astellas has launched EVRENZO in Germany, the United Kingdom, the Netherlands, and Austria. This approval triggered a total of $

120.0

million milestone payable to the Company by Astellas under the Astellas Europe Agreement. Accordingly, the consideration of $

120.0

million associated with these milestones was included in the transaction price and allocated to performance obligations under the Astellas Europe Agreement, all of which was recognized as revenue during the year ended December 31, 2021 from performance obligations satisfied.

The aggregate amount of the considerations received under the Astellas Europe Agreement through December 31, 2023 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.

Under the Astellas Europe Agreement, Astellas has an option to purchase roxadustat bulk drug product in support of commercial supplies. During the first quarter of 2021, the Company entered into an EU Supply Agreement with Astellas (“Astellas EU Supply Agreement”) to define general forecast, order, supply and payment terms for Astellas to purchase roxadustat bulk drug product from FibroGen in support of commercial supplies. The related drug product revenue is described under the *Drug Product Revenue, Net* section below.

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, 2023, 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 $

12.3

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 $

220.7

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. Through the third quarter of 2021 upon the approval of CKD, revenue was recognized over time based on progress toward complete satisfaction of the performance obligation. The Company used an input method to measure progress toward the satisfaction of the performance obligation, which was based on costs of labor hours and out-of-pocket expenses incurred relative to total expected costs to be incurred. Subsequently, the Company accounts for the development services for the indications related to chemotherapy-induced anemia and myelodysplastic syndromes 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.

License Revenue and Development Revenue Recognized Under the Astellas Agreements

License amounts identified below are included in the “License revenue” line item in the consolidated statements of operations. All other elements identified below are included in the “Development and other revenue” line item in the consolidated statements of operations.

Amounts recognized as license revenue and development revenue under the Astellas Japan Agreement were as follows for the years ended December 31, 2023, 2022 and 2021 (in thousands):

		Years Ended December 31,		
Agreement	**Performance Obligation**	**2023**	**2022**	**2021**
Astellas Japan Agreement	Development revenue	$ 210	$ 284	$ 248

The transaction price related to consideration received through December 31, 2023 and accounts receivable has been allocated to each of the following performance obligations under the Astellas Japan Agreement, along with any associated deferred revenue as follows (in thousands):

Astellas Japan Agreement	**Total Consideration Through December 31, 2023**
License	$ 100,347
Development revenue	17,092
Total license and development revenue	$ 117,439

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, 2023 under the Astellas Japan Agreement. The Company does

no

t expect material variable consideration from estimated future co-development billing beyond the development period in the transaction price related to the Astellas Japan Agreement.

Amounts recognized as license revenue and development revenue under the Astellas Europe Agreement were as follows for the years ended December 31, 2023, 2022 and 2021 (in thousands):

		Years Ended December 31,		
Agreement	**Performance Obligation**	**2023**	**2022**	**2021**
Astellas Europe Agreement	License revenue	$ —	$ 22,590	$ 108,434
	Development revenue	$ 6,452	$ 9,624	$ 21,679

The transaction price related to consideration received through December 31, 2023 and accounts receivable has been allocated to each of the following performance obligations under the Astellas Europe Agreement, along with any associated deferred revenue as follows (in thousands):

Astellas Europe Agreement	**Total Consideration Through December 31, 2023**
License	$ 618,975
Development revenue	286,717
Total license and development revenue	$ 905,692

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, 2023 under the Astellas Europe Agreement. The Company does

no
t expect material variable consideration from estimated future co-development billing beyond the development period in the transaction price related to the Astellas Europe Agreement.

AstraZeneca Agreements

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

Effective July 30, 2013, the Company entered into a collaboration agreement with AstraZeneca for the development and commercialization of roxadustat for the treatment of anemia in the U.S. and all other countries in the world, other than China, not previously licensed under the Astellas Europe and Astellas Japan Agreements ("AstraZeneca U.S./RoW Agreement"). The AstraZeneca U.S./RoW Agreement was terminated on February 23, 2024 (except South Korea). China is covered by a separate agreement with AstraZeneca described below. Under the terms of the AstraZeneca U.S./RoW Agreement, AstraZeneca paid upfront, non-contingent, non-refundable and time-based payments totaling $

374.0
million (such amounts were fully received as of June 2016). Under the AstraZeneca U.S./RoW Agreement, AstraZeneca also agreed to pay an aggregate of approximately $

875.0
million in potential milestone payments, comprised of (i) up to $

65.0
million in milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $

325.0
million in milestone payments upon achievement of specified regulatory milestone events, (iii) up to $

160.0
million in milestone payments related to activity by potential competitors and (iv) up to approximately $

325.0
million in milestone payments upon the achievement of specified commercial sales events.

Under the AstraZeneca U.S./RoW Agreement, the Company and AstraZeneca equally share in the development costs of roxadustat not already paid for by Astellas, up to a total of $

233.0
million (i.e. the Company's share of development costs is $

116.5
million, which was reached in 2015). Development costs incurred by FibroGen during the development period in excess of the $

233.0
million (aggregated spend) are fully reimbursed by AstraZeneca.

The aggregate amount of the considerations received under the AstraZeneca U.S./RoW Agreement through December 31, 2023 totals $

439.0
million, excluding drug product revenue that is discussed under the *Drug Product Revenue, Net* section below.

In 2020, the Company entered into a Master Supply Agreement with AstraZeneca under the AstraZeneca U.S./RoW Agreement ("AstraZeneca Master Supply Agreement") to define general forecast, order, supply and payment terms for AstraZeneca to purchase roxadustat bulk drug product from FibroGen in support of commercial supplies. The related drug product revenue is described under the *Drug Product Revenue, Net* section below.

AstraZeneca China Agreement

Effective July 30, 2013, the Company (through its subsidiaries affiliated with China) entered into a collaboration agreement with AstraZeneca for the development and commercialization (but not manufacture) of 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 totaling $

28.2
million (such amounts were fully received in 2014). Under the AstraZeneca China Agreement, the Company is also eligible to receive from AstraZeneca an aggregate of approximately $

348.5
million in potential milestone payments, comprised of (i) up to $

15.0
million in milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $

146.0
million in milestone payments upon achievement of specified regulatory milestone events, and (iii) up to approximately $

187.5
million in milestone payments upon the achievement of specified commercial sales and other events. The AstraZeneca China Agreement is structured as a 50/50 profit or loss share (as defined), which was amended under the AstraZeneca China Amendment in 2020 as discussed below, and provides for joint development costs (including capital and equipment costs for construction of the manufacturing plant in China), to be shared equally during the development period.

The aggregate amount of the considerations received for milestone and upfront payments under the AstraZeneca China Agreement through December 31, 2023 totals $

77.2
million.

On September 18, 2023, the Company received the formal notice, from Beijing Medical Products Administration, of renewal of its right to continue to market roxadustat in China through 2028. The Company evaluated the regulatory milestone payment associated with this renewal under the AstraZeneca China Agreement and concluded that this milestone was achieved in the third quarter of 2023. Accordingly, the consideration of $

4.0

million associated with this milestone was included in the transaction price and allocated to performance obligations under the AstraZeneca U.S./RoW Agreement and the AstraZeneca China Agreement, $

3.5

million of which was recognized as revenue during the year ended December 31, 2023 from performance obligations satisfied or partially satisfied. As of December 31, 2023, the $

4.0

million milestone was recorded as a contract asset and was fully netted against the contract liabilities (deferred revenue) related to the AstraZeneca U.S./RoW Agreement and AstraZeneca China Agreement.

AstraZeneca China Amendment

In July 2020, FibroGen China Anemia Holdings, Ltd., FibroGen 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.

Under the AstraZeneca China Amendment, with effect from April 1, 2020, AstraZeneca’s co-promotion expenses for their sales and marketing efforts are subject to a cap of a percentage of net sales. In addition, the AstraZeneca China Amendment has allowed for a higher cost of manufacturing incurred by FibroGen Beijing to be included in the profit or loss share calculation, subject to an annual cap, among other changes.

The co-promotion expenses for the years ended December 31, 2023, 2022 and 2021, capped at a percentage of net roxadustat sales in China, were $

4.6
million, $

4.4
million and $

4.7
million, respectively, included in the selling, general and administrative expenses.

Under the AstraZeneca China Amendment, profit/loss share between FibroGen Beijing and AstraZeneca is based on a calculation of the current period net roxadustat sales in China and deductible expenses pursuant to the AstraZeneca China Agreement. Based on the calculation revised under the AstraZeneca China Amendment, profit was achieved during 2020. As a result, the Company recorded a corresponding one-time profit share liability to AstraZeneca, the balance of which was $

7.1
million and $

7.3
million as of December 31, 2023 and 2022, respectively, in accrued and other current liabilities in the consolidated balance sheet.

Substantially all direct roxadustat product sales to distributors in China are made by Falikang, while FibroGen Beijing continues to sell roxadustat product directly in one province in China. FibroGen Beijing manufactures and supplies commercial product to Falikang based on a gross transaction price, adjusted for the estimated profit share. In addition, AstraZeneca bills the co-promotion expenses to Falikang and to FibroGen Beijing, respectively, for its services provided to the respective entity. AstraZeneca is entitled to reimbursement of its sales and marketing expenses up to a cumulative capped amount of a percentage of net sales. Once such amount is reached, AstraZeneca will bill the co-promotion expenses based on actual costs as incurred plus a markup on a prospective basis, which is currently expected to continue through 2033. Development costs continue to be shared 50/50 between the Parties.

The related net product revenue recognized from the sales to Falikang and the sales directly to distributors are discussed under the *Product Revenue, Net* section below.

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. The key points the Company considered in reaching this conclusion are as follows:

1. While the two agreements were largely negotiated separately, those negotiations proceeded concurrently, and were intended to be completed contemporaneously, presuming AstraZeneca decided to proceed with licenses in all regions available.

2. Throughout negotiations for both agreements, the Company and the counterparties understood and considered the possibility that one arrangement may be executed without the execution of the other arrangement. However, the preference for the Company and the counterparties during the negotiations was to execute both arrangements concurrently.

3. The two agreements were executed as separate agreements because different development, regulatory and commercial approaches required certain terms of the agreements to be structured differently, rather than because the Company or the counterparties considered the agreements to be fundamentally separate negotiations.

Accordingly, as the agreements are being accounted for as a single arrangement, upfront and other non-contingent consideration received and to be received has been and will be 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.

As of December 31, 2023, the transaction price for the AstraZeneca U.S./RoW Agreement and the AstraZeneca China Agreement, excluding manufacturing services that is discussed separately below, included $

402.2
million of non-contingent upfront payments, $

118.0
million of variable consideration related to payments for milestones considered probable of being achieved, $

614.6
million of variable consideration related to co-development billings, offset by $

7.1
million of variable consideration related to the above-mentioned one-time profit share under the AstraZeneca China Amendment.

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.

For revenue recognition purposes, the Company determined that the terms of its collaboration agreements with AstraZeneca begin on the effective date and end upon the completion of all performance obligations contained in the agreements. 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 requirement to continue funding development for a substantive period of time and the loss of product rights, along with non-refundable upfront payments already remitted by AstraZeneca, represent substantive termination penalties that create significant disincentive for AstraZeneca to exercise its right to terminate the agreement.

For the technology license under the AstraZeneca U.S./RoW Agreement, SSP was determined based on a two-step process. The first step involved determining an implied royalty rate that would result in the net present value of future cash flows to equal to zero (i.e. where the implied royalty rate on the transaction would equal the target return for the investment). This results in an upper bound estimation of the magnitude of royalties that a hypothetical acquirer would reasonably pay for the forecasted cash flow stream. The Company's cash flow forecasts were derived from probability-adjusted revenue and expense projections. 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. The second step involved applying the implied royalty rate, which was determined to be

40
%, against the probability-adjusted projected net revenues by territory and determining the value of the license as the net present value of future cash flows after adjusting for taxes. The discount rate utilized was

17.5
%.

AstraZeneca U.S./RoW Agreement:

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 the AstraZeneca U.S./RoW Agreement, the license was delivered at the beginning of the agreement term. The Company concluded that AstraZeneca has the knowledge and capabilities to fully exploit the license under the AstraZeneca U.S./RoW Agreement without the Company's further involvement. Finally, 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 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. Therefore, the Company has concluded that the license is distinct and represents a performance obligation. The portion of the transaction price allocated to this performance obligation based on a relative SSP basis is recognized as revenue in its entirety at the point in time the license transfers to AstraZeneca.

(2) Co-development services. 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 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, and such an allocation is consistent with the allocation objective. Through the end of 2021, revenue was recognized over time based on progress toward complete satisfaction of the performance obligation. The Company used an input method to measure progress toward the satisfaction of the performance obligation related to CKD approval, 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. Subsequently, the Company accounts for the development services for other significant indications related to chemotherapy-induced anemia and myelodysplastic syndromes separately as services are provided.

(3) 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.

(4) Information sharing and committee service. These promises are satisfied throughout the course of the agreement as services are provided.

Items (2)-(4) 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 delivering 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.

(5) Manufacturing commercial supplies of products. This promise is distinct as services are not interrelated with any of the other performance obligations. Revenue is recognized as supplies are shipped for commercial use during the commercialization period. The drug product revenue amount represents variable consideration and is estimated based on the quantity of product shipped and an estimated price for each individual purchase order. The estimated price is based on the contractual transfer price percentage applied on the estimated weighted average net sales price, which is estimated to be realized by AstraZeneca from the end sale of roxadustat in its approved territories. See the *Drug Product Revenue, Net* section below.

