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, 2022

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, 2022, was approximately $975.1 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, 2023 was 94,182,915.

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, 2022 (the "Annual Report") incorporate information by reference from the definitive proxy statement for the registrant's 2023 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, 2022 ("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.
- As a company, we have limited late-stage development and commercialization experience, and the time and resources required to develop such experience are significant.
- 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 complete response letter we received from the FDA for roxadustat has decreased the likelihood of approval and successful commercialization of roxadustat in the U.S. and potentially other markets. There is a significant risk that our U.S./Rest of World Collaboration Agreement with AstraZeneca will be amended or terminated.
- 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 of roxadustat or pamrevlumab 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 Astellas or AstraZeneca were to prioritize other initiatives over their collaborations with us, our ability to successfully develop and commercialize our product candidates 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 experience delays or technical problems associated with technology transfer, scale-up, or validation of our biologics 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 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, 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; 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.

Cash flows from Falikang and cash flows into FibroGen Beijing are currently intended to remain onshore in China. 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 and paying down certain debt obligations. To date, no such debt repayments have occurred, nor have there been any other payments or distributions from FibroGen Beijing to entities or investors outside of China. 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 a leading biopharmaceutical company discovering, developing and commercializing a pipeline of first-in-class therapeutics. Our lead product candidate and product are pamrevlumab and roxadustat, respectively.

Pamrevlumab, a human monoclonal antibody targeting connective tissue growth factor, is in Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis, locally advanced unresectable pancreatic cancer, and Duchenne muscular dystrophy. To date, we have retained exclusive worldwide rights for pamrevlumab.

Roxadustat is an oral small molecule inhibitor of hypoxia-inducible factor prolyl hydroxylase ("HIF-PH") 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.

We are well positioned over the next 18 months to report topline results from seven pivotal clinical studies with two different drug candidates:

- ***Pamrevlumab*** **-** our first-in-class antibody developed to inhibit the activity of connective tissue growth factor ("CTGF"), a common factor in fibrotic and fibro-proliferative disorders characterized by persistent and excessive scarring that can lead to organ dysfunction and failure. Our pivotal clinical trials in this indication are:
  - LELANTOS-1, a Phase 3 study of pamrevlumab in non-ambulatory Duchenne muscular dystrophy ("DMD") – topline data expected in the second quarter of 2023;
  - ZEPHYRUS-1, a Phase 3 study of pamrevlumab in idiopathic pulmonary fibrosis ("IPF") – topline data expected in mid-2023;
  - LELANTOS-2, a Phase 3 study of pamrevlumab in ambulatory DMD – topline data expected in the third quarter of 2023;
  - LAPIS, a Phase 3 study of pamrevlumab in locally advanced unresectable pancreatic cancer ("LAPC") – topline data expected in in the first half of 2024; and
  - ZEPHYRUS-2, a second Phase 3 study of pamrevlumab in IPF – topline data expected in mid-2024.
- ***Roxadustat*** **-** our commercial-stage product, an oral small molecule inhibitor of HIF-PH activity that acts by stimulating the body's natural pathway of erythropoiesis, or red blood cell production. Our pivotal clinical trials in this indication are:
  - MATTERHORN, a Phase 3 study of roxadustat in myelodysplastic syndromes ("MDS") – topline data expected in the second quarter of 2023; and
  - Phase 3 study in China of roxadustat in chemotherapy-induced anemia ("CIA") – topline data expected in the second quarter of 2023.

Our goal is to build a diversified pipeline with novel drugs that will address unmet patient needs in oncology, immunology, and fibrosis. We expect to file up to two INDs in the second half of 2023: one for an antibody targeting CCR8; and the other for an antibody targeting Galectin-9.

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

PAMREVLUMAB FOR THE TREATMENT OF FIBROSIS AND CANCER

Our research and discovery work indicate that CTGF is a critical common element in the progression of serious diseases associated with fibrosis.

From our library of human monoclonal antibodies that bind to different parts of the CTGF protein and block various aspects of CTGF biological activity, we selected pamrevlumab, for which we have exclusive worldwide rights. In preclinical studies we demonstrated that pamrevlumab disrupts the fibrosis-promoting activity of CTGF, and based on those data believe that it can inhibit the central role of CTGF in causing diseases associated with fibrosis. Our data to date indicate that pamrevlumab is a promising and highly differentiated product candidate with broad potential to treat a number of fibrotic diseases and cancers.

We have sponsored clinical trials of pamrevlumab in IPF, pancreatic cancer, DMD, liver fibrosis, and diabetic kidney disease. 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 and Orphan Drug designations to pamrevlumab for the treatment of IPF, LAPC, and DMD (with DMD also receiving Rare Pediatric Disease designation).

To date, we have retained exclusive worldwide rights for pamrevlumab. We are advancing our brand development activities for pamrevlumab in preparation for potential launches in IPF, LAPC and DMD.

In the next 18 months, we expect to report topline results from each of our five ongoing Phase 3 studies of pamrevlumab.

Overview of Fibrosis

Fibrosis is an aberrant response of the body to tissue injury that may be caused by trauma, inflammation, infection, cell injury, or cancer. The normal response to injury involves the activation of cells that produce collagen and other components of the extracellular matrix ("ECM") that are part of the healing process. This healing process helps to fill in tissue voids created by the injury or damage, segregate infections or cancer, and provide strength to the recovering tissue. Under normal circumstances, where the cause of the tissue injury is limited, the scarring process is self-limited and the scar resolves to approximate normal tissue architecture. However, in certain disease states, this process is prolonged and excessive and results in progressive tissue scarring, or fibrosis, which can cause organ dysfunction and failure as well as, in the case of certain cancers, promote cancer progression.

Excess CTGF levels are associated with fibrosis. CTGF increases the abundance of myofibroblasts, a cell type that drives wound healing, and stimulates them to deposit ECM proteins such as collagen at the site of tissue injury. In the case of normal healing of a limited tissue injury, myofibroblasts eventually die by programmed cell death, or apoptosis, and the fibrous scarring process recedes.

Multiple proteins and signaling pathways have been implicated in the fibrotic process, many of which converge on CTGF, a central mediator of fibrosis. In the case of cancer, tumor-associated fibrotic tissue can promote tumor cell survival and metastasis. CTGF is a secreted glycoprotein produced by fibroblasts, endothelium, mesangial cells and other cell types, including cancers, and is induced by a variety of regulatory modulators, including TGF-ß and VEGF. CTGF expression has been demonstrated to be up-regulated in fibrotic tissues. Thus, we focused on targeting CTGF to block or inhibit its activity to mitigate, stop or reverse tissue fibrosis. In addition, since CTGF is implicated in nearly all forms of fibrosis, we believe pamrevlumab has the potential to provide clinical benefit in a wide range of clinical indications that are characterized by fibrosis.

Until recently, it was believed that fibrosis was an irreversible process. It is now generally understood that the process is dynamic and potentially amenable to reversal. Based on studies in animal models of fibrosis of the liver, kidney, muscle and cardiovascular system, it has been shown that fibrosis can be reversed. It has also been demonstrated in humans that fibrosis caused by hepatitis virus can be reversed (Chang et al. Hepatology (2010)). Additionally, we generated data in human and animal studies suggesting that lung fibrosis progression can be slowed, arrested, or possibly reversed in some instances upon treatment with pamrevlumab.

IDIOPATHIC PULMONARY FIBROSIS

Understanding IPF and Current Therapies

IPF is a form of progressive pulmonary fibrosis, or abnormal scarring, which destroys the structure and function of the lungs. As tissue scarring progresses in the lungs, transfer of oxygen into the bloodstream is increasingly impaired. Average life expectancy at the time of confirmed diagnosis of IPF is estimated to be between three to five years, with approximately two-thirds of patients dying within five years of diagnosis. Thus, the survival rates are comparable to some of the most deadly cancers. The cause of IPF is unknown but is believed to be related to injury to the alveolar epithelial cells, inflammation and fibrosis.

Patients with IPF experience debilitating symptoms, including shortness of breath and difficulty performing routine functions, such as walking and talking. Other symptoms include chronic dry, hacking cough, fatigue, weakness, discomfort in the chest, loss of appetite, and weight loss. Over the last decade, refinements in diagnosis criteria and enhancements in high-resolution computed tomography imaging technology ("quantitative HRCT") have enabled more reliable diagnosis of IPF without the need for a lung biopsy.

Based on numerous sources, we estimate the U.S. prevalence and incidence of IPF to be approximately 120,000 cases, and 30,000 new cases per year, respectively, and the global prevalence of IPF to be 330,000 cases (including the major regions of U.S., Europe, Japan, and China. We believe that with the availability of technology to enable more accurate diagnoses, the number of individuals diagnosed per year with IPF will continue to increase.

There are currently two anti-fibrotic therapies approved to treat IPF in Europe and the U.S., pirfenidone and nintedanib, which have shown the commercial potential in IPF with over $4 billion in worldwide sales in 2021. Hoffmann-La Roche ("Roche") reported worldwide sales of approximately $1.12 billion in 2021 for Esbriet (pirfenidone). Boehringer Ingelheim Pharma GmbH & Co. KG ("Boehringer Ingelheim") reported total sales of approximately $2.9 billion for Ofev (nintedanib) in 2021.

Phase 3 Clinical Trials of Pamrevlumab in IPF

We are conducting two Phase 3 trials of pamrevlumab in IPF patients, ZEPHYRUS-1 and ZEPHYRUS-2.

Similar to PRAISE, our randomized and completed Phase 2 trial in 101 IPF patients described below, both of these Phase 3 studies are double-blind, placebo-controlled trials with a primary efficacy endpoint of change in forced vital capacity ("FVC") at 48 weeks. FVC is a lung function test measuring the volume of air exhaled by a patient.

We amended the ZEPHYRUS-2 protocol to harmonize the primary endpoint between the U.S. and Europe as change in FVC. Previously the primary endpoint for Europe was disease progression (as defined below), with change in FVC as a key secondary endpoint. This change makes the primary endpoint for both studies consistent with other recent pivotal trials in IPF that formed the basis of regulatory approval in the U.S. and Europe.

Secondary efficacy endpoints for each study include disease progression (defined by a decline in FVC percent predicted of greater than or equal to 10% or death), acute IPF exacerbation, and quantitative changes in lung fibrosis volume from baseline.

We have completed enrollment of ZEPHYRUS-1, our first Phase 3 trial of pamrevlumab in 356 IPF patients, and we expect topline data from ZEPHYRUS-1 in mid-2023.

We continue to enroll patients in ZEPHYRUS-2, our second Phase 3 trial of pamrevlumab in approximately 340 IPF patients, and we expect topline data from ZEPHYRUS-2 in mid-2024.

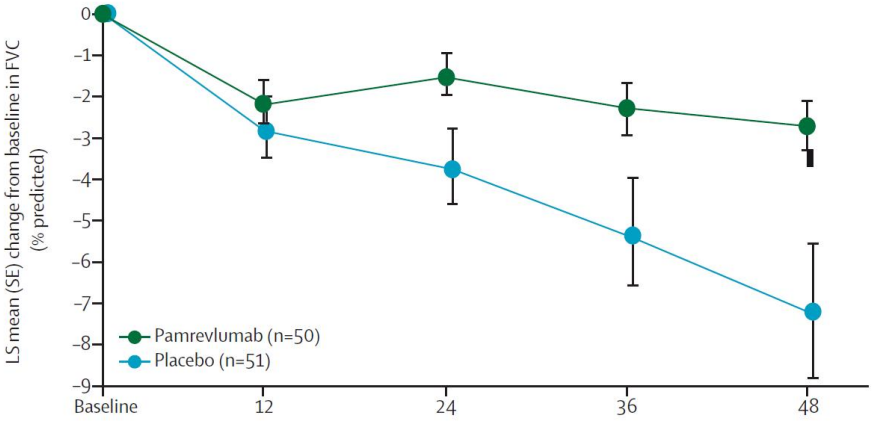
Phase 2 Clinical Trial of Pamrevlumab in IPF

Positive results from PRAISE were published in *The Lancet Respiratory Medicine (September 2019).* PRAISE was designed to evaluate the safety and efficacy of pamrevlumab in patients with mild-to-moderate IPF (baseline FVC percentage predicted of 55%), as well as topline results from two sub-studies that were added to evaluate the safety of combining pamrevlumab with approved IPF therapies.

In the double-blind, placebo-controlled 48-week portion of this study, 103 patients were randomized (1:1) to receive either 30mg/kg of pamrevlumab or placebo intravenously every three weeks. Lung function assessments were conducted at baseline and at Weeks 12, 24, 36 and 48. Quantitative HRCT assessments of lung fibrosis volume were performed at baseline and at Weeks 24 and 48.

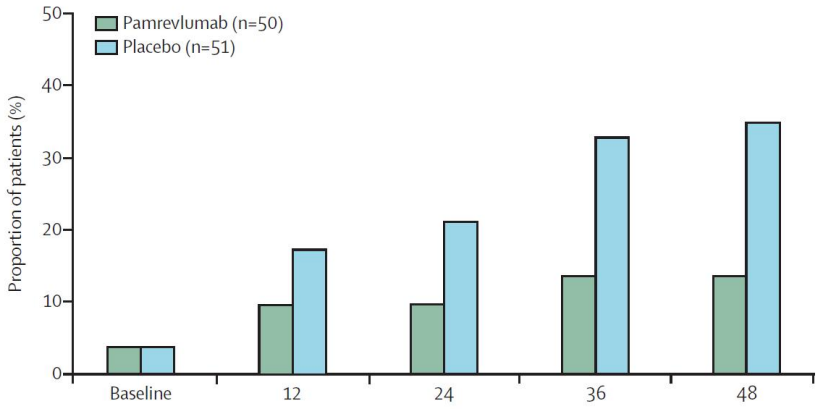
Pamrevlumab met the primary efficacy endpoint of change of FVC percent predicted, a measure of a patient's lung volume as a percentage of what would be expected for such patient's age, race, sex and height. The average decline (least squares mean) in FVC percent predicted from baseline to Week 48 was 2.9 in the pamrevlumab arm (n=50) as compared to an average decline of 7.2 in the placebo arm (n=51), a statistically significant difference of 4.33 (p=0.033).

FVC Change by Visit



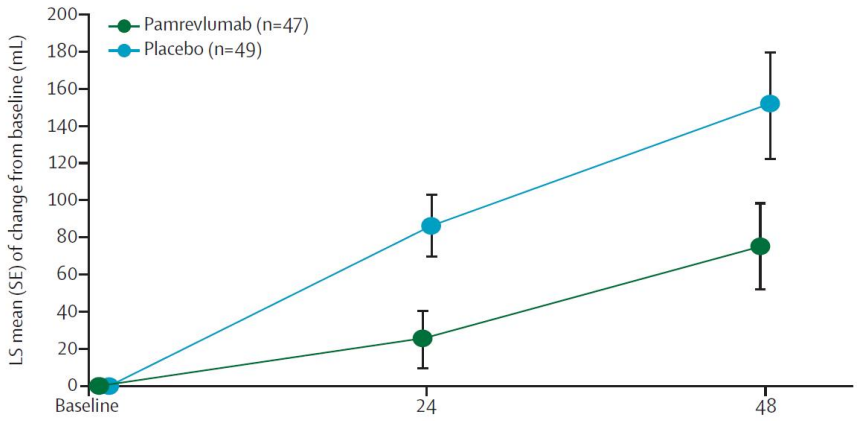
Pamrevlumab-treated patients had an average decrease (least squares mean) in FVC of 129 ml at Week 48 compared to an average decrease of 308 ml in patients receiving placebo, a statistically significant difference of 178 ml (p=0.0249, using a linear slope analysis in the intent-to-treat population). This represents a 57.9% relative difference. In addition, the pamrevlumab-treated arm had a lower proportion of patients (10%) who experienced disease progression (defined by a decline in FVC percent predicted of greater than or equal to 10% or death), than did the placebo arm (31.4%) at Week 48 (p=0.0103).

Proportion of Patients with Decline in Percentage of Predicted FVC of 10% or Greater, or Death, by Visit



In this study, we measured change in quantitative lung fibrosis ("QLF") from baseline to Week 24 and Week 48 using quantitative HRCT. The pamrevlumab arm achieved a statistically significant reduction in the rate of progression of lung fibrosis compared to placebo using HRCT to measure QLF. The change in QLF volume from baseline to Week 24 for pamrevlumab-treated patients was 24.8 ml vs. 86.4 ml for placebo, with a treatment difference of -61.6 ml (p=0.009). The change in QLF volume from baseline to 48 weeks was 75.4 ml in pamrevlumab-treated patients vs. 151.5 ml in patients on placebo, with a treatment difference of -76.2 ml (p=0.038).

Change from Baseline in Volume of Quantitative Lung Fibrosis (mL) in the Intention-to-Treat Population



As in our previous open label Phase 2 study, a correlation between FVC percent predicted and QLF was confirmed at both Weeks 24 and 48 in this study.

We are not aware of any other IPF therapies that have shown a statistically significant effect on lung fibrosis as measured by quantitative HRCT analysis.

The treatment effects of pamrevlumab were demonstrated not only on change in FVC, a measure of pulmonary function and IPF disease progression, and change in fibrosis using quantitative HRCT, but pamrevlumab-treated patients also showed a trend of clinically meaningful improvement in a measure of health-related quality of life using the St. George's Respiratory Questionnaire vs. a reduction in quality of life seen in placebo patients over the 48 weeks of treatment. The St. George's Respiratory Questionnaire quality of life measurement has been validated in chronic obstructive pulmonary disease. In the subgroup of patients that were evaluated by the UCSD Shortness of Breath Questionnaire, pamrevlumab-treated patients had a significant attenuation of their worsening dyspnea in comparison to placebo patients.

Pamrevlumab was well-tolerated in the placebo-controlled study. The treatment-emergent adverse events were comparable between the pamrevlumab and placebo arms and the adverse events in the pamrevlumab arm were consistent with the known safety profile of pamrevlumab. In this study, as compared with the placebo group, fewer pamrevlumab patients were hospitalized, following an IPF-related or respiratory treatment-emergent adverse event, or died for any reason.

Open-Label Phase 2 Clinical Trial of Pamrevlumab in IPF

Our completed open-label extension of Study 049, a Phase 2 open-label, dose-escalation study to evaluate the safety, tolerability, and efficacy of pamrevlumab in 89 patients with IPF, was consistent with the results from our randomized, double-blind, placebo-controlled Phase 2 clinical trial PRAISE. We presented data from our open-label Phase 2 IPF extension study (049) at the International Colloquium on Lung and Airway Fibrosis in November 2016, reporting that no safety issues were observed during prolonged treatment with pamrevlumab.

PANCREATIC CANCER

Understanding Pancreatic Cancer and Current Therapies

Certain solid malignant tumors have a prominent fibrosis component consisting mostly of ECM that contributes to metastasis and progressive disease. ECM is the connective tissue framework of an organ or tissue.

Pancreatic ductal adenocarcinoma, or pancreatic cancer, is the third leading cause of cancer deaths in the U.S. According to the American Cancer Society, approximately 64,500 people will be diagnosed with pancreatic cancer in the U.S. in 2023, and approximately 50,500 people will die of pancreatic cancer. Of all people diagnosed with pancreatic cancer in the U.S. between 2011 and 2017, the 5-year survival rate was 11%. 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 cased 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. For those with resectable tumors, 50% survive 17 to 27 months post-diagnosis and ~20% achieve five-year survival. 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.

Pancreatic cancer is aggressive and typically not diagnosed until it is largely incurable. Most patients are diagnosed after the age of 45, and according to the American Cancer Society, 94% of patients die within five years from diagnosis. 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 from 6.8 months with gemcitabine. 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 program for pamrevlumab as a therapy for LAPC. We completed enrollment of 284 patients, 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 expect topline data for the primary endpoint of overall survival in the first half of 2024.

Clinical Development in Metastatic Pancreatic Cancer

In June 2021, the Pancreatic Cancer Action Network's (PanCAN) Precision Promise[SM] adaptive trial platform included pamrevlumab in combination with standard of care chemotherapy treatments for pancreatic cancer (gemcitabine and Abraxane®), in its study for patients with metastatic pancreatic cancer. The pamrevlumab portion of the trial is still ongoing. Drug candidates in the Precision Promise study will continue to progress (including from Phase 2 to Phase 3) unless stopped sooner for safety or futility. The pamrevlumab combination therapy is offered to patients as either a first- or second-line treatment option. Pamrevlumab was the first experimental treatment arm to be offered as a first-line treatment in PanCAN's innovative Precision Promise trial. 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.

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 has 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 the pamrevlumab combination can convert inoperable pancreatic cancer to operable, or resectable, cancer. Tumor removal is the only 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.

Patients with LAPC have a median survival of less than 12 months, only slightly better than patients with metastatic pancreatic cancer, whereas patients with resectable pancreatic cancer have a much better prognosis with median survival of approximately 23 months and some patients being cured. 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 is 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.

DUCHENNE MUSCULAR DYSTROPHY

Understanding DMD and Current Therapies

In the U.S., approximately one in every 5,000 boys have DMD, and approximately 20,000 children are diagnosed with DMD globally each year. There are currently no approved disease-modifying treatments. Despite taking steroids to mitigate progressive loss of muscle function, a majority of children with DMD are non-ambulatory by adolescence and median survival is age 25.

DMD is an inherited disorder of one of the dystrophin genes resulting in absence of the dystrophin protein and abnormal muscle structure and function, leading to progressively diminished mobility as well as pulmonary function and cardiac function, which result in early death. Constant myofiber breakdown results in persistent activation of myofibroblasts and altered production of ECM resulting in extensive fibrosis in skeletal muscles of DMD patients. Desguerre et al. (2009) showed that muscle fibrosis was the only myo-pathologic parameter that significantly correlated with poor motor outcome as assessed by quadriceps muscle strength, manual muscle testing of upper and lower limbs, and age at ambulation loss. Numerous pre-clinical studies including those in the mdx model of DMD suggest that CTGF contributes to the process by which muscle is replaced by fibrosis and fat and that CTGF may also impair muscle cell differentiation during muscle repair after injury.

Phase 3 Clinical Trial of Pamrevlumab

Non-Ambulatory DMD Patients

LELANTOS-1 is our double-blind, placebo-controlled Phase 3 clinical trial evaluating pamrevlumab as a treatment for DMD, in combination with systemic corticosteroids. LELANTOS-1 completed enrollment of 99 non-ambulatory DMD patients randomized at a 1:1 ratio to pamrevlumab or placebo for a treatment period of 52 weeks. The primary endpoint will assess change in upper limb function from baseline to Week 52 and additional endpoints will include pulmonary, cardiac, performance, and fibrosis assessments. We expect topline data from this study in the second quarter of 2023.

Ambulatory DMD Patients

LELANTOS-2 is our double-blind, placebo-controlled Phase 3 trial evaluating pamrevlumab in DMD, in combination with systemic corticosteroids. We completed enrollment of 73 ambulatory patients aged 6-12, randomized at a 1:1 ratio to pamrevlumab or placebo for a treatment period of 52 weeks. The primary efficacy endpoint will assess ambulatory function, measured by the change in North Star Ambulatory Assessment from baseline to Week 52. We expect topline data from this study in the third quarter of 2023.

Phase 2 Open-Label Clinical Trial of Pamrevlumab in DMD

In June 2019 at the Parent Project Muscular Dystrophy meeting, we reported topline results from this 21-patient open-label single-arm trial in non-ambulatory DMD patients. This one-year administrative analysis compared our Phase 2 data to previously published natural disease history studies of DMD patients. While we cannot make direct comparisons between our trial and previously published data due to, among other things, differences in subject numbers, baseline characteristics, inclusion/exclusion criteria, treatment protocols, and analysis methods, pamrevlumab was well tolerated and compares favorably to published studies for FVC percent predicted and other clinical outcomes.

In pulmonary function tests, the results from our study indicate a potential reduction in the one-year decline in FVC percent predicted from baseline for pamrevlumab-treated patients when compared to FVC data of DMD patients (whether such patients were taking steroids or not) published in 2019 by Ricotti. In addition, pamrevlumab showed less decline in both percent predicted forced expiratory volume as compared to previously published study results of Meier in 2016, and in percent predicted peak expiratory flow rate, compared to what was observed in the study by Ricotti in 2019.

In muscle function tests, the majority of the results of this Phase 2 study showed the mean change from baseline in pamrevlumab-treated patients appeared to be more favorable than previously published data. Our results showed a mean increase in grip-strength score in both dominant and non-dominant hands at one year of treatment with pamrevlumab, while earlier results from a 2015 study by Seferian showed a decline at one year as expected.

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 CKD anemia in China, Europe, Japan and numerous other countries.

Roxadustat Mechanism of Action

Roxadustat is an orally administered reversible inhibitor of HIF-PH. Inhibition of prolyl hydroxylase stabilizes HIF, which then forms a complex that initiates transcription of a number of genes involved in the erythropoietic process. This in turn stimulates a coordinated response that includes the increase of plasma endogenous erythropoietin (“EPO”) levels and reduction of hepcidin, a key regulator of iron homeostasis, ultimately resulting in increased oxygen delivery to tissues.

In anemia of CKD, roxadustat temporarily inhibits HIF-PH, stimulating a coordinated erythropoietic response.

Patients taking roxadustat typically have a transient increase in circulating endogenous EPO levels at peak concentration within or near the physiologic range naturally experienced by humans adapting to hypoxic conditions such as at high altitude, following blood donation, or impaired lung function, such as pulmonary edema.

By contrast, erythropoiesis stimulating agents (“ESAs”) act only to stimulate erythroid maturation without a corresponding increase in iron availability, and are typically dosed at well above the natural physiologic range of EPO. The sudden demand for iron stimulated by ESA-induced erythropoiesis can lead to functional or absolute iron deficiency. In addition, the lack of a coordinated increase in iron availability with ESAs may explain the hyporesponsiveness of patients with inflammation to this class of drugs. It also explains why patients taking ESAs need more IV iron supplementation and red blood cell transfusions than patients taking roxadustat do. Not only are IV iron and blood transfusions more costly than oral iron, but both are also associated with increased risk of hospitalization and death.

The differentiated mechanism of action of roxadustat, which involves induction of the body’s own natural pathways to achieve a more complete erythropoiesis, has the potential to provide a safe and effective treatment for anemia, including in the presence of inflammation, which normally limits iron availability.

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 12% to 14% 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 a majority of this growth, benefiting from inclusion in the 2019 and 2021 National Reimbursement Drug Lists.

In 2022, roxadustat sales volume grew over 80% and it was the top CKD anemia brand in China with a 34% value share within the segment of ESAs and HIF-PH inhibitors. Roxadustat remains the only HIF-PH inhibitor currently on the market in China and we have seen broad adoption across the three segments of hemodialysis, peritoneal dialysis, and non-dialysis.

In 2023, we expect continued and robust growth of roxadustat sales in China due to continued adoption by patients and doctors. Multiple treatment guidelines and expert consensus in China describe or recommend HIF-PH inhibitors as a treatment for CKD anemia - and roxadustat specifically. We believe this increased awareness and confidence in the class will provide strong support for continued expansion of roxadustat sales.

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 2023, we will focus on expanding the population treated with roxadustat, as well as duration of treatment which we believe is important to managing the risks associated with anemia in CKD.

Europe - Roxadustat Commercial Program

In Europe, our partner Astellas continues the commercial launch of EVRENZO® (roxadustat). EVRENZO is approved for the treatment of anemia associated with CKD in both non-dialysis and dialysis patients. EVRENZO is the only HIF-PH inhibitor currently on the market in Europe. In 2023, we expect sales of roxadustat for CKD anemia in Europe to accelerate due to reimbursement and launches in additional European countries.

Japan - Roxadustat Commercial Program

In Japan, our partner Astellas continues the commercial launch 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. The supplemental NDA for the use of roxadustat in patients with anemia of CKD not on dialysis was approved in November 2020 by the Pharmaceuticals and Medical Devices Agency. EVRENZO is one of five HIF-PH inhibitors currently on the market in Japan.

United States - Roxadustat Development

There are approximately 39 million CKD patients in the U.S., an estimated six million of whom have anemia.

When ESAs were introduced in 1989, they dramatically reduced the need for blood transfusions in CKD patients, which was a material development since transfusions reduce the patient’s opportunity for a kidney transplant and increase the risk of infections and complications such as heart failure and allergic reactions. However, multiple randomized clinical trials with ESAs suggested safety risks of ESA therapies, and as a result, the anemia guidelines and approved labels have changed to more restrictive use of ESAs.

In the dialysis-dependent population, most patients start receiving ESAs when the patient is transitioning to dialysis care. As of the end of 2018, there were over 550,000 CKD patients on dialysis in the U.S., a large majority of whom required anemia therapy.

There were approximately 127,000 incident dialysis patients in 2018. Despite the higher risk of blood transfusions, cardiovascular events, and hospitalization in patients with anemia, only 14.6% of patients in 2018 were treated with ESAs prior to initiating dialysis notwithstanding a mean hemoglobin level of 9.3 g/dL at the time of dialysis initiation. These treatment figures at the time of dialysis initiation demonstrate how undertreated CKD anemia is currently in non-dialysis patients.

In August 2021, the U.S. FDA issued a CRL regarding roxadustat's NDA for the treatment of anemia due to CKD in adult patients, stating that it could not be approved in its present form.

ANEMIA ASSOCIATED WITH MYELODYSPLASTIC SYNDROMES

MDS is 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 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 producing symptoms, including 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, and 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.

Even among the eligible subpopulation, the effectiveness of ESAs in treating anemia in MDS remains limited, with the best clinical study results showing 40% to 60% erythroid response rates, in studies where significantly high doses of ESAs were used, enrolled patients had low serum EPO levels, and in lower-risk categories. 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

We completed enrollment of the Phase 3 arm of MATTERHORN, our Phase 2/3 placebo-controlled, double-blind clinical trial of roxadustat for the treatment of anemia in MDS in the U.S. and Europe. The Phase 3 portion of this trial is studying roxadustat in 140 transfusion-dependent, lower-risk MDS patients, in which subjects are randomized 3:2 to receive roxadustat or placebo three-times-weekly. The primary endpoint is the proportion of patients who achieve transfusion independence for 56 consecutive days within the first 28 weeks with secondary endpoints and safety evaluated at 52 weeks. We expect topline 28-Week data from this study in the second quarter of 2023.

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.

Approximately 40% of total solid tumor cancer patients, or approximately 6.8 million people, undergo chemotherapy each year globally, including 3.2 million in China. Between 60% and 80% of these patients develop anemia. 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 experiencing CIA with the desirable goals of improvement in anemia-related symptoms and the avoidance of blood transfusion, which increases 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 published from 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.

Market Opportunity for Roxadustat in Chemotherapy-Induced Anemia

China has 4-5 million solid tumor patients, of which approximately 75% receive chemotherapy. Of that population, an estimated 50% (over 1.5 million patients) become anemic, and among them, 40% are considered moderate to severe, defined as Hb < 10 g/dL. This addressable population is largely untreated, with an ESA usage rate of under 10%. We further estimate that the population where anemia has led to chemotherapy dose reduction or delay is around 20-25%.

We believe this population could benefit from treatment with roxadustat, and the oral administration of HIF-PH inhibitors for this very sick population could be a particularly attractive feature over ESAs.

Phase 3 Clinical Trial in Chemotherapy-Induced Anemia

We have completed enrollment of our active-controlled Phase 3 clinical trial in China of roxadustat in CIA for non-myeloid malignancies. The primary efficacy endpoint is the mean change in hemoglobin level from baseline to the level averaged over Weeks 9-13. This trial has enrolled 159 subjects and we expect topline data from this study in the second quarter of 2023.

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.

RESEARCH AT FIBROGEN

Our research programs at FibroGen are grounded in our three areas of expertise: HIF biology, 2-oxoglutarate enzymology, and CTGF biology. More recently, we added two immuno-oncology programs via a partnership with HiFiBiO Therapeutics ("HiFiBiO") and are actively working to further expand the preclinical pipeline in our therapeutic focus areas of oncology, immunology, and fibrosis.

We have applied our expertise in the field of HIF-PH inhibition to develop an understanding of other areas of HIF biology with important therapeutic implications. This consistent progression of discovery has led to findings relating to HIF-mediated effects associated with inflammatory pathways, various aspects of iron metabolism, insulin sensitivity and glucose and fat metabolism, neurological disease, and ischemic injury. There are at least three different HIF-PH enzymes that are known to regulate the stability of HIF — these enzymes are commonly referred to in the scientific literature as PHD1, PHD2 and PHD3. Studies of genetically modified mice, in which the individual HIF-PH enzymes have been deleted, have revealed that PHD2 plays the major role in regulation of erythropoiesis by HIF. In contrast, PHD1 and PHD3 appear to play less important roles in HIF-mediated erythropoiesis, but instead have been implicated in other important biological pathways. We believe that both pan-PHD and PHD-selective inhibitors could have important therapeutic applications beyond anemia.

The HIF-PH enzymes that are the targets of roxadustat belong to a broader family of enzymes known as 2-oxoglutarate ("2OG")-dependent oxygenases. In humans, this family comprises more than 60 members that play important roles in a diverse range of biological processes including collagen biosynthesis, oxygen sensing, epigenetic regulation, nucleic acid modification/repair, and lipid metabolism. The first members of this enzyme family to be characterized were the collagen prolyl hydroxylases, which play a critical role in the biosynthesis of collagen and as a result, are potential targets for the treatment of fibrotic disease. Other members of the 2OG-dependent oxygenase family with relevance to human disease include the Jumonji domain-containing histone demethylases, which are emerging cancer targets.

The fact that all members of the 2OG-dependent oxygenase enzyme family use 2OG as a co-substrate makes them viable targets for small molecule inhibitors that compete with 2OG. FibroGen has been a leader in inhibition of enzymes belonging to this family, and our internal medicinal chemistry efforts generated a library of novel compounds designed to target the 2OG-dependent oxygenase family.

We are also applying our knowledge of CTGF to investigate new clinical opportunities for pamrevlumab. We are exploring additional indications in which CTGF-driven fibrosis has been implicated in disease progression and mortality, as well as expanded cancer subtypes for which CTGF biology has been shown to support tumor survival and metastasis.

More recently we in-licensed two preclinical immuno-oncology assets. The first is FG-3165, an antibody that inhibits Galectin-9, a secreted protein implicated in suppression of anti-tumor immune response in multiple solid tumors, and shown to be a driver of cancer progression in acute myeloid leukemia. The other is FG-3163, an antibody targeting the CCR8 protein designed to deplete immune suppressive T regulatory cells from the tumor microenvironment. Multiple preclinical studies demonstrated that depletion of T regulatory cells in solid tumors results in enhanced immune response and reduction in tumor size, particularly when combined with immune checkpoint inhibition. We expect to file INDs for up to two of these programs in the second half of 2023.

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, 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. For the fiscal year ended December 31, 2020, 59% of our revenue was related to our collaboration agreements, and 41% 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

We have two agreements with AstraZeneca for the development and commercialization of roxadustat for anemia, one for China (the “AstraZeneca China Agreement”), and one for the U.S. and all other countries not previously licensed to Astellas (the “AstraZeneca U.S./RoW Agreement”). Under these agreements, we provided AstraZeneca the right to develop and commercialize roxadustat for anemia in these territories. We share responsibility with AstraZeneca for clinical development activities required for U.S. regulatory approval of roxadustat, and FibroGen will transfer the U.S. NDA to AstraZeneca upon approval. AstraZeneca will hold the equivalent regulatory filings in the other licensed countries.

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 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 an agreed upon transfer price, which includes a gross transfer price, net of a calculated 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 15, *Segment and Geographic Information*, to our consolidated financial statements under Item 8 of this Annual Report.

HiFiBiO

In June 2021, we entered into an exclusive license and option agreement with 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. We expect to file INDs for up to two of these programs in the second half of 2023.

LICENSING ACTIVITIES

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 have billed a $3.0 million milestone in the first quarter of 2023 based on Eluminex implanting a biosynthetic cornea in the first patient of its clinical trial in China. 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 8, *Liability Related to Sale of Future Revenues*, 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 anemia in CKD, IPF, pancreatic cancer, and DMD. 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 IPF, pancreatic cancer, and DMD, 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.

When any of our product candidates are approved, they will compete with currently marketed products, and product candidates that may be approved for marketing in the future, for treatment of the indications described below.

In addition, we will likely face competition from other companies developing treatments of other anemia indications that we may also seek to pursue in the future or that may be sold in indications we are pursuing but for which they are not yet approved. We may face competition for patient recruitment, enrollment for clinical trials, and potentially in commercial sales. There may also be new therapies for renal-related diseases that could limit the market or level of reimbursement available for roxadustat.

Roxadustat

Approved Medicines

Drugs that will compete with roxadustat are expected to include ESAs, particularly in those patient segments where ESAs are used. Currently available ESAs include epoetin alfa (EPOGEN®, marketed by Amgen Inc. in the U.S., Procrit® and Erypo®/Eprex®, marketed by Johnson & Johnson, Inc., and Espo® marketed by Kyowa Hakko Kirin in Japan and China), darbepoetin (Amgen/Kyowa Hakko Kirin's Aranesp® and NESP®) and Mircera® marketed by Roche outside the U.S. and by Vifor Pharma, a Roche licensee, in the U.S. and Puerto Rico, as well as biosimilar versions of these currently marketed ESA products. ESAs have been used in the treatment of anemia in CKD for more than 30 years, serving a significant majority of dialysis patients. While non-dialysis CKD anemia patients who are not under the care of nephrologists, including those with diabetes and hypertension, do not typically receive ESAs and are often left untreated, some non-dialysis patients under nephrology or hematology care may be receiving ESA therapy. It may be difficult to encourage healthcare providers and patients to switch to roxadustat from products with which they have become familiar.

Biosimilars

The first biosimilar ESA, Pfizer's Retacrit® (epoetin zeta), entered the U.S. market in November 2018. Market penetration of Retacrit and the potential addition of other biosimilar ESAs currently under development may alter the competitive and pricing landscape of anemia therapy in CKD patients on dialysis under the end-stage renal disease bundle. The patents for Amgen's EPOGEN® (epoetin alfa) expired in 2004 in Europe, and the final material patents in the U.S. expired in May 2015. Several biosimilar versions of currently marketed ESAs are available for sale in Europe, China and other territories. In the U.S., a few ESA biosimilars are currently under development. Sandoz, a division of Novartis, markets Binocrit® (epoetin alfa) in Europe and may file a biosimilar Biologics License Application in the U.S.

Product Candidates in Development

We may also face competition from potential new anemia therapies currently on the market or in clinical development, including in those patient segments not adequately addressed by ESAs. Companies that are currently developing HIF-PH inhibitors for anemia in CKD indications include GlaxoSmithKline plc ("GSK"), Bayer Corporation ("Bayer"), Akebia Therapeutics, Inc. ("Akebia"), Otsuka Pharmaceutical, Akebia's partner in the U.S. and Europe, Japan Tobacco, and Zydus Lifesciences Ltd. (formerly known as Cadila Healthcare Ltd.) (India) ("Zydus"). In March 2021, Akebia submitted an NDA to the FDA for vadadustat for the treatment of anemia due to CKD in patients on dialysis and not on dialysis. On March 30, 2022, Akebia announced that it received a Complete Response Letter from the FDA for vadadustat for the treatment of anemia due to CKD. In November of 2022, Akebia announced that it had filed a Formal Dispute Resolution Request related to the CRL for vadadustat. In October 2021, Otsuka Pharmaceutical submitted an initial marketing authorization application to the EMA for vadadustat for the treatment of anemia associated with CKD in adults. In June 2022, Akebia announced that it had regained rights to vadadustat in various territories, including Europe, upon termination of the Collaboration and License Agreement with Otsuka Pharmaceutical.

GSK announced in February 2023 that the FDA approved daprodustat to treat anemia of CKD in adults who have been receiving dialysis for at least four months. GSK's marketing authorization application for daprodustat is pending with the EMA.

Japan

In Japan, roxadustat faces the following competitive drugs being sold for the treatment of anemia in CKD for patients who are on dialysis and not on dialysis: vadadustat by Mitsubishi Tanabe Pharmaceutical Corporation, Akebia's collaboration partner, daprodustat by GSK and its partner Kyowa Hakko Kirin, molidustat by Bayer, and enarodustat by Japan Tobacco (to be sold by Torii Pharmaceuticals Ltd).

China

In China, ESA is considered the standard of care for the treatment of anemia in CKD, and locally manufactured epoetin alfa is offered by 15 local manufacturers including the market leader EPIAO that is marketed by 3SBio Inc. We may face potential competition from other HIF-PH inhibitors. Companies active in the U.S. such as Akebia, Bayer, and GSK have been authorized by the National Medical Products Administration ("NMPA") to conduct trials in China to support their ex-China regulatory filings. A number of domestic companies, including Jiangsu Hengrui Medicine Co., Ltd., Nicoya Therapeutics (Shanghai) Co. Ltd (licensed from Guandong Sunshine Health Investment Co., Ltd.), 3SBio Inc., and Hangzhou Andao Pharmaceutical Co., have been permitted by the NMPA to conduct clinical trials in their locally developed HIF-PH inhibitor investigational compounds for the treatment of anemia in CKD. Domestic companies are also in-licensing global compounds to be developed as domestic drugs, including China Medical System which in-licensed Desidustat, a compound that is approved in India, from Zydus for greater China in January 2020. In January 2021, China Medical System Holdings Ltd. was granted approval by the Chinese NMPA to begin trials for Desidustat in patients with anemia of CKD, including dialysis and non-dialysis patients. Shenzhen Salubris Pharmaceutical Co., Ltd., a domestic company in China, in-licensed Enarodustat from Japan Tobacco and received NMPA approval in the third quarter of 2020 to initiate Phase 3 studies. We will also face competition from generics who could enter the market after expiry of our patents in China, and two potential market players have already started bioequivalence studies, including Chia Tai-Tiangqing Pharmaceutical Holdings and CSPA Pharmaceutical Group.

CIA and MDS

Reblozyl® (luspatercept) was approved by the FDA in April 2020 for the treatment of anemia in adults with MDS with ring sideroblasts or myelodysplastic/myeloproliferative neoplasms with ring sideroblasts and thrombocytosis who need regular red blood cell transfusions and have not responded well to or cannot receive an ESA. It is the first and only erythroid maturation agent approved in the U.S., Europe, and Canada and is part of a global collaboration between Acceleron Pharma, Inc. and Bristol Myers Squibb. In addition, Geron Corporation recently released positive data from its ongoing Phase 3 clinical trial of imetelstat in lower risk MDS.

Large Dialysis Organizations

The majority of the current CKD anemia market focuses on dialysis patients who visit dialysis centers on a regular basis, typically three times a week, and are administered anemia therapies as part of the visit. Collectively, DaVita Healthcare Partners Inc. ("DaVita") and Fresenius Medical Care AG & Co. KGaA ("Fresenius"), two of the largest operators of dialysis clinics in the U.S., provide dialysis care to more than 80% of U.S. dialysis patients, and have historically executed long-term contracts including rebate terms with Amgen. Successful penetration in this market will likely require our partner AstraZeneca to enter into a definitive agreement with Fresenius, DaVita, or other dialysis organizations, on favorable pricing terms and on a timely basis.

Pamrevlumab

We are currently in Phase 3 development of pamrevlumab in IPF, LAPC, metastatic pancreatic cancer, and DMD. Most of our competitors have significantly more resources and expertise in development, commercialization and manufacturing, particularly due to the fact that we have not yet established a partnership for pamrevlumab. For example, both Roche and Boehringer Ingelheim, which market products for the treatment of IPF in the U.S., have successfully developed and commercialized drugs in various indications and have built sales organizations that we do not currently have; both have more resources and more established relationships when competing with us for patient recruitment and enrollment for clinical trials or, if we are approved, in the market.

Idiopathic Pulmonary Fibrosis

If approved and launched commercially to treat IPF, pamrevlumab is expected to compete with Roche's Esbriet® (pirfenidone), and Boehringer Ingelheim's Ofev® (nintedanib). It may be difficult to encourage treatment providers and patients to switch to pamrevlumab from an oral product with which they are already familiar to a product delivered via in-office infusion. Furthermore, there are multiple generic alternatives of pirfenidone in the U.S. and nintedanib may be produced as a generic in the near future. We may also face competition from potential new IPF therapies in recruitment and enrollment in our clinical trials and potentially in commercialization.

Pamrevlumab is a monoclonal antibody that may be more expensive and less convenient than oral small molecules such as nintedanib and pirfenidone. Other potential competitive product candidates in various stages of development for IPF include Boehringer Ingelheim's BI 1015550. Boehringer Ingelheim enrolled its first patient in the fourth quarter of 2022 in its Phase 3 trial of BI 1015550, a novel investigational phosphodiesterase 4B (PDE4B) inhibitor of IPF. Roche has discontinued its Phase 3 trial evaluating the efficacy and safety of PRM-151, a recombinant human pentraxin-2 (rhPTX-2), compared to placebo in patients with IPF. United Therapeutics Corporation is enrolling patients in its Phase 3 trial of treprostinil in IPF.

Pancreatic Cancer

We are developing pamrevlumab to be used in combination with chemotherapy (either FOLFIRINOX or gemcitabine plus nab-paclitaxel) in pancreatic cancer. If approved, we would face competition from Celgene's Abraxane® (nab-paclitaxel), gemcitabine, and FOLFIRINOX, a combination chemotherapy regimen of folic acid, 5-fluouracil, oxaliplatin and irinotecan. Gemcitabine and/or nab-paclitaxel are the current standard of care in the first-line treatment of metastatic pancreatic cancer. In 2015, Merrimack Pharmaceuticals Inc. ("Merrimack") received FDA approval for the use of ONIVYDE (irinotecan liposome injection, acquired by Ipsen in 2017) for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy, and the combination therapy with Abraxane and gemcitabine became the first-line standard of care in these patients. As treatments for pancreatic cancer have shown limited success to date, combination therapies are expected, but the incremental cost may slow a new product adoption in the market, at least until the generic versions of Abraxane becomes available. In addition, we may also face competition from other agents seeking approval in combination with gemcitibine and nab-paclitaxel such as Rafael Pharma's defactinib/CPI-613 and Merrimack's istiratumab.

Duchenne Muscular Dystrophy

If approved and launched commercially to treat DMD, pamrevlumab is expected to face competition from drugs that have been approved in major markets such as the U.S., European Union, and Japan.

Sarepta Therapeutics Inc.'s ("Sarepta") Exondys 51™ (eteplirsen) is approved in the U.S. to treat patients who have a mutation of the dystrophin gene amenable to exon 51 skipping, representing approximately 13% of patients with DMD. In Europe, Sarepta received a negative opinion for its marketing application for eteplirsen from the EMA in September 2018. Sarepta's Vyondys 53™ (golodirsen) is approved in the U.S. for patients with a confirmed genetic mutation that is amenable to exon 53 skipping, which accounts for approximately 8% of the DMD population. Sarepta's Amondys 45™ (casimersen) is approved in the U.S. for patients with a confirmed genetic mutation that is amenable to exon 45 skipping, which accounts for approximately 8% of the DMD population. Sarepta filed a Biologics License Application for the accelerated approval of SRP-9001 (delandistrogene moxeparvovec) to treat ambulant patients with DMD and has a May 2023 Prescription Drug User Fee Act date.

PTC Therapeutics' product Translarna™ (ataluren) received a conditional approval in Europe in 2014, which was renewed in November 2016 with a request for a new randomized placebo-controlled 18-month study by the Committee for Medicinal Products for Human Use of the EMA; however, the FDA informed the sponsor in a CRL in October 2017, as well as in its response to PTC Therapeutics' appeal, that the FDA is unable to approve the application in its current form. While Translarna™ targets a different set of DMD patients from those targeted by Sarepta's Exondys 51®, it is also limited to a subset of patients who carry a specific mutation. Conversely, pamrevlumab is intended to treat DMD patients without limitation to type of mutation.

Pamrevlumab may also face competition from other drugs currently in clinical development in patient recruiting and enrollment in clinical trials, and, if approved, in commercialization. Examples of those compounds currently under clinical development are the drug candidates from Pfizer, Sarepta and Italfarmaco Group.

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.

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 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 regulations. 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, the physicians 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"), 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 which 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, which could negatively impact our profitability.

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 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 will take effect progressively starting in fiscal year 2023, although they may be 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, the Biden administration released an additional executive order on October 14, 2022, directing U.S. Department of Health and Human Services to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether these or similar policy initiatives will be implemented in the future. Congress is also considering additional health reform measures.

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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. 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 have a material adverse impact on our profitability.

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. 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 to one of the patents listed with the FDA by the innovator BLA holder. The BPCIA is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and interpretation are subject to uncertainty.

Orphan Drug Act

Pamrevlumab has received orphan drug designation in IPF, LAPC, and DMD 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.

The EMA has granted Orphan Medicinal Product Designation to pamrevlumab for the treatment of DMD. Orphan Medicinal Product Designation status in Europe has similar but not identical benefits in that jurisdiction.

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 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 is also 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 protects undisclosed data from drug studies and prevents the approval of an application made by another company that uses the undisclosed data for the approved drug. In practice, the NMPA has not established an effective mechanism to enforce data exclusivity. The NMPA issued a draft regulation on regulatory data protection on April 25, 2018 for public comments but this draft regulation has yet to be finalized and implemented.

In addition, if an approved drug manufactured in China qualifies as an innovative drug or an improved new drug before December 1, 2019, such drugs will be eligible for a monitoring surveillance period for up to five years. During this post-marketing observation period, the NMPA will not accept marketing authorization applications filed by another company for the same product. Nor will the NMPA approve marketing authorization applications filed by another company to produce, change dosage form of or import the drug while the innovative or improved new drug is under observation for the purpose of protecting public health. The approved manufacturer is 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.

Each of the data exclusivity period and the observation period runs from the date of approval for production of the NCE or innovative or improved new drug, as the case may be.

INTELLECTUAL PROPERTY

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.

Our extensive worldwide patent portfolio includes multiple granted and pending patent applications relating to roxadustat and pamrevlumab. Currently granted patents relating to composition-of-matter for roxadustat and for pamrevlumab are expected, for each product candidate, to expire in 2024 or 2025, in each case exclusive of any patent term extension that may be available. U.S. and foreign patents relating to crystalline forms of roxadustat are expected to expire in 2033, exclusive of any extension. Additional patents and patent applications relating to manufacturing processes, formulations, and various therapeutic uses, including treatment of specific indications and improvement of clinical parameters, provide further protection for product candidates.

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

Our roxadustat patent portfolio includes multiple granted U.S. patents offering protection for roxadustat, including protection for composition-of-matter, for pharmaceutical compositions, and for methods for treating anemia. Exclusive of any patent term extension, the last of the granted U.S. patents relating to the composition-of-matter of roxadustat is due to expire in 2025, and granted foreign patents are due to expire in 2024. U.S. and foreign patents relating to crystalline forms of roxadustat are due to expire in 2033, and U.S. and foreign patents relating to photostable formulations of roxadustat are due to expire in 2034.

In 2020, oppositions were filed against our European Patent No. 2872488 (the "`488 Patent"), which claims a crystalline form of roxadustat, and our European Patent No. 3003284 (the "`284 Patent"), which claims photostable formulations of roxadustat. Similar challenges have been filed in China against patents which claim a crystalline form of roxadustat. Final resolution of the opposition proceedings will take time and we cannot be assured that these patents will survive these proceedings as originally granted or at all.

If roxadustat is approved in the U.S. prior to expiration of the U.S. composition of matter protection, a full five-year patent term extension under the Hatch-Waxman act will be available, which extension would expire in 2030. Refer to *"Government Regulation — Regulatory Exclusivity for Approved Products — U.S. Patent Term Restoration."*

We also hold various U.S. and foreign granted patents and pending patent applications directed to roxadustat manufacturing processes, formulations, and methods for use.

Roxadustat China Patent Portfolio

Our roxadustat China patent portfolio includes granted patents covering composition-of-matter, pharmaceutical compositions, methods of use, and manufacturing processes, as well as medicaments for treating anemia and other conditions. Pending the oppositions referenced in the previous section, patents relating to roxadustat composition-of-matter and crystalline forms are due to expire in 2024 and 2033, respectively.

HIF Anemia-Related Technologies Patent Portfolio

We also have an extensive worldwide patent portfolio providing broad protection for proprietary technologies relating to the treatment of anemia and associated conditions. This portfolio currently contains granted patents and pending patent applications providing exclusivity for use of compounds falling within various and overlapping classes of HIF-PH inhibitors to achieve various therapeutic effects.