AstraZeneca China Agreement:

The promised services that were analyzed are consistent with the AstraZeneca U.S./RoW Agreement, except for license to the Company's technology existing at the effective date of the agreement, described as follows:

• *License to the Company's technology existing at the effective date of the agreement.* The license was delivered at the beginning of the agreement term. However, the AstraZeneca China Agreement has contractual limitations that might affect AstraZeneca's ability to fully exploit the license and therefore, potentially, the conclusion as to whether the license is distinct in the context of the agreement. In the AstraZeneca China Agreement, AstraZeneca does not have the right to manufacture commercial supplies of the drug. In order to determine whether this characteristic of the arrangement should lead to a conclusion that the license was not distinct in the context of the agreement, the Company considered the ability of AstraZeneca to benefit from the license on its own or together with other resources readily available to AstraZeneca.

For the AstraZeneca China Agreement, the Company retained manufacturing rights as an essential part of a strategy to pursue domestic regulatory pathway for product approval, which requires the regulatory licensure of the manufacturing facility in order to commence commercial shipment. The prospects for the collaboration as a whole would have been substantially different had manufacturing rights been provided to AstraZeneca. The Company holds the rights to manufacture commercial drug product in China. Therefore, AstraZeneca cannot benefit from the license on its own or together with other readily available resources. Accordingly, all the promises identified, including the license, co-development services and manufacturing of commercial supplies, under the AstraZeneca China Agreement have been bundled into a single performance obligation and amounts of the transaction price allocable to this performance obligation are deferred until control of the manufactured commercial drug product has begun to transfer to AstraZeneca.

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. For the Company's direct sales of commercial drug product, revenue is recognized when control of the promised good is transferred to the customer in an amount that reflects the consideration that the Company expects to be entitled to in exchange for the product. See the *Product Revenue, Net* section below.

License Revenue and Development Revenue Recognized Under the AstraZeneca Agreements

Amounts recognized as license revenue and development revenue under the AstraZeneca U.S./RoW Agreement and the AstraZeneca China Agreement were as follows for the years ended December 31, 2023, 2022 and 2021 (in thousands):

		Years Ended December 31,		
Agreement	**Performance Obligation**	**2023**	**2022**	**2021**
AstraZeneca U.S./RoW Agreement and AstraZeneca China Agreement	License revenue	$ 2,649	$ —	$ —
	Development revenue	9,473	12,519	48,345

The transaction price related to consideration received through December 31, 2023 and accounts receivable has been allocated to each of the following performance obligations under the AstraZeneca U.S./RoW Agreement and the AstraZeneca China Agreement, along with any associated deferred revenue as follows (in thousands):

AstraZeneca U.S./RoW Agreement and AstraZeneca China Agreement	**Cumulative Revenue Through December 31, 2023**	**Deferred Revenue at December 31, 2023**	**Total Consideration Through December 31, 2023**
License	$ 344,493	$ —	$ 344,493
Co-development, information sharing & committee services	625,111	—	625,111
China performance obligation *	195,789	179,851	375,640
Total license and development revenue	$ 1,165,393	$ 179,851 **	$ 1,345,244

* China performance obligation revenue is recognized as product revenue, as described in details under *Product Revenue, Net* section below.

** Contract assets and liabilities related to rights and obligations in the same contract are recorded net on the consolidated balance sheets. As of December 31, 2023, deferred revenue included $

153.4
million related to the AstraZeneca U.S./RoW and the AstraZeneca China Agreement, which represents the net of $

179.9
million of deferred revenue presented above and a $

26.5
million unbilled milestone and co-development revenue under the AstraZeneca China Amendment.

There was

no
license revenue or development revenue resulting from changes to estimated variable consideration in the current period relating to performance obligations satisfied or partially satisfied in previous periods for the year ended December 31, 2023. The remainder of the transaction price related to the AstraZeneca U.S./RoW Agreement and the AstraZeneca China Agreement includes $

2.3
million of variable consideration from estimated future co-development billing and is expected to be recognized over the remaining development service period, except for amounts allocated to the China performance obligation. The amount allocated to the China performance obligation is expected to be recognized as the Company transfers control of the commercial drug product to Falikang, and is expected to continue through 2033, which reflects the Company's best estimates, taking into account its estimated loss of exclusivity upon expiry of its composition of matter patent in 2024, its existing patent portfolio, and competition from generics.

Product Revenue, Net

Product revenue, net from the sales of roxadustat commercial product in China was as follows for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Direct Sales:			
Gross revenue	$ 13,190	$ 12,366	13,727
Discounts and rebates	(1,298)	(665)	(1,740)
Sales returns	2	1	83
Direct sales revenue, net	11,894	11,702	12,070
Sales to Falikang:			
Gross transaction price	154,817	112,544	97,531
Profit share	(66,254)	(43,716)	(34,759)
Net transaction price	88,563	68,828	62,772
Decrease (increase) in deferred revenue	492	2,339	(27,204)
Sales to Falikang revenue, net	89,055	71,167	35,568
Total product revenue, net	$ 100,949	$ 82,869	$ 47,638

Direct Sales

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

The discounts and rebates consisted of the price adjustments recorded based on government-listed price guidance and estimated channel inventory levels, the contractual sales rebate calculated based on the stated percentage of gross sales by each distributor in the distribution agreement entered between FibroGen and each distributor, and other rebates and discounts, as well as sales return allowance. The total discounts and rebates were immaterial for the periods presented.

Due to the Company's legal right to offset, at each balance sheet date, the rebates and discounts are presented as reductions to gross accounts receivable from the distributor, or as a current liability to the distributor to the extent that the total amount exceeds the gross accounts receivable or when the Company expects to settle the discount in cash. The Company's legal right to offset is determined at the individual distributor level. The contract liabilities were included in accrued and other current liabilities in the consolidated balance sheet and were immaterial as of December 31, 2023 and 2022. The rebates and discounts were reflected as reductions to gross accounts receivable for direct sales and were immaterial as of December 31, 2023 and 2022.

Sales to Falikang – China Performance Obligation

Substantially all direct roxadustat product sales to distributors in China are made by Falikang. FibroGen Beijing manufactures and supplies commercial product to Falikang. The net 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. Any net transaction price in excess of the revenue recognized is added to the deferred balance to date, and will be recognized in future periods as the performance obligation is satisfied.

Periodically, the Company updates its assumptions such as total sales quantity, performance period, gross transaction price, profit share and other inputs including foreign currency translation impact, among others. Following updates to its estimates, the Company recognized $

0.5

million from the previously deferred revenue of the China performance obligation during the year ended December 31, 2023. The product revenue recognized for the year ended December 31, 2023 included a decrease in revenue of

2.9

million resulting from changes to estimated variable consideration in the current period relating to performance obligation satisfied in previous periods. Comparatively, following updates to its estimates, the Company recognized $

2.3

million from the previously deferred revenue of the China performance obligation during the year ended December 31, 2022.

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

	Balance at December 31, 2022	Additions	Recognized as Revenue	Currency Translation and Other	Balance at December 31, 2023
Product revenue - AstraZeneca China performance obligation - deferred revenue	$ (175,646)	$ (94,099)	$ 89,055	$ 839	$ (179,851)

Deferred revenue includes amounts allocated to the China performance obligation under the AstraZeneca arrangement as revenue recognition associated with this unit of accounting is tied to the commercial launch of the products within China and to when the control of the manufactured commercial products is transferred to AstraZeneca. As of December 31, 2023, approximately $

32.0

million of the above deferred revenue related to the China unit of accounting was included in short-term deferred revenue, which represents the amount of deferred revenue associated with the China unit of accounting that is expected to be recognized within the next 12 months, associated with the commercial sales in China.

Due to the Company's legal right to offset, at each balance sheet date, the rebates and discounts, mainly related to profit sharing, are presented as reductions to gross accounts receivable from Falikang, which was $

3.0

million and $

0.5

million as of December 31, 2023 and 2022, respectively.

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, 2023, 2022 and 2021 (in thousands):

	Years Ended December 31, 2023	2022	2021
Astellas Japan Agreement	$ 15,656	$ 9,480	$ 2,056
Astellas Europe Agreement	3,097	1,606	1,130
AstraZeneca U.S./RoW Agreement	—	—	(2,224)
Drug product revenue, net	$ 18,753	$ 11,086	$ 962

Astellas Japan Agreement

During the year ended December 31, 2021, the Company updated its estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment, and accordingly recorded adjustments to the drug product revenue of $

2.1

million. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect the changes in the estimated bulk product strength mix intended to be manufactured by Astellas, estimated cost to convert the API to bulk product tablets, and estimated yield from the manufacture of bulk product tablets, among others.

During the first quarter of 2022, the Company fulfilled a shipment obligation under the terms of Astellas Japan Amendment, and recognized related drug product revenue of $

9.8

million in the same period. During the fourth quarter of 2022, the Company fulfilled a shipment obligation under the terms of Astellas Japan Amendment, and recognized related drug product revenue of $

8.4

million in the same period. In addition, the Company updated its estimate of variable consideration related to the API shipments fulfilled under the terms of Japan Amendment with Astellas, and recorded a reduction to the drug product revenue of $

8.7

million during the year ended December 31, 2022. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect foreign currency translation impact, the changes in the estimated bulk product strength mix intended to be manufactured by Astellas, estimated cost to convert the API to bulk product tablets, and estimated yield from the manufacture of bulk product tablets, among others.

During the second quarter of 2023, the Company fulfilled two shipment obligations under the terms of Astellas Japan Amendment, and recognized related drug product revenue of $

14.4

million in the same period. In addition, the Company updated its estimate of variable consideration related to the API shipments fulfilled under the terms of Astellas Japan Amendment and accordingly recorded an adjustment to the drug product revenue of $

1.3

million for the year ended December 31, 2023. Specifically, the change in estimated variable consideration was based on the API held by Astellas at period end, adjusted to reflect the changes in the estimated bulk product strength mix intended to be manufactured by Astellas, foreign exchange impacts and estimated yield from the manufacture of bulk product tablets, among others. As of December 31, 2023, the balances related to the API price true-up under the Astellas Japan Agreement were $

1.2

million in accrued liabilities and $

0.7

million in other long-term liabilities, representing the Company's best estimate of the timing for these amounts to be paid. As of December 31, 2022, the related balance in accrued liabilities was $

6.5

million.

Astellas Europe Agreement

During the first quarter of 2021, the Company transferred bulk drug product from process validation supplies for commercial purposes under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement. The Company recorded the consideration of $

11.8

million from this inventory transfer as deferred revenue as of December 31, 2021, due to a high degree of uncertainty associated with the final consideration. During the fourth quarter of 2021, 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 $

1.0

million as drug product revenue, and recorded $

8.3

million as deferred revenue as of December 31, 2021, due to a high degree of uncertainty associated with the final consideration. In addition, during the fourth quarter of 2021, the Company updated its estimate of variable consideration related to the bulk drug product inventory transfers fulfilled under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement, and recorded an unbilled contract asset of $

49.8

million, which was offset by related deferred revenue under the Astellas Europe Agreement and Astellas EU Supply Agreement. 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, among others.

During the second quarter of 2022, 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 $

1.0

million as drug product revenue, and recorded $

23.2

million as deferred revenue due to a high degree of uncertainty associated with the variable consideration for revenue recognition purposes. During the first quarter of 2022, the Company billed and received $

49.2

million from Astellas related to the annual transfer price true up for bulk drug product transferred for commercial purposes. This amount was recorded in deferred revenue and netted against an unbilled contract asset as of December 31, 2021. 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, during the year ended December 31, 2022, the Company reclassified a total of $

57.4

million from the related deferred revenue to accrued liabilities, which was paid to Astellas during 2023.

During the fourth quarter of 2023, 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 $

0.8

million as drug product revenue, and recorded $

17.7

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, 2023, the Company reclassified $

38.7

million from the related deferred revenue to accrued liabilities. As of December 31, 2023, the related balance in accrued liabilities was $

38.6

million, representing the Company's best estimate that this amount will be paid within the next 12 months.

In addition, the Company recognized royalty revenue of $

2.3

million and $

0.6

million as drug product revenue from the deferred revenue under the Astellas Europe Agreement during the years ended December 31, 2023 and 2022, 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, 2022	Additions	Recognized as Revenue	Reclassified to Accrued Liability / Accounts Payable	Balance at December 31, 2023
Drug product revenue - deferred revenue:					

	(	(			(
Astellas Europe Agreement	$ 40,303	$ 17,674	$ 2,306	$ 38,746	$ 16,925

AstraZeneca U.S./RoW Agreement

During the years ended December 31, 2021 and 2020, the Company shipped bulk drug product to AstraZeneca as commercial supply under the terms of the Master Supply Agreement. Based on the complete response letter issued by the U.S. Food and Drug Administration in August 2021, the Company evaluated the impact of these developments in revising its estimates of variable consideration associated with drug product revenue. As a result, the Company updated the estimated transaction price for these shipments, and recorded $

11.2

million as deferred revenue as of December 31, 2021. The related drug product revenue was $(

2.2

) million for the year ended December 31, 2021.

During the first quarter of 2022, the Company evaluated the current developments in the U.S. market, and updated its estimates of variable consideration associated with bulk drug product shipments to AstraZeneca in prior years as commercial supply. As a result, during the year ended December 31, 2022, the Company reclassified $

11.2

million from the related deferred revenue to accrued liabilities, which remained unchanged as of December 31, 2023, representing its best estimate that this amount will be paid within the next 12 months.