Various legal challenges have been initiated against this portfolio in several territories, including in Europe, the United Kingdom, and Japan. Regardless of the final outcome of any such actions, the potential narrowing or revocation of any of these patents does not affect our exclusivity for roxadustat or our freedom-to-operate with respect to use of roxadustat for the treatment of anemia in these or in other territories. A settlement has been reached in the litigation in Canada, resulting in the discontinuance of the action and leaving FibroGen's Canadian patents valid and enforceable.

In April 2020, in response to an invalidation action brought against certain of our United Kingdom patents by Akebia, the United Kingdom court handed down a decision invalidating certain FibroGen United Kingdom patents. In August 2021, the United Kingdom Court of Appeal handed down a decision favorable to FibroGen, declaring several of the patents valid. Akebia has applied to the Supreme Court of the United Kingdom for permission to appeal the Court of Appeal ruling.

Pamrevlumab Patent Portfolio

Our pamrevlumab patent portfolio includes U.S. patents providing composition-of-matter protection for pamrevlumab and related antibodies, and for methods of using such in the treatment of fibroproliferative disorders, including IPF, liver fibrosis, and pancreatic cancer. 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. Corresponding foreign patents are due to expire, exclusive of any patent term extension, in 2024.

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.

We also hold additional granted U.S. and foreign patents and pending patent applications directed to the use of pamrevlumab to treat IPF, DMD, pancreatic cancer, liver fibrosis, and other disorders.

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.

HUMAN RESOURCES

We had a total of 592 employees at FibroGen as of January 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 2022, we conducted a company-wide employee engagement survey. We had an overall participation rate of 92% with over 90% of employees reporting that they felt highly engaged. Further, for the first time 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 88%. 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. We also believe that to be an employer of choice, we must support the communities in which we live and operate. In 2022, we re-launched our high school and college internship program which provides opportunities for people of color and/or economically disadvantaged youth to contribute and learn for eight 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 up to 20 hours of 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, 3 of 9 members (33%) identify as Asian or Hispanic ethnicity. Notably, our U.S. workforce is 55% female. Our U.S. employees that self-report ethnicity are 66% 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, 33.3% identify as Asian or Hispanic. Our China workforce is 58% female, and of our China Executives (Vice President and above) 50% are female. 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 2023 is to increase female diversity at the executive director level and above.

In addition to furthering our investments in our human resources, we plan to continue our efforts in 2023 in critical environmental, social, and governance (“ESG”) areas. In 2022, we performed an ESG assessment of our operations and determined a number of goals for 2023, including adopting a policy to increase patient diversity in clinical trials and perform a climate impact analysis once the SEC adopts their 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 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.

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 of 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, 2022 ("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 currently 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 a substantial portion of our efforts and financial resources in the research and development of pamrevlumab and roxadustat.

Our near-term success depends in large part on pamrevlumab, which is in clinical development for idiopathic pulmonary fibrosis ("IPF"), locally advanced unresectable pancreatic cancer ("LAPC"), metastatic pancreatic cancer, and Duchenne muscular dystrophy ("DMD"). Pamrevlumab requires substantial further development and commercialization investments, and, at this time, we do not have a collaboration partner to support this compound. In addition, pamrevlumab is a monoclonal antibody, which may require greater financial resources than for our small molecule, roxadustat.

Our near-term prospects also depend in large part on our continued development and commercialization of roxadustat in the People's Republic of China ("China"), Japan, Europe, the United States ("U.S."), and elsewhere. Roxadustat has been approved in the European Union, Great Britain, China, Japan, and other countries for the treatment of anemia in chronic kidney disease ("CKD") for patients who are on dialysis and not on dialysis. However, we received a complete response letter ("CRL") for roxadustat in CKD anemia in the U.S. from the Food and Drug Administration ("FDA"). While we continue to co-commercialize roxadustat in China with AstraZeneca AB ("AstraZeneca") and develop roxadustat in the U.S. for the treatment of anemia in patients with myelodysplastic syndromes ("MDS"), we have not been able to agree on a path forward for AstraZeneca to fund further roxadustat development in the U.S. for CKD anemia and there is a significant risk we will be unable to do so. There is also a significant risk that the U.S./RoW Agreement, a collaboration agreement we entered into with AstraZeneca for roxadustat for the treatment of anemia in the U.S. and all territories not previously licensed to Astellas, except China ("AstraZeneca U.S./RoW Agreement"), will be amended or terminated.

With an eye toward our longer-term success, we are investing in new drug programs to expand our early-stage clinical pipeline. While we see great potential value in our early-stage pipeline, these programs are years away from commercialization, and the success of any development program is not guaranteed. Our near-term prospects and the price of our common stock most heavily rely on the success of our lead products pamrevlumab and roxadustat.

As a company, we have limited late-stage and commercialization experience, and the time and resources required to develop such experience are significant.

We are running multiple Phase 3 clinical trials simultaneously with multiple readouts in 2023 and 2024, while also commercializing roxadustat with our collaboration partners. As a Company, we have limited resources and limited experience handling such a large number of data readouts and possible regulatory filings.

For pamrevlumab, which we have not partnered, we do not have a sales infrastructure and we have limited experience in the sales, marketing or distribution of pharmaceutical products in any country.

To the extent that we would undertake sales and marketing of any of our products directly, there are risks involved with establishing our own sales, marketing and distribution capabilities. Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;

- our inability to effectively manage geographically dispersed commercial teams;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercial organization.

With respect to roxadustat, we are dependent in part on the commercialization capabilities of our collaboration partners, AstraZeneca and Astellas Pharma Inc. ("Astellas"). If either such partner were to terminate its agreement with us, we would have to commercialize on our own or with another third party. We will have limited control over the commercialization efforts of such third parties, and any of them may fail to devote the necessary resources and attention to sell and market roxadustat effectively.

Successful development and commercialization of any of our products requires us to establish and further develop our clinical, regulatory, and commercialization capabilities, including but not limited to, medical affairs, marketing, product reimbursement, sales, price reporting, pharmacovigilance, supply-chain, and distribution. These efforts require resources and time to either develop or acquire expertise in these areas and there is a risk that we are unsuccessful or we fail to comply with rules or regulations applicable to development or commercialization of our products. There is also a risk that we are delayed due to the need to develop these capabilities or due to a lack of resources. All of which would adversely affect our business and financial condition.

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 submission for approval, the 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 clinical trials are necessary to demonstrate the safety and efficacy of a product candidate,
- disagreement over the design or implementation of our clinical trials;
- our product candidates may exhibit an unacceptable safety signal at any stage of development;

- we, or the clinical research organizations ("CROs") or investigators that conduct clinical trials on our behalf, may fail 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.;
- we or third-party contractors manufacturing our product candidates may not maintain current good manufacturing practices ("cGMP"), successfully pass inspection or meet other applicable manufacturing regulatory requirements;
- regulatory authorities may require us to exclude the use of patient data from unreliable clinical trials, or may not agree with our interpretation of the data from our preclinical trials and clinical trials; or
- collaboration partners may not 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 jeopardize our or our collaboration partners' abilities to obtain regulatory approval for our product candidates in one or more indications.

The FDA or other regulatory authorities may require more information (including additional preclinical or clinical data to support approval), which may delay or prevent approval or cause us to abandon the development program altogether.

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. For example, while we have received approval of our marketing authorization applications for roxadustat in the European Union, Great Britain, China, Japan, and other countries for the treatment of anemia in CKD for patients who are on dialysis and not on dialysis, we received a CRL in CKD anemia in the U.S. from the FDA regarding roxadustat's NDA for the treatment of anemia due to CKD, stating that it could not be approved in its present form. In addition, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process or commercial uptake in other countries.

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.

The CRL we received from the FDA for roxadustat has decreased the likelihood of approval and successful commercialization of roxadustat in the U.S. and potentially other markets. There is a significant risk that our U.S./Rest of World Collaboration Agreement with AstraZeneca will be amended or terminated.

In August 2021, the FDA issued a CRL regarding roxadustat's NDA for the treatment of anemia due to CKD in adult patients, stating that it could not be approved in its present form. The CRL and the subsequent delay due to discussions with AstraZeneca have decreased the likelihood of approval and successful commercialization of roxadustat in the U.S. and therefore will decrease and/or delay expected revenue. While we continue to commercialize roxadustat in China with AstraZeneca, and develop roxadustat in the U.S. for the treatment of anemia in patients with MDS, we have not been able to agree on a path forward for AstraZeneca to fund further roxadustat development in the U.S. and there is a significant risk we will be unable to do so. There is also a significant risk that the AstraZeneca U.S./RoW Agreement will be amended or terminated. Any of these risks could have a material impact on our business, operating results, and financial condition.

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 of roxadustat or pamrevlumab 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, or clinical site initiation or retention problems associated with the Severe Acute Respiratory Syndrome Coronavirus 2 and the resulting Coronavirus Disease ("COVID-19") pandemic;
- 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;
- ability to enroll patients in clinical trials during the COVID-19 pandemic (particularly for IPF);
- 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. There have been other products, including erythropoiesis stimulating agents ("ESAs"), for which safety concerns have been uncovered following approval by regulatory authorities. Such safety concerns have led to labeling changes or withdrawal of ESAs products from the market. While roxadustat is chemically unique from ESAs, it or any of our product candidates may be subject to known or unknown risks. 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 are not able to obtain regulatory approval of roxadustat in the U.S. in CKD anemia, 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 all indications being studied (IPF, LAPC, metastatic pancreatic cancer, and DMD). 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, including delays in availability due to the COVID-19 pandemic;
- 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, including the COVID-19 pandemic, 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.

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, such as superiority or non-inferiority, in certain endpoints, populations or sub-populations, or using certain statistical methods of analysis, the FDA and European Medicines Agency ("EMA") will each conduct their own benefit-risk analysis and may reach different conclusions, using different statistical methods, different endpoints or definitions thereof, or different patient populations or sub-populations. Furthermore, while we may seek regulatory advice or agreement in key commercial markets prior to and after application for marketing authorization, regulatory authorities may change their approvability criteria based on the data, their internal analyses and external factors, including discussions with expert advisors. For example, while we have received approval of our marketing authorization applications for roxadustat in the European Union, Great Britain, China, Japan, and other countries for the treatment of anemia in CKD for patients who are on dialysis and not on dialysis, we received a CRL in CKD anemia in the U.S. from the FDA. 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. While we have and will present to regulatory authorities certain pre-specified and post hoc (not pre-specified) sub-populations, sub-group, and sensitivity analyses (for example, incident dialysis), multiple secondary endpoints, and multiple sets of stratification factors and analytical methods (such as long-term follow up analyses), including adjusted and censored data, regulatory authorities may reject these analyses, methods, or even parts of our trial design or certain data from our studies, the rationale for our pre-specified non-inferiority margins or other portions of our statistical analysis plans. 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.

Even if we are able to obtain regulatory approval of our product candidates, the label we obtain may limit the indicated uses for which our product candidates may be marketed.

With respect to roxadustat, regulatory approvals obtained could limit the approved indicated uses for which roxadustat may be marketed. For example, our label approved in Japan, includes the following warning: "Serious thromboembolism such as cerebral infarction, myocardial infarction, and pulmonary embolism may occur, possibly resulting in death, during treatment with roxadustat." Additionally, in the U.S., ESAs have been subject to significant safety warnings, including the boxed warnings on their labels. The safety concerns relating to ESAs may result in labeling for roxadustat containing similar warnings. Any label for roxadustat may contain other warnings or limit the market opportunity or approved indications for roxadustat. These warnings could include warnings against exceeding specified hemoglobin targets and other warnings that derive from the safety issues associated with ESAs, even if our Phase 3 clinical trials do not themselves raise safety concerns.

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 patents.

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, enrollment for clinical trials.

Refer to Item 1. "*Business - Competition*" in our Annual Report for a discussion of the specific companies that are on the market or in late-stage development with which we may compete.

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. For example, our current National Reimbursement Drug List reimbursement pricing for China is effective for a standard two-year period (between January 1, 2022 to December 31, 2023), after which time we will have to renegotiate a new price for roxadustat.

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 Astellas or AstraZeneca were to prioritize other initiatives over their collaborations with us, our ability to successfully develop and commercialize our product candidates would suffer.

We have entered into collaboration agreements with respect to the development and commercialization of our lead product candidate, roxadustat, with Astellas and AstraZeneca. These agreements provide for reimbursement of our development costs by our collaboration partners and also provide for commercialization of roxadustat throughout the major territories of the world.

Our agreements with Astellas and AstraZeneca provide each of them with the right to terminate their respective 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 respective 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 develop and commercialize roxadustat could suffer.

In 2021, we received a CRL for roxadustat for the treatment of anemia due to CKD in adult patients in the U.S. While we continue to co-commercialize roxadustat in China with AstraZeneca and develop roxadustat in the U.S. for the treatment of anemia in patients with MDS, we have not been able to agree on a potential path forward for AstraZeneca to fund further roxadustat development in the U.S. for CKD anemia and there is a significant risk we will be unable to do so. There is also a significant risk that the AstraZeneca U.S./RoW Agreement will be amended or terminated. Our collaborations are exclusive for roxadustat and preclude us from entering into additional collaboration agreements with other parties in those geographies and indications already licensed.

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.

Our collaboration partners also have certain rights to control decisions regarding the development and commercialization of our product candidates with respect to which they are providing funding. If we have a disagreement over strategy and activities with our collaboration partners, our plans for obtaining regulatory approval may be revised and negatively affect the anticipated timing and potential for success of our product candidates. Even if a product under a collaboration agreement receives regulatory approval, we will remain substantially dependent on the commercialization strategy and efforts of our collaboration partners, and our collaboration partners have limited or no experience in commercialization of an anemia drug. If our collaboration partners are unsuccessful in their commercialization efforts, our results will be negatively affected.

With respect to our collaboration agreements for roxadustat, there are additional complexities in that our collaboration partners, Astellas and AstraZeneca, and we must reach consensus on certain portions of our development programs and regulatory activities. In addition, there are aspects of commercial operations that require cooperation among the collaboration partners, including safety data reporting. Multi-party decision-making is complex and involves significant time and effort, and there can be no assurance that the parties will cooperate or reach consensus, or that one or both of our partners will not ask to proceed independently in some or all of their respective territories or functional areas of responsibility in which the applicable collaboration partner would otherwise be obligated to cooperate with us. Any disputes or lack of cooperation with us by either Astellas or AstraZeneca, or both, may negatively impact the timing or success of our regulatory approval applications.

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 takes 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, and could impact 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, dialysis centers 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 large pharmaceutical companies often have significantly more extensive agreements and relationships with such third-party providers, and such third-party providers may prioritize the requirements of such large pharmaceutical companies 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, and our current commercial manufacturing plants in China are not expected to satisfy the requirements necessary to support development and commercialization outside of China. Other than in and for China specifically, we do not expect to independently manufacture our products. We currently rely, and expect to continue to rely, on third parties to scale-up, manufacture and supply roxadustat and our other product candidates outside of China. 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; and
- 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, including disruption resulting from the COVID-19 pandemic, affecting our manufacturers, distributors or suppliers.

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 experience delays or technical problems associated with technology transfer, scale-up, or validation of our biologics manufacturing.

We have entered into an initial commercial supply agreement for the manufacture of pamrevlumab with Samsung Biologics Co., Ltd. ("Samsung") and are transitioning our manufacturing of pamrevlumab from Boehringer Ingelheim to Samsung. However, we may experience delays or technical problems associated with:

- technology transfer of the manufacturing process to Samsung;
- scale-up and production of cGMP batches;
- analytical method validation and transfer to Samsung;
- process validation, including process characterization and process performance qualification batches; and
- set up and execution of appropriate stability studies.

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 cease some of our pamrevlumab clinical trials. 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. 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.

We also carry the risk that if all three indications are successful, the commercial demand may exceed planned production supply at Samsung. In this event, it may be necessary to find third party manufacturers who have the capacity and capability to produce the required quantities of pamrevlumab. This may be subject to availability of such manufacturers since there are only a limited number of suppliers who have the larger scale bioreactors that are needed for commercial pamrevlumab supply. If we need to find a supplier in China, there may be additional delays in importing custom raw materials and supplements into China.

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.

We do not have an alternative supplier of certain components of our commercial products and product candidates. While we have obligations for second-source suppliers in our roxadustat collaboration agreements, we may be unable to enter into long-term commercial supply arrangements for some of our other products, or do so on commercially reasonable terms, which could have a material adverse impact upon our business. 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, active pharmaceutical ingredients ("API"), and drug product to meet our and our collaboration partners' needs to date, the lead-time and regulatory approvals required to source from and into countries outside of the U.S. increase the risk of delay and potential shortages of supply.

Risks Related to Our Intellectual Property

If our efforts to protect our proprietary 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 proprietary information or technology could compromise our competitive position. Moreover, we are, have been, and may in the future be involved in legal proceedings involving our intellectual property and initiated by third parties, 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, competitors with significantly greater resources could threaten our ability to commercialize our product candidates. Discoveries are generally published in the scientific literature well after their actual development, and patent applications in the U.S. and other countries are typically not published until 18 months after their filing, and in some cases are never published. Therefore, we cannot be certain that our licensors or we were the first to make the inventions claimed in our owned and licensed patents or patent applications, or that our licensors or we were the first to file for patent protection covering such inventions. Subject to meeting other requirements for patentability, for U.S. patent applications filed prior to March 16, 2013, the first to invent the claimed invention is entitled to receive patent protection for that invention while, outside the U.S., the first to file a patent application encompassing the invention is entitled to patent protection for the invention. The U.S. moved to a “first to file” system under the Leahy-Smith America Invents Act, effective March 16, 2013. This system also includes procedures for challenging issued patents and pending patent applications, which creates additional uncertainty. We have, are, and may again become involved in, opposition 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 or pamrevlumab. 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. For example, various challenges against our HIF anemia-related technologies patent portfolio are ongoing in several territories, including Europe, the United Kingdom, and Japan. Regardless of final outcome, the potential narrowing or revocation of any of the HIF anemia-related technology patents does not affect our exclusivity for roxadustat or our freedom-to-operate with respect to use of roxadustat for the treatment of anemia in these or other territories.

Oppositions were filed against European Patent No. 2872488 (the "`488 Patent"), which claims a crystalline form of roxadustat, and against European Patent No. 3003284 (the "`284 Patent"), which claims photostable formulations of roxadustat. Similar challenges have been filed in China against patents which claim a crystalline form of roxadustat. Final resolution of such proceedings will take time, and we cannot be assured that these patents will ultimately survive 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, 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 proliferation of counterfeit pharmaceuticals has grown in recent years and may continue to grow in the future. 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. For example, while we have received approval of our marketing authorization applications for roxadustat in the European Union, Great Britain, China, Japan, and other countries for the treatment of anemia in CKD for patients who are on dialysis and not on dialysis, we received a CRL for roxadustat in CKD anemia in the U.S. from the FDA. 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, 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, 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; 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 information, 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 United States, federal, state, and local governments have enacted numerous 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 other similar laws (e.g., wiretapping laws). For example, the California Consumer Privacy Act of 2018 ("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.

Other states, such as Virginia and Colorado, have also passed comprehensive data privacy and security laws, and similar laws are being considered in several other states, as well as at the federal and local levels. These developments may 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., an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK 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 impose strict requirements for processing personal data, including health-related information. For example, under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; 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 may be subject to new and emerging data privacy regimes in Asia, including China's Personal Information Protection Law, Japan's Act on the Protection of Personal Information, and Singapore's Personal Data Protection Act.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the U.S. or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the United Kingdom ("UK") have significantly restricted the transfer of personal data to the U.S. and other countries whose data privacy and security laws they believe are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. 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, 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 U.S. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the U.S., or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the U.S., are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, we are or may become contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other 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, such as compliance with certain certifications or self-regulatory principles, 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.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant 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.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. 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; 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 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.

Remediation 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 are implementing an enterprise resource planning ("ERP") system in the first quarter of 2023, which will replace our existing operating and financial systems, to improve the efficiency of certain financial and transactional processes. This ERP system may place additional burdens on employees to learn and adapt our processes to effectively operate under the ERP system, and potential risks during such implementation. 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 the 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 will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA of 2022 will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing U.S. Department of Health and Human Services to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. 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.

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 the differing impact of the COVID-19 pandemic on each region.

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 an independent registered public accounting firm that is not subject to inspection by the Public Company Accounting Oversight Board ("PCAOB"), which may negatively impact investor sentiment towards FibroGen or our China operations, which could adversely affect the market price of our common stock.

The majority of audit work incurred for the audit report included in the 2021 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 as a firm that the PCAOB was unable to inspect.

However, we estimate that between 30% and 40% of the total audit hours for our December 31, 2022 audit were provided by PricewaterhouseCoopers Zhong Tian LLP, which is headquartered in China. PricewaterhouseCoopers Zhong Tian LLP was identified in the report issued by the PCAOB on December 16, 2021 as a firm the PCAOB was unable to inspect.

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. As PricewaterhouseCoopers Zhong Tian LLP is located in China, a jurisdiction where the PCAOB has been unable to conduct inspections without the approval of the Chinese authorities, they are not currently subject to inspection. 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.

On December 29, 2022, the Accelerating Holding Foreign Companies Accountable Act (the "AHFCAA") was signed into law as part of a package of bills. The AHFCAA reduces the number of consecutive non-inspection years required for triggering the listing and trading prohibitions under the HFCA Act from three years to two years, thus reducing the time period before our securities may be prohibited from trading or delisted.

On December 16, 2021, the PCAOB issued a report on its determination that it is unable to inspect or investigate completely PCAOB-registered accounting firms headquartered in China and in Hong Kong. PricewaterhouseCoopers Zhong Tian LLP was named in this report.

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. The HFCAA does not apply to registrants that retain a principal accountant that is headquartered in the U.S. and subject to PCAOB inspection. Accordingly, the HFCAA does not currently apply to us.

On December 15, 2022, the PCAOB announced that it was able to conduct inspections and investigations completely of PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong in 2022. The PCAOB vacated its previous 2021 determinations accordingly. While vacating those determinations, 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.

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, including the potential delisting 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. We view the likelihood to be remote that our operations will fundamentally change so as to require our principal auditor to be located in China or Hong Kong. Additionally, it is possible 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. There are currently no such proposals.

Inspections of auditors conducted by the PCAOB in territories outside of China have at times identified deficiencies in those auditors' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections of audit work undertaken in China prevents the PCAOB from evaluating the effectiveness of such audits and such auditors' quality control procedures. The component of our audit that was performed by PricewaterhouseCoopers Zhong Tian LLP and the work papers associated with such audit work is not currently subject to inspection by the PCAOB. As a result, investors are deprived of the potential benefits of such PCAOB inspections for this portion of our audit, which could cause investors and potential investors in our common stock to lose confidence in the audit procedures conducted by our U.S. auditor's China-based subsidiary, which may negatively impact investor sentiment towards us or our China operations, which in turn could adversely affect the market price of our common stock.

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 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 will be obligated to comply with continuing cGMP requirements and 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, our product suppliers and 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 and 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 the Ex-China market. Natural disasters or other unanticipated catastrophic events, including power interruptions, water shortages, storms, fires, pandemics (including the COVID-19 pandemic), earthquakes, terrorist attacks, government appropriation of our facilities, and wars, could significantly impair our ability to operate our manufacturing facilities. Further, the climate of geopolitical tensions in China affecting global supply chains may impact our ability to continually meet market demand. 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. 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 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. Our current National Reimbursement Drug List reimbursement pricing is effective for a standard two-year period (between January 1, 2022 to December 31, 2023), after which time we will have to negotiate a new price for roxadustat. Sales of roxadustat in China may ultimately 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 for 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 is 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 do not currently rely on revenue from China to fund our operations outside of China. However, 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, 2022, approximately $71.2 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 COVID-19

Our business could continue to be adversely affected by the ongoing COVID-19 global pandemic.

The COVID-19 pandemic may continue to negatively impact our and/or our partners' sales of roxadustat, clinical programs and timelines, and general productivity, the magnitude of which will depend, in part, on the progression of the disease, the efficacy of various mitigation efforts, including vaccines and other therapeutics in preventing and treating current and future COVID-19 variants, and restrictions (including lockdowns) governments impose in response to new outbreaks of COVID-19 variants.

During the pandemic, we have seen impacts from COVID-19 on various parts of our operations and at varying degrees. Currently, the greatest risks from COVID-19 are regarding enrollment of our ZEPHYRUS-2 Phase 3 IPF trial and our sales and manufacturing operations in China. There is a risk that our sales, manufacturing, clinical trials and operations could be further affected by additional or continued COVID-19 outbreaks or lockdowns, which could slow or pause enrollment, site initiation, manufacturing or sales. In addition, while we are trying to mitigate the effect of COVID-19 on existing patients, it is possible that some patients may not be able to continue to comply with protocols, which could further delay our clinical trial progress.

We believe we have sufficient stock of roxadustat and pamrevlumab supplies for our near-term expected commercial and clinical requirements. However, we only have a limited stockpile of these products, and therefore, further outbreaks of COVID-19, lockdowns like the ones in China, disruptions in shipping, or product expiration due to slowed clinical trials, could create supply shortages in our global supply chains. COVID-19 has also created increased demand for the limited global biologics manufacturing capacity, and for manufacturing supplies, including vials, reagents, supplements and media. Any such supply disruptions could adversely impact our clinical development and ability to generate revenues from our approved products and our business, financial condition, results of operations and growth prospects could be materially adversely affected.

Due to these and potentially additional business disruptions, there may be delays to any of our business areas including those outlined above, as well as in regulatory, distribution, warehousing and other development, commercialization and launch efforts. In addition, COVID-19 presents an ongoing health risk to our employees, including members of senior management. Health risks and remote work could affect the productivity of our workforce. The full extent of these potential effects is unknown, but any of which could have a material impact on our business, operating results, and financial condition.

To the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "*Risk Factors*" section.

Risks Related to the Operation of Our Business

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

We are a biopharmaceutical company with two lead product candidates in clinical development, roxadustat for anemia in CKD, MDS, and chemotherapy-induced anemia, and pamrevlumab for IPF, pancreatic cancer, and DMD. 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, 2022, 2021 and 2020 were $293.7 million, $290.0 million and $189.3 million, respectively. As of December 31, 2022, we had an accumulated deficit of $1.6 billion. As of December 31, 2022, we had capital resources consisting of cash, cash equivalents and short-term investments of $422.0 million plus $4.3 million of long-term investments classified as available for sale securities. In addition, as of December 31, 2022, we had $16.3 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, expand 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 financings. 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 financing arrangement with an affiliate of NovaQuest Capital Management ("NovaQuest") that 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.