Eluminex Agreements

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

Under the terms of the agreement with Eluminex, as amended and restated in January 2022, Eluminex made an $

8.0

million upfront payment to FibroGen during the first quarter of 2022. In addition, FibroGen may receive up to a total of $

64.0

million in future manufacturing, clinical, regulatory, and commercial milestone payments for the biosynthetic cornea program, as well as $

36.0

million in commercial milestones for the first recombinant collagen III product that is not the biosynthetic cornea. FibroGen will also be eligible to receive mid single-digit to low double-digit royalties based upon worldwide net sales of cornea products, and low single-digit to mid single-digit royalties based upon worldwide net sales of other recombinant human collagen type III products that are not cornea products.

The Company accounted for this agreement under ASC 606, *Revenue from Contracts with Customers*, and identified

one

performance obligation at inception of the agreement related to the granting of the license rights to the investigational biosynthetic cornea derived from recombinant human collagen Type III. The Company based its assessment on the determination that Eluminex can benefit from the granted license on its own by developing and commercializing the underlying product using its own resources. All components of the transaction price in the agreement were allocated to the single performance obligation. The remaining future variable consideration related to future manufacturing, clinical, regulatory milestone payments as described above were fully constrained because the Company cannot conclude that it is probable that a significant reversal of the amount of cumulative revenue recognized will not occur, given the inherent uncertainties of success with these future milestones. For commercial milestones and royalties, the Company determined that the license is the predominant item to which the royalties or sales-based milestones relate and revenue will be recognized when the corresponding milestones and royalties are earned.

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

1.5
million.

For the year ended December 31, 2023, the Company recognized a $

3.0
million milestone payment based on Eluminex implanting a biosynthetic cornea in the first patient of its clinical trial in China, a $

3.0
million manufacturing related milestone payment and a $

1.0
million upfront payment, as license revenue for the performance obligation satisfied and included in license revenue in the consolidated statement of operations. In addition, the Company recognized a $

0.5
million upfront payment related to patent transfer under the A&R Eluminex Agreement as other revenue and included in development and other revenue in the consolidated statement of operations.

During the year ended December 31, 2021, the Company recognized an $

8.0
million upfront payment to FibroGen as license revenue for the performance obligation satisfied and included in license revenue in the consolidated statement of operations.

During the first quarter of 2022, FibroGen and Eluminex entered into a separate contract manufacturing agreement, under which the Company was responsible for supplying the cornea product at cost plus

10
% of its product manufacturing costs until its manufacturing technology is fully transferred to Eluminex, which occurred by the end of 2023. Supply of the cornea product will be managed by a separate agreement and is considered a separate performance obligation. The related contract manufacturing revenue was recorded as other revenue and included in development and other revenue in the consolidated statement of operations.

Amounts recognized as revenue under the agreements with Eluminex were as follows for the years ended December 31, 2023 and 2022 (in thousands):

		Years Ended December 31,		
Agreement	**Performance Obligation**	**2023**	**2022**	**2021**
Eluminex	License revenue	$ 7,000	$ —	$ 8,000
	Other revenue - patent transfer	500	$ —	$ —
	Other revenue - contract manufacturing	$ 966	$ 1,761	$ —

4. Exclusive License and Option to Acquire Fortis Therapeutics

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

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

Pursuant to the guidance under 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, 2023. The transaction was accounted for as an asset acquisition under ASC 805, *Business Combinations*, as substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable IPR&D asset.

The fair value of the consideration transferred was

zero
. If FibroGen exercises the option to acquire Fortis, it will pay Fortis an option exercise payment of $

80.0
million, and thereafter, legacy Fortis shareholders would be eligible to receive from FibroGen up to $

200.0
million in contingent payments associated with the achievement of various regulatory approvals. If FibroGen acquires Fortis, it would also be responsible to pay UCSF, an upstream licensor to Fortis, development milestone fees and a single digit royalty on net sales of therapeutic or diagnostic products arising from the licensing arrangement between Fortis and UCSF. If FibroGen chooses not to acquire Fortis, its exclusive license to FG-3246 would expire.

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

Fortis has authorized and issued common shares and Series A preferred shares. As of the Option Acquisition Date and December 31, 2023, the Company owned approximately 2 % of Fortis' Series A preferred shares, which was acquired previously and carried at zero cost. The NCI attributable to the common shares is classified as nonredeemable NCI, as it is 100 % owned by third party shareholders. The NCI attributable to the approximately 98 % of Series A preferred shares owned by other investors are classified as redeemable NCI in temporary equity, as the preferred shares are redeemable by the non-controlling shares holders upon occurrence of certain events out of the Company's control.

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

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

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

Net identifiable assets, liabilities and non-controlling interests	(236)
	$)
Loss on asset acquisition	(236)
	$)

The Company used a third party valuation specialist to determine the fair value of the IPR&D assets using a risk-adjusted net present value discounted cash flow model (the “rNPV”) with the following key assumptions: (i) estimated cash flow forecasts of peak sales, sales penetration, remaining IPR&D related product development costs, and other related general and administrative costs; (ii) probabilities of technical success of future underlying Phase II and Phase III clinical trials and ensuing probability of regulatory approval related to the IPR&D assets; and (iii) estimate of a risk-adjusted discount rate of

16.5
%. The acquired IPR&D assets were determined to have no alternative future use. Accordingly, the Company expensed fair value of the acquired IPR&D assets of $

24.4
million as research and development expense in the consolidated statements of operations for the year ended December 31, 2023.

The fair value of Fortis (enterprise value) and the fair value of nonredeemable NCI and redeemable NCI were determined based on the above-mentioned option exercise payment of $

80.0
million and contingent payments up to $

200.0
million, weighted with probability and expected timing of the underlying events consistent with the assumptions under the rNPV, and discounted by the Company’s estimated market level cost of debt.

As of December 31, 2023, total assets and liabilities of Fortis were immaterial. For the period from the Option Acquisition Date to December 31, 2023, Fortis’ net income (losses) was immaterial.

5. Equity method investment - Variable Interest Entity

Falikang is a distribution entity jointly owned by AstraZeneca and FibroGen Beijing. FibroGen Beijing owns

51.1
% of the outstanding shares of Falikang.

Pursuant to the guidance under ASC 810, the Company concluded that Falikang qualifies as a VIE. As Falikang is a distribution entity and AstraZeneca is the final decision maker for all the roxadustat commercialization activities, the Company lacks the power criterion, while AstraZeneca meets both the power and economic criteria under the ASC 810 to direct the activities of Falikang that most significantly impact its performance. Therefore, the Company is not the primary beneficiary of this VIE for accounting purposes. As a result, the Company accounts for its investment in Falikang under the equity method, and Falikang is not consolidated into the Company's consolidated financial statements. The Company records its total investments in Falikang as an equity method investment in an unconsolidated VIE in the consolidated balance sheet. In addition, the Company recognizes its proportionate share of the reported profits or losses of Falikang as investment gain or loss in unconsolidated VIE in the consolidated statement of operations and as an adjustment to its investment in Falikang in the consolidated balance sheet. The Company may provide shareholder loans to Falikang to meet necessary financial obligations as part of its operations. To date, there has been no such loans. During the year ended December 31, 2023, the Company received $

2.3
million of dividend distribution from Falikang.

The Company's equity method investment in Falikang was as follows for the year ended December 31, 2023 (in thousands):

Entity	Ownership Percentage	Balance at December 31, 2022	Share of Net Income	Dividend Received	Currency Translation	Balance at December 31, 2023
Falikang	51.1 %	$ 5,061	$ 2,638	$ (2,255)	$ (154)	$ 5,290

Falikang is considered as a related party to the Company. See Note 16, *Related Party Transactions*, for related disclosures.

On an ongoing basis, the Company re-evaluates the VIE assessment based on changes in facts and circumstances, including but not limited to, the shareholder loans received by Falikang and the execution of any future significant agreements between Falikang and its shareholders and/or other third parties. In addition, the Company assesses the impairment of its equity method investment whenever events or changes in circumstances indicate that a decrease in value of the investment has occurred that is other than temporary. There has been no such event or change in circumstances to date.

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, 2023			
	Level 1	Level 2	Level 3	Total
Money market funds	$ 12,288	$ —	$ —	$ 12,288
Corporate bonds	—	13,992	—	13,992
Commercial paper	—	88,289	—	88,289
U.S. government bonds	42,797	4,994	—	47,791
Agency bonds	—	9,830	—	9,830
Total	$ 55,085	$ 117,105	$ —	$ 172,190

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

The Company's Level 2 investments are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar investments, issuer credit spreads, benchmark investments, prepayment/default projections based on historical data and other observable inputs. During the years ended December 31, 2023 and 2022, the transfers of assets between levels was a total of $

20.4
million and $

10.5

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. There were

no

transfers of assets between levels for the year ended December 31, 2021.

7. Leases

The Company's long-term property lease with Alexandria for its corporate headquarters in San Francisco, California, had an initial term of 15 years, scheduled to expire in 2023 . The original lease was accounted for as a finance lease.

On June 1, 2021, the Company entered into an amendment with Alexandria to extend the lease to 2028 ("Lease Amendment"). Under the terms of the Lease Amendment, the Company has

two

optional rights to each extend the lease for an additional five years . The lease contract provides for a fixed annual rent, with scheduled increases of

two

percent that occur on each anniversary of the rent commencement date through 2023 , and with scheduled increases of

three

percent that occur on each anniversary of the rent commencement date through 2028 . This lease requires the Company to pay all costs of ownership, operation, and maintenance of the premises, including without limitation all operating costs, insurance costs, and taxes.

The Company determined that the Lease Amendment was a lease modification, effective June 1, 2021, and thus reassessed the lease classification, remeasured the related lease liability using an updated discount rate, and adjusted the related right-of-use asset under the lease modification guidance under the ASC 842. Accordingly, on June 1, 2021, the Company determined that the modified lease be accounted for as an operating lease, and therefore derecognized the previous finance lease right-of-use asset of $

24.6

million and the related finance lease liability of $

32.6

million, and recognized an operating lease right-of-use asset of $

93.2

million and the related operating lease liability of $

101.2

million. Starting June 1, 2021, the cash payment related to this lease was classified as an operating activity.

During the first quarter of 2021, after FibroGen Beijing's previous long-term lease agreement expired, the Company entered into a new lease agreement with the landlord for the same pilot plant located in Beijing Yizhuang Biomedical Park of BDA. The new lease term is five year , scheduled to expire in 2026 , and is treated as an operating lease. Accordingly, the Company recorded $

3.4

million in the operating right-of-use assets and total operating lease liabilities, respectively. The lease contract provides for fixed quarterly rent payments, and requires the Company to pay operating and maintenance costs.

The Company currently has several additional real estate leases for office spaces in Shanghai and Beijing, China, which are treated as operating leases. These leases have lease terms ranging from one to five years , expiring in 2026 . These lease contracts provide for fixed quarterly rent payments, and require the Company to pay operating and maintenance costs, and a fixed amount for property management fees.

In addition, the Company has several immaterial lease arrangements in China and U.S. for office equipment and automobile leases, with contracted lease terms ranging from one to six years , treated as finance leases or operating leases.

The Company's lease assets and related lease liabilities were as follows (in thousands):

	Balance Sheet Line Item	December 31, 2023	2022
Assets			
Finance:			
Right-of-use assets cost		$ 2,478	$ 2,367
Accumulated amortization		(2,325)	(1,932)
Finance lease right-of-use assets, net	Other assets	153	435
Operating:			
Right-of-use assets cost		103,010	101,990
Accumulated amortization		(34,917)	(22,097)
Operating lease right-of-use assets, net	Operating lease right-of-use assets	68,093	79,893
Total lease assets		$ 68,246	$ 80,328
Liabilities			
Current:			
Finance lease liabilities	Accrued and other current liabilities	$ 40	$ 36
Operating lease liabilities	Operating lease liabilities, current	14,077	10,292
Non-current:			
Finance lease liabilities	Other long-term liabilities	104	137
Operating lease liabilities	Operating lease liabilities, non-current	66,537	79,593
Total lease liabilities		$ 80,758	$ 90,058

The components of lease expense were as follows (in thousands):

	Statement of Operations Line Item	Years Ended December 31, 2023	2022	2021
Finance lease cost:				
Amortization of right-of-use assets	Cost of goods sold; Research and development; Selling, general and administrative expenses	$ 412	$ 587	$ 4,639

Interest on lease liabilities	Interest expense	1	—	628
Operating lease cost	Cost of goods sold; Research and development; Selling, general and administrative expenses	17,006	17,125	10,722
Sublease income	Selling, general and administrative expenses	(3,024)	(3,373)	(1,271)
Total lease cost		$ 14,395	$ 14,339	$ 14,718

Supplemental cash flow information related to leases were as follows (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 14,463	$ 15,497	$ 10,022
Operating cash flows from finance leases	9	2	629
Financing cash flows from finance leases	148	135	5,489
Non-cash: Right-of-use assets obtained in exchange for new lease liabilities:			
Finance leases	131	261	450
Operating leases	1,278	1,704	3,585
Non-cash: Increase (decrease) resulting from lease modification:			
Finance lease right-of-use assets	—	—	(24,654)
Operating lease right-of-use assets	—	—	93,222
Finance lease liabilities, current	—	—	(12,587)
Operating lease liabilities, current	—	—	9,221
Finance lease liabilities, non-current	—	—	(20,009)
Operating lease liabilities, non-current	—	—	91,943

Lease term and discount rate were as follows:

	December 31,	
	2023	2022
Weighted-average remaining lease term (years):		
Finance leases	3.9	4.9
Operating leases	4.8	5.8
Weighted-average discount rate:		

Finance leases	6.17 %	6.20 %
Operating leases	4.75 %	4.75 %

Maturities of lease liabilities as of December 31, 2023 are as follows (in thousands):

Year Ending December 31,	Finance Leases	Operating Leases
2024	$ 47	$ 17,554
2025	39	18,836
2026	39	18,082
2027	37	18,476
2028	—	17,401
Total future lease payments	162	90,349
Less: Interest	(18)	(9,735)
Present value of lease liabilities	$ 144	$ 80,614

8. Balance Sheet Components

Cash and Cash Equivalents

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

	December 31, 2023	2022
Cash	$ 63,396	$ 135,819
Commercial paper	36,016	—
Money market funds	12,288	19,881
U.S. government bonds	1,988	—
Total cash and cash equivalents	$ 113,688	$ 155,700

At December 31, 2023 and 2022, a total of $

32.2
million and $

92.5
million, respectively, of the Company's cash and cash equivalents were held outside of the U.S. in its foreign subsidiaries to be used primarily for its China operations.

Investments

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

	December 31, 2023			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Corporate bonds	$ 13,988	$ 9	$ (5)	$ 13,992
Commercial paper	52,273	—	—	52,273
U.S. government bonds	45,783	20	—	45,803
Agency bonds	9,830	1	(1)	9,830
Total investments	$ 121,874	$ 30	$ (6)	$ 121,898

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

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

	December 31, 2023					
	Less than 12 Months		12 Months or More		Total	
	Estimated Fair Value	Gross Unrealized Holding Losses	Estimated Fair Value	Gross Unrealized Holding Losses	Estimated Fair Value	Gross Unrealized Holding Losses
Corporate bonds	$ —	$ —	$ 3,495	$ (5)	$ 3,495	$ (5)

U.S. government bonds	4,984	—	—	—	4,984	—
Agency bonds	4,987	(1)	—	—	4,987	(1)
Total	$ 9,971	$ (1)	$ 3,495	$ (5)	$ 13,466	$ (6)

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

The contractual maturities of all available-for-sale investments were with in one year as of December 31, 2023.

The Company periodically reviews its available-for-sale investments for other-than-temporary impairment. The Company considers factors such as the duration, 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. During the three years ended December 31, 2023, the Company did

no
t recognize any other-than-temporary impairment loss.

Inventories

Inventories consisted of the following (in thousands):

	December 31,	
	2023	2022
Raw materials	$ 1,376	$ 1,241
Work-in-progress	34,614	36,003
Finished goods	5,575	3,192
Total inventories	$ 41,565	$ 40,436

The provision to write-down excess and obsolete inventory were immaterial as of December 31, 2023 and December 31, 2022.

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2023	2022
Contract assets	$ 26,481	$ 17,488
Deferred revenues from associated contracts	(26,481)	(17,488)
Net contract assets	—	—
Insurance proceeds receivable for litigation settlement	28,500	
Prepaid assets	6,644	9,730
Other current assets	6,711	4,353
Total prepaid expenses and other current assets	$ 41,855	$ 14,083

The unbilled contract assets as of December 31, 2023 and 2022 included $

22.5
million and $

17.5
million, respectively, related to unbilled co-development revenue under the AstraZeneca China Amendment. In addition, the unbilled contract assets as of December 31, 2023 included the $

4.0
million unbilled regulatory milestone payment under the AstraZeneca China Agreement. See the *AstraZeneca China Agreement* section in Note 3, *Collaboration Agreements, License Agreement and Revenues*, for details.

As of December 31, 2023, 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. See the *Accrued and Other Current Liabilities* section below, and the *Legal Proceedings and Other Matters* section in Note 12, *Commitments and Contingencies*, for details.

Property and Equipment

Property and equipment consisted of the following (in thousands):

	December 31,	
	2023	2022
Leasehold improvements	$ 102,109	$ 102,580
Laboratory equipment	22,757	21,175
Machinery	9,454	9,642
Computer equipment	9,490	9,486
Furniture and fixtures	6,184	6,200
Construction in progress	62	204
Total property and equipment	$ 150,056	$ 149,287
Less: accumulated depreciation	(136,930)	(128,682)
Property and equipment, net	$ 13,126	$ 20,605

Depreciation expense for the years ended December 31, 2023, 2022 and 2021 was $

9.5
million, $

10.0
million and $

10.2
million, respectively.

Accrued and Other Current Liabilities

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

	December 31,	
	2023	2022
Preclinical and clinical trial accruals	$ 27,663	$ 57,780
API and bulk drug product price true-up	50,978	75,055
Litigation settlement	28,500	—
Payroll and related accruals	20,267	22,562

Accrued co-promotion expenses - current	10,309	36,677
Roxadustat profit share to AstraZeneca	7,084	7,280
Property taxes and other taxes	6,615	7,691
Professional services	7,103	5,480
Current portion of liability related to sale of future revenues	5,654	—
Accrued restructuring charge	3,697	—
Other	5,021	7,248
Total accrued and other current liabilities	$ 172,891	$ 219,773

The accrued liabilities of $

51.0

million for API and bulk drug product price true-up as of December 31, 2023 resulted from changes in estimated variable consideration associated with the API shipments fulfilled under the terms of the Astellas Japan Amendment, the bulk drug product transferred under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement, and the bulk drug product shipments to AstraZeneca under the terms of the AstraZeneca Master Supply Agreement. See the *Drug Product Revenue, Net* section in Note 3, *Collaboration Agreements, License Agreement and Revenues,* for details.

As of December 31, 2023, the accrued litigation settlement of $

28.5

million was related to the Company's agreement in principle with plaintiffs to settle the class action lawsuit. See the *Prepaid Expenses and Other Current Assets* section above, and the *Legal Proceedings and Other Matters* section in Note 12, *Commitments and Contingencies*, for details.

On July 14, 2023, the Company approved a restructuring plan (the “Plan”) to lower the Company’s operating expenses. The Plan included a reduction to the Company’s U.S. workforce of approximately

32

%. As a result, the Company recorded a total of $

12.6

million non-recurring restructuring charge during the third quarter of 2023, primarily consisting of notice period and severance payments, accrued vacation, and employee benefits contributions. During the year ended December 31, 2023, total cash payments under the Plan was $

8.9

million. The remaining accrued restructuring charge was $

3.7

million as of December 31, 2023 and will be substantially paid out by early 2024. The Plan is in connection with the Company’s efforts to streamline operations to align with the Company’s business goals.

9. Senior Secured Term Loan Facilities

On April 29, 2023, the Company entered into a financing agreement (“Financing Agreement”) with investment funds managed by Morgan Stanley Tactical Value, as lenders (the “Lenders”), and Wilmington Trust, National Association, as the administrative agent, providing for senior secured term loan facilities consisting of (i) a $

75.0

million initial term loan (the “Initial Term Loan”), (ii) a $

37.5

million delayed draw term loan that will be funded upon the achievement of certain clinical development milestones (“Delayed Draw Term Loan 1”) and, (iii) an uncommitted delayed draw term loan of up to $

37.5

million to be funded at the Lenders sole discretion, (“Delayed Draw Term Loan 2” and, together with the Initial Term Loan and Delayed Draw Term Loan 1, the “Term Loans”).

Pursuant to the Financing Agreement, the Lenders have funded the Initial Term Loan. The clinical development milestones which could have triggered Delayed Draw Term Loan 1 were not achieved, and the Lenders have not funded Delayed Draw Term Loan 2. As such, these features have expired as of December 31, 2023.

The Term Loans shall accrue interest at a fixed rate of

14.0

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

On May 8, 2023, the Company received $

74.1

million, representing the Initial Term Loan of $

75.0

million net of $

0.9

million issuance costs. The issuance costs and the related transaction costs, totaling $

3.7

million is amortized as interest expense using the effective interest method over the term of the Initial Term Loan and are reported on the balance sheet as a direct deduction from the amount of the Initial Term Loan. The effective annual interest rate of the Initial Term Loan was

16.13

% for the year ended December 31, 2023. The Company recorded interest expense of $

7.4

million for the year ended December 31, 2023. As of December 31, 2023, the related accrued interest was $

0.4

million. The Company was in compliance with all debt covenants associated with the senior secured term loan facilities as of December 31, 2023, including maintaining a minimum balance of $

30

million of unrestricted cash and cash equivalents held in accounts in the U.S.

The Company has determined that certain other features embedded within the Loan should be bifurcated and accounted for separately as a derivative. At inception and as of December 31, 2023, the fair values of such derivatives were negligible due to the low probability of the underlying events.

The Company’s senior secured term loan facilities as of December 31, 2023 were as follows (in thousands):

	December 31, 2023

Principal of senior secured term loan facilities	$	75,000
Less: Unamortized issuance costs and transaction costs		(3,066)
Senior secured term loan facilities, ending balance		71,934
Less: Current Portion classified to accrued and other current liabilities		—
Senior secured term loan facilities, non-current	$	71,934

10. Liability Related to Sale of Future Revenues

On November 4, 2022, the Company entered into a Revenue Interest Financing Agreement (the “RIFA”) with NQ Entity, L.P. (“NovaQuest”), pursuant to which the Company granted a percentage interest in the Company’s future revenues under the Astellas Agreements, for a consideration of $

50.0
million (“Investment Amount”) before advisory fees.

Effective as of November 2022, the Company sold to 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 under the Astellas Agreements. In November 2022, the Company received $

49.8
million from NovaQuest at an initial funding on November 17, 2022, representing the gross proceeds of $

50.0
million (the “Initial 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 total debt discount and transaction costs of $

1.7
million, is amortized as interest expense based on the projected balance of the liability as of the beginning of each period. The Company estimated an effective annual interest rate of approximately

16.03
% and

19.67
% for the years ended December 31, 2023 and 2022, respectively.

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 table below shows the activity of the liability related to sale of future revenues for the year ended December 31, 2023:

	Year Ended December 31, 2023
Liability related to sale of future revenues - beginning balance	$ 49,333
Interest expense recognized	7,734
Liability related to sale of future revenues - ending balance	57,067
Less: Current portion classified to accrued and other current liabilities	(5,654)
Liability related to sale of future revenues, non-current	$ 51,413

During the years ended December 31, 2023 and 2022, the Company recognized, under Astellas Agreements, drug product revenue of $

18.8
million and $

11.1
million, respectively. In addition, during the year ended December 31, 2022, the Company recognized, under Astellas Agreements, license revenue of $

22.6
million and development revenue of $

2.4
million related to a $

25.0
million regulatory milestone. See Note 3, *Collaboration Agreements, License Agreement and Revenue*, for details.

During the years ended December 31, 2023 and 2022, the Company recognized the related non-cash interest expense of $

7.7
million and $

1.0
million, respectively.

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

125.0
million by 2031.

11. 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, 2023 and 2022, the Company had U.S. Dollar equivalent of $

10.4
million and $

10.1
million of principal outstanding, respectively, and $

7.3
million and $

6.8
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 these loans are not repayable by FibroGen Europe until it has distributable funds.

12. Commitments and Contingencies

Contract Obligations

As of December 31, 2023, the Company had the following outstanding non-cancelable purchase obligations (in thousands):

	Purchase Obligations Due In The Year Ending December 31,		
	2024	2025	Total
Manufacture and supply of pamrevlumab	$ 17,995	$ 4,827	$ 22,822

Manufacture and supply of roxadustat	573	1,146	1,719
Other purchases and programs	11,750	—	11,750
Total	$ 30,318	$ 5,973	$ 36,291

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 7, *Leases*, for details of the Company's operating and finance lease payment obligations. See Note 9, *Senior Secured Term Loan Facilities,* Note 10, *Liability Related to Sale of Future Revenues* and Note 11, *Product Development Obligations* for details of the respective obligations.

Some of the Company’s license agreements provide for periodic maintenance fees over specified time periods, as well as payments by the Company upon the achievement of development, regulatory and commercial milestones. As of December 31, 2023, future milestone payments for research and preclinical stage development programs consisted of up to approximately $

697.9

million in total potential future milestone payments under the Company’s license agreements with HiFiBiO (for Gal-9 and CCR8), Medarex, Inc. and others. These milestone payments generally become due and payable only upon the achievement of certain developmental, clinical, regulatory and/or commercial milestones. The event triggering such payment or obligation has not yet occurred.

Legal Proceedings and Other Matters

From time to time, the Company is a party to various legal actions, both inside and outside the U.S., arising in the ordinary course of its business or otherwise. The Company accrues amounts, to the extent they can be reasonably estimated, that the Company believes will result in a probable loss (including, among other things, probable settlement value) to adequately address any liabilities related to legal proceedings and other loss contingencies. A loss or a range of loss is disclosed when it is reasonably possible that a material loss will incur and can be estimated, or when it is reasonably possible that the amount of a loss, when material, will exceed the recorded provision. The Company did not have any material accruals for any active legal action, except for the class action settlement mentioned below, in its consolidated balance sheet as of December 31, 2023, as the Company could not predict the ultimate outcome of these matters, or reasonably estimate the potential exposure.