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

On November 4, 2022, we entered into a revenue interest financing agreement ("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, 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.

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

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

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

Our obligations under the RIFA 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;
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital; and
- if we fail to comply with the terms of the RIFA, resulting in an event of default that is not cured or waived, NovaQuest could seek to enforce their security interest in assets relating to roxadustat that secures such indebtedness.

To the extent we incur additional debt, the risks described above could increase.

Most of our recent revenue has been earned from collaboration partners for our product candidates under development.

If either or both of our Astellas and AstraZeneca collaborations were to be terminated, we could require significant additional capital in order to proceed with development and commercialization of our product candidates, including with respect to our potential commercialization of roxadustat for the treatment of anemia caused by CKD or MDS, or we may require additional partnering in order to help fund such development and commercialization. While we continue to commercialize roxadustat in China with AstraZeneca, and develop roxadustat in the U.S. for the treatment of anemia in patients with MDS, we have not been able to agree on a path forward for AstraZeneca to fund further roxadustat development in the U.S. for CKD anemia and there is a significant risk we will be unable to do so. There is also a significant risk that the AstraZeneca U.S./RoW Agreement will be amended or terminated. 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 our development or commercialization efforts or other operations.

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, including Enrique Conterno, our Chief Executive Officer. The loss of the services of Mr. Conterno or 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, particularly as we expand our commercialization operations. 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. 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 three 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 10, *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, 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 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. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

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

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

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

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps 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); 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 reveals 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, and has been affected by the COVID-19 pandemic, including economic disruption resulting from the related shelter-in-place and stay-at-home governmental orders.

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, such as the COVID-19 pandemic. 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.

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 10, *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 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, 2022, 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 10, *Commitments and Contingencies*, to the consolidated financial statements.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

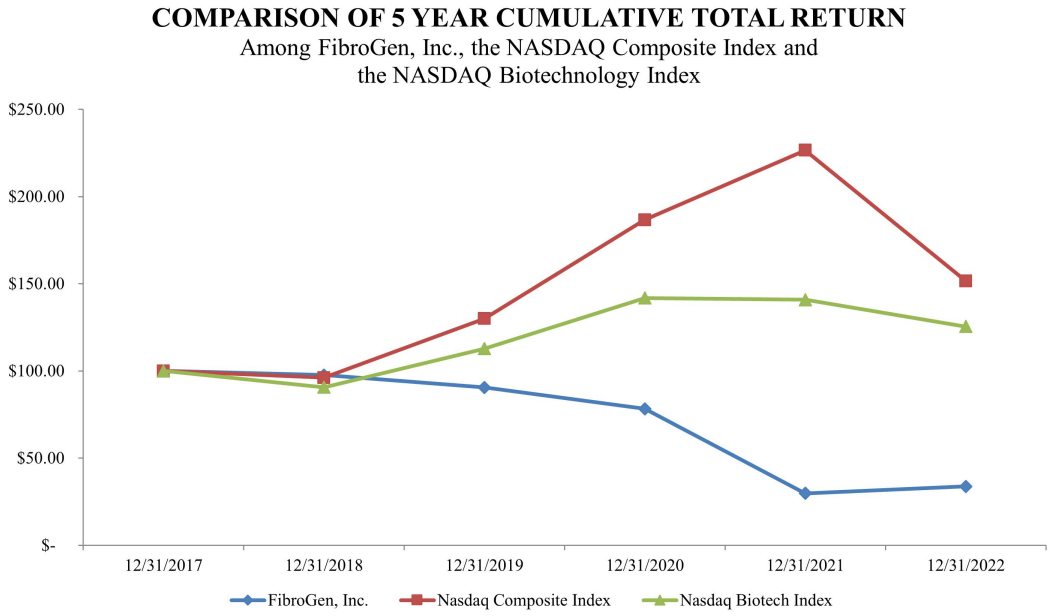
ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

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, 2017 to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes an initial investment of $100 on December 31, 2017, 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, 2023, there were 113 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, 2022 ("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 2022 and 2021 items and year-over-year comparisons between 2022 and 2021. Discussions of 2020 items and year-over-year comparisons between 2021 and 2020 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, 2021, filed with the SEC on February 28, 2022.

BUSINESS OVERVIEW

We are headquartered in San Francisco, California, with subsidiary offices in Beijing and Shanghai, People's Republic of China ("China"). We are a leading biopharmaceutical company discovering, developing and commercializing a pipeline of first-in-class therapeutics. We apply our pioneering expertise in hypoxia-inducible factor ("HIF") biology, 2-oxoglutarate enzymology, and connective tissue growth factor biology to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer.

We have a pipeline of late-stage clinical programs as well as preclinical drug candidates at various stages of development that include both small molecules and biologics. Our goal is to build a diversified pipeline with novel drugs that will address unmet patient needs in oncology, immunology, and fibrosis.

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, other markets in the Americas, Australia/New Zealand, and Southeast Asia.

Financial Highlights

	Years Ended December 31,		
	2022	2021	2020
	(in thousands, except for per share data)		
Result of Operations			
Revenue	$ 140,734	$ 235,309	$ 176,319
Operating costs and expenses	441,759	523,839	368,199
Net loss	(293,654)	(290,023)	(189,291)
Net loss per share - basic and diluted	$ (3.14)	$ (3.14)	$ (2.11)

	December 31, 2022	December 31, 2021
	(in thousands)	
Balance Sheet		
Cash and cash equivalents	$ 155,700	$ 171,223
Short-term and long-term investments	$ 270,656	$ 401,763
Accounts receivable	$ 16,299	$ 17,401

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 Beijing Falikang Pharmaceutical Co. Ltd. (“Falikang”); and
- $11.1 million of drug product revenue related to active pharmaceutical ingredient (“API”) deliveries to Astellas.

As comparison, our revenue for the year ended December 31, 2021 included the revenues recognized related to the following:

- $120.0 million regulatory milestones recognized under our collaboration agreement with Astellas associated with the approval by European Commission of EVRENZO® (roxadustat) for the treatment of adult patients with symptomatic anemia associated with CKD during the third quarter of 2021. Of this amount, $108.4 million was recognized as license revenue and the remainder included as development revenue;
- $70.3 million of development revenue recognized under our collaboration agreements with our partners Astellas and AstraZeneca;
- $47.6 million of net product revenue from roxadustat commercial sales in China, mostly from sales to Falikang; and
- $8.0 million upfront license payment recognized under our license agreement (defined below) with Eluminex Biosciences (Suzhou) Limited (“Eluminex”).

Operating costs and expenses decreased for the year ended December 31, 2022 compared to the prior year as a result of the net effect of the following:

- $60.0 million for acquired in-process research and development asset from HiFiBiO Therapeutics (“HiFiBiO”) in the prior year, which did not recur in the current year;
- $19.1 million lower employee-related expenses and $5.6 million lower stock-based compensation expenses primarily due to lower headcount as part of the cost reduction effort we started to implement in the second half of 2021 following the CRL for roxadustat in CKD anemia in the U.S., and payroll tax refunds received during the year ended December 31, 2022, partially offset by overall merit increase during the current year;
- $15.0 million lower clinical trial expenses associated with roxadustat post-approval safety studies and Phase 3 trials for pamrevlumab;
- $2.3 million lower outside services expenses due to lower promotional expenses and sample costs for roxadustat in China.
- $7.4 million higher cost of goods sold due to higher roxadustat product sales;
- $7.1 million higher drug development expenses associated with drug substance and drug product manufacturing activities primarily related to pamrevlumab; and
- $6.7 million higher legal expenses primarily due to a one-time favorable patent-related court ruling recorded in the prior year.

Our research and development expenses were $296.8 million, $387.0 million and $252.9 million for the years ended December 31, 2022, 2021 and 2020, respectively. Since inception and through December 31, 2022, we have incurred a total of approximately $2.9 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. As a result, operating expenses have decreased and may continue to decrease in certain areas over time.

The actual probability of success for each of our product candidates and clinical programs, and our ability to generate product revenue and become profitable, depends upon a variety of factors, including the quality of the product candidate, clinical results, investment in the program, competition, manufacturing capability, commercial viability, and our and our partners’ ability to successfully execute our development and commercialization plans. For a description of the numerous risks and uncertainties associated with product development, refer to the “*Risk Factors*” section of this Annual Report.

During the year ended December 31, 2022, we had a net loss of $293.7 million, or net loss per basic and diluted share of $3.14, as compared to a net loss of $290.0 million, or net loss per basic and diluted share of $3.14 for the prior year, primarily due to a decrease in revenues, almost entirely offset by a decrease in operating costs and expenses.

Cash and cash equivalents, investments and accounts receivable totaled $442.7 million at December 31, 2022, a decrease of $147.7 million from December 31, 2021, primarily due to cash used in operations and investment in our pre-clinical pipeline, partially offset by the proceeds received from sale of future revenues.

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 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.

During the third quarter of 2021, the $8.0 million upfront license payment was recognized as license revenue for the performance obligations satisfied. See the *Eluminex Agreements* section in Note 3, *Collaboration Agreements, License Agreement and Revenues*, to the consolidated financial statements for details.

Collaboration Partnerships for Roxadustat

Our current and future research, development, manufacturing and commercialization efforts with respect to roxadustat depend on funds from our collaboration agreements with Astellas and AstraZeneca. See Note 3, *Collaboration Agreements, License Agreement and Revenues*, to the 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, 2022 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 will allow Astellas to manufacture roxadustat drug product for commercialization in Japan (the “Astellas Japan Amendment”). The related drug product revenue was $9.5 million and $2.1 million for the years ended December 31, 2022 and 2021, respectively.

During the first quarter of 2021, we entered into an EU Supply Agreement with Astellas under the Astellas Europe Agreement to define general forecast, order, supply and payment terms for Astellas to purchase roxadustat bulk drug product from FibroGen in support of commercial supplies (the “Astellas EU Supply Agreement”). The related drug product revenue was $1.6 million and $1.1 million for the years ended December 31, 2022 and 2021, respectively.

In addition, as of December 31, 2022, Astellas had a separate investment of $80.5 million in the equity of FibroGen, Inc.

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 not previously licensed to Astellas (the "AstraZeneca U.S./RoW Agreement"), except China. In July 2013, through our China subsidiary and related affiliates, we entered into the China 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, 2022 totals $516.2 million.

Under the AstraZeneca China Agreement, which is conducted through FibroGen China Anemia Holdings, Ltd., FibroGen (China) Medical Technology Development Co., Ltd. ("FibroGen Beijing"), and FibroGen International (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 year ended December 31, 2022. The related drug product revenue was ($2.2) million for year ended December 31, 2021.

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 September 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 4, *Equity method investment - Variable Interest Entity*, to the consolidated financial statements for details.

Since Falikang became fully operational in January 2021, 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 an agreed upon transfer price, which includes gross transfer price, net of calculated profit share. AstraZeneca now 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 2028. 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, 2022 and 2021, we recognized $71.2 million and $35.6 million of net product revenue from the sales to Falikang, respectively, and $11.7 million and $12.1 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.

FibroGen, Inc. and AstraZeneca concurrently amended the AstraZeneca U.S./RoW Agreement to reflect minor changes in the governance structure under the AstraZeneca China Agreement.

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, 2022 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, 2022	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. While we continue to commercialize roxadustat in China with AstraZeneca, and develop roxadustat in the U.S. for the treatment of anemia in patients with myelodysplastic syndromes ("MDS"), we have not been able to agree on a path forward for AstraZeneca to fund further roxadustat development for CKD anemia in the U.S. Therefore, we do not expect to receive most or all of these potential AstraZeneca U.S./RoW Agreement milestones from AstraZeneca.

RESULTS OF OPERATIONS

Revenue

	Years Ended December 31,			Change 2022 vs. 2021	
	2022	2021	2020	$	%
			(dollars in thousands)		
Revenue:					
License revenue	$ 22,590	$ 116,434	$ 14,323	$ (93,844)	(81) %
Development and other revenue	24,189	70,275	80,592	(46,086)	(66) %
Product revenue, net	82,869	47,638	72,498	35,231	74 %
Drug product revenue	11,086	962	8,906	10,124	1,052 %
Total revenue	$ 140,734	$ 235,309	$ 176,319	$ (94,575)	(40) %

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 16%, 50% and 8% of total revenues for the years ended December 31, 2022, 2021 and 2020, 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, 2022, we expect the future development services to continue through 2024. 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 2028, which reflects our best estimates. Other revenues consist of contract manufacturing revenue and sales of research and development material and have not been material for any of the periods presented. Development and other revenues represented 17%, 30% and 46% of total revenues for the years ended December 31, 2022, 2021 and 2020, 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 59%, 20% and 41% of total revenue for the years ended December 31, 2022, 2021 and 2020, 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 launch in Japan and Europe. We recognize drug product revenue when we fulfill the inventory transfer obligations. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the drug product revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period when the uncertainty associated with the variable consideration is subsequently resolved. Actual amounts of consideration ultimately received in the future may differ from our estimates, for which we will adjust these estimates and affect the drug product revenue in the period such variances become known. Drug product revenues represented 8%, 0%, and 5% of total revenues for the years ended December 31, 2022, 2021 and 2020, 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. We expect that any revenues we generate will fluctuate from quarter to quarter due to the uncertain timing and amount of such payments and sales.

Total revenue decreased $94.6 million, or 40.0% for the year ended December 31, 2022 compared to the year ended December 31, 2021 for the reasons discussed in the sections below.

License Revenue

	Years Ended December 31,			Change 2022 vs. 2021	
	2022	2021	2020	$	%
			(dollars in thousands)		
License revenue:					
Astellas	$ 22,590	$ 108,434	$ 14,323	$ (85,844)	(79) %
Eluminex	—	8,000	—	(8,000)	(100) %
Total license revenue	$ 22,590	$ 116,434	$ 14,323	$ (93,844)	(81) %

License revenue decreased $93.8 million, or 81% for the year ended December 31, 2022 compared to the year ended December 31, 2021.

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.

License revenue recognized under our collaboration agreements with Astellas for the year ended December 31, 2021 represented the allocated revenue related to a total of $120.0 million regulatory milestones associated with the approval by European Commission of EVRENZO® (roxadustat) for the treatment of adult patients with symptomatic anemia associated with CKD during the third quarter of 2021.

License revenue recognized under our license agreement with Eluminex for the year ended December 31, 2021 represented the $8.0 million upfront license payment for the performance obligations satisfied.

Development and Other Revenue

	Years Ended December 31,			Change 2022 vs. 2021	
	2022	2021	2020	$	%
			(dollars in thousands)		
Development revenue:					
Astellas	$ 9,908	$ 21,927	$ 19,174	$ (12,019)	(55) %
AstraZeneca	12,519	48,345	61,418	(35,826)	(74) %
Total development revenue	22,427	70,272	80,592	(47,845)	(68) %
Other revenue	1,762	3	—	1,759	58,633 %
Total development and other revenue	$ 24,189	$ 70,275	$ 80,592	$ (46,086)	(66) %

Development and other revenue decreased $46.1 million, or 66% for the year ended December 31, 2022 compared to the year ended December 31, 2021.

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. Comparatively, development revenue recognized under our collaboration agreements with Astellas for the year ended December 31, 2021 included the allocated revenue of $11.6 million related to the above-mentioned $120.0 million associated with the approvals in EU achieved during the third quarter of 2021.

In addition, development revenue recognized under our collaboration agreements with Astellas decreased in co-development billings related to the development of roxadustat under our collaboration agreements with Astellas for the year ended December 31, 2022 as a result of the substantial completion of Phase 3 trials for roxadustat.

Development revenue recognized under our collaboration agreements with AstraZeneca for the year ended December 31, 2022 was impacted by the decrease in CKD-related co-development billings in the U.S.

Other revenue recognized for the year ended December 31, 2022 was primarily related to our contract manufacturing agreement with Eluminex, under which we are responsible for supplying the cornea product at 110% of our product manufacturing costs until our manufacturing technology is fully transferred to Eluminex.

Product Revenue, Net

	Years Ended December 31,			Change 2022 vs. 2021	
	2022	2021	2020	$	%
			(dollars in thousands)		
Direct Sales:					
Gross revenue	$ 12,366	$ 13,727	$ 89,027	$ (1,361)	(10) %
Price adjustment	242	(982)	—	1,224	(125) %
Non-key account hospital listing award	49	95	(9,325)	(46)	(48) %
Contractual sales rebate	(624)	(832)	(6,189)	208	(25) %
Other discounts and rebates	(332)	(21)	(923)	(311)	1,481 %
Sales returns	1	83	(92)	(82)	(99) %
Direct sales revenue, net	11,702	12,070	72,498	(368)	(3) %
Sales to Falikang:					
Gross transaction price	112,544	97,531	—	15,013	15 %
Profit share	(43,716)	(34,759)	—	(8,957)	26 %
Net transaction price	68,828	62,772	—	6,056	10 %
Decrease (increase) in deferred revenue	2,339	(27,204)	—	29,543	(109) %
Sales to Falikang revenue, net	71,167	35,568	—	35,599	100 %
Total product revenue, net	$ 82,869	$ 47,638	$ 72,498	$ 35,231	74 %

In January 2021, Falikang became fully operational and substantially all direct product sales to distributors in China were made by Falikang, while FibroGen Beijing continued to sell product directly in one province in China. Total product revenue, net increased $35.2 million, or 74% for the year ended December 31, 2022 compared to the year ended December 31, 2021.

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 decreased $0.4 million, or 3% for the year ended December 31, 2022 compared to the year ended December 31, 2021. The gross product revenue from direct sales to distributors decreased $1.4 million, or 10% for the year ended December 31, 2022 compared to the year ended December 31, 2021, primarily due to the lower National Reimbursement Drug List price effective in the first quarter of 2022 and unfavorable foreign currency translation rate of Renminbi against the U.S. dollar during the current year period, partially offset by an increase in sales volume.

The discounts and rebates primarily consisted of the contractual sales rebate that were calculated based on the stated percentage of gross sales by each distributor in the distribution agreement. The discounts and rebates for the year ended December 31, 2021 included $1.0 million of price adjustments recorded based on government-listed price guidance and estimated channel inventory levels. The remaining discounts and rebates were immaterial for the years ended December 31, 2022 and 2021 due to the transition from direct sales to sales to Falikang.

FibroGen Beijing manufactures and supplies commercial product to Falikang based on an agreed upon transfer price, which includes gross transfer price, net of calculated profit share. We recognize revenue upon the transfer of control of commercial products to Falikang in an amount that reflects the allocation of 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 $35.6 million, or 100% for the year ended December 31, 2022 compared to the year ended December 31, 2021. The gross transfer price increased $15.0 million and the calculated profit share increased $9.0 million for the year ended December 31, 2022 compared to the year ended December 31, 2021, respectively, primarily due to the increase in sales volume, offset by the lower National Reimbursement Drug List price effective in the first quarter of 2022, and unfavorable foreign currency translation rate of Renminbi against the U.S. dollar during the current year period.

Periodically, we update our assumptions such as total sales quantity, performance period and other inputs including foreign currency translation impact, among others. Following updates to our estimates, we recognized $2.3 million from the previously deferred revenue of the China performance obligation during the year ended December 31, 2022, and deferred $27.2 million from the net transaction price to Falikang, which we included in the related deferred revenue of the China performance obligation during the year ended December 31, 2021.

Drug Product Revenue

	Years Ended December 31,			Change 2022 vs. 2021	
	2022	2021	2020	$	%
			(dollars in thousands)		
Drug product revenue:					
Astellas Japan Agreement	$ 9,480	$ 2,056	$ 4,281	$ 7,424	361 %
Astellas Europe Agreement	1,606	1,130	—	476	42 %
AstraZeneca U.S./RoW Agreement	—	(2,224)	4,625	2,224	100 %
Total drug product revenue:	$ 11,086	$ 962	$ 8,906	$ 10,124	1,052 %

Drug product revenue increased $10.1 million, or 1,052% for the year ended December 31, 2022 compared to the year ended December 31, 2021.

Astellas Japan Agreement

During the year ended December 31, 2021, we updated our 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, 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. This amount was included in accrued liabilities and as of December 31, 2022, the related balance in accrued liabilities was $6.5 million, representing our best estimate that this amount will be paid within the next 12 months.

Astellas Europe Agreement

During the first quarter of 2021, we 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. We 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, 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 $8.3 million as deferred revenue as of December 31, 2021, due to a high degree of uncertainty associated with the final consideration.

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.

During the first quarter of 2022, we billed and received $49.2 million from Astellas related to the annual transfer price true up for bulk drug product transferred for commercial purposes. We recorded this amount in deferred revenue and netted it against an unbilled contract asset as of December 31, 2021. 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, representing our best estimate that this amount will be paid within the next 12 months.

In addition, we recognized royalty revenue of $0.6 million and $0.2 million as drug product revenue from the deferred revenue under the Astellas Europe Agreement for the years ended December 31, 2022 and 2021, 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

We shipped bulk drug product to AstraZeneca as commercial supply under the terms of the AstraZeneca Master Supply Agreement in 2020 and during the first half of 2021. Following the CRL for roxadustat in CKD anemia in the U.S. received in August 2021, we evaluated the impact of these developments in revising our estimates of variable consideration associated with drug product revenue. As a result, we updated the estimated transaction price for these shipments and recorded a reduction to drug product revenue of $(2.2) million for the year ended December 31, 2021, and recorded $11.2 million as deferred revenue as of December 31, 2021.

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. As of December 31, 2022, the related balance in accrued liabilities was $11.2 million, representing our best estimate that this amount will be paid within the next 12 months.

Operating Costs and Expenses

	Years Ended December 31,			Change 2022 vs. 2021	
	2022	2021	2020	$	%
			(dollars in thousands)		
Operating costs and expenses					
Cost of goods sold	$ 20,280	$ 12,871	$ 8,869	$ 7,409	58 %
Research and development	296,791	387,043	252,924	(90,252)	(23) %
Selling, general and administrative	124,688	123,925	106,406	763	1 %
Total operating costs and expenses	$ 441,759	$ 523,839	$ 368,199	$ (82,080)	(16) %

Total operating expenses decreased $82.1 million, or 16%, for the year ended December 31, 2022 compared to the year ended December 31, 2021, for the reasons discussed in the sections below.

Cost of goods sold

Cost of goods sold increased $7.4 million, or 58%, for the year ended December 31, 2022 compared to the year ended December 31, 2021.

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 $15.1 million for the year ended December 31, 2022, as compared to $9.3 million for the year ended December 31, 2021, an increase of $5.8 million, resulting from the increase in the sales volume, partially offset by improved unit cost efficiency primarily due to higher production volume.

Cost of goods sold associated with the roxadustat drug product revenue in the U.S. was $3.8 million and $3.6 million for the years ended December 31, 2022 and 2021, respectively, associated with the costs of API or bulk drug product delivered to Astellas and AstraZeneca in the respective periods. We expect costs of goods sold to increase in relation to drug product revenue as we deplete inventories that we had expensed prior to receiving regulatory approvals.

Cost of goods sold for the year ended December 31, 2022 also included manufacturing costs $1.4 million 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. Following the CRL for roxadustat in CKD anemia in the U.S., we have implemented a cost reduction effort and, 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, 2022, 2021 and 2020:

Product Candidate	Phase of Development	Years Ended December 31, 2022	2021		2020
			(in thousands)		
Pamrevlumab	Phase 2/3	$ 198,764	$ 188,534		$ 111,728
Roxadustat	Phase 3	46,469	97,245		122,962
Other research and development expenses		51,558	101,264	*	18,234
Total research and development expenses		$ 296,791	$ 387,043		$ 252,924

* 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 $90.3 million, or 23%, for the year ended December 31, 2022 compared to the year ended December 31, 2021 as a result of the net effect of the following:

- Decrease of $60.0 million for acquired in-process research and development asset from HiFiBiO, which incurred in the prior year;
- Decrease of $16.4 million in employee-related costs and decrease of $5.7 million in stock-based compensation expenses primarily due to lower headcount as part of the cost reduction effort we started to implement in the second half of 2021 following the CRL for roxadustat in CKD anemia in the U.S., and payroll tax refunds received during the year ended December 31, 2022, partially offset by overall merit increase during the current year;
- Decrease of $15.0 million in clinical trials costs, primarily due to Phase 3 trials for pamrevlumab and CKD studies for roxadustat reaching to their completion; and
- Increase of $7.1 million in drug development expenses associated with drug substance and drug product manufacturing activities primarily related to pamrevlumab.

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. Following the CRL for roxadustat in CKD anemia in the U.S., we have implemented a cost reduction effort and, as a result, SG&A expenses have decreased in certain areas and may continue to decrease over time.

SG&A expenses remained relatively flat for the year ended December 31, 2022 compared to the year ended December 31, 2021, as a result of the net effect of the following:

- Decrease of $2.7 million in employee-related costs primarily due to payroll tax refunds received during the year ended December 31, 2022, lower headcount in the general and administrative functions as part of the cost reduction effort we started to implement in the second half of 2021, partially offset by overall merit increase during the current year;
- Decrease of $2.3 million in outside services expenses due to lower promotional expenses and sample costs for roxadustat in China; and
- Increase of $6.7 million in legal expenses primarily due to a one-time favorable patent-related court ruling recorded in the prior year.

Interest and Other, Net

	Years Ended December 31,			Change 2022 vs. 2021	
	2022	2021	2020	$	%
	(dollars in thousands)				
Interest and other, net:					
Interest expense	$ (1,440)	$ (1,075)	$ (2,402)	$ (365)	34 %
Interest income and other income (expenses), net	7,596	(1,078)	5,553	8,674	805 %
Total interest and other, net	$ 6,156	$ (2,153)	$ 3,151	$ 8,309	386 %

Interest Expense

Interest expense relates to our finance lease liabilities accretion primarily for our leased facilities in San Francisco and China. Interest expense also includes interest related to the Technology Development Center of the Republic of Finland product development obligations.

Interest expense increased $0.4 million, or 34% for the year ended December 31, 2022 compared to the year ended December 31, 2021, primarily due to the $1.0 million interest expense related to sale of future revenues under the revenue interest financing agreement ("RIFA") with an affiliate of NovaQuest Capital Management ("NovaQuest"). See Note 8, *Liability Related to Sale of Future Revenues*, to the consolidated financial statements for details. The increase was partially offset by the decrease due to the lease modification and renewal in 2021 being classified as operating leases, as compared to finance leases previously.