Between April 2021 and May 2021,

five

putative securities class action complaints were filed against FibroGen and certain of its current and former executive officers (collectively, the "Defendants") in the U.S. District Court for the Northern District of California. The lawsuits allege that Defendants violated the Securities Exchange Act of 1934 by making materially false and misleading statements regarding FibroGen's Phase 3 clinical studies data and prospects for U.S. Food and Drug Administration approval. On August 30, 2021, the Court consolidated the actions and appointed a group of lead plaintiffs. On October 17, 2023, the parties reached an agreement in principle to settle the class action at $

28.5

million. Accordingly, as of December 31, 2023, the Company recorded the $

28.5

million in accrued and other current liabilities in the consolidated balance sheet. The Company maintains insurance that covers exposure related to the class action lawsuit. As the amount is fully recoverable under the Company's insurance policies, the Company recorded a corresponding receivable in prepaid expenses and other current assets in the consolidated balance sheet. The determination that the recorded receivables are probable of collection is based on the terms of the applicable insurance policies and communications with the insurers. Another case, filed on May 25, 2023, against the same defendants, asserting similar claims as the class action and additional common-law and California state fraud claims was voluntarily dismissed on December 20, 2023.

Between July 30, 2021 and December 5, 2023,

six

shareholder derivative complaints were filed, naming as defendants certain of our current and former officers and certain current and former members of our board, as well as FibroGen as nominal defendants (the "Derivative Lawsuits"). Of these Derivative Lawsuits, three were filed in the Delaware Court of Chancery, two were filed in the U.S. District Court for the District of Delaware (the "Delaware Federal Derivative Actions"), and one was filed in the U.S. District Court for the Northern District of California (the "California Federal Derivative Action"). The plaintiffs assert state and federal claims based on some of the same alleged misstatements as the securities class action complaint. The complaints seek unspecified damages, attorneys' fees, and other costs. The status of the six Derivative Lawsuits is currently as follows:

- Two of the Delaware Chancery Derivative actions, filed on April 14, 2022, and June 1, 2023, have been consolidated (the "Delaware Chancery Consolidated Derivative"). On February 1, 2024, Defendants moved to dismiss the Delaware Chancery Consolidated Derivative action. In another derivative action, filed in the Delaware Court of Chancery on December 3, 2023, Defendants have not been served;
- The Delaware Federal Derivative actions remain stayed. One is stayed pending the resolution of the putative securities class action, and the other is stayed pending resolution of the motion to dismiss the Delaware Chancery Consolidated Derivative action; and
- The California Federal Derivative action was voluntarily dismissed on January 22, 2024.

The Company believes that the claims asserted in the Derivative Lawsuits are without merit and it intends to vigorously defend against them. However, any litigation is inherently uncertain, and any judgment or injunctive relief entered against FibroGen or any adverse settlement could materially and adversely impact its business, results of operations, financial condition, and prospects.

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

Between 2022 and 2023, the Company's Board of Directors received five litigation demands from purported shareholders of the Company, asking the Board of Directors to investigate and take action against certain current and former officers and directors of the Company for alleged wrongdoing based on the same allegations in the pending derivative and securities class action lawsuits. The Company may in the future receive such additional demands.

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

Indemnification Agreements

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

13. Equity and Stock-based Compensation

Common Stock

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,	
	2023	2022
Common stock outstanding	98,770	94,166
Stock options outstanding	11,104	9,088
RSUs outstanding	4,404	3,669
Shares reserved for future stock options and RSUs grant	10,769	11,524
Shares reserved for future ESPP offering	5,952	5,373
Total shares of common stock reserved	130,999	123,820

At-the-Market Program

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

200.0
million (the "ATM Program").

For the year ended December 31, 2023, the Company sold

2,472,090
shares under the ATM Program, for proceeds of approximately $

48.4
million, net of commissions to Sales Agents, at a weighted-average offering prices per share of $

19.63

Stock Plans

Stock Option and RSU Plans

Under the Company's Amended and Restated 2005 Stock Plan ("2005 Stock Plan"), the Company may issue shares of Common Stock and options to purchase Common Stock and other forms of equity incentives to employees, directors and consultants. Options granted under the 2005 Stock Plan may be incentive stock options or nonqualified stock options. Incentive stock options may be granted only to employees and officers of the Company. Nonqualified stock options and stock purchase rights may be granted to employees, directors and consultants. The board of directors has the authority to determine to whom options will be granted, the number of options, the term and the exercise price. Options are to be granted at an exercise price not less than fair market value for an incentive stock option or a nonqualified stock option. Options generally vest over four years . Options expire no more than 10 years after the date of grant. Upon the effective date of the registration statement related to the Company's initial public offering, the 2005 Plan was amended to cease the grant of any additional awards thereunder, although the Company will continue to issue common stock upon the exercise of previously granted stock options under the 2005 Plan.

In September 2014, the Company adopted a 2014 Equity Incentive Plan (the "2014 Plan") which became effective on November 13, 2014. The 2014 Plan is the successor equity compensation plan to the 2005 Plan. The 2014 Plan will terminate on November 12, 2024 . The 2014 Plan provides 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 are determined by the Company at the time of issuance and generally have a four year vesting schedule (

25
% vesting on the first anniversary of the vesting base date and quarterly thereafter over the next 3 years). Options generally expire ten years from the date of grant unless the optionee is a 10% stockholder, in which case the term will be five years from the date of grant. Unvested options exercised are subject to the Company's repurchase right. Shares reserved for issuance increases on January 1 of each year commencing on January 1, 2016 and ending on January 1, 2024 by the lesser of (i) the amount equal to

4
% of the number of shares issued and outstanding on December 31 immediately prior to the date of increase or (ii) such lower number of shares as may be determined by the board of directors. As of December 31, 2023 , the Company has reserved

10,768,935
shares of its common stock that remains unissued for issuance under the 2014 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, 2023 and 2022,

no

shares of Common Stock were subject to repurchase by the Company.

In February 2023, the Company granted

159,150
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

280,450
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, 2023,

68,541
shares of the PRSUs have vested and been released.

In February 2023, the Company granted

159,150
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

280,450
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 FibroGen's common stock as compared to companies in the NBI index, and continued employment with the Company. During the year ended December 31, 2023,

110,370
shares of the TSR awards have vested and been released.

Stock option transactions, including forfeited options granted under the 2014 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, 2022	9,088	$ 29.19		
Granted	5,738	7.27		
Exercised	(122)	12.42		
Forfeited	(1,725)	22.49		
Expired	(1,875)	34.38		
Outstanding at December 31, 2023	11,104	18.21	7.26	$ 83
Vested and expected to vest, December 31, 2023	10,224	19.21	7.11	68
Exercisable at December 31, 2023	4,688	$ 30.66	5.04	$ —

The estimated weighted-average fair value of the stock options granted during the years ended December 31, 2023, 2022 and 2021 was $ 7.27 , $ 14.72 and $ 35.58 , respectively. The total intrinsic value of options exercised during the years ended December 31, 2023, 2022 and 2021 was $ 0.9 million, $ 0.8 million and $ 13.1 million, respectively.

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, 2022	3,669	$ 18.80
Granted	4,612	11.61
Vested	(2,002)	14.70

Forfeited	(1,875)	20.58
Unvested at December 31, 2023	4,404	$ 12.37

The numbers of PRSUs and TSR awards granted included in the table above reflect the shares that could be eligible to vest at 100% of target number of shares.

Among the vested RSUs during the year ended December 31, 2023, 1,648,201 shares were released and issued, while the remaining was withheld for the related payroll taxes. The estimated weighted-average fair value of the awards granted during the years ended December 31, 2023, 2022 and 2021 was $11.61, $14.68 and $30.19, respectively.

ESPP

In September 2014, the Company adopted a 2014 ESPP that became effective on November 13, 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 1,600,000 shares of its common stock for issuance under the 2014 ESPP and shares reserved for issuance increases January 1 of each year, which commenced on January 1, 2016, by the lesser of (i) a number of shares equal to 1% of the total number of outstanding shares of common stock on December 31 immediately prior to the date of increase; (ii) 1,200,000 shares or (iii) such number of shares as may be determined by the board of directors. There were 361,911 shares, 327,298 shares and 213,505 shares purchased by employees under the 2014 Purchased Plan for the years ended December 31, 2023, 2022 and 2021, respectively.

Stock-Based Compensation

Stock-based compensation expense was recorded directly to research and development and selling, general and administrative expense for the years ended December 31, 2023, 2022 and 2021 was as follows (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Research and development	$ 25,462	$ 34,861	$ 40,547
Selling, general and administrative	25,305	30,740	30,614
Total stock-based compensation expense	$ 50,767	$ 65,601	$ 71,161

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,		
	2023	2022	2021
Stock Options			
Expected term (in years)	6.1	5.7	5.7
Expected volatility	92.8 %	66.8 %	61.9 %
Risk-free interest rate	3.0 %	2.2 %	0.8 %
Expected dividend yield	—	—	—
Weighted average estimated fair value	$ 4.67	$ 7.88	$ 20.21
ESPPs			
Expected term (in years)	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0

Expected volatility	56.7 - 271.2 %	58.5 - 97.6 %	47.1 - 104.4 %
Risk-free interest rate	0.2 - 5.2 %	0.1 - 4.5 %	0.0 - 2.2 %
Expected dividend yield	—	—	—
Weighted average estimated fair value	$ 5.64	$ 8.60	$ 12.40

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,	
	2023	2022
TSR awards		
Expected term (in years)	3.9	3.9
Expected volatility	69.0 - 73.3 %	69.0 %
Risk-free interest rate	1.8 - 4.2 %	1.8 %
Expected dividend yield	—	—
Weighted average estimated fair value	$ 28.90	$ 24.01

As of December 31, 2023, there was $

25.6

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 2.81 years. As of December 31, 2023, there was $

35.6

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 2.09 years.

Subsidiary Stock and Non-Controlling Interests

FibroGen Europe

As of December 31, 2023 and 2022, respectively, FibroGen Europe had a total of

42,619,022

shares of Preferred Stock outstanding, of which there were

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 FibroGen, Inc. Common Stock. 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.

Upon the initial public offering and as described above, all eligible FibroGen Europe preferred shares were exchanged for

958,996

shares of FibroGen Common Stock. No other FibroGen Europe shares have the right to be exchanged for FibroGen, Inc. Common Stock.

FibroGen Cayman

FibroGen Cayman had

6,758,000

Series A Preference Shares outstanding as of December 31, 2023 and 2022, respectively. 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 Company, 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 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

%.

In January 2013, FibroGen Cayman entered into a $

0.6

million convertible promissory note. The note bears simple interest at a rate of two percent (

2.00

%) per annum, accrued on an annual basis in arrears. The outstanding principal balance and unpaid accrued interest on the note is due and payable upon the earlier of (a) the effectiveness of the initial public offering of FibroGen Cayman or (b) the eight year anniversary of the date of the note. During the year ended December 31, 2021, at the option of the lender, the $

0.7

million total outstanding principal balance and unpaid accrued interest on the note were converted into Series A Preferred Stock of FibroGen Cayman, and was recorded as an addition to the non-controlling interest of the Company.

Non-Controlling Interests

Non-controlling interest positions related to the issuance of subsidiary stock as described above are reported as a separate component of consolidated equity from the equity attributable to the Company's stockholders at December 31, 2023 and 2022. 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 the subsidiary.

For the nonredeemable NCI and redeemable NCI resulting from the acquisition of Fortis during the year ended December 31, 2023, see Note 4, *Exclusive License and Option to Acquire Fortis Therapeutics*, for details.

14. Net Loss Per Share

Potential common shares that would have the effect of increasing diluted earnings per share are considered to be anti-dilutive and as such, these shares are not included in the calculation of diluted earnings per share. The Company reported a net loss for each of the years ended December 31, 2023, 2022 and 2021. 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,		
	2023	2022	2021
Employee stock options	10,596	9,520	8,461
RSUs, PRSUs and TSR awards	3,793	2,137	1,538
ESPP	594	305	417
	14,983	11,962	10,416

15. Income Taxes

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

	Years Ended December 31,		
	2023	2022	2021
Domestic	$ (328,475)	$ (307,056)	$ (268,499)
Foreign	41,608	12,187	(22,184)
Loss before provision for income taxes	$ (286,867)	$ (294,869)	$ (290,683)

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

	Years Ended December 31,		
	2023	2022	2021
Current:			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	3	358	347

Total current	3	358	347
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
Total deferred	—	—	—
Total provision for income taxes	$ 3	$ 358	$ 347

The following is the reconciliation between the statutory federal income tax rate and the Company's effective tax rate:

	Years Ended December 31,		
	2023	2022	2021
Tax at statutory federal rate	21.0 %	21.0 %	21.0 %
State tax	— %	— %	— %
Stock-based compensation expense	(1.1)%	(2.5)%	(1.8)%
Net operating losses not benefitted	(17.9)%	(16.3)%	(16.8)%
Foreign net operating losses not benefitted	3.0 %	0.9 %	(1.6)%
Deduction limitation on executive compensation	(0.5)%	(0.2)%	(0.3)%
Global intangible low-taxed income	(4.3)%	(2.8)%	(0.4)%
Other	(0.2)%	(0.2)%	(0.2)%
Total	— %	(0.1)%	(0.1)%

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

	December 31,	
	2023	2022
Federal and state net operating loss carryforwards	$ 175,257	$ 166,708
Tax credit carryforwards	123,156	106,131
Foreign net operating loss carryforwards	48,396	49,990
Capitalized research and development expenses	81,697	45,125
Stock-based compensation	9,155	8,616
Lease obligations	17,189	18,442
Reserves and accruals	5,475	4,929

Deferred revenue	24,792	21,624
Intangible assets	63,146	69,159
Other	698	1,277
Subtotal	548,961	492,001
Less: Valuation allowance	(534,967)	(477,969)
Net deferred tax assets	13,994	14,032
Fixed assets	(10,511)	(13,101)
Non-deductible accrued expenses	(3,483)	(931)
Net deferred tax liabilities	(13,994)	(14,032)
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 increased by $

57.0
million, $

68.2
million and $

72.0
million for the years ended December 31, 2023, 2022 and 2021, respectively. 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, 2023, the Company had net operating loss carryforwards available to offset future taxable income of approximately $

796.7
million and $

147.2
million for federal and state tax purposes, respectively. $

292.4
million of the federal net operating loss carryforwards will begin to expire in 2026 if not utilized, while the remainder can be carried forward indefinitely. The state net operating loss carryforward will begin to expire in 2028 if not utilized. The Company also had foreign net operating loss carryforwards of approximately $

235.1
million, which expire between 2024 and 2033 if not utilized.