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 $8.7 million, for the year ended December 31, 2022 compared to the year ended December 31, 2021, primarily due to an impact of $7.9 million resulting from a reduction to other expenses recorded during the second quarter of 2022 to release the previously estimated late payment fees related to value added tax in China, upon the receipt of a written evidence from China's State Taxation Administration, which confirmed the transfer of certain intellectual property rights in 2020 relating to our Chinese business between our wholly owned subsidiaries is exempted from value added tax. In addition, the interest income from our investments was higher for the year ended December 31, 2022 compared to the year ended December 31, 2021 due to higher average investment balances and higher interest rate during the current year.

Provision for Income Taxes

	Years Ended December 31,		
	2022	2021	2020
	(dollars in thousands)		
Loss before income taxes	$ (294,869)	$ (290,683)	$ (188,729)
Provision for income taxes	358	347	360
Effective tax rate	(0.1) %	(0.1) %	(0.2) %

The provisions for income taxes for the years ended December 31, 2022 and 2020 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.

During 2020, we transferred certain intellectual property rights relating to our Chinese business between our wholly owned subsidiaries that are based in different tax jurisdictions. The transferor entity was not subject to income taxes in its local jurisdiction. The acquiring entity of the intellectual property is entitled to amortize the acquisition price of the intangible assets for tax purposes. In accordance with ASU 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory*, we recognized a deferred tax asset of $78.7 million for the temporary difference arising from the acquirer's excess tax basis. Furthermore, based upon the weight of available evidence, we recognized a full valuation allowance against this deferred tax asset since it does not currently believe that realization of this gross deductible temporary difference is more likely than not. Accordingly, this inter-company transfer did not have a material impact to our consolidated financial statements.

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, and was immaterial for the years ended December 31, 2022 and 2021. See Note 4, *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) and from the execution of collaboration agreements involving license payments, milestones and reimbursement for development services.

As of December 31, 2022, we had cash and cash equivalents of $155.7 million, compared to $171.2 million as of December 31, 2021. 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, 2022, we had short-term investments of $266.3 million and long-term investments of $4.3 million, respectively, compared to $234.0 million and $167.8 million, respectively, as of December 31, 2021. As of December 31, 2022, a total of $92.5 million of our cash and cash equivalents was held outside of the U.S. in our foreign subsidiaries, including $71.2 million held in China, to be used primarily for our China operations.

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, we received $49.8 million from NovaQuest, representing the gross proceeds of $50.0 million net of initial issuance costs, in consideration for a portion of future revenues we will receive from Astellas. For additional details about this financing transaction, see Note 8, *Liability Related to Sale of Future Revenues*, to the consolidated financial statements.

Cash flows from Falikang, a distribution joint venture between FibroGen Beijing and AstraZeneca, and cash flows into FibroGen Beijing, are currently intended to remain onshore in China. 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. To date, no such debt repayments have occurred, nor have there been any other payments or distributions from FibroGen Beijing to entities or investors outside of China. 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, 2022, 2021 and 2020 (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Net cash provided by (used in):			
Operating activities	$ (145,933)	$ (82,232)	$ 81,602
Investing activities	89,116	(426,972)	452,487
Financing activities	46,776	(563)	13,343
Effect of exchange rate changes on cash and cash equivalents	(5,482)	2,597	4,695
Net increase (decrease) in cash and cash equivalents	$ (15,523)	$ (507,170)	$ 552,127

Operating Activities

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. See the *Drug Product Revenue* section in Note 3, *Collaboration Agreements, License Agreement and Revenues*, to the consolidated financial statements for details. 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. See the *Drug Product Revenue* section in Note 3, *Collaboration Agreements, License Agreement and Revenues*, to the consolidated financial statements for details.

Net cash used in operating activities was $82.2 million for the year ended December 31, 2021 and consisted primarily of net loss of $290.0 million adjusted for non-cash items and non-operating activities of $147.7 million and a net increase in operating assets and liabilities of $60.1 million. The significant non-cash items included stock-based compensation expense of $71.2 million, expense for acquired in-process research and development asset from HiFiBiO of $60.0 million, depreciation expense of $10.2 million, and amortization of finance lease ROU of $4.6 million. The significant items in the changes in operating assets and liabilities included the increases resulting from the following:

- Deferred revenue of $57.6 million, primarily related to the above-mentioned $25.9 million and $11.2 million of the deferred considerations of the bulk drug product shipped to Astellas and AstraZeneca, respectively, due to a high degree of uncertainty associated with the final consideration, and $27.2 million of the deferred revenue from the sales to Falikang associated with the China performance obligation. The change in deferred revenue was also driven by the extension of the estimated future non-contingent development period and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca;
- Accounts receivable of $25.2 million, primarily driven by the timing of the receipt of upfront payments and the recognition of revenues under our collaboration agreements with Astellas and AstraZeneca;
- Accrued and other liabilities of $16.4 million, primarily driven by $14.2 million increase in co-promotion expenses at December 31, 2021 that is anticipated to be paid within the next 12 months, offset by $12.0 million decrease in contract liabilities to pharmaceutical distributors at December 31, 2021 due to settlement during the year. The accrued and other liabilities were also impacted by the timing of invoicing and payment;

The increases were partially offset by the decreases resulting from the following:

- Inventories of $14.2 million, driven by the increased inventory level primarily related to FibroGen Beijing's productions of roxadustat for commercial sales purposes and inventory capitalized in the U.S.;
- Other long-term liabilities of $12.1 million, primarily due to the decrease in the co-promotional expenses with AstraZeneca for its sales and marketing efforts related to the commercial launch of roxadustat in China that are not expected to be paid in the next year;
- Prepaid expenses and other current assets of $9.9 million, primarily due to the unbilled upfront license payment from Eluminex of $8.0 million, and prepayments made for roxadustat API manufacturing activities; and
- Other assets of $4.4 million, primarily related to the increases in various licenses.

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 $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.

Net cash used in investing activities was $427.0 million for the year ended December 31, 2021 and consisted primarily of $484.1 million of cash used in purchases of available-for-sale securities, $25.0 million of cash paid for the acquired in-process research and development asset and $5.2 million of cash used in purchases of property and equipment, partially offset by $83.1 million of proceeds from maturities of investments and $4.2 million of proceeds from sales of available-for-sale securities.

Financing Activities

Financing activities primarily reflect proceeds from strategic financing arrangement, 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 $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 Employee Share Purchase Plan ("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.

Net cash used in financing activities was $0.6 million for the year ended December 31, 2021 and consisted primarily of $7.4 million of cash paid for payroll taxes on restricted stock unit releases, and $5.5 million of repayments of finance lease liabilities, partially offset by $12.7 million of proceeds from the issuance of common stock upon exercise of stock options and purchases under our ESPP.

Material Cash Requirements

We started generating revenue from commercial sales of roxadustat product in China in the third quarter of 2019. Even with the expectation of increases in revenue from product sales, we anticipate that we will continue to generate losses for the foreseeable future. Following the CRL for roxadustat in CKD anemia in the U.S., we have implemented a cost reduction effort, and as a result, operating expenses have decreased and may continue to decrease in certain areas over time compared to our previous internal plans. To date, we have funded certain portions of our research and development and manufacturing efforts globally through collaboration partners and capital investment. There is no guarantee that sufficient funds will be available to continue to fund these development efforts through commercialization or otherwise. Although AstraZeneca is currently funding all non-China collaboration expenses not reimbursed by Astellas, including development of MDS in the U.S., we expect our operating costs and expenses to increase as we invest in commercialization of pamrevlumab and development of our other programs. Additionally, we have not been able to agree on a path forward for AstraZeneca to fund further roxadustat development in the U.S. for CKD anemia. 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 unknown factors that may adversely affect our business, such as the COVID-19 pandemic or other factors outlined under Part I, Item 1A "*Risk Factors*" in this Annual Report. 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 and long-term investments and accounts receivable, together with the financing amount under the RIFA received in November 2022, 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 could turn out to be wrong, or may change over time, and we could utilize our available financial resources sooner than we currently expect. 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 development and commercialization prospects and could otherwise negatively impact our business.

Commitments and Contingencies

Contractual Obligations

At December 31, 2022, 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	$ 103,741	$ 13,959	$ 89,782
Purchase obligations	53,755	27,909	25,846
Liability related to sale of future revenues	125,000	—	125,000
Total payments	$ 282,496	$ 41,868	$ 240,628

Our lease liabilities are primarily related to our real estate leases for office spaces in the U.S. and China. See Note 6, *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 10, *Commitments and Contingencies*, to the consolidated financial statements for details.

Under the RIFA with NovaQuest, as of December 31, 2022, we had $49.3 million of liability related to sale of future revenues on the consolidated balance sheets. Based on our current estimates of drug product revenue and revenue from milestone payments under the Astellas Agreements, and taking into the consideration of the terms under the RIFA, we anticipate to reach a payment cap up to $125.0 million by 2031. See Note 8, *Liability Related to Sale of Future Revenues*, to the 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, 2022, 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 $72.8 million that are disclosed in Note 13, *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, 2022, 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, 2022, our FibroGen Europe Oy (“FibroGen Europe”) subsidiary had $10.1 million of principal outstanding and $6.8 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 9, *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, 2022, 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 and Adopted Accounting Guidance

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations are based on our 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 its collaboration arrangements was 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 4, *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:
    - Gross transaction price: The gross transaction price is based on a percentage of Falikang's net sales to its distributors, which takes into account Falikang's operating expenses and its payments to AstraZeneca for roxadustat sales and marketing efforts, capped at a percentage of Falikang's net roxadustat sales.
    - Profit share: The gross transaction price is then adjusted for an estimated amount to achieve the 50/50 profit share from current period roxadustat net sales in China. The adjustments to date have been a reduction to the transaction price and the related accounts receivable from Falikang.

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

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 the following estimates of variable consideration:

- Price adjustment: When China's National Healthcare Security Administration releases price guidance for roxadustat under the National Reimbursement Drug List, any channel inventories that have not been sold through by distributors, or to patients by hospitals and retailers, would be eligible for a price adjustment under the price protection. The price adjustment is calculated based on estimated channel inventory levels;
- Contractual sales rebate: The contractual sales rebate is calculated based on the stated percentage of gross sales by each distributor in the distribution agreement entered between FibroGen and each distributor. The contractual sales rebate is recorded as a reduction to revenue at the point of sale to the distributor;

- Non-key account hospital listing award: A one-time fixed-amount award is offered to a distributor who successfully lists the product with an eligible hospital, and who meets certain requirements. For the year ended December 31, 2020, the non-key account hospital listing award was capitalized when the distributor meets eligibility requirements, and amortized as reduction to product revenue over future sales orders made by the distributor until exhausted. For the year ended December 31, 2021, the non-key account hospital listing award was immaterial and recorded as a reduction to revenue when distributor meets eligibility requirements;
- Other discounts and rebates, including key account hospital sales rebate and transfer fee discount, are generally based on a percentage of eligible gross sales made by the distributor and recorded as a reduction to revenue at the point of sale to the distributor; and
- Sales returns: 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 above 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 above 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 the distributor's legal right to offset, at each balance sheet date, we present the liability for rebates and discounts as reductions of 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 launch in Japan and Europe. We recognize drug product revenue when we fulfill the inventory transfer obligations.

The amount of variable consideration that is included in the transaction price may be constrained, and 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, 2022, 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, 2022. Given the nature of our investments as of December 31, 2022, 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, 2022 and 2021, 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, 2022, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 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, 2022, 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 $71.2 million for the year ended December 31, 2022. 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 27, 2023

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

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

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 155,700	$ 171,223
Short-term investments	266,308	233,967
Accounts receivable, net ($12,088 and $10,930 from related parties)	16,299	17,401
Inventories	40,436	31,015
Prepaid expenses and other current assets	14,083	20,453
Total current assets	492,826	474,059
Restricted time deposits	2,072	2,072
Long-term investments	4,348	167,796
Property and equipment, net	20,605	28,277
Equity method investment in unconsolidated variable interest entity	5,061	3,825
Operating lease right-of-use assets	79,893	91,112
Other assets	5,282	6,680
Total assets	$ 610,087	$ 773,821
Liabilities, stockholders' equity (deficit) and non-controlling interests		
Current liabilities:		
Accounts payable	$ 30,758	$ 26,097
Accrued and other current liabilities ($63,886 and $4 to a related party)	219,773	172,599
Deferred revenue ($9,259 and $3,201 to related parties)	12,739	15,857
Operating lease liabilities, current	10,292	10,944
Total current liabilities	273,562	225,497
Product development obligations	16,917	17,613
Deferred revenue, net of current ($31,044 and $25,891 to a related party)	185,722	186,801
Operating lease liabilities, non-current	79,593	88,776
Liability related to sale of future revenues, non-current	49,333	—
Other long-term liabilities	6,440	26,021
Total liabilities	611,567	544,708
Commitments and Contingencies (Note 10)		
Stockholders' equity (deficit):		
Preferred stock, $0.01 par value; 125,000 shares authorized; no shares issued and outstanding at December 31, 2022 and 2021	—	—
Common stock, $0.01 par value; 225,000 shares authorized at December 31, 2022 and 2021; 94,166 and 92,881 shares issued and outstanding at December 31, 2022 and 2021	942	929
Additional paid-in capital	1,541,019	1,476,414
Accumulated other comprehensive loss	(5,720)	(4,163)
Accumulated deficit	(1,557,688)	(1,264,034)
Total stockholders' equity (deficit)	(21,447)	209,146
Non-controlling interests	19,967	19,967
Total equity (deficit)	(1,480)	229,113
Total liabilities, stockholders' equity (deficit) and non-controlling interests	$ 610,087	$ 773,821

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,		
	2022	**2021**	**2020**
Revenue:			
License revenue (includes $22,590, $108,434 and $14,323 from a related party)	$ 22,590	$ 116,434	$ 14,323
Development and other revenue (includes $9,908, $21,928 and $19,174 from a related party)	24,189	70,275	80,592
Product revenue, net (includes $71,167, $35,568 and $0 from a related party)	82,869	47,638	72,498
Drug product revenue (includes $11,086, $3,186 and $4,281 from a related party)	11,086	962	8,906
Total revenue	140,734	235,309	176,319
Operating costs and expenses:			
Cost of goods sold	20,280	12,871	8,869
Research and development	296,791	387,043	252,924
Selling, general and administrative	124,688	123,925	106,406
Total operating costs and expenses	441,759	523,839	368,199
Loss from operations	(301,025)	(288,530)	(191,880)
Interest and other, net			
Interest expense	(1,440)	(1,075)	(2,402)
Interest income and other income (expenses), net	7,596	(1,078)	5,553
Total interest and other, net	6,156	(2,153)	3,151
Loss before income taxes	(294,869)	(290,683)	(188,729)
Provision for income taxes	358	347	360
Investment income (loss) in unconsolidated variable interest entity	1,573	1,007	(202)
Net loss	$ (293,654)	$ (290,023)	$ (189,291)
Net loss per share - basic and diluted	$ (3.14)	$ (3.14)	$ (2.11)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	93,582	92,349	89,854

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,		
	2022	2021	2020
Net loss	$ (293,654)	$ (290,023)	$ (189,291)
Other comprehensive income (loss):			
Foreign currency translation adjustments	75	1,235	(3,207)
Available-for-sale investments:			
Unrealized gain (loss) on investments, net of tax effect	(1,632)	(899)	(545)
Other comprehensive gain (loss), net of taxes	(1,557)	336	(3,752)
Comprehensive loss	$ (295,211)	$ (289,687)	$ (193,043)

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	
	Shares	Amount	Capital	Loss	Deficit	Interests	Total
Balance at December 31, 2019	87,657,489	$ 877	$ 1,300,725	$ (747)	$ (784,720)	$ 19,271	$ 535,406
Net loss	—	—	—	—	(189,291)	—	(189,291)
Change in unrealized gain or loss on investments	—	—	—	(545)	—	—	(545)
Foreign currency translation adjustments	—	—	—	(3,207)	—	—	(3,207)
Shares issued from stock plans, net of payroll taxes paid	3,783,144	37	26,329	—	—	—	26,366
Stock-based compensation	—	—	72,720	—	—	—	72,720
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 11)	—	—	—	—	—	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)

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,		
	2022	2021	2020
Operating activities			
Net loss	$ (293,654)	$ (290,023)	$ (189,291)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation	10,017	10,170	11,678
Amortization of finance lease right-of-use assets	587	4,639	10,369
Net accretion of premium and discount on investments	1,619	2,482	103
Unrealized loss on equity investments	—	30	—
Investment income in unconsolidated variable interest entity	(1,573)	(1,007)	202
(Gain) / loss on disposal of property and equipment	(1)	233	933
Stock-based compensation	65,601	71,161	72,720
Expense for acquired in-process research and development asset	—	60,000	—
Non-cash interest expense related to sale of future revenues	1,036	—	—
Realized loss on sales of available-for-sale securities	5	—	258
Changes in operating assets and liabilities:			
Accounts receivable, net ($(1,158), $(6,803) and $718 from related parties)	765	25,180	(11,973)
Inventories	(10,999)	(14,158)	(9,175)
Prepaid expenses and other current assets ($0, $889 and $124,321 from a related party)	4,916	(9,854)	123,492
Operating lease right-of-use assets	10,908	4,209	(24)
Other assets	263	(4,412)	5,843
Accounts payable ($0, $(1,118) and $1,118 from a related party)	5,909	805	17,731
Accrued and other liabilities ($63,882, $(20) and $(36,859) from a related party)	90,556	16,380	30,914
Operating lease liabilities, current	(547)	503	134
Deferred revenue ($11,211, $21,549 and $7,169 from related parties)	(4,130)	57,637	45,077
Accrued interest for finance lease liabilities	33	(75)	(177)
Operating lease liabilities, non-current	(8,994)	(4,043)	(143)
Other long-term liabilities	(18,250)	(12,089)	(27,069)
Net cash provided by (used in) operating activities	(145,933)	(82,232)	81,602
Investing activities			
Purchases of property and equipment	(3,741)	(5,186)	(3,994)
Payment made for acquired in-process research and development asset	(35,000)	(25,000)	—
Payment made for investment in unconsolidated variable interest entity	—	—	(3,896)
Proceeds from equity transfer of unconsolidated variable interest entity	—	—	1,063
Proceeds from sale of property and equipment	6	—	—
Purchases of available-for-sale securities	(164,023)	(484,144)	(8,192)
Proceeds from sales of available-for-sale securities	7,382	4,214	10,606
Proceeds from maturities of investments	284,492	83,144	456,900
Net cash provided by (used in) investing activities	89,116	(426,972)	452,487
Financing activities			
Repayments of finance lease liabilities	(135)	(5,489)	(12,620)
Repayments of lease obligations	(403)	(403)	(403)
Cash paid for payroll taxes on restricted stock unit releases	(5,167)	(7,372)	(11,463)
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	4,184	12,701	37,829
Net cash provided by (used in) financing activities	46,776	(563)	13,343
Effect of exchange rate change on cash and cash equivalents	(5,482)	2,597	4,695
Net increase (decrease) in cash and cash equivalents	(15,523)	(507,170)	552,127
Total cash and cash equivalents at beginning of period	171,223	678,393	126,266
Total cash and cash equivalents at end of period	$ 155,700	$ 171,223	$ 678,393
Supplemental cash flow information:			
Interest payments	$ 104	$ 94	$ 135
Balance in accounts payable and accrued liabilities related to purchases of property and equipment	428	1,009	884
Balance in accrued liabilities related to acquired in-process research and development asset	—	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. The 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 a leading biopharmaceutical company developing and commercializing a pipeline of first-in-class therapeutics. The Company applies its pioneering expertise in hypoxia-inducible factor (“HIF”) biology, 2-oxoglutarate enzymology, and connective tissue growth factor to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer.

Pamrevlumab, a human monoclonal antibody targeting connective tissue growth factor, is in Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis, locally advanced unresectable pancreatic cancer and Duchenne muscular dystrophy. 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 Phase 3 clinical development for: anemia associated with myelodysplastic syndromes, in the U.S. and Europe, and chemotherapy-induced anemia in China.

The Company has a pipeline of late-stage clinical programs as well as preclinical drug candidates at various stages of development that include both small molecules and biologics. FibroGen’s goal is to build a diversified pipeline with novel drugs that will address unmet patient needs in oncology, immunology, and fibrosis.

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, FibroGen Europe and FibroGen China Anemia Holdings, Ltd. (“FibroGen Cayman”). All inter-company transactions and balances have been eliminated in consolidation. For any variable interest entity (“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 discovery, development and commercialization of novel therapeutics to treat serious unmet medical needs.

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no impact on previously reported financial position, results of operations, or cash flows.

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, 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,	
	2022	2021
Falikang — Related party	65%	—%
Astellas — Related party	9%	63%
AstraZeneca	16%	34%

As of December 31, 2022, the aggregate accounts receivable related to roxadustat sales in China from distributors represented 10% of the consolidated accounts receivable, with no material balance from any individual distributor. As of December 31, 2021, the accounts receivable related to roxadustat sales in China from Beijing Falikang Pharmaceutical Co., Ltd. (“Falikang”) and direct sales to distributors were not material.

Other Risks and Uncertainties

The Company’s future results of operations involve a number of risks and uncertainties. Factors that could affect the Company’s future operating results and cause actual results to vary materially from expectations include, but are not limited to, the results of clinical trials and the achievement of milestones, research developments, actions by regulatory authorities, market acceptance of the Company’s product candidates, competition from other products and larger companies, the liquidity and capital resources of the Company, intellectual property protection for the Company's proprietary technology, strategic relationships, and dependence on key individuals, suppliers, clinical organization, and other third parties.

Cash, Cash Equivalents 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. 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 $2.1 million at each of December 31, 2022 and 2021. As of December 31, 2022 and 2021, a total of $92.5 million and $91.2 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.

Investments

As of December 31, 2022, 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. Marketable equity securities are equity securities with readily determinable fair value, and are measured and recorded at fair value. 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, 2022, 2021 and 2020 and the allowance for doubtful accounts as of December 31, 2022 and 2021 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.

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, none of the Company's long-lived assets were impaired. The Company had no impairment of long-lived assets for the years ended December 31, 2022 and 2021. The Company's impairment of long-lived assets for the year ended December 31, 2020 was immaterial.

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 8, *Liability Related to Sale of Future Revenues*. The difference between the carrying amount of the initial liability and the gross proceeds received is accounted for as a discount. The Company recognizes interest expense based on an estimated effective annual interest rate, which is affected by the amount and timing of revenues recognized and changes in the timing of forecasted revenues. Quarterly, the Company reassesses the expected revenues and the timing of such revenues, recalculates the amortization and effective interest rate and adjusts the accounting prospectively as needed.

Revenue Recognition

Revenues under collaboration agreements

The Company's collaboration agreements include multiple performance obligations comprised of promised services, or bundles of services, that are distinct. Services that are not distinct are combined with other services in the agreement until they form a distinct bundle of services. The Company's process for identifying performance obligations and an enumeration of each obligation for each agreement is outlined in Note 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 4, *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:
    - Gross transaction price: The gross transaction price is based on a percentage of Falikang's net sales to its distributors, which takes into account Falikang's operating expenses and its payments to AstraZeneca for roxadustat sales and marketing efforts, capped at a percentage of Falikang's net roxadustat sales.
    - Profit share: The gross transaction price is then adjusted for an estimated amount to achieve the 50/50 profit share from current period roxadustat net sales in China. The adjustments to date have been a reduction to the transaction price and the related accounts receivable from Falikang.

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

Any net transaction price in excess of the revenue recognized is deferred, and will be recognized over future periods as the performance obligations are satisfied.

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 the following estimates of variable consideration:

- Price adjustment: When China's National Healthcare Security Administration releases price guidance for roxadustat under the National Reimbursement Drug List, any channel inventories that have not been sold through by distributors, or to patients by hospitals and retailers, would be eligible for a price adjustment under the price protection. The price adjustment is calculated based on estimated channel inventory levels;
- Contractual sales rebate: The contractual sales rebate is calculated based on the stated percentage of gross sales by each distributor in the distribution agreement entered between FibroGen and each distributor. The contractual sales rebate is recorded as a reduction to revenue at the point of sale to the distributor;
- Non-key account hospital listing award: A one-time fixed-amount award is offered to a distributor who successfully lists the product with an eligible hospital, and who meets certain requirements. For the year ended December 31, 2020, the non-key account hospital listing award was capitalized when the distributor meets eligibility requirements, and amortized as reduction to product revenue over future sales orders made by the distributor until exhausted. For the years ended December 31, 2022 and 2021, the non-key account hospital listing award was immaterial and recorded as a reduction to revenue when distributor meets eligibility requirements;

- Other discounts and rebates, including key account hospital sales rebate and transfer fee discount, are generally based on a percentage of eligible gross sales made by the distributor and recorded as a reduction to revenue at the point of sale to the distributor; and
- Sales returns: Distributors 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 above 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 above 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 distributor's legal right to offset, at each balance sheet date, the liability for rebates and discounts are presented as reductions of 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 distributor's legal right of offset is calculated at the individual distributor level.

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 launch 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 up to a total of an additional $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. We expect to file INDs on product candidates for both the CCR8 and Galectin-9 programs in 2023.

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, 2022, all programs were at the early stage of development and 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.

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.

During 2020, the Company transferred certain intellectual property rights relating to its Chinese business between its wholly owned subsidiaries that are based in different tax jurisdictions. See Note 13, *Income Taxes*, for more information. The establishment of a deferred tax asset from the intra-entity transfer of intangible assets required the Company to make significant estimates and assumptions to determine the fair value of intellectual property rights transferred, which include but are not limited to, its expectations of discount rate, revenue volume and price. The accuracy of these estimates could be affected by unforeseen events or actual results, and the sustainability of the Company’s future tax benefits is dependent upon the acceptance of these valuation estimates and assumptions by the taxing authorities.

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 and Adopted Accounting Guidance

In March 2020, the Financial Accounting Standards Board ("FASB") issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting* ("*ASU 2020-04*"), which provides companies with optional financial reporting alternatives to reduce the cost and complexity associated with the accounting for contracts and hedging relationships affected by reference rate reform. Subsequently in January 2021, the FASB issued ASU 2021-01, *Reference Rate Reform (Topic 848): Scope*, which clarifies ASU 2020-04 and provides certain optional expedients that allow derivative instruments impacted by changes in the interest rate used for margining, discounting or contract price alignment to qualify for certain optional relief. ASU 2021-01 is effective in the same timeframe as ASU2020-04. The Company did not elect to apply any of the expedients or exceptions as of and for the years ended December 31, 2022 and 2021. In December 2022, the FASB issued ASU 2022-06, *Reference Rate Reform (Topic 848): Deferral of the Sunset Date of Topic 848*, which deferred the sunset date in Topic 848 from December 31, 2022 to December 31, 2024. The Company has certain lease arrangements that were accounted for with reference to the London Inter-Bank Offered Rate ("LIBOR"). The Company has evaluated the options for transitioning away from LIBOR for these arrangements and concluded that there is no material impact on its consolidated financial statements and related disclosures affected by reference rate reform.

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.

During the fourth quarter of 2020, the Japanese Ministry of Health, Labour and Welfare approved EVRENZO® (roxadustat) for the treatment of anemia of CKD in adult patients not on dialysis. This approval triggered a $15.0 million milestone payable to the Company by Astellas under the Astellas Japan Agreement. Accordingly, the consideration of $15.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the Astellas Japan Agreement in the fourth quarter of 2020, substantially all of which was recognized as revenue during the year ended December 31, 2020 from performance obligations satisfied or partially satisfied.

The aggregate amount of the considerations received under the Astellas Japan Agreement, through December 31, 2022 totals $105.1 million excluding drug product revenue that is discussed under the *Drug Product Revenue* section below.

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 launch 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* 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, 2022 totals $685.0 million, excluding drug product revenue that is discussed under the *Drug Product Revenue* section below.

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* 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, 2022, 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 $12.1 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 $219.2 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. In the Astellas Japan Agreement, Astellas does not have the right to manufacture commercial supplies of the drug. In order to determine whether this characteristic of the agreement should lead to a conclusion that the license was not distinct in the context of the agreement, the Company considered the ability of Astellas to benefit from the license together with other resources readily available to Astellas. 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 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.

Manufacturing rights. In the case of the Astellas Japan Agreement, the Company retained manufacturing rights largely because of the way the parties chose for FibroGen to be compensated under the agreement. At the time the agreement was signed, the Company believed that it was more advantageous upon commercialization to have a transfer price revenue model in place as opposed to a traditional sales-based model. The manufacturing process does not require specialized knowledge or expertise uniquely held by FibroGen, and notwithstanding contractual restrictions, Astellas could employ manufacturing services from readily available third parties in order to benefit from the license. Therefore, along with the foregoing paragraph, the Company determined that the license in Japan is a distinct performance obligation despite the retention of manufacturing rights by the Company.

In summary, the Company concludes that item (1) represents a 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* 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, 2022, 2021 and 2020 (in thousands):

		Years Ended December 31,		
Agreement	**Performance Obligation**	**2022**	**2021**	**2020**
Astellas Japan Agreement	License revenue	$ —	$ —	$ 14,323
	Development revenue	$ 284	$ 248	$ 1,220

The transaction price related to consideration received through December 31, 2022 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	**Cumulative Revenue Through December 31, 2022**	**Deferred Revenue at December 31, 2022**	**Total Consideration Through December 31, 2022**
License	$ 100,347	$ —	$ 100,347
Development revenue	16,882	—	16,882
Total license and development revenue	$ 117,229	$ —	$ 117,229

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, 2022. The Company does not expect material variable consideration from estimated future co-development billing beyond the development period in the transaction price related to the Astellas Japan Agreement.

Amounts recognized as license revenue and development revenue under the Astellas Europe Agreement were as follows for the years ended December 31, 2022, 2021 and 2020 (in thousands):

		Years Ended December 31,		
Agreement	**Performance Obligation**	**2022**	**2021**	**2020**
Astellas Europe Agreement	License revenue	$ 22,590	$ 108,434	$ —
	Development revenue	$ 9,624	$ 21,679	$ 17,954

The transaction price related to consideration received through December 31, 2022 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	**Cumulative Revenue Through December 31, 2022**	**Deferred Revenue at December 31, 2022**	**Total Consideration Through December 31, 2022**
License	$ 618,975	$ —	$ 618,975
Development revenue	280,265	—	280,265
Total license and development revenue	$ 899,240	$ —	$ 899,240

The license revenue and development revenue recognized under the Astellas Europe Agreement for the year ended December 31, 2022 included an increase in revenue of $25.0 million relating to performance obligations satisfied during the year. The remainder of the transaction price related to the Astellas Europe Agreement includes $5.0 million of variable consideration from estimated future co-development billing and is expected to be recognized over the remaining development service period.

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"). 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 will 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. AstraZeneca will pay the Company tiered royalty payments on AstraZeneca's future net sales (as defined in the agreement) of roxadustat in the low 20% range. In addition, the Company will receive a transfer price for shipment of commercial product based on a percentage of AstraZeneca's net sales (as defined in the agreement) in the low- to mid-single digit range.

The aggregate amount of the considerations received under the AstraZeneca U.S./RoW Agreement through December 31, 2022 totals $439.0 million, excluding drug product revenue that is discussed under the *Drug Product Revenue* 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* 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 discussed below in the third quarter of 2020, 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, 2022 totals $77.2 million.

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 September 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, the interim period is defined as the period from April 1, 2020 to the time when Falikang is fully operational. Falikang became fully operational in January 2021. The calculation for profit or loss share related to sales of roxadustat in China has changed for the period from April 1, 2020 onwards. With effect from April 1, 2020, the Parties have changed the method under which commercial expenses incurred by AstraZeneca are calculated and billed. AstraZeneca's co-promotion expenses for their sales and marketing efforts are now 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.

As a result, the interim period during the year ended December 31, 2020 primarily included the following activities:

- Co-promotion expenses: The AstraZeneca China Amendment revised the payment arrangements and calculation of the historical unpaid co-promotion expenses to AstraZeneca for its sales and marketing efforts associated with the commercial sales for roxadustat in China since the product launch. Under the AstraZeneca China Amendment, a portion of the historical unpaid co-promotion expenses was adjusted to reduce the amount owed by FibroGen Beijing and the current period co-promotion expenses are capped at a percentage of net roxadustat sales in China. As a result, in the third quarter of 2020, the Company reversed approximately $84.4 million of previously accrued co-promotion expenses payable, which was recorded as a reduction to selling, general and administrative expenses, where these expenses were initially recorded during the periods from the initiation of commercial activities in the first quarter of 2019 to the second quarter of 2020. The co-promotion expenses for the years ended December 31, 2022, 2021 and 2020, capped at a percentage of net roxadustat sales in China, were $4.4 million, $4.7 million and $27.2 million, respectively, included in the selling, general and administrative expenses.
- Profit share: 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 the third and fourth quarter of 2020. As a result, the Company recorded a profit share liability of $7.3 million and $7.9 million to AstraZeneca as of December 31, 2022 and 2021, respectively, in the accrued and other current liabilities, which correspondingly reduced the deferred revenue related to the performance obligation in accordance with the AstraZeneca China Agreement.

Since Falikang became fully operational in January 2021, 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, which is adjusted for the estimated profit share. In addition, AstraZeneca now 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 2028. 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, 2022, 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, $114.0 million of variable consideration related to payments for milestones considered probable of being achieved, $610.5 million of variable consideration related to co-development billings, offset by $7.3 million of variable consideration related to 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* 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, once Falikang is fully operational, which commenced in January 2021, 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, 2022, 2021 and 2020 (in thousands):

		Years Ended December 31,		
Agreement	**Performance Obligation**	**2022**	**2021**	**2020**
AstraZeneca U.S./RoW Agreement and AstraZeneca China Agreement	License revenue	$ —	$ —	$ —
	Development revenue	12,519	48,345	61,508
	China performance obligation	$ —	$ —	$ (90)

The transaction price related to consideration received through December 31, 2022 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, 2022**	**Deferred Revenue at December 31, 2022**		**Total Consideration Through December 31, 2022**
License	$ 341,844	$ —		$ 341,844
Co-development, information sharing & committee services	615,639	—		615,639
China performance obligation *	106,734	175,646		282,380
Total license and development revenue	$ 1,064,217	$ 175,646	**	$ 1,239,863

* 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, 2022, deferred revenue included $158.2 million related to the AstraZeneca U.S./RoW and the AstraZeneca China Agreement, which represents the net of $175.6 million of deferred revenue presented above and a $17.5 million unbilled 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, 2022. The remainder of the transaction price related to the AstraZeneca U.S./RoW Agreement and the AstraZeneca China Agreement includes $9.6 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 2028, which reflects our best estimates.

Product Revenue, Net

Product revenue, net from the sales of roxadustat commercial product in China was as follows for the years ended December 31, 2022, 2021 and 2020 (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Direct Sales:			
Gross revenue	$ 12,366	$ 13,727	89,027
Price adjustment	242	(982)	—
Non-key account hospital listing award	49	95	(9,325)
Contractual sales rebate	(624)	(832)	(6,189)
Other discounts and rebates	(332)	(21)	(923)
Sales returns	1	83	(92)
Direct sales revenue, net	11,702	12,070	72,498
Sales to Falikang:			
Gross transaction price	112,544	97,531	—
Profit share	(43,716)	(34,759)	—
Net transaction price	68,828	62,772	—
Decrease (increase) in deferred revenue	2,339	(27,204)	—
Sales to Falikang revenue, net	71,167	35,568	—
Total product revenue, net	$ 82,869	$ 47,638	$ 72,498

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 total discounts and rebates were $0.7 million, $1.7 million and $16.4 million for the years ended December 31, 2022, 2021 and 2020, respectively. The discounts and rebates consisted of 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. The contractual sales rebate was $0.6 million, $0.8 million and $6.2 million, for the years ended December 31, 2022, 2021 and 2020, respectively. The discounts and rebates for the year ended December 31, 2021 also consisted of $1.0 million of price adjustments recorded based on government-listed price guidance and estimated channel inventory levels. In the second quarter of 2020, the Company amended the agreement with its pharmaceutical distributors, which triggered accounting modifications particularly related to the non-key account hospital listing award. As a result, for the year ended December 31, 2020, the non-key account hospital listing award was $9.3 million, which was recorded as a reduction to the revenue and calculated based on eligible non-key account hospital listings to date achieved by each distributor with certain requirements met during the period. All other rebates and discounts, including sales return allowance were immaterial for the periods presented.

The rebates and discounts that the Company's pharmaceutical distributors have earned are eligible to be applied against future sales orders, 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 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 calculated at the individual distributor level. The following table includes a roll-forward of the related contract liabilities (in thousands):

	Balance at December 31, 2021	Additions	Deduction	Currency Translation and Other	Balance at December 31, 2022
Product revenue - Direct sales - contract liabilities	$ (3,176)	$ (653)	$ 3,222	$ 217	$ (390)

The above contract liabilities were included in accrued and other current liabilities in the consolidated balance sheet. As of December 31, 2022 and 2021, the total rebates and discounts reflected as reductions to gross accounts receivable for direct sales was $0.9 and $1.1 million, respectively.

Sales to Falikang – China Performance Obligation

Since Falikang became fully operational in January 2021, 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, which is adjusted to account for the 50/50 profit share for the period.

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 over future periods as the performance obligations are satisfied.

Periodically, the Company updates its assumptions such as total sales quantity, performance period and other inputs including foreign currency translation impact, among others. 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 product revenue recognized for the year ended December 31, 2022 included an increase in revenue of $1.4 million resulting from changes to estimated variable consideration in the current period relating to performance obligations satisfied in previous periods.

Comparatively, following updates to its estimates, the Company deferred $27.2 million from the net transaction price to Falikang, which was included in the related deferred revenue of the China performance obligation during the year ended December 31, 2021.

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, 2021	Additions	Recognized as Revenue	Currency Translation and Other	Balance at December 31, 2022
Product revenue - AstraZeneca China performance obligation - deferred revenue	$ (171,516)	$ (77,195)	$ 71,167	$ 1,898	$ (175,646)

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, 2022, approximately $21.0 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 $0.5 million and $13.4 million as of December 31, 2022 and 2021, respectively.

Drug Product Revenue

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, 2022, 2021 and 2020 (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Astellas Japan Agreement	$ 9,480	$ 2,056	$ 4,281
Astellas Europe Agreement	1,606	1,130	—
AstraZeneca U.S./RoW Agreement	—	(2,224)	4,625
Drug product revenue	$ 11,086	$ 962	$ 8,906

Astellas Japan Agreement

During the year ended December 31, 2020, the Company fulfilled shipment obligations under the terms of Astellas Japan Amendment with Astellas, and recognized related drug product revenue of $8.2 million in the same period. During the year ended December 31, 2020, the Company updated its estimate of variable consideration related to the API shipments fulfilled under the terms of the Astellas Japan Amendment, and accordingly recorded a reduction of $4.0 million to the drug product revenue. Specifically, the change in estimated variable consideration was based on the API held by Astellas at the 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 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. This amount was included in accrued liabilities and as of December 31, 2022, the related balance in accrued liabilities was $6.5 million, representing the Company’s best estimate that this amount will be paid within the next 12 months.

Astellas Europe Agreement

During the fourth quarter of 2020, the Company transferred bulk drug product from process validation supplies for commercial purposes under the terms of the Astellas Europe Agreement. As a result, the Company recorded $6.0 million as deferred revenue as of December 31, 2020, due to a high degree of uncertainty associated with the final consideration.

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.

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. 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. As of December 31, 2022, the related balance in accrued liabilities was $57.4 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 $0.6 million and $0.2 million as drug product revenue from the deferred revenue under the Astellas Europe Agreement during the years ended December 31, 2022 and 2021, 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

During the first half of 2021 and during the year ended December 31, 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 and $4.6 million for the years ended December 31, 2021 and 2020, respectively.

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. As of December 31, 2022, the related balance in accrued liabilities was $11.2 million, representing its best estimate that this amount will be paid within the next 12 months.

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, 2021	Additions	Recognized as Revenue	Reclassified to Accrued Liability / Accounts Payable	Balance at December 31, 2022
Astellas Japan Agreement	$ (1,974)	$ (2,226)	$ —	$ 4,200	$ —
Astellas Europe Agreement	(25,891)	(72,408)	619	57,377	(40,303)
AstraZeneca U.S./RoW Agreement	(11,171)	—	—	11,171	—
Drug product revenue - deferred revenue	$ (39,036)	$ (74,634)	$ 619	$ 72,748	$ (40,303)

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 on January 21, 2022, Eluminex made an $8.0 million upfront payment to FibroGen during the first quarter of 2022, which was recognized as license revenue for the performance obligation satisfied and included in license revenue in the consolidated statement of operations during the year ended December 31, 2021.

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 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.

During the first quarter of 2022, FibroGen and Eluminex entered into a separate contract manufacturing agreement, under which the Company is responsible for supplying the cornea product at cost plus 10% of its product manufacturing costs until its manufacturing technology is fully transferred to Eluminex. 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, 2022 and 2021 (in thousands):

		Years Ended December 31,	
Agreement	**Performance Obligation**	**2022**	**2021**
Eluminex	License revenue	$ —	$ 8,000
	Other revenue - contract manufacturing	$ 1,761	$ —

4. 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. Falikang has not incurred material profit or loss to date. 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.

The Company's equity method investment in Falikang was as follows for the year ended December 31, 2022 (in thousands):

Entity	Ownership Percentage	Balance at December 31, 2021	Share of Net Income	Currency Translation	Balance at December 31, 2022
Falikang	51.1%	$ 3,825	$ 1,573	$ (337)	$ 5,061

Falikang is considered as a related party to the Company. See Note 14, *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.

The Company assessed 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.

5. 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, 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

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Money market funds	$ 58,801	$ —	$ —	$ 58,801
Corporate bonds	—	182,646	—	182,646
Commercial paper	—	69,079	—	69,079
U.S. government bonds	91,522	—	—	91,522
Agency bonds	—	23,275	—	23,275
Asset-backed securities	—	27,087	—	27,087
Foreign government bonds	—	9,154	—	9,154
Total	$ 150,323	$ 311,241	$ —	$ 461,564

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 year ended December 31, 2022, the transfers of assets between levels was a total of $10.5 million transfer from Level 1 to Level 2 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 years ended December 31, 2021 and 2020.

6. 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 2025. 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, scientific devices and automobile leases, with contracted lease terms ranging from one to five 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, 2022	December 31, 2021
Assets			
Finance:			
Right-of-use assets cost		$ 2,367	$ 2,165
Accumulated amortization		(1,932)	(1,404)
Finance lease right-of-use assets, net	Other assets	435	761
Operating:			
Right-of-use assets cost		101,990	100,912
Accumulated amortization		(22,097)	(9,800)
Operating lease right-of-use assets, net	Operating lease right-of-use assets	79,893	91,112
Total lease assets		$ 80,328	$ 91,873
Liabilities			
Current:			
Finance lease liabilities	Accrued and other current liabilities	$ 36	$ 11
Operating lease liabilities	Operating lease liabilities, current	10,292	10,944
Non-current:			
Finance lease liabilities	Other long-term liabilities	137	3
Operating lease liabilities	Operating lease liabilities, non-current	79,593	88,776
Total lease liabilities		$ 90,058	$ 99,734

The components of lease expense were as follows (in thousands):

	Statement of Operations Line Item	Years Ended December 31, 2022	2021	2020
Finance lease cost:				
Amortization of right-of-use assets	Cost of goods sold; Research and development; Selling, general and administrative expenses	$ 587	$ 4,639	$ 10,369
Interest on lease liabilities	Interest expense	—	628	1,932
Operating lease cost	Cost of goods sold; Research and development; Selling, general and administrative expenses	17,125	10,722	1,151
Sublease income	Selling, general and administrative expenses	(3,373)	(1,271)	(1,201)
Total lease cost		$ 14,339	$ 14,718	$ 12,251

Supplemental cash flow information related to leases were as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 15,497	$ 10,022	$ 951
Operating cash flows from finance leases	2	629	1,896
Financing cash flows from finance leases	135	5,489	12,620
Non-cash: Right-of-use assets obtained in exchange for new lease liabilities:			
Finance leases	261	450	662
Operating leases	1,704	3,585	1,072
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,	
	2022	2021
Weighted-average remaining lease term (years):		
Finance leases	4.9	1.1
Operating leases	5.8	6.8
Weighted-average discount rate:		
Finance leases	6.20%	4.64%
Operating leases	4.75%	4.75%

Maturities of lease liabilities as of December 31, 2022 are as follows (in thousands):

Year Ending December 31,	Finance Leases	Operating Leases
2023	$ 44	$ 13,915
2024	41	17,302
2025	40	18,448
2026	39	18,000
2027	36	18,476
Beyond 2027	—	17,400
Total future lease payments	200	103,541
Less: Interest	(27)	(13,656)
Present value of lease liabilities	$ 173	$ 89,885

7. Balance Sheet Components

Cash and Cash Equivalents

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

	December 31,	
	2022	2021
Cash	$ 135,819	$ 111,422
Commercial paper	—	1,000
Money market funds	19,881	58,801
Total cash and cash equivalents	$ 155,700	$ 171,223

At December 31, 2022 and 2021, a total of $92.5 million and $91.2 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, 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

	December 31, 2021			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Corporate bonds	$ 183,136	$ 2	$ (492)	$ 182,646
Commercial paper	68,079	—	—	68,079
U.S. government bonds	91,840	—	(318)	91,522
Agency bonds	23,339	—	(64)	23,275
Asset-backed securities	27,105	—	(18)	27,087
Foreign government bonds	9,165	—	(11)	9,154
Total investments	$ 402,664	$ 2	$ (903)	$ 401,763

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, 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)

	December 31, 2021					
	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	$ 177,124	$ (492)	$ —	$ —	$ 177,124	$ (492)
U.S. government bonds	91,522	(318)	—	—	91,522	(318)
Agency bonds	23,274	(64)	—	—	23,274	(64)
Asset-backed securities	27,087	(18)	—	—	27,087	(18)
Foreign government bonds	9,155	(11)	—	—	9,155	(11)
Total	$ 328,162	$ (903)	$ —	$ —	$ 328,162	$ (903)

The contractual maturities of the available-for-sale investments were as follows (in thousands):

	December 31, 2022	
	Amortized Cost	Estimated Fair Value
Within one year - Bond and mutual funds	$ 268,709	$ 266,308
After one year through three years	4,480	4,348
Total investments	$ 273,189	$ 270,656

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, 2022, the Company did not recognize any other-than-temporary impairment loss.

Inventories

Inventories consisted of the following (in thousands):

	December 31,	
	2022	2021
Raw materials	$ 1,241	$ 1,363
Work-in-progress	36,003	21,499
Finished goods	3,192	8,153
Total inventories	$ 40,436	$ 31,015

The provision to write-down excess and obsolete inventory were immaterial as of December 31, 2022 and December 31, 2021.

Prepaid expenses and other current assets

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

	December 31,	
	2022	2021
Contract assets	$ 17,488	$ 66,909
Deferred revenues from associated contracts	(17,488)	(58,909)
Net unbilled contract assets	—	8,000
Prepaid assets	9,730	7,383
Other current assets	4,353	5,070
Total prepaid expenses and other current assets	$ 14,083	$ 20,453

The unbilled contract assets of $17.5 million as of December 31, 2022 was related to unbilled co-development revenue under the AstraZeneca China Amendment. The unbilled contract assets as of December 31, 2021 included $49.8 million related to transfer price true up for bulk drug product under the Astellas Europe Agreement, $9.1 million related to unbilled co-development revenue under the AstraZeneca China Amendment, and the $8.0 million unbilled upfront license payment under the Eluminex Agreement. See the *Eluminex Agreements* section in Note 3, *Collaboration Agreements, License Agreement and Revenues*, for details.

Property and Equipment

Property and equipment consisted of the following (in thousands):

	December 31,	
	2022	2021
Leasehold improvements	$ 102,580	$ 103,352
Laboratory equipment	21,175	19,300
Machinery	9,642	8,339
Computer equipment	9,486	9,670
Furniture and fixtures	6,200	6,201
Construction in progress	204	2,423
Total property and equipment	$ 149,287	$ 149,285
Less: accumulated depreciation	(128,682)	(121,008)
Property and equipment, net	$ 20,605	$ 28,277

Depreciation expense for the years ended December 31, 2022, 2021 and 2020 was $10.0 million, $10.2 million and $11.7 million, respectively.

Accrued and Other Current Liabilities

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

	December 31,	
	2022	2021
Preclinical and clinical trial accruals	$ 57,780	$ 56,283
API and bulk drug product price true-up	75,055	—
Acquired in-process research and development asset	—	35,000
Payroll and related accruals	22,562	20,909
Accrued co-promotion expenses - current	36,677	25,746
Contract liabilities to pharmaceutical distributors	390	3,176
Roxadustat profit share to AstraZeneca	7,280	7,895
Property taxes and other taxes	7,691	12,610
Professional services	5,480	6,074
Other	6,858	4,906
Total accrued and other current liabilities	$ 219,773	$ 172,599

The accrued liabilities of $75.1 million for API and bulk drug product price true-up as of December 31, 2022 resulted from changes in estimated variable consideration of $6.5 million associated with the API shipments fulfilled under the terms of the Astellas Japan Amendment, $57.4 million associated with the bulk drug product transferred under the terms of the Astellas Europe Agreement and the Astellas EU Supply Agreement, and $11.2 million associated with the bulk drug product shipments to AstraZeneca under the terms of the AstraZeneca Master Supply Agreement. See the *Drug Product Revenue* section in Note 3, *Collaboration Agreements, License Agreement and Revenues*, for details.

The acquired IPR&D asset of $35.0 million as of December 31, 2021 was related to the upfront payment to HiFiBiO under the HiFiBiO Agreement. See Note 2, *Summary of Significant Accounting Policies - License Acquisition Agreement*, for details.

8. 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. The Company has evaluated the terms of the RIFA and concluded that the Investment Amount should be accounted for as debt because the risks and rewards to NovaQuest are limited by the terms of the transaction.

Under the terms of the Astellas Agreements, the Company is entitled to drug product revenue and milestone payments upon occurrence of certain events. See the *Astellas Agreements* section in Note 3, *Collaboration Agreements, License Agreement and Revenue*, for details.

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. 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 this transaction as long-term debt as of December 31, 2022.

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 is 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 ("True-Up Payment One"). 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.

The payments to NovaQuest will be accounted for as a reduction of debt. The total debt discount and transaction costs of $1.7 million, will be 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 19.67% for the year ended December 31, 2022. Over the course of the RIFA, the effective interest rate will be 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 will reassess the expected total revenue and the timing of such revenue, recalculate the amortization of debt discount and transactions costs and effective interest rate, and adjust the accounting prospectively as needed.

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.

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, and drug product revenue of $11.1 million. See Note 3, *Collaboration Agreements, License Agreement and Revenue*, for details. During the year ended December 31, 2022, the Company recognized the related non-cash interest expense of $1.0 million.

The table below shows the activity of the liability related to sale of future revenues for the year ended December 31, 2022:

	Year Ended December 31, 2022
Liability related to sale of future revenues - beginning balance	$ —
Proceeds from sale of future revenues, gross	50,000
Less: Initial issuance costs	(250)
Less: Transaction costs	(1,453)
Interest expense recognized	1,036
Liability related to sale of future revenues - ending balance	49,333
Less: Current portion classified within accrued and other current liabilities	—
Liability related to sale of future revenues, non-current	$ 49,333

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.

9. 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, 2022 and 2021, the Company had U.S. Dollar equivalent of $10.1 million and $10.7 million of principal outstanding, respectively, and $6.8 million and $6.9 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.

10. Commitments and Contingencies

Contract Obligations

As of December 31, 2022, the Company had the following outstanding non-cancelable purchase obligations (in thousands):

	Purchase Obligations Due In The Year Ending December 31,		
	2023	2024	Total
Manufacture and supply of pamrevlumab	$ 85	$ 22,310	$ 22,395
Manufacture and supply of roxadustat	6,126	2,369	8,495
Other purchases and programs	21,698	1,167	22,865
Total	$ 27,909	$ 25,846	$ 53,755

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 6, *Leases*, for details of the Company's operating and finance lease payment obligations. See Note 8, *Liability Related to Sale of Future Revenues*, and Note 9, *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, 2022, 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 in its consolidated balance sheet as of December 31, 2022, 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. Plaintiffs filed their consolidated amended complaint on October 29, 2021 and a corrected consolidated amended complaint on November 19, 2021 (the "Complaint"). The Complaint alleges false and misleading statements between December 2018 and June 2021 and seeks to represent a class of persons or entities that purchased FibroGen securities between December 20, 2018 and July 15, 2021. On July 15, 2022, the court issued an order denying Defendants' motions to dismiss. Defendants answered the Complaint on September 13, 2022 and discovery is ongoing. On January 27, 2023, Plaintiffs filed a motion for class certification. Defendants' opposition is due April 28, 2023.