At December 31, 2023, the Company had approximately $

143.3

million of federal and $

50.8

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 2024 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 IRC Section 382. The Company did not perform an IRC Section 382 analysis and any previous ownership changes may result in a limitation that will reduce the total amount of net operating loss and tax credit carryforwards disclosed that can be utilized. Subsequent ownership changes may affect the limitation in future years.

On August 16, 2022, the Inflation Reduction Act of 2022 (“IRA”) was signed into law. Among other changes to the Internal Revenue Code, the IRA imposes a

15

% corporate alternative minimum tax on certain corporations and

1

% excise tax on public company stock buybacks for tax years beginning after December 31, 2022. The tax provisions in the IRA did not have a material impact on the Company’s consolidated financial statements and related disclosures.

Uncertain Tax Positions

The Company had unrecognized tax benefits of approximately $

81.0

million as of December 31, 2023. Approximately $

0.6

million of unrecognized tax benefits, if recognized, would affect the effective tax rate. The interest accrued as of December 31, 2023 and 2022 was immaterial.

A reconciliation of the beginning and ending amounts of unrecognized income tax benefits during the three years ended December 31, 2023 is as follows (in thousands):

	Federal and State
Balance as of December 31, 2020	$ 48,574
Decrease due to prior positions	(245)
Increase due to current year position	8,415
Foreign exchange rate differential	927
Balance as of December 31, 2021	57,671
Increase due to prior positions	6,954
Increase due to current year position	9,074
Foreign exchange rate differential	(908)
Balance as of December 31, 2022	72,791
Decrease due to prior positions	(154)

Increase due to current year position	8,805
Foreign exchange rate differential	(477)
Balance as of December 31, 2023	$ 80,965

Unrecognized tax benefits may change during the next twelve months for items that arise in the ordinary course of business. The Company does not anticipate a material change to its unrecognized tax benefits over the next twelve months that would affect the Company's effective tax rate.

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 2014 to 2023 . The Company is not currently under audit in any tax jurisdiction.

16. Related Party Transactions

Astellas is an equity investor in the Company and considered a related party. During the years ended December 31, 2023, 2022 and 2021, the Company recorded license and development revenue related to collaboration agreements with Astellas of $

6.7
million, $

32.5
million, and $

130.4
million, respectively. During the years ended December 31, 2023, 2022 and 2021, the Company also recorded drug product revenue from Astellas of $

18.8
million, $

11.1
million, and $

3.2
million, respectively. See Note 3, *Collaboration Agreements, License Agreement and Revenues*, for details.

The Company's expense related to collaboration agreements with Astellas was immaterial for each of the three years ended December 31, 2023.

As of December 31, 2023 and 2022, accounts receivable from Astellas were $

0.8
million and $

1.5
million, respectively.

As of December 31, 2023 and 2022, total deferred revenue from Astellas were $

16.9
million and $

40.3
million, respectively.

As of December 31, 2023, the amount due to Astellas, included in accrued and other current liabilities, and other long-term liabilities, totaled $

40.5
million. As of December 31, 2022, the amount due to Astellas, included in accrued and other current liabilities, was and $

63.9
million.

Falikang, an entity jointly owned by FibroGen Beijing and AstraZeneca is an unconsolidated VIE accounted for as an equity method investment, and considered as a related party to the Company. FibroGen Beijing owns

51.1
% of Falikang's equity. See Note 5, *Equity method investment - Variable Interest Entity*, for details.

For the years ended December 31, 2023, 2022 and 2021, the net product revenue from sales to Falikang were $

89.1
million, $

71.2
million and $

35.6
million, respectively. See the *Product Revenue, Net* section in Note 3, *Collaboration Agreements, License Agreement and Revenues*, for details. The other income from Falikang were immaterial for each of the three years ended December 31, 2023.

For the years ended December 31, 2023, 2022 and 2021, the investment income (loss) in Falikang was $

2.6
million, $

1.6
million, and $

1.0
million, respectively. During the year ended December 31, 2023, the Company received $

2.3
million of dividend distribution from Falikang. As of December 31, 2023 and 2022, the Company's equity method investment in Falikang were $

5.3
million and $

5.1
million, respectively. See Note 5, *Equity method investment - Variable Interest Entity*, for details.

As of December 31, 2023 and 2022 accounts receivable, net, from Falikang were $

5.2
million and $

10.5
million, respectively.

17. Segment and Geographic Information

The Company has determined that the chief executive officer is the chief operating decision maker ("CODM"). The CODM reviews financial information presented for the Company's various clinical trial programs as well as results on a consolidated basis. License revenues and development revenues received are not allocated to various programs for purposes of determining a profit measure and resource allocation decisions are made by the CODM based primarily on consolidated results. As such, the Company has concluded that it operates as

one
segment. Supplemental enterprise-wide information has been 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,		
	2023	2022	2021
China	$ 109,375	$ 84,631	$ 55,640
Europe	9,549	33,820	131,243
Japan	15,867	9,764	2,305
United States	12,961	12,519	46,121
Total revenue	$ 147,752	$ 140,734	$ 235,309

Geographic Assets

Property and equipment, net by geographic location are as follows (in thousands):

	December 31,	
	2023	2022
United States	$ 4,785	$ 10,094
China	8,341	10,511
Total property and equipment	$ 13,126	$ 20,605

Finance lease right-of-use assets and operating lease right-of-use assets, net by geographic location are as follows (in thousands):

	December 31,	
	2023	2022
United States	$ 132	$ 424
China	21	11
Total finance lease right-of-use assets	$ 153	$ 435
United States	$ 64,939	$ 76,273
China	3,154	3,620
Total operating lease right-of-use assets	$ 68,093	$ 79,893

Customer Concentration

The Company's revenues to date have been generated from the following collaboration partners and distribution entity that individually accounted for 10% or more of the Company's total revenue or accounts receivable:

	Percentage of Revenue Years Ended December 31,			Percentage of Accounts Receivable December 31,	
	2023	2022	2021	2023	2022
Falikang — Related party	60%	51%	15%	42%	65%
Astellas — Related party	17%	31%	57%	7%	9%
AstraZeneca	8%	9%	20%	33%	16%

Substantially all direct product sales to distributors in China were made by Falikang. No individual distributor represented over 10% of the total revenue for the years ended December 31, 2023 and 2022. The aggregate accounts receivable from direct sales to distributors as of December 31, 2023 and 2022 were immaterial.

18. Subsequent Event

On February 23, 2024, the Company and AstraZeneca entered into an agreement to terminate the AstraZeneca U.S./RoW Agreement dated July 30, 2013 (as amended). Pursuant to the termination and transition agreement, AstraZeneca is returning all of their non-China roxadustat rights to the

Company, with the exception of South Korea, and providing certain assistance during a transition period. The Company's collaboration agreement with AstraZeneca for roxadustat in China remains in place.

As a part of this termination and transition agreement, the Company and AstraZeneca will settle the outstanding balances relating to past transactions related to manufacturing and AstraZeneca will receive tiered mid-single digit royalties on FibroGen's sales of roxadustat in the terminated territories, or thirty-five percent of all revenue FibroGen receives if it licenses or sells such rights to a third-party. Neither party incurred any early termination penalties. The Company is currently evaluating the accounting impact of this transaction as it relates to the first quarter of 2024.

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, 2023	$ 477,969	$ 56,998	$ —	$ —	$ 534,967
Year ended December 31, 2022	$ 409,810	$ 68,159	$ —	$ —	$ 477,969
Year ended December 31, 2021	$ 337,824	$ 71,986	$ —	$ —	$ 409,810
Allowances for rebates, discounts and adjustments					
Year ended December 31, 2023	$ 1,349	$ 63,475	$ (849)	$ (60,964)	$ 3,011
Year ended December 31, 2022	$ 14,443	$ 39,082	$ 1,050	$ (53,226)	$ 1,349
Year ended December 31, 2021	$ 548	$ 44,258	$ (734)	$ (29,629)	$ 14,443

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, 2023 ("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, 2023, 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, 2023.

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, 2023, 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, 2023 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.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2023 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report that appears herein.

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 most recent fiscal quarter ended December 31, 2023 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023 (the “2024 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 2024 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 2024 Proxy Statement.

Code of Conduct

We have adopted a Code of Business Conduct that applies to all of our directors, officers and employees. A copy of our Code of Business Conduct can be found on our website (www.FibroGen.com) under “Corporate Governance.” The contents of our website are not a part of this 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,” “Compensation Committee Interlocks and Insider Participation” and “Compensation Committee Report” appearing in our 2024 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 2024 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 2024 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to the proposal title “Proposal 3 - Ratification of Selection of Independent Registered Public Accounting Firm” appearing in our 2024 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 150. 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 of FibroGen, Inc.	8-K	001-36740	3.1	11/21/2014
3.2	Amended and Restated Bylaws of FibroGen, Inc.	S-1/A	333-199069	3.4	10/23/2014
4.1	Form of Common Stock Certificate.	8-K	001-36740	4.1	11/21/2014
4.2	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
4.3	Common Stock Purchase Agreement by and between FibroGen, Inc. and AstraZeneca AB, dated as of October 20, 2014.	S-1/A	333-199069	4.17	10/24/2014
4.4	Description of Capital Stock of FibroGen, Inc	10-K	001-36740	4.4	3/2/2020
10.1(i)+	FibroGen, Inc. Amended and Restated 2005 Stock Plan.	S-1	333-199069	10.3(i)	10/1/2014
10.1(ii)+	Forms of stock option agreement, restricted stock purchase agreement and stock appreciation right agreement under the FibroGen, Inc. Amended and Restated 2005 Stock Plan.	S-1	333-199069	10.3(ii)	10/1/2014

10.1(iii)+	Form of stock option agreement under the FibroGen, Inc. Amended and Restated 2005 Stock Plan applicable to options exchanged pursuant to FibroGen, Inc.'s 2010 amendment and exchange offer.	S-1	333-199069	10.3(iii)	10/1/2014
10.1(iv)+	Form of 2010 amendment to the form of stock option agreement under the FibroGen, Inc. Amended and Restated 2005 Stock Plan applicable to options amended pursuant to FibroGen, Inc.'s 2010 amendment and exchange offer.	S-1	333-199069	10.3(iv)	10/1/2014
10.1(v)+	Form of 2013 amendment to the form of stock option agreement under the FibroGen, Inc. Amended and Restated 2005 Stock Plan applicable to options amended or exchanged pursuant to FibroGen, Inc.'s 2010 amendment and exchange offer.	S-1	333-199069	10.3(v)	10/1/2014
10.2+	FibroGen, Inc. 2014 Equity Incentive Plan and forms of agreement thereunder.	S-1/A	333-199069	10.4	11/12/2014
10.3+	FibroGen, Inc. 2014 Employee Stock Purchase Plan.	S-1/A	333-199069	10.5	11/12/2014
10.4+	FibroGen, Inc. Non-Employee Director Compensation Policy, as amended.	10-Q	001-36740	10.3	5/8/2023
10.5*+	FibroGen, Inc. Bonus Plan.	—	—	—	—
10.6	Lease Agreement by and between FibroGen, Inc. and X-4 Dolphin LLC, dated as of September 22, 2006; as amended by First Amendment to Lease by and between FibroGen, Inc. and X-4 Dolphin LLC, dated as of October 10, 2007; as amended by Second Amendment to Lease by and between FibroGen, Inc. and X-4 Dolphin LLC, dated as of June 29, 2009; as amended by Third Amendment to Lease by and between FibroGen, Inc. and Are-San Francisco No. 43, LLC (as successor in interest to X-4 Dolphin LLC), dated as of May 19, 2011; as amended by Fourth Amendment to Lease by and between FibroGen, Inc. and Are-San Francisco No. 43, LLC, dated as of September 8, 2011.	S-1	333-199069	10.8	10/1/2014