On July 30, 2021, a purported shareholder derivative (the "California Federal Derivative") complaint was filed in the U.S. District Court for the Northern District of California. The California Federal Derivative complaint names as defendants FibroGen's current and former officers and directors, as well as FibroGen as nominal defendant, and asserts state and federal claims based on some of the same alleged misstatements as the securities class action complaint. The California Federal Derivative complaint seeks unspecified damages, attorneys' fees, and other costs. On December 23, 2022, Plaintiff filed an amended complaint. On February 21, 2023, Defendants filed a motion to dismiss on the basis that the lawsuit was brought in the improper forum. Plaintiffs' opposition is due April 7, 2023. On December 27, 2021, a second purported shareholder derivative (the "Delaware Federal Derivative") complaint was filed in the U.S. District Court for the District of Delaware. The Delaware Federal Derivative complaint names FibroGen's current and former officers and directors as defendants, as well as FibroGen as nominal defendant, and asserts state and federal claims based on some of the same alleged misstatements as the securities class action complaint, as well as allegations of insider trading against certain defendants. The Delaware Federal Derivative complaint seeks unspecified damages, attorneys' fees, and other costs. The Delaware Federal Derivative action has been stayed pending resolution of any motions for summary judgment in the securities class action. On April 14, 2022, a third purported shareholder derivative (the "Delaware Chancery Derivative") complaint was filed in the Delaware Court of Chancery. The Delaware Chancery Derivative complaint names substantially the same defendants as the other purported shareholder derivative actions and asserts similar claims based upon similar allegations. The Delaware Chancery Derivative complaint seeks unspecified damages, attorneys' fees, and other costs. On January 17, 2023, Defendants moved to dismiss on the basis of demand futility. Plaintiffs' opposition is due on March 17, 2023.

The Company believes that the claims 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 August 3, 2022 and August 4, 2022, the Company's Board of Directors received three 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 has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the estimated fair value of these arrangements is minimal.

11. 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,	
	2022	2021
Common stock outstanding	94,166	92,881
Stock options outstanding	9,088	8,967
RSUs outstanding	3,669	2,304
Shares reserved for future stock options and RSUs grant	11,524	10,253
Shares reserved for future ESPP offering	5,373	4,771
Total shares of common stock reserved	123,820	119,176

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, 2022, the Company has reserved 11,523,829 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, 2022 and 2021, no shares of Common Stock were subject to repurchase by the Company.

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. As of December 31, 2022, all the PRSUs have not become vested.

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. As of December 31, 2022, all the TSR awards have not become vested.

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, 2021	8,967	$ 34.84		
Granted	2,902	14.72		
Exercised	(179)	8.24		
Expired	(1,847)	34.36		
Forfeited	(755)	32.89		
Outstanding at December 31, 2022	9,088	29.19	7.03	$ 6,232
Vested and expected to vest, December 31, 2022	8,614	29.61	6.93	5,770
Exercisable at December 31, 2022	4,730	$ 35.07	5.45	$ 1,438

The estimated weighted-average fair value of the stock options granted during the years ended December 31, 2022, 2021 and 2020 was $14.72, $35.58 and $31.55, respectively. The total intrinsic value of options exercised during the years ended December 31, 2022, 2021 and 2020 was $0.8 million, $13.1 million and $89.6 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, 2021	2,304	$ 30.60
Granted	3,151	14.68
Vested	(1,142)	27.72
Forfeited	(644)	25.06
Unvested at December 31, 2022	3,669	$ 18.80

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, 2022, 779,539 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, 2022, 2021 and 2020 was $14.68, $30.19 and $29.99, 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 327,298 shares, 213,505 shares and 143,876 shares purchased by employees under the 2014 Purchased Plan for the years ended December 31, 2022, 2021 and 2020, 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, 2022, 2021 and 2020 was as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Research and development	$ 34,861	$ 40,547	$ 46,229
Selling, general and administrative	30,740	30,614	26,491
Total stock-based compensation expense	$ 65,601	$ 71,161	$ 72,720

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 its ESPP. Historically, the expected volatility for all other stock-based compensation types was based upon a blend of the Company's and comparable public entities' historical volatility. Since the third quarter of 2020, the expected volatility for all other stock-based compensation types is currently based upon the Company's historical volatility data.
- 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,		
	2022	2021	2020
Stock Options			
Expected term (in years)	5.7	5.7	5.7
Expected volatility	66.8 %	61.9 %	67.1 %
Risk-free interest rate	2.2 %	0.8 %	0.8 %
Expected dividend yield	—	—	—
Weighted average estimated fair value	$ 7.88	$ 20.21	$ 18.36
ESPPs			
Expected term (in years)	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0
Expected volatility	58.5 - 97.6 %	47.1 - 104.4 %	47.5 - 77.1 %
Risk-free interest rate	0.1 - 4.5 %	0.0 - 2.2 %	0.1 - 2.9 %
Expected dividend yield	—	—	—
Weighted average estimated fair value	$ 8.60	$ 12.40	$ 17.53

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, 2022	
TSR awards		
Expected term (in years)	3.9	
Expected volatility	69.0	%
Risk-free interest rate	1.8	%
Expected dividend yield	—	
Weighted average estimated fair value	$ 24.01	

As of December 31, 2022, there was $40.8 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 2.43 years. As of December 31, 2022, there was $46.9 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 2.59 years.

Non-Controlling Interests and Subsidiary Stock

Non-Controlling Interests

Non-controlling interest positions related to the issuance of subsidiary stock as described below are reported as a separate component of consolidated equity from the equity attributable to the Company's stockholders at December 31, 2022 and 2021. 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.

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.

Upon the initial public offering and as described below, 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 Europe

As of December 31, 2022 and 2021, 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.

FibroGen Cayman

FibroGen Cayman had 6,758,000 Series A Preference Shares outstanding as of December 31, 2022 and 2021, 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%.

12. 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, 2022, 2021 and 2020. 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 and 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,		
	2022	2021	2020
Employee stock options	9,520	8,461	6,694
RSUs, PRSUs and TSR awards	2,137	1,538	564
ESPP	305	417	306
	11,962	10,416	7,564

13. Income Taxes

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

	Years Ended December 31,		
	2022	2021	2020
Domestic	$ (307,056)	$ (268,499)	$ (195,617)
Foreign	12,187	(22,184)	6,888
Loss before provision for income taxes	$ (294,869)	$ (290,683)	$ (188,729)

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

	Years Ended December 31,		
	2022	2021	2020
Current:			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	358	347	360
Total current	358	347	360
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
Total deferred	—	—	—
Total provision for income taxes	$ 358	$ 347	$ 360

The following is the reconciliation between the statutory federal income tax rate and the Company's effective tax rate:

	Years Ended December 31,		
	2022	2021	2020
Tax at statutory federal rate	21.0%	21.0%	21.0%
State tax	—%	—%	—%
Stock-based compensation expense	(2.5)%	(1.8)%	2.4%
Benefit due to intercompany transfer of assets	—%	—%	41.7%
Valuation allowance on intercompany transfer of assets	—%	—%	(41.7)%
Net operating losses not benefitted	(16.3)%	(16.8)%	(23.2)%
Foreign net operating losses not benefitted	0.9%	(1.6)%	0.7%
Deduction limitation on executive compensation	(0.2)%	(0.3)%	(0.8)%
Global intangible low-taxed income	(2.8)%	(0.4)%	—%
Other	(0.2)%	(0.2)%	(0.3)%
Total	(0.1)%	(0.1)%	(0.2)%

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

	December 31,	
	2022	2021
Federal and state net operating loss carryforwards	$ 166,708	$ 167,135
Tax credit carryforwards	106,131	78,832
Foreign net operating loss carryforwards	49,990	38,117
Capitalized research and development expenses	45,125	—
Stock-based compensation	8,616	10,050
Lease obligations	18,442	20,415
Reserves and accruals	4,929	6,067
Deferred revenue	21,624	20,101
Intangible assets	69,159	84,625
Other	1,277	825
Subtotal	492,001	426,167
Less: Valuation allowance	(477,969)	(409,810)
Net deferred tax assets	14,032	16,357
Fixed assets	(13,101)	(16,357)
Non-deductibale accrued expenses	(931)	—
Net deferred tax liabilities	(14,032)	(16,357)
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 $68.2 million, $72.0 million and $124.0 million for the years ended December 31, 2022, 2021 and 2020, 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.

During 2020, the Company transferred certain intellectual property rights relating to its Chinese business between its wholly owned subsidiaries that are based in different tax jurisdictions. The transferor entity was not subject to income taxes in its local jurisdiction. The acquiring entity of the intellectual property is entitled to amortize the acquisition price of the intangible assets for tax purposes. In accordance with ASU 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory*, the Company recognized a deferred tax asset of $78.7 million for the temporary difference arising from the acquirer's excess tax basis. Furthermore, based upon the weight of available evidence, the Company recognized a full valuation allowance against this deferred tax asset since it does not currently believe that realization of this gross deductible temporary difference is more likely than not. Accordingly, this inter-company transfer did not have a material impact to the Company's consolidated financial statements.

At December 31, 2022, the Company had net operating loss carryforwards available to offset future taxable income of approximately $758.3 million and $140.1 million for federal and state tax purposes, respectively. These carryforwards will begin to expire in 2026 for federal and 2028 for state purposes, if not utilized before these dates. The Company also had foreign net operating loss carryforwards of approximately $242.6 million, which expire between 2023 and 2032 if not utilized.

At December 31, 2022, the Company had approximately $121.6 million of federal and $46.6 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 2023 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 reviewed its stock ownership for year ended December 31, 2022 and concluded no ownership changes occurred which would result in a reduction of its net operating loss or in its research and development credits expiring unused. If additional ownership change occurs, the utilization of net operating loss and credit carryforwards could be significantly reduced.

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 Company does not expect these provisions to have a material impact on its consolidated financial statements and related disclosures.

Uncertain Tax Positions

The Company had unrecognized tax benefits of approximately $72.8 million as of December 31, 2022. Approximately $0.7 million of unrecognized tax benefits, if recognized, would affect the effective tax rate. The interest accrued as of December 31, 2022 and 2021 was immaterial.

A reconciliation of the beginning and ending amounts of unrecognized income tax benefits during the three years ended December 31, 2022 is as follows (in thousands):

	Federal and State
Balance as of December 31, 2019	$ 32,263
Decrease due to prior positions	(137)
Increase due to current year position	16,448
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

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 2013 to 2022. The Company is not currently under audit in any tax jurisdiction.

14. Related Party Transactions

Astellas is an equity investor in the Company and considered a related party. During the years ended December 31, 2022, 2021 and 2020, the Company recorded license and development revenue related to collaboration agreements with Astellas of $32.5 million, $130.4 million, and $33.5 million, respectively. During the years ended December 31, 2022, 2021 and 2020, the Company also recorded drug product revenue from Astellas of $11.1 million, $3.2 million, and $4.3 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, 2022.

As of December 31, 2022 and 2021, accounts receivable from Astellas were $1.5 million and $10.9 million, respectively.

As of December 31, 2022 and 2021, total deferred revenue from Astellas were $40.3 million and $27.9 million, respectively.

As of December 31, 2022, the amount due to Astellas was $63.9 million. As of December 31, 2021, the amount due to Astellas was immaterial.

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 4, *Equity method investment - Variable Interest Entity*, for details.

For the years ended December 31, 2022 and 2021, the net product revenue from sales to Falikang were $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, 2022.

For the years ended December 31, 2022, 2021 and 2020, the investment income (loss) in Falikang was $1.6 million, $1.0 million, and $(0.2) million, respectively. As of December 31, 2022 and 2021, the Company's equity method investment in Falikang were $5.1 million and $3.8 million, respectively. See Note 4, *Equity method investment - Variable Interest Entity*, for details.

As of December 31, 2022, accounts receivable, net, from Falikang were $10.5 million. As of December 31, 2021, accounts receivable, net, from Falikang was zero.

As of December 31, 2022, the total deferred revenue from Falikang was zero. As of December 31, 2021, the total deferred revenue from Falikang was $1.2 million.

15. 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,		
	2022	2021	2020
China	$ 84,631	$ 55,640	$ 73,361
Europe	33,820	131,243	17,954
Japan	9,764	2,305	19,824
United States	12,519	46,121	65,180
Total revenue	$ 140,734	$ 235,309	$ 176,319

Geographic Assets

Property and equipment, net by geographic location are as follows (in thousands):

	December 31,	
	2022	2021
United States	$ 10,094	$ 15,002
China	10,511	13,275
Total property and equipment	$ 20,605	$ 28,277

Finance lease right-of-use assets and operating lease right-of-use assets, net by geographic location are as follows (in thousands):

	December 31,	
	2022	2021
United States	$ 424	$ 730
China	11	31
Total finance lease right-of-use assets	$ 435	$ 761
United States	$ 76,273	$ 87,113
China	3,620	3,999
Total operating lease right-of-use assets	$ 79,893	$ 91,112

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			Percentage of Accounts Receivable	
	Years Ended December 31,			December 31,	
	2022	2021	2020	2022	2021
Falikang — Related party	51%	15%	—%	65%	—%
Astellas — Related party	31%	57%	21%	9%	63%
AstraZeneca	9%	20%	37%	16%	34%

In January 2021, Falikang became fully operational and substantially all direct product sales to distributors in China were made by Falikang, while FibroGen Beijing continued to sell roxadustat product directly through pharmaceutical distributors in one province in China during 2021 and in one province in 2022. No individual distributor represented over 10% of the total revenue for the years ended December 31, 2022 and 2021. The aggregate accounts receivable from direct sales to distributors as of December 31, 2022 and 2021 were immaterial.

For the year ended December 31, 2020, the aggregate revenue from distributors represented 42% of the consolidated revenue, with no individual distributor representing over 10% of the total revenue. As of December 31, 2020, the aggregate accounts receivable from distributors represented 64% of the consolidated accounts receivable, with no material balance from any individual distributor.

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, 2022	$ 409,810	$ 68,159	$ —	$ —	$ 477,969
Year ended December 31, 2021	$ 337,824	$ 71,986	$ —	$ —	$ 409,810
Year ended December 31, 2020	$ 213,847	$ 123,977	$ —	$ —	$ 337,824
Allowances for rebates, discounts and adjustments					
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
Year ended December 31, 2020	$ 1,102	$ 16,497	$ (14,867)	$ (2,184)	$ 548

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, 2022 ("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, 2022, 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, 2022.

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, 2022, 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, 2022 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, 2022 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, 2022 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

We are implementing an enterprise resource planning ("ERP") system, which will replace our existing operating and financial systems in the U.S. in the first quarter of 2023. While we expect the ERP implementation to improve the efficiency of certain financial and transactional processes, the related changes will materially affect our internal control over financial reporting beginning in the first quarter of 2023, and we have been monitoring such changes during the implementation process.

ITEM 9B. OTHER INFORMATION

On February 27, 2023, we entered into an Amended and Restated Equity Distribution Agreement with Goldman Sachs & Co., LLC and BofA Securities, Inc., which amended and restated our 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. The Amended and Restated Equity Distribution Agreement is filed as Exhibit 10.44 to this Form 10-K.

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 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2022 (the “2023 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 2023 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 2023 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 2023 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 2023 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 2023 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to the proposal title “Ratification of Selection of Independent Registered Public Accounting Firm” appearing in our 2023 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 page158. 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.	—	—	—	—
10.5+	FibroGen, Inc. 2018 Bonus Plan.	8-K	001-36740	10.5	2/16/2018
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 James Schoeneck, dated as of September 18, 2019.	10-Q	001-36740	10.7	11/12/2019
10.38+	Offer Letter, by and between FibroGen, Inc. and Enrique Conterno, dated as of December 17, 2019.	10-K	001-36740	10.34	3/2/2020

10.39+	Offer Letter, by and between FibroGen, Inc. and Thane Wettig, dated as of May 7, 2020.	10-Q	001-36740	10.1	8/6/2020
10.40+	Offer Letter, by and between FibroGen, Inc. and Mark Eisner, dated as of October 22, 2020.	10-K	001-36740	10.44	3/1/2021
10.41+	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
10.42+	Form of Executive Officer Change in Control and Severance Agreement.	10-K	001-36740	10.35	3/2/2020
10.43†	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
10.44*	Amended and Restated Equity Distribution Agreement by and between FibroGen, Inc. and Goldman Sachs & Co. LLC and BofA Securities, Inc., dated February 27, 2023.	—	—	—	—
10.45*†	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.	—	—	—	—
10.46*†	Revenue Interest Financing Agreement by and between FibroGen, Inc. and NQ Project Phoebus, L.P., dated as of November 4, 2022.	—	—	—	—
10.47*†	Letter Agreement by and among Astellas Pharma Inc., Astellas Pharma Europe Ltd., and FibroGen, Inc., effective as of November 4, 2022.	—	—	—	—
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).	—	—	—	—
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	—	—	—	—
101.CAL*	Inline XBRL Calculation Linkbase Document	—	—	—	—
101.DEF*	Inline XBRL Definition Linkbase Document	—	—	—	—
101.LAB*	Inline XBRL Labels Linkbase Document	—	—	—	—
101.PRE*	Inline XBRL Taxonomy Presentation 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 27, 2023	By:	/s/ Enrique Conterno
		Enrique Conterno Chief Executive Officer *(Principal Executive Officer)*
Date: February 27, 2023	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 Enrique Conterno 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/ Enrique Conterno **Enrique Conterno**	Chief Executive Officer *(Principal Executive Officer)*	February 27, 2023
/s/ Juan Graham **Juan Graham**	Senior Vice President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 27, 2023
/s/ James A. Schoeneck **James A. Schoeneck**	Chairman of the Board and Director	February 27, 2023
/s/ Suzanne Blaug **Suzanne Blaug**	Director	February 27, 2023
/s/ Aoife Brennan **Aoife Brennan, M.B., B.Ch.**	Director	February 27, 2023
/s/ Benjamin F. Cravatt **Benjamin F. Cravatt, Ph.D.**	Director	February 27, 2023
/s/ Jeffrey L. Edwards **Jeffrey L. Edwards**	Director	February 27, 2023
/s/ Jeffrey W. Henderson **Jeffrey W. Henderson**	Director	February 27, 2023
/s/ Maykin Ho **Maykin Ho, Ph.D.**	Director	February 27, 2023
/s/ Gerald Lema **Gerald Lema**	Director	February 27, 2023

FibroGen, Inc.

Non-Employee Director Compensation Policy

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

Eligible Directors

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

Annual Cash Compensation

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

1. Annual Board Service Retainer:
   a. All Directors: $50,000

2. Annual Committee Chair Service Fee (in lieu of non-Chair Service fee):
   a. Chairman of the Audit Committee: $20,000
   b. Chairman of the Compensation Committee: $17,500
   c. Chairman of the Nominating and Governance Committee: $10,000

3. Annual Committee Member (non-Chair) Service Fee:
   a. Audit Committee: $10,000
   b. Compensation Committee: $7,500
   c. Nominating and Governance Committee: $5,000

4. Annual Non-Executive Chairperson/Lead Independent Director Service Retainer:
   a. Lead Independent Director: $22,500
   b. Non-Executive Chairperson: $100,000

5. Annual Scientific Advisory Board Service Fee:
   a. $25,000

Equity Compensation

Equity awards will be granted under the FibroGen, Inc. 2014 Equity Incentive Plan (or any successor thereto, the "***Plan***"). All stock options granted under this policy will be non-statutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying Company common stock on the date of grant, and a term of ten (10) years from the date of grant (subject to earlier termination in connection with a termination of service or a corporate transaction as provided in the Plan). All equity awards granted under this Policy will be documented on the applicable form of equity award agreement most recently approved for use by the Board (or a duly authorized committee thereof) for Directors. The terms of the equity awards described in this Policy will be automatically adjusted upon any Capitalization Adjustment (as defined and provided for under the Plan).

1. Initial Grant: On the date of the Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Director will be automatically, and without further action by the Board, granted a stock option award with an aggregate value of $142,000 and a Restricted Stock Unit ("RSU") grant with an aggregate value of $142,000. Such options will vest in equal quarterly installments over three years from the grant date, subject to the Director's Continuous Service. A Director who, in the one year prior to his or her initial election to serve on the Board as a Director, served as an employee of FibroGen or one of its subsidiaries, will not be eligible for an initial grant.

2. Annual Grant: On the date of each Company annual stockholder meeting, each person who is elected or appointed as a Director, and each other Director who continues to serve as a Director immediately after such annual stockholder meeting, will be automatically, and without further action by the Board, granted a stock option award with an aggregate value of $142,000 and an RSU grant with an aggregate value of $142,000. Such options and RSUs will vest upon the earlier of (x) June 16 of the following year and (y) the following year's annual stockholder meeting, subject to the Director's Continuous Service.

3. Prorated Annual Grants. If a Director is elected or appointed to the Board at a time other than at the annual stockholder meeting, then on the date of such election or appointment (or, if such date is not a market trading day, the first market trading day thereafter), the Director will be automatically, and without further action by the Board, granted (a) a stock option award with an aggregate value of $142,000 multiplied by the Applicable Fraction (as defined below) and (b) an RSU grant with an aggregate value of $142,000 multiplied by the Applicable Fraction (a "***Prorated Annual Grant***"). The "***Applicable Fraction***" means a fraction with (a) a numerator equal to the number of days between the date of the Director's initial election or appointment to the Board and the date which is the first anniversary of the date of the most recent annual stockholder meeting occurring before the Director is elected or appointed to the Board, and (b) a denominator equal to 365.

4. Option Value. The value of a stock option to be granted under the Director Compensation Policy shall be determined using the same method the Company uses to calculate stock option awards to its employees, as approved by the Compensation Committee of the Board, using the grant date fair value, rounding down to the nearest share.

5. RSU Value. The number of shares subject to RSUs granted under the Director Compensation Policy shall be determined based on the closing price on the NASDAQ of the Company's common on the grant date, rounded down to the nearest share.

6. Vesting. Vesting of awards granted under this Policy will cease if the Director resigns from the Board or otherwise ceases to serve as a Director, unless the Board determines that the circumstances warrant continuation of vesting. All equity awards granted under this Policy will vest in full immediately prior to a Change in Control (as defined in the Plan), subject to the Director's Continuous Service (as defined in the Plan) as of the day prior to the closing of the Change in Control.

Reimbursement of Expenses

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

Philosophy

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

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

Exhibit 10.44

FIBROGEN, INC.

Common Stock ($0.01 par value)
Having an Aggregate Offering Price of up to
$200 Million

Amended and Restated Equity Distribution Agreement

February 27, 2023

Goldman Sachs & Co. LLC
200 West Street
New York, New York 10282

BofA Securities, Inc.
One Bryant Park
New York, NY 10036

Ladies and Gentlemen:

Reference is made to the Equity Distribution Agreement, dated August 8, 2022 (the "**Original Agreement**"), by and between FibroGen, Inc., a Delaware corporation (the "**Company**") and Goldman Sachs & Co. LLC (the "**Existing Manager**").

The Company and the Existing Manager wish to amend and restate the Original Agreement effective on and after the date hereof in order to include BofA Securities, Inc. as an additional sales agent (together with the Existing Manager, each a "**Manager**" and, collectively the "**Managers**").

The Company confirms its agreement with the Managers and the Original Agreement is hereby amended and restated as follows (as amended and restated, the "**Agreement**"):

1. Description of Shares. The Company proposes to issue and sell through or to the Managers, as sales agents and/or principals, shares of the Company's common stock, $0.01 par value (the "**Common Stock**") having an aggregate offering price of up to $200 million (the "**Shares**"), from time to time during the term of this Agreement and on the terms set forth in Section 3 of this Agreement. The Company hereby appoints the Managers as the exclusive agents of the Company for the purpose of making offers and sales of the Shares pursuant to this Agreement. The Company agrees that whenever it determines to sell the Shares directly to a Manager as principal, it will enter into a separate agreement (each, a "**Terms Agreement**") in substantially the form of Annex I hereto, relating to such sale in accordance with Section 3 of this Agreement. Certain terms used herein are defined in Section 19 hereof.

2. Representations and Warranties. The Company represents and warrants to, and agrees with, the Managers at the Execution Time and on each such time the following representations and warranties are repeated or deemed to be made pursuant to this Agreement, as set forth below.

(a) Form S-3. The Company meets the requirements for use of Form S-3 under the Act and has prepared and filed with the Commission an automatic shelf registration statement on Form S-3, including a Base Prospectus and a prospectus related to the Shares, for registration under the Act of the offering and sale of the Shares and other securities of the Company. Such Registration Statement, including any amendments thereto filed prior to any such time this representation is repeated or deemed to be made, automatically became effective on August 8, 2022 and no stop order suspending the effectiveness of the Registration Statement has been issued under the Act and no proceedings for that purpose have been instituted or are pending or, to the knowledge of the Company, are contemplated or threatened by the Commission, and any request on the part of the Commission for additional or supplemental information has been complied with. The Prospectus will contain all information required by the Act and the rules thereunder, and, except to the extent the Managers shall agree in writing to a modification, shall be in all substantive respects in the form furnished to the Existing Manager prior to the Initial Execution Time or prior to any such time this representation is repeated or deemed to be made. The Registration Statement, at the Initial Execution Time, each such time this representation is repeated or deemed to be made, and at all times during which a prospectus is required by the Act to be delivered (whether physically or through compliance with Rule 172 or any similar rule) in connection with any offer or sale of Shares, meets the requirements set forth in Rule 415(a)(1)(x). The initial Effective Date of the Registration Statement was not earlier than the date three years before the Initial Execution Time. Any reference herein to the Registration Statement, the Base Prospectus, the Prospectus or any Interim Prospectus Supplement shall be deemed to refer to and include the documents incorporated by reference therein pursuant to Item 12 of Form S-3 which were filed under the Exchange Act on or before the Effective Date of the Registration Statement or the issue date of the Base Prospectus, the Prospectus or any Interim Prospectus Supplement, as the case may be and, with respect to times after the Effective Time, shall include such documents filed under the Exchange Act after the Effective Date of the Registration Statement or the issue date of the Base Prospectus, the Prospectus or any Interim Prospectus Supplement, as the case may be, and deemed to be incorporated therein by reference and at or before such times; and any reference herein to the terms “amend,” “amendment” or “supplement” with respect to the Registration Statement, the Base Prospectus, the Prospectus or any Interim Prospectus Supplement shall be deemed to refer to and include the filing of any document under the Exchange Act after the Effective Date of the Registration Statement or the issue date of the Base Prospectus, the Prospectus or any Interim Prospectus Supplement, as the case may be, deemed to be incorporated therein by reference. Notwithstanding the foregoing, the representations and warranties in this subsection shall not apply to statements in or omissions from the Registration Statement or any post-effective amendment or the Prospectus or any amendments or supplements thereto, made in reliance upon and in conformity with information furnished to the Company in writing by the Managers relating to the Managers expressly for use therein.