10.7	Lease for Premises in Beijing BDA Biomedical Park by and among Beijing FibroGen Medical Technology Development Co., Ltd., Beijing Economic and Technology Investment Development Parent Company and Beijing BDA International Biological Pharmaceutical Investment Management Co., Ltd., effective as of February 1, 2013, as supplemented by the Supplementary Agreement to Lease of Premises in Beijing BDA Biomedical Park by and among Beijing FibroGen Medical Technology Development Co., Ltd., Beijing Economic Technology Investment Development Parent Company and Beijing BDA International Biological Pharmaceutical Investment Management Co., Ltd., dated as of January 30, 2013.	S-1	333-199069	10.9	10/1/2014
10.8+	Form of Employment Offer Letter.	S-1	333-199069	10.10	10/1/2014
10.9†	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
10.9(i)†	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
10.10†	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†	Amended and Restated License, Development and Commercialization Agreement (China) by and among FibroGen China Anemia Holdings, Ltd., Beijing FibroGen Medical Technology Development Co., Ltd., FibroGen International (Hong Kong) Limited and AstraZeneca AB, effective as of July 30, 2013.	10-Q	001-36740	10.3	11/5/2020
10.16†	Amended and Restated License, Development and Commercialization Agreement (for the U.S. and Certain Other Territories) by and between FibroGen, Inc. and AstraZeneca AB, effective as of July 30, 2013.	10-Q	001-36740	10.2	11/5/2020
10.17	Research and Commercialization Agreement by and among FibroGen, Inc., GenPharm International Inc., Medarex, Inc. and FibroPharma, Inc., effective as of July 9, 1998.	S-1	333-199069	10.21	10/1/2014
10.18	Amendment No. 1 to Research and Commercialization Agreement by and among FibroGen, Inc., GenPharm International Inc., Medarex, Inc. and FibroPharma, Inc., effective as of June 30, 2001.	S-1	333-199069	10.22	10/1/2014
10.19†	Amendment No. 2 to Research and Commercialization Agreement by and among FibroGen, Inc., GenPharm International Inc., Medarex, Inc. and FibroPharma, Inc., effective as of January 28, 2002.	10-Q	001-36740	10.6	11/5/2020

10.20+	Form of Indemnity Agreement by and between FibroGen, Inc. and its directors and officers.	S-1/A	333-199069	10.27	10/23/2014
10.21†	State-Owned Construction Land Use Right Granting Contract by and between FibroGen (China) Medical Technology Development Co., Ltd. and The Bureau of Land and Resources of Cangzhou, dated as of February 24, 2017.	10-Q	001-36740	10.32	5/9/2017
10.22†	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
10.23†	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
10.24†	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
10.25†	Second Amended and Restated License, Development and Commercialization Agreement by and among FibroGen China Anemia Holdings, Ltd., FibroGen China Medical Technology Development Co., Ltd., FibroGen International (Hong Kong) Limited, and AstraZeneca AB, effective July 1, 2020.	10-Q	001-36740	10.3	8/6/2020
10.26†	Amendment No. 1 to the Amended and Restated License, Development and Commercialization Agreement by and between FibroGen, Inc. and AstraZeneca AB, effective July 1, 2020.	10-Q	001-36740	10.4	8/6/2020
10.27†	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

10.28†	Master Supply Agreement by and between FibroGen, Inc. and AstraZeneca UK Limited, effective September 10, 2020.	10-Q	001-36740	10.9	11/5/2020
10.29†	Master Services Agreement by and between FibroGen, Inc. and Samsung Biologics Co., Ltd., effective as of October 30, 2020.	10-K	001-36740	10.35	3/1/2021
10.30†	Product Specific Agreement by and between FibroGen, Inc. and Samsung Biologics Co., Ltd., effective as of October 30, 2020.	10-K	001-36740	10.36	3/1/2021
10.31†	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
10.32†	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
10.33	Sixth Amendment to the Lease by and between ARE-San Francisco No., 43, LLC and FibroGen, Inc. as of June 1, 2021.	10-Q	001-36740	10.1	8/9/2021
10.34†	Exclusive License and Option Agreement by and between FibroGen, Inc. and HiFiBiO (HK) Limited (D.B.A. HiFiBiO Therapeutics), as of June 16, 2021.	10-Q	001-36740	10.2	8/9/2021
10.35†	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
10.36+	Offer Letter, by and between FibroGen, Inc. and Christine Chung, dated as of June 17, 2008.	10-K	001-36740	10.32	3/2/2020
10.37+	Offer Letter by and between FibroGen, Inc. and Juan Graham, effective as of July 30, 2021.	10-Q	001-36740	10.2	11/9/2021
10.38+	Form of Executive Officer Change in Control and Severance Agreement.	10-K	001-36740	10.35	3/2/2020

10.39†	Amended and Restated Exclusive License Agreement by and between FibroGen, Inc. and Eluminex Biosciences (Suzhou) Limited as of January 21, 2022.	10-Q	001-36740	10.1	5/9/2022
10.40	Amended and Restated Equity Distribution Agreement by and between FibroGen, Inc. and Goldman Sachs & Co. LLC and BofA Securities, Inc., dated February 27, 2023.	10-K	001-36740	10.44	2/27/2023
10.41†	Amendment No. 1 to Product Specific Agreement - Clinical Product Drug Substance by and between FibroGen, Inc. and Samsung Biologics Co., Ltd., effective as of October 25, 2022.	10-K	001-36740	10.45	2/27/2023
10.42†	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
10.43†	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
10.44†	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
10.45+	Form of Executive Officer Change in Control and Severance Agreement.	10-Q	001-36740	10.4	5/8/2023
10.46+	Offer Letter, dated July 23, 2023, between FibroGen, Inc. and Thane Wettig.	8-K	001-36740	10.1	7/25/2023
10.47+	Consulting Agreement, dated July 23, 2023, between FibroGen, Inc. and Enrique Conterno.	8-K	001-36740	10.2	7/25/2023
10.48†	Amended and Restated Exclusive License Agreement by and among FibroGen, Inc., FibroGen (China) Medical Technology Development Co., Ltd., and Eluminex Biosciences Suzhou) Limited, dated April 19, 2023.	10-Q	001-36740	10.4	8/7/2023

10.49†	Financing Agreement by and among FibroGen, Inc., certain of its subsidiaries, NHTV Fairview Holding LLC, NHTV II Fairview Holding LLC, MSTV Fund II Employees Fairview Holding LLC, and Wilmington Trust, National Association, dated as of April 29, 2023.	10-Q	001-36740	10.5	8/7/2023
10.50†	Evaluation Agreement by and between FibroGen, Inc. and Fortis Therapeutics, Inc., dated May 5, 2023.	10-Q	001-36740	10.6	8/7/2023
10.51†	Option Agreement and Plan of Merger by and among FibroGen, Inc., Fortis Therapeutics, Inc., and Shareholder Representative Services LLC, dated as of May 5, 2023.	10-Q	001-36740	10.7	8/7/2023
10.52+	Consulting Agreement, dated September 11, 2023, between FibroGen, Inc. and Mark Eisner.	8-K	001-36740	10.1	9/6/2023
10.53*†	Amendment No. 1 to the Second Amended and Restated Exclusive License Agreement, dated as of November 16, 2023.	—	—	—	—
21.1	Subsidiaries of FibroGen, Inc.	10-Q	001-36740	21.1	8/9/2021
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 FibroGen, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-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.

FIBROGEN, INC.

Date: February 26, 2024	By:	/s/ Thane Wettig Thane Wettig Chief Executive Officer *(Principal Executive Officer)*
Date: February 26, 2024	By:	/s/ Juan Graham Juan Graham 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 Juan Graham, 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)*	February 26, 2024
/s/ Juan Graham **Juan Graham**	Senior Vice President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 26, 2024
/s/ James A. Schoeneck **James A. Schoeneck**	Chairman of the Board and Director	February 26, 2024
/s/ Suzanne Blaug **Suzanne Blaug**	Director	February 26, 2024
/s/ Aoife Brennan **Aoife Brennan, M.B., B.Ch.**	Director	February 26, 2024
/s/ Benjamin F. Cravatt **Benjamin F. Cravatt, Ph.D.**	Director	February 26, 2024
/s/ Jeffrey L. Edwards **Jeffrey L. Edwards**	Director	February 26, 2024
/s/ Jeffrey W. Henderson **Jeffrey W. Henderson**	Director	February 26, 2024
/s/ Maykin Ho **Maykin Ho, Ph.D.**	Director	February 26, 2024
/s/ Gerald Lema **Gerald Lema**	Director	February 26, 2024

FIBROGEN, INC.

BONUS PLAN

Exhibit 10.5

The FibroGen, Inc. (“FibroGen” or the “Company”) Bonus Plan (the “Plan”) is a discretionary plan, designed to reward eligible participants for the achievement of corporate goals, as well as individual goals that are consistent with the company’s objectives and organizational priorities on an annual basis.

The Plan will govern bonuses paid to eligible participants for work performed during the period from January 1 to December 31 of a calendar year (“Plan Year”), with assessments and bonuses to be paid in the following calendar year (“Review Year”).

1. Purpose of the Plan

The Plan is designed to:

- Provide a bonus program that helps achieve overall corporate goals and enhances shareholder value;
- Reward individuals for achievement of corporate and individual goals;
- Encourage teamwork among all disciplines within the Company;
- Offer an attractive bonus program to help attract and retain key employees.

2. Plan Governance

The Compensation Committee of the Board of Directors or such other committee as the Board of Directors may determine (any such committee, the “Committee”) is responsible for reviewing and approving the Plan and any proposed modifications to the Plan.

The CEO of FibroGen is responsible for administration of the Plan, provided that the Committee is responsible for reviewing and approving all compensation for the executive officers of FibroGen. All interpretations and determinations of the Committee under the Plan will be final and binding.

3. Eligibility

This Plan applies solely to employees of FibroGen whom the Company, in its sole discretion, determines meet the eligibility requirements set forth below (“Participant”).

To be eligible to receive a discretionary bonus award under this Plan, a Participant must satisfy each of the following eligibility conditions:

a. Must be a regular status employee as such status is determined by FibroGen in its sole discretion;
b. Must be hired on or before September 30th of the Plan Year;
c. Must attain achievement of performance goals at the end of the Plan Year,
d. Must have been continuously employed during the Plan Year and on the actual date of bonus payment distribution;
e. Must not be providing services to FibroGen as, or classified as (whether or not such classification is upheld upon review by an applicable legal authority), a temporary employee or intern or as an independent contractor, consultant, or agent, under a written or oral contract;
f. Must not have at any time until the date that bonuses are paid under the Plan, (a) violated any provision of FibroGen’s Code of Conduct or any other written Company policy, or (ii) entered into an employment termination or separation agreement (not including agreements entered into in connection with the commencement or continuation of employment), or (iii) been subject to a performance improvement plan.

A Participant will have no right to receive and will not have been deemed to have earned any Bonus if the preceding conditions are not met.

4. Corporate and Individual Performance

The CEO will present to the Committee a list of the overall corporate goals (Corporate Goals") for the Plan year, which is subject to approval by the Committee February 28. All Participants in the Plan will then develop a list of key individual goals ("Individual Goals") no later than March 31 which will be subject to approval by their manager no later than April 15 and will be used as the basis of the performance review and individual performance rating ("Individual Performance Rating").

The total bonus pool for the Plan will be based on achievement of the Plan Year Corporate Goals and, where applicable, the Individual Performance Rating.

5. Bonus Awards

Bonus awards are based on achievement of the Plan Year Corporate Goals and, where applicable, the Individual Performance Rating. The Bonus will be calculated by using the actual base salary earned during the Plan Year for exempt employees, and using the actual earnings during the Plan Year for non-exempt employees as defined by law, and further include weighting factor, target bonus percentage, and goal multipliers as identified below.

6. Weighting Factor

The relative weight between the Plan Year Corporate Goals and, where applicable, the Individual Performance Rating components will vary based on levels within the organization as determined by and in the sole discretion of the Committee. The weighting factors will be reviewed annually and adjusted, as necessary or appropriate, by and in the sole discretion of the Committee.

7. Target Bonus Percentages

The Bonus payout amount will be determined by applying a "target bonus percentage" to the actual base salary earned during the Plan Year, as determined by and in the sole discretion of the Committee.

The actual base salary earned during the Plan Year multiplied by the target bonus percentage will be used to establish the target Bonus for the Plan Year.

8. GOAL MULTIPLIERS

Corporate Goal Multiplier

In its sole discretion, the Committee will determine the "total corporate goal multiplier" based upon measurement of corporate performance versus the pre-established corporate goals. The Committee will evaluate each corporate goal and shall provide a goal multiplier for such goal based on the achievement of the goal with a range of 0% for goals for which the performance was unacceptable to 150% for goals for which the performance significantly exceeded the goal or was excellent in view of prevailing conditions.

Individual Goal Multiplier

The "individual goal multiplier" will be determined by taking into account the Participant's achievement of their individual goals, utilizing the same metrics as used for the corporate goal evaluation.

Goals under the Plan will be set based on performance criteria set forth in Exhibit A hereto.

9. Calculation of Bonus Amount

The example below shows a sample Bonus amount calculation under the Plan. First, a target Bonus amount is calculated for each Plan participant by multiplying the Participant's actual base salary earned during the Plan Year by the target bonus percentage. This dollar figure is then divided between the corporate component and the individual component based on the weighting factor for that position. This calculation establishes specific dollar target Bonus amounts for the performance period for each of the corporate and individual components.

At the end of the Plan Year, the corporate and individual goal multipliers will be established using the criteria described above. The corporate goal multiplier, which is based on overall corporate performance, is used to calculate the corporate component of the Bonus amount for all Plan participants. This is accomplished by multiplying the target corporate Bonus amount established for each individual by the total corporate goal multiplier. The individual goal multiplier, which is based on an individual's performance rating, is used in the same way to calculate the actual individual component of the Bonus amount.

Example: Actual Bonus Amount Calculation	
Salary Paid During Plan Year	$100,000
Target Bonus Percentage	10%
Target Bonus Amount	$10,000
Target Bonus Components:	
Target Bonus Amount based on corporate performance (50%)	$5,000
Target Bonus Amount based on individual performance (50%)	$5,000
Corporate Goal Multiplier	80%
Individual Goal Multiplier	105%
Actual Bonus Amount Calculation:	
Corporate Bonus Amount	$4,000 ($5,000 x 80%)
Individual Bonus Amount	$5,250 ($5,000 x 105%)
Actual Cash Bonus Amount (prior to taxes)	$9,250

10. Bonus Payments

Annual performance reviews for Plan participants will be completed by January 31 of the Review Year or as soon thereafter as practicable. Payments of actual Bonus amounts (less applicable taxes) will be made as soon as practical, but no later than March 15 of the Review Year. The calculation and payment of bonus awards under this Plan will occur as soon as administratively practicable following the completion of the applicable Plan Year and the Committee's determination and approval of any applicable bonus awards, but no later than March 15 of the Review Year.