(b) Successor Registration Statement. To the extent that the Registration Statement is not available for the sales of the Shares as contemplated by this Agreement, the Company shall file a new registration statement with respect to any additional Common Stock necessary to complete such sales of the Shares and shall cause such registration statement to become effective as promptly as practicable. After the effectiveness of any such registration statement, all references to “Registration Statement” included in this Agreement shall be deemed to include such new registration statement, including all documents incorporated by reference therein pursuant to Item 12 of Form S-3, and all references to “Base Prospectus” included in this Agreement shall be deemed to include the final form of prospectus, including all documents incorporated therein by reference, included in any such registration statement at the time such registration statement became effective.

(c) No Material Misstatements or Omissions in the Registration Statement. On each Effective Date, at the Execution Time, at each deemed effective date with respect to the Managers pursuant to Rule 430B(f)(2) under the Act, at each Applicable Time, at each Settlement Date, at each Time of Delivery and at all times during which a prospectus is required by the Act to be delivered (whether physically or through compliance with Rule 172 or any similar rule) in connection with any offer or sale of Shares, the Registration Statement complied and will comply in all material respects with the applicable requirements of the Act and the rules thereunder and did not and will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading; and on the date of any filing pursuant to Rule 424(b), at each Applicable Time, on each Settlement Date, at each Time of Delivery and at all times during which a prospectus is required by the Act to be delivered (whether physically or through compliance with Rule 172 or any similar rule) in connection with any offer or sale of Shares, the Prospectus (together with any supplement thereto) complied and will comply in all material respects with the applicable requirements of the Act and the rules thereunder and did not and will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided*, *however*, that the Company makes no representations or warranties as to the information contained in or omitted from the Registration Statement or the Prospectus (or any supplement thereto) in reliance upon and in conformity with information furnished in writing to the Company by the Managers specifically for inclusion in the Registration Statement or the Prospectus (or any supplement thereto).

(d) Disclosure Package. At the Initial Execution Time, at the Execution Time, at each Applicable Time, at each Settlement Date and each Time of Delivery, the Disclosure Package does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The preceding sentence does not apply to statements in or omissions from the Disclosure Package based upon and in conformity with written information furnished to the Company by the Managers specifically for use therein.

(e) Incorporated Documents. The documents incorporated or deemed to be incorporated by reference in the Registration Statement and the Prospectus (i) at the time they were or hereafter are filed with the Commission, complied and will comply in all material respects with the requirements of the Exchange Act and the rules and regulations of the Commission thereunder and (ii) when read together with the other information in the Prospectus and the Disclosure Package at any Applicable Time and when read together with the other information in the Prospectus at the date of the Prospectus and at any Settlement Date or Time of Delivery, will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(f) Ineligible Issuer. The Company is not an “ineligible issuer” (as defined in Rule 405 under the Act).

(g) Notice of Other Sales. Prior to the execution of this Agreement, the Company has not, directly or indirectly, offered or sold any Shares by means of any “prospectus” (within the meaning of the Act) or used any “prospectus” (within the meaning of the Act) in connection with the offer or sale of the Shares, and from and after the execution of this Agreement, the Company will not, directly or indirectly, offer or sell any Shares by means of any “prospectus” (within the meaning of the Act) or use any “prospectus” (within the meaning of the Act) in connection with the offer or sale of the Shares, other than the Prospectus, as amended or supplemented from time to time in accordance with the provisions of this Agreement; the Company has not, directly or indirectly, prepared, used or referred to any Issuer Free Writing Prospectus in connection with the offering and sale of the Shares.

(h) No Stop Orders. The Registration Statement is not the subject of a pending proceeding or examination under Section 8(d) or 8(e) of the Act, and the Company is not the subject of a pending proceeding under Section 8A of the Act in connection with the offering of the Shares.

(i) Regulation M. The Common Stock constitutes an “actively-traded security” exempted from the requirements of Rule 101 of Regulation M under the Exchange Act by subsection (c)(1) of such rule.

(j) Sales Agency Agreements. The Company has not entered into any other sales agency agreements or other similar arrangements with any agent or any other representative in respect of any at the market offering (within the meaning of Rule 415(a)(4) under the Act) of the Shares.

(k) Offering Materials. The Company has not distributed and will not distribute, prior to the termination of this Agreement, any offering material in connection with the offering and sale of the Shares other than the Prospectus and any Issuer Free Writing Prospectus reviewed and consented to by the Managers and identified in Schedule I hereto.

(l) No Material Adverse Change in Business. Neither the Company nor any of its subsidiaries has sustained since the date of the latest audited financial statements included or incorporated by reference in the Disclosure Package and the Prospectus any material loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, otherwise than as set forth or contemplated in the Disclosure Package and the Prospectus; and, since the respective dates as of which information is given in the Registration Statement, Disclosure Package and the Prospectus, there has not been any material change in the capital stock (other than as a result of (A) the exercise of any stock options outstanding as of the date of this Agreement or warrants outstanding as of the date of this Agreement, (B) the award of stock options in the ordinary course of business pursuant to the Company's equity incentive plans or (C) the repurchase of shares of stock in connection with any early exercise of stock options by option holders from employees terminating their service to the Company, in each case as such options, warrants and equity incentive plans are described in the Disclosure Package or the Prospectus) or long-term debt of the Company or any of its subsidiaries or any material adverse change, or any development involving a prospective material adverse change, in or affecting the general affairs, management, financial position, stockholders' equity or results of operations of the Company and its subsidiaries, otherwise than as set forth or contemplated in the Registration Statement, Disclosure Package and the Prospectus.

(m) Title to Property. The Company and its subsidiaries have good and marketable title in fee simple to all real property and good and marketable title to all personal property owned by them, in each case free and clear of all liens, encumbrances and defects except as described in the Registration Statement, the Disclosure Package and the Prospectus or as do not materially affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company or any of its subsidiaries; and any real property and buildings held under lease by the Company or any of its subsidiaries are held by them under valid, subsisting and enforceable leases or subleases (subject to the effects of (A) bankruptcy, insolvency, fraudulent conveyance, fraudulent transfer, reorganization, moratorium or other similar laws relating to or affecting the rights or remedies of creditors generally; (B) the application of general principles of equity (including, without limitation, concepts of materiality, reasonableness, good faith and fair dealing, regardless of whether enforcement is considered in proceedings at law or in equity); and (C) applicable law and public policy with respect to rights to indemnity and contribution) with such limitations on the Company or its subsidiaries as are not material and do not interfere with the use made and proposed to be made of such real property and buildings by the Company or any of its subsidiaries.

(n) Good Standing. The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the State of Delaware, with power and authority (corporate and other) to own its properties and conduct its business as described in the Registration Statement, Disclosure Package and the Prospectus, and has been duly qualified as a foreign corporation for the transaction of business and is in good standing under the laws of each other jurisdiction in which it owns or leases properties or conducts any business so as to require such qualification, or is subject to no material liability or disability by reason of the failure to be so qualified or be in good standing in any such jurisdiction; and each subsidiary of the Company has been duly incorporated or formed and is validly existing as a corporation or other business organization in good standing under the laws of its jurisdiction of incorporation or formation, and has been duly qualified as a foreign corporation or other business organization for the transaction of business and is in good standing under the laws of each other jurisdiction in which it owns or leases properties or conducts any business so as to require such qualification, or is subject to no material liability or disability by reason of the failure to be so qualified or be in good standing in any such jurisdiction.

(o) Capitalization. The Company has an authorized capitalization as set forth in the Registration Statement, the Disclosure Package and the Prospectus and all of the issued shares of capital stock of the Company have been duly and validly authorized and issued and are fully paid and non-assessable and conform to the description thereof contained in the Registration Statement, the Disclosure Package and the Prospectus; and all of the issued shares of capital stock and equity interests of each subsidiary of the Company have been duly and validly authorized and issued, are fully paid and non-assessable and (except for directors' qualifying shares) are owned directly or indirectly by the Company, free and clear of all liens, encumbrances, equities or claims.

(p) Due Authorization of the Shares. The Shares have been duly and validly authorized and, when the Shares are issued and delivered against payment therefor as provided herein, such Shares will be duly and validly issued and fully paid and non-assessable and will conform to the description of the Common Stock contained in the Registration Statement, the Disclosure Package and the Prospectus.

(q) No Preemptive or Registration Rights. Except as described in the Registration Statement, the Disclosure Package and the Prospectus, there are no (i) preemptive rights or other rights to subscribe for or to purchase or any restriction upon the voting or transfer of, any equity securities of the Company or any of its subsidiaries or (ii) outstanding options or warrants to purchase any securities of the Company or any of its subsidiaries. Neither the filing of the Registration Statement nor the offering or sale of the Shares as contemplated by this Agreement gives rise to any rights for or relating to the registration of any securities of the Company, except such rights as have been waived or satisfied.

(r) No Conflict or Violation. (i) The issue and sale of the Shares and the compliance by the Company with this Agreement and (ii) the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated herein and in the Registration Statement, the Disclosure Package and the Prospectus (including the issuance and sale of the Shares and the application of the use of the proceeds from the sale of the Shares as described therein under the caption "Use of Proceeds"), in each case, do not and will not, whether with or without the giving of notice or passage of time or both (A) materially conflict with or result in a material breach or violation of any of the terms or provisions of, or constitute a material default under, any indenture, mortgage, deed of trust, loan agreement, lease or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any of the property or assets of the Company or any of its subsidiaries is subject, (B) will not conflict with or result in a breach or violation of any of the terms or provisions of the Amended and Restated Certificate of Incorporation or Amended and Restated Bylaws of the Company or the corresponding governing documents of any of its subsidiaries and (C) will not conflict with or result in a breach or violation of any of the terms or provisions of any statute or any order, rule or regulation of any court or governmental agency or body having jurisdiction over the Company or any of its subsidiaries or any of their properties; and no consent, approval, authorization, order, registration or qualification of or with any such court or governmental agency or body is required for the issue and sale of the Shares or the consummation by the Company of the transactions contemplated by this Agreement, except for the registration under the Act of the Shares, the approval by the Financial Industry Regulatory Authority ("**FINRA**") of the terms and arrangements and such consents, approvals, authorizations, registrations or qualifications as may be required under state securities or Blue Sky laws in connection with the purchase and distribution of the Shares by the Managers.

(s) Absence of Violations, Defaults and Conflicts. Neither the Company nor any of its subsidiaries is (i) in violation of its articles of incorporation or bylaws (or similar organizational documents), (ii) in default in the performance or observance of any material obligation, agreement, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement, lease or other agreement or instrument to which it is a party or by which it or any of its properties may be bound or (iii) in violation or default of any statute, law, rule, regulation, judgment, order or decree of any court, regulatory body, administrative agency, governmental body, arbitrator or other authority having jurisdiction over the Company, its subsidiaries or any of their properties, as applicable; except in the case of (iii), for such defaults as would not, individually or in the aggregate, have a Material Adverse Effect (as defined below).

(t) Due Authorization. The execution and delivery of, and the performance by the Company of its obligations under, this Agreement (including but not limited to the issuance and sale of the Shares and the use of proceeds from the sale of the Shares as described in the Registration Statement, the Disclosure Package and the Prospectus under the caption "Use of Proceeds") have been duly and validly authorized by all necessary corporate action on the part of the Company and this Agreement has been duly executed and delivered by the Company.

(u) Summaries of Law and Documents. The statements set forth in the Registration Statement, the Disclosure Package and the Prospectus under the captions "Description of Capital Stock", insofar as they purport to constitute a summary of the terms of the Shares, and under the captions "Business—Roxadustat for the Treatment of Anemia in Chronic Kidney Disease in China", "Business—Government Regulation", "Business—Intellectual Property", "Risk Factors— Risks Related to Our Intellectual Property", "Risk Factors—Risks Related to Government Regulation" and "Certain Relationships and Related Party Transactions", insofar as they purport to describe the provisions of the laws and documents referred to therein, are accurate, complete and fair in all material respects.

(v) Filings and Governmental Licenses. The Company and its subsidiaries have filed or caused to be filed with the appropriate governmental entities all forms, statements, reports, and documents (including all exhibits, amendments, and supplements thereto) (each a "**Filing**") required to be filed by it with respect to the respective businesses of the Company and its subsidiaries and each of their facilities under all applicable laws and the respective rules and regulations thereunder, all of which complied in all respects with all applicable requirements of the appropriate law and rules and regulations thereunder in effect on the date each such Filing was made, except where the failure to do so would not reasonably be expected to have a Material Adverse Effect. The Company and its subsidiaries (i) hold all licenses, registrations, certificates, clearances, approvals, certifications, exemptions, authorizations and permits from governmental authorities (collectively, "**Governmental Licenses**") which are necessary to the conduct of the business now operated by them, except for such Governmental Licenses the failure of which to hold would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, (ii) are in compliance with the terms and conditions of all Governmental Licenses, and all Governmental Licenses are valid and in full force and effect, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, and (iii) have not received any written notice of proceedings relating to the revocation or modification of any Governmental License.

(w) Payment of Taxes. The Company and each of its subsidiaries has filed all material U.S. federal, state, local and foreign tax returns which have been required to be filed and have paid all taxes indicated by such returns and all assessments received by them or any of them to the extent that such taxes have become due, except for any such taxes being contested in good faith and for which an adequate reserve or accrual has been established in accordance with U.S. generally accepted principles of accounting ("**GAAP**").

(x) Possession of Intellectual Property. To the knowledge of the Company, the Company and its subsidiaries own or possess licenses to practice and use all material inventions, patent applications, patents, trademarks, trade names, service names, copyrights, trade secrets, domain names, technology, know-how and other intellectual property described in the Registration Statement, the Disclosure Package, and the Prospectus as being owned or licensed by them or which are necessary for the conduct of their respective businesses as currently conducted or as currently proposed to be conducted as described in the Registration Statement, the Disclosure Package, and the Prospectus (collectively, "**Intellectual Property**"). To the knowledge of the Company, there are no third parties who have or will be able to establish ownership rights in or to any Intellectual Property owned or purported to be owned by the Company or each of its subsidiaries, or any right to practice or use any Intellectual Property owned or purported to be owned by or exclusively licensed to the Company or any of its subsidiaries, except for customary reversionary rights of third-party licensors. To the knowledge of the Company, neither the Company nor any of its subsidiaries is infringing, misappropriating, diluting, or otherwise violating, or has infringed, misappropriated, diluted, or otherwise violated, any intellectual property rights of third parties with respect to the Company's development, manufacture, and, if approved, commercialization, of the roxadustat and pamrevlumab products described in the Registration Statement, the Disclosure Package, and the Prospectus in a manner that, in the aggregate, would have a Material Adverse Effect. To the knowledge of the Company, the Company has disclosed to Managers and described in the Registration Statement, the Disclosure Package, and the Prospectus all material information regarding ownership, third-party rights, and any obligations to pay a material royalty on, to grant a license or option to, or to provide other material consideration to any third party with respect to the Intellectual Property To the knowledge of the Company, all employees, consultants, agents, and contractors engaged in the development of Intellectual Property on behalf of the Company or any of its subsidiaries have executed invention assignment agreements whereby such employees, consultants, agents, and contractors presently assign all of their right, title, and interest in and to such Intellectual Property to the Company, and to the Company's knowledge, no such agreement has been breached or violated. To the Company's knowledge, no employee, consultant, agent, or contractor of the Company or any of its subsidiaries is in or has ever been in violation in any material respect of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement nondisclosure agreement or any restrictive covenant to or with a former employer or other third party where the basis of such violation relates to such individual's engagement with the Company or actions undertaken while employed or engaged with the Company in a manner that, individually or in the aggregate, would have a Materially Adverse Effect. There is no pending or, to the Company's knowledge, no threatened action, suit, proceeding, or claim by third parties asserting that the Company or any of its subsidiaries infringes, misappropriates, dilutes, or otherwise violates, or would, upon the manufacturing or commercialization of the roxadustat or pamrevlumab products described in the Registration Statement, the Disclosure Package, and the Prospectus, infringe, misappropriate, dilute, or otherwise violate any intellectual property rights of third parties, and neither the Company nor any of its subsidiaries has received any notice of any claim of infringement, misappropriation, or other violation of, or conflict with, any such rights of third parties. Except as disclosed in the Registration Statement, the Disclosure Package, and the Prospectus, there is no pending or, to the Company's knowledge, no threatened action, suit, proceeding, or claim by others (i) asserting breach of an agreement pursuant to which Intellectual Property was licensed to the Company or to one of its subsidiaries, (ii) challenging the Company's or any of its subsidiaries' rights in or to any Intellectual Property (except in the ordinary course of patent prosecution) or (iii) challenging the validity, enforceability, or scope of any Intellectual Property (except in the ordinary course of patent prosecution) that would have a Material Adverse Effect. There is no pending, or to the knowledge of the Company, no threatened action, suit, proceeding, or claim by the Company or any of its subsidiaries that a third party infringes, misappropriates, or otherwise violates or conflicts with any Intellectual Property owned, purported to be owned, or exclusively licensed to the Company or any of its subsidiaries in a manner that would have a Material Adverse Effect. To the knowledge of the Company, (i) the roxadustat and pamrevlumab products described in the Registration Statement, the Disclosure Package, and the Prospectus as under development and/or commercialization fall within the scope of the claims of one or more patents or patent applications owned by, or exclusively licensed to, the Company, (ii) no government funding, facilities, or resources belonging to a university, college, other educational institution or research center were used in development of the Intellectual Property, and (iii) no government funding, facilities, or resources belonging to a university, college, or other educational institution or research center has any claim or right in or to any Intellectual Property that is owned or purported to be owned by the Company or any of its subsidiaries

(y) Patents. To the knowledge of the Company, (i) all patents and patent applications included in the Intellectual Property have been duly and properly filed, and each such issued patent is being diligently maintained and each such pending patent application is being diligently prosecuted; (ii) the Company has complied with its duty of candor and disclosure to the U.S. Patent and Trademark Office (the "**U.S. PTO**") and to any relevant foreign patent authority having similar requirements in connection with such patents and patent applications included in the Intellectual Property for which it has filing, prosecution, and/or maintenance responsibilities; and (iii) the Company is not aware of any prior art or public or commercial activity or other facts required to be disclosed to the U.S. PTO or any relevant foreign patent authority that was not disclosed and that, if disclosed, would preclude the grant of a patent in connection with any such patent application, and of which failure to disclose would reasonably be expected to form the basis of a finding of invalidity or unenforceability with respect to any patents that have been issued with respect to such patent applications.

(z) Regulatory Compliance. (i) The Company has operated and currently is in compliance in all respects with all Health Care Laws (as defined below) applicable to the ownership, testing, development, manufacture, sales, marketing, promotion, packaging, processing, use, distribution, storage, import, export or disposal of any of the Company's product candidates or any product manufactured or distributed by the Company; (ii) the Company and its subsidiaries (A) possess, and are in compliance with the terms of, all Governmental Licenses including, without limitation, all Governmental Licenses required by the United States Food and Drug Administration ("FDA") and/or by any other governmental agencies, which Governmental Licenses are in full force and effect, (B) have not received any notice from any governmental agency relating to the revocation or modification of any Governmental Licenses that, if determined adversely to the Company or its subsidiaries, would reasonably be expected to have a material impact on the Company and (C) are not aware of any other action by any governmental agency to limit, suspend, terminate or revoke any Governmental License held by the Company or any of its subsidiaries; (iii) (A) the studies, tests and preclinical and clinical trials conducted by or on behalf of or sponsored by the Company were, and if still pending are being, conducted in all material respects in accordance with standard medical and scientific research procedures and controls, all Governmental Licenses, and all Health Care Laws (B) none of the studies, tests and preclinical and clinical trials conducted by or on behalf of or sponsored by the Company involved any investigator who has been disqualified as a clinical investigator or has been found by the FDA to have engaged in scientific misconduct, (C) the Company is not aware of any studies, tests or trials the results of which reasonably call into question the clinical trial results described or referred to in the Registration Statement, Disclosure Package and the Prospectus and (D) except as disclosed in the Registration Statement, Disclosure Package and the Prospectus, the Company and its subsidiaries have not received any communication, notice or correspondence from any governmental agencies requiring the termination, material modification or suspension of any studies, tests or preclinical and clinical trials conducted by or on behalf of or sponsored by the Company; (iv) each description of any studies, tests or preclinical and clinical trials conducted by or on behalf of or sponsored by the Company contained in the Registration Statement, Disclosure Package and the Prospectus is accurate and complete in all material respects and fairly presents the data about and derived from such studies, tests and trials; (v) all testing, manufacturing, packaging, processing, labeling, distribution, marketing, promotion, storage, import, export or disposal of the Company's or its subsidiaries' products by the Company, its subsidiaries or to the Company's knowledge, their suppliers, vendors or partners have been conducted in compliance with all applicable laws, rules and regulations, including applicable Health Care Laws; (vi) neither the Company nor any subsidiary has received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental or regulatory authority or third party alleging that any product, operation, or activity is in violation of any Health Care Laws or Governmental Licenses and the Company has no knowledge that any such governmental or regulatory authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (vii) neither the Company nor any subsidiary has received any FDA Form 483, written notice of adverse finding, warning letter, untitled letter or other correspondence or written notice from any governmental or regulatory authority alleging or asserting noncompliance with any applicable laws or regulations, including the Health Care Laws, or the terms of any Governmental Licenses; (viii) (A) the Company and each subsidiary has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Health Care Laws or Governmental Licenses, (B) all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct in all material respects and not misleading on the date filed (or were corrected or supplemented by a subsequent submission), and (C) the Company is not aware of any reasonable basis for any material liability with respect to such filings; and (D) neither the Company nor its subsidiaries have, and to the knowledge of the Company, the Company's officers, employees and agents have not, made any untrue statement of a material fact or fraudulent statement to any governmental or regulatory authority or failed to disclose a material fact required to be disclosed to any governmental or regulatory authority; (ix) the Company is not a party to and does not have any ongoing reporting obligations pursuant to any corporate integrity agreements, deferred or non-prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any governmental agency; and (x) neither the Company or any of its subsidiaries or their employees, officers, directors or, to the Company's knowledge, agents, has been excluded, suspended or debarred from participation in any government health care program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

The term "**Health Care Laws**" means Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh (the Medicare statute), Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (the Medicaid statute) and any other law governing or pertaining to a government healthcare program; the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); the civil False Claims Act, 31 U.S.C. §§ 3729 et seq.; the criminal False Claims Act 42 U.S.C. 1320a-7b(a); any criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286, 287, 1035, 1347, 1349 and the health care fraud criminal provisions under the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §§ 1320d et seq., ("**HIPAA**"); the Civil Monetary Penalties Law, 42 U.S.C. §§ 1320a-7a; the Physician Payments Sunshine Act, 42 U.S.C. § 1320a-7h; the Exclusions Law, 42 U.S.C. § 1320a-7; HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, 42 U.S.C. §§ 17921 et seq., and the regulations promulgated thereunder ("**HITECH**"); the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq.; the Public Health Service Act, 42 U.S.C. §§ 201 et seq.; the regulations promulgated pursuant to such laws; and any similar federal, state, local and foreign laws and regulations, in each case as amended.

(aa) Privacy Laws. The Company and its subsidiaries are, and at all prior times were, in material compliance with all applicable data privacy and security laws and regulations, including without limitation, as applicable, the General Data Protection Regulation 2016/679 (the "**GDPR**"), the UK Data Protection Act 2018 ("**DPA**"), the UK General Data Protection Regulation as defined by the DPA as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (together with the DPA, the "UK GDPR"), and HIPAA, as amended by HITECH (collectively, "**Privacy Laws**"). To ensure compliance with the Privacy Laws, and contractual obligations, industry standards, and any other legal obligations related to data privacy and security, the Company and its subsidiaries have in place, comply with, and take appropriate steps reasonably designed to ensure compliance in all material respects with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of Personal Data (the "**Policies**") as applicable. "**Personal Data**" means all personal, personally identifiable, sensitive, confidential or regulated data. The Company and its subsidiaries since inception have at all times made all disclosures to users or customers required by applicable Privacy Laws, and has provided accurate notice of its Policies then in effect to its customers, employees, third party vendors and representatives as required by applicable Privacy Laws, except where the failure to do so would not, individually or in the aggregate, have a Material Adverse Effect. None of such disclosures made or contained in any of the Policies have been inaccurate, misleading, deceptive or in violation of any Privacy Laws or Policies in any material respect. The Company further certifies that, neither it nor any subsidiary: (i) has received written notice of any actual or potential liability under or relating to, or actual or potential material violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law. The execution, delivery and performance of this Agreement or any other agreement referred to in this Agreement will not result in a breach of violation of any Privacy Laws or Policies.

(bb) IT Systems. Except as would not have a Material Adverse Effect, the Company's and its subsidiaries' information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "**IT Systems**") are: (i) adequate for, and operate and perform in all material respects as required in connection with the operation of the business of the Company and its subsidiaries as currently conducted; and (ii) free and clear of all bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. The Company and its subsidiaries have implemented and maintained appropriate controls, policies, procedures, and safeguards designed to maintain and protect their material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and data (including all Personal Data) used in connection with their businesses, reasonably consistent with industry standards and practices, or as required by applicable regulatory standard; and there have been no breaches, violations, outages or unauthorized uses of or accesses to the IT Systems and data (including all Personal Data) except for those that have been remedied without material cost or liability or the duty to notify any other person, nor any incidents under internal review or investigations relating to the same. The Company and its subsidiaries have complied with and are presently in material compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, and all industry guidelines, standards, policies and contractual obligations relating to the privacy and security of IT Systems and Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification. Neither the Company nor its subsidiaries has been notified of, and each of them has no knowledge of any event or condition that could result in, any security breach or incident, unauthorized access or disclosure or other compromise to its IT Systems and Personal Data except, in each case, for any such matter as would not reasonably be expected to have a Material Adverse Effect. The Company and its subsidiaries have implemented backup and disaster recovery technology consistent with industry standards and practice.

(cc) Statistical and Market-Related Data. Any statistical, industry-related and market-related data included in the Registration