Bonus payments shall be paid in accordance with the Company's usual payroll procedures in effect from time to time and shall be subject to state and federal income taxes, social security taxes, deductions authorized by Employee, and such other deductions as laws in force may require.

Bonus payments for Participants hired by FibroGen after January 1 of a Plan Year will be subject to proration in the sole discretion of FibroGen based on the number of full months (rounded to the nearest full month) that a Participant worked in the Plan Year, however, FibroGen reserves the right to, in its sole discretion, pro-rate bonuses based on days or on any other basis. For example, the pro-ration factor for a Participant who is eligible to participate in the Plan for the entire applicable Plan Year will be 1.00; for a Participant who is eligible to participate in the Plan for one-half of the Plan Year, the pro-ration factor will be .50. Participants in the following situations may have a pro-ration factor less than 1.00: (a) new hires and individuals who become eligible Participants during the applicable Plan Year; (b) individuals who transfer between an exempt and non-exempt position within FibroGen; (c) Participants who work less than the applicable full-time standard work week of forty (40) hours; and (d) Participants who take unpaid time off or a leave of absence beyond the maximum leave of absence period protected under federal or state law or local ordinance.

Any bonus payment provided for under the Plan is completely discretionary, and is not considered earned or accrued by a Participant until it is actually paid.

If employment with FibroGen terminates, for any reason, prior to the date a bonus payment is made, an individual will not be eligible to receive any bonus payment

11. Maximum Bonus Payout

To the extent a bonus is paid under this Plan, the maximum bonus payable to any individual shall be one hundred fifty percent (150%) of the individual's target bonus. The CEO may recommend to the Committee (other than for the CEO), and the Committee may determine in its sole discretion to increase or decrease any individual's bonus based on individual performance.

12. Company's Absolute Right to Alter or Abolish the Plan

The Committee reserves the right in its absolute discretion to terminate and/or abolish all or any portion of the Plan at any time or to alter the terms and conditions under which a Bonus will be paid. In the event of the Plan's termination prior to the payment of a Bonus, such Bonus will not be payable under this Plan. Such discretion may be exercised any time before, during, and after the Plan year is completed. No participant shall have any right to receive any payment until actual delivery of such compensation.

Notwithstanding the generality of the foregoing, at FibroGen's discretion, and subject to compliance in all events with, and if and only if permitted by applicable federal and state securities laws and the listing rules and requirements of any stock exchange or trading market on which the Company's common stock is listed or traded, all or a portion of a Bonus payment may be made in vested shares of the Company's common stock. Any such issuance of shares will be made pursuant to an award granted under the Company's 2014 Equity Incentive Plan, or a successor plan thereto. No payment in stock or other equity under this Plan may be made if such issuance or payment would conflict with any such securities laws or listing rules or requirements.

The Committee, in its sole discretion, may also determine whether to increase the payout under the Plan for extraordinary achievement or to reduce payout if economic and business conditions warrant such action.

13. Compensation Subject to Clawback Policy

All compensation received pursuant to this policy is subject to any clawback policy adopted by FibroGen.

14. General Guidelines, Terms and Conditions of the Plan

a. Eligibility to participate in this Plan during any Plan Year: (a) does not create any right or entitlement to participate in this Plan in the future or other bonus plans that may be established or maintained by FibroGen, (b) does not constitute a guarantee or establish an obligation for the Company to maintain a similar plan, award similar bonus benefits, or calculate bonuses according to the same or similar formulas in the future, and (c) does not guarantee that any bonus will actually be paid for that Plan Year and in some cases a Participant may not receive a bonus under the Plan.

b. Any bonus payment awarded under this Plan is a discretionary form of compensation that is outside a Participant's normal, regular or expected compensation, and in no way represents any portion of a Participant's salary, compensation, or other remuneration for the purpose of calculating any of the following payments: termination, severance, bonuses, long-service awards, overtime premiums, pension or retirement benefits, and any other similar payments and extra benefits.

c. No bonus payment made under this Plan shall be counted as compensation for purposes of any other employee benefit plan, Plan or agreement sponsored, maintained or contributed by the Company unless expressly provided for in such employee benefit plan or agreement.

d. Participants who are not actively employed by FibroGen at the time that the payment would otherwise be made under this Plan shall not receive such payment unless and until the Participant returns to active service with FibroGen. This term does not apply to any person on a legally protected leave of absence at the time bonuses are paid.

e. FibroGen reserves the right to interpret this Plan on a fully discretionary basis and to take any action, or to decline to take any action, in relation to the administration or interpretation of the Plan including but not limited to determining eligibility for participation in the Plan, and to determine the amount, if any, to be paid under the Plan. The Committee or its designee shall be the ultimate sole and final arbiter of any disputes under the Plan, in its sole and absolute discretion.

f. FibroGen's authority as set forth herein shall be exercised by the Committee, except to the extent the Committee delegates all or some of that authority to FibroGen management.

g. FibroGen has adopted this Plan voluntarily and reserves the right to change, suspend or discontinue this Plan, or any individual's participation in this Plan, at any time, with or without cause and with or without prior written notice.

h. The Plan is unfunded and no provision of the Plan shall require FibroGen, for purpose of satisfying any Plan obligations, to purchase assets or place any assets in a trust or other entity or otherwise to segregate any assets for such purposes. Nothing contained in this Plan nor any action taken pursuant to its provisions shall create or be construed to create a fiduciary relationship between FibroGen and any Participant or other person.

i. Nothing in this Plan or FibroGen's policies and practices in administering this Plan constitutes an express or implied contract or other agreement concerning the duration of any participant's employment with the Company. The employment relationship of each participant is "at will" and may be terminated at any time by the Company or by the participant with or without cause, and with or without notice.

j. This plan is not intended to be subject to Section 409A of the Internal Revenue Code of 1986, as amended.

Exhibit 10.5

EXHIBIT A

The Performance Criteria that will be used to establish goals under the Plan may be based on any one of, or combination of, the following as determined by the Committee: (1) earnings (including earnings per share and net earnings); (2) earnings before interest, taxes and depreciation; (3) earnings before interest, taxes, depreciation and amortization; (4) total stockholder return; (5) return on equity or average stockholder's equity; (6) return on assets, investment, or capital employed; (7) stock price; (8) margin (including gross margin); (9) income (before or after taxes); (10) operating income; (11) operating income after taxes; (12) pre-tax profit; (13) operating cash flow; (14) sales or revenue targets; (15) increases in revenue or product revenue; (16) expenses and cost reduction goals; (17) improvement in or attainment of working capital levels; (18) economic value added (or an equivalent metric); (19) market share; (20) cash flow; (21) cash flow per share; (22) share price performance; (23) debt reduction; (24) customer satisfaction; (25) stockholders' equity; (26) capital expenditures; (27) debt levels; (28) operating profit or net operating profit; (29) workforce diversity; (30) growth of net income or operating income; (31) billings; (32) pre-clinical development related compound goals; (33) financing; (34) regulatory milestones, including approval of a compound; (35) stockholder liquidity; (36) corporate governance and compliance; (37) product commercialization; (38) intellectual property; (39) personnel matters; (40) progress of internal research or clinical programs; (41) progress of partnered programs; (42) partner satisfaction; (43) budget management; (44) clinical achievements; (45) completing phases of a clinical study (including the treatment phase); (46) announcing or presenting preliminary or final data from clinical studies; in each case, whether on particular timelines or generally; (47) timely completion of clinical trials; (48) submission of INDs and NDAs and other regulatory achievements; (49) partner or collaborator achievements; (50) internal controls, including those related to the Sarbanes-Oxley Act of 2002; (51) research progress, including the development of programs; (52) investor relations, analysts and communication; (53) manufacturing achievements (including obtaining particular yields from manufacturing runs and other measurable objectives related to process development activities); (54) strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property; (55) establishing relationships with commercial entities with respect to the marketing, distribution and sale of the Company's products (including with group purchasing organizations, distributors and other vendors); (56) supply chain achievements (including establishing relationships with manufacturers or suppliers of active pharmaceutical ingredients and other component materials and manufacturers of the Company's products); (57) co-development, co-marketing, profit sharing, joint venture or other similar arrangements; (58) individual performance goals; (59) corporate development and planning goals; and (60) other measures of performance selected by the Committee (as applicable).

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

Exhibit 10.53

AMENDMENT NO. 1 TO THE SECOND AMENDED AND RESTATED EXCLUSIVE LICENSE AGREEMENT

This **AMENDMENT NO. 1 TO THE SECOND AMENDED AND RESTATED EXCLUSIVE LICENSE AGREEMENT** (this "**Amendment 1**") is made and entered into as of November 16, 2023 ("**Amendment 1 Effective Date**") by and between **FIBROGEN (CHINA) MEDICAL TECHNOLOGY DEVELOPMENT CO., LTD.** (珐博进（中国）医药技术开发有限公司) ("**FGC**") and **ELUMINEX BIOSCIENCES (SUZHOU) LIMITED** (典晶生物医药科技（苏州）有限公司) ("**Eluminex**"). FGC and Eluminex are each referred to herein as a "**Party**" and collectively, as the "**Parties**".

WHEREAS, the Parties have entered into a **SECOND AMENDED AND RESTATED EXCLUSIVE LICENSE AGREEMENT** on April 19, 2023 (the "**Agreement**");

WHEREAS, the Parties have entered into an ASSET SALES, TRANSFER AND TERMINATION AGREEMENT effective November 16, 2023 (the "**Asset Transfer Agreement**") to transfer certain assets to Eluminex's possession allowing Eluminex to directly manufacture Cornea Products;

WHEREAS, after the transfer of such assets, FGC will no longer be responsible for providing Cornea Products and technology transition assistance with regard to Cornea Products under the Agreement;

WHEREAS, under the Agreement, certain dates and obligations to provide certain services must be modified to reflect the change in manufacturing status;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are acknowledged, the Parties duly execute this Amendment 1 and agree as follows:

1. Effective as of the **Transfer Commencement Date** (as defined in the Asset Transfer Agreement), the Agreement is hereby amended as follows:

1.1. The [***] Product Manufacture Technology Transfer Completion Date** appearing in Section 5.4 shall occur on the **Transfer Commencement Date.**

1.2. The [***] Manufacture Technology Transfer** appearing in Section 5.4 of the Agreement is deemed to be complete on the **Transfer Commencement Date.**

1.3. **FGC's** obligation to provide Transition Assistance as required by Section 5.6 of the Agreement shall be deemed complete [*] and FGC shall have no further obligation to provide any transition assistance under Section 5.6 of the Agreement.

2. Miscellaneous. Any and all Sections of the Agreement not conflicting with the terms of this Amendment 1 shall remain unchanged. Any terms and phrases used herein, if not otherwise expressly defined by this Amendment 1, shall have the same meaning as under the Agreement. This Amendment 1 shall form part of the Agreement and the Parties expressly agree to be bound by the terms and conditions thereof.

IN WITNESS WHEREOF, the Parties have caused this Amendment 1to be executed by their duly authorized representatives as of the Amendment 1 Effective Date.

FibroGen (China) Medical Technology Development Co., Ltd.
珐博进（中国）医药技术开发有限公司

Chop:

Date:

Eluminex Biosciences (Suzhou) Limited.
典晶生物医药科技（苏州）有限公司

Chop:

Date:

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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-200348, No. 333-213816, No. 333-216369, No. 333-233204, No. 333-258655, No. 333-266667 and 333-273765) of FibroGen, Inc. of our report dated February 26, 2024 relating to the financial statements, financial statement schedule and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

San Jose, California
February 26, 2024

Exhibit 31.1

CERTIFICATION

I, Thane Wettig, certify that;

1. I have reviewed this Form 10-K of FibroGen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2024

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

Exhibit 31.2

CERTIFICATION

I, Juan Graham, certify that;

1. I have reviewed this Form 10-K of FibroGen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2024

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

Exhibit 32.1

CERTIFICATION

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

1. The Company's Annual Report on Form 10-K for the year ended December 31, 2023 (the "Annual Report"), to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 26th day of February 2024.

/s/ Thane Wettig	/s/ Juan Graham
Thane Wettig	Juan Graham
Chief Executive Officer	Senior Vice President and Chief Financial Officer

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 FibroGen, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 97.1

FIBROGEN, INC.

INCENTIVE COMPENSATION RECOUPMENT POLICY

1. INTRODUCTION

The Compensation Committee of the Board of Directors (the "***Compensation Committee***", and the "***Board***") of FibroGen, Inc., a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. DEFINITIONS

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Compensation Committee***" means the Compensation Committee of the Board.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means an executive officer as defined under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regard to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4. Recoupment

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. Administration

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. Severability

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall

not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. No Impairment of Other Remedies

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("**SOX 304**") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this Policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

8. Amendment; Termination

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. Successors

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. Required Filings

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

* * * * *

FibroGen, Inc.

Incentive Compensation Recoupment Policy

Form of Executive Acknowledgment

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the FibroGen, Inc. Incentive Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with FibroGen, Inc. (the "***Company***") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

Agreed and Acknowledged:

Name:

Title:

Date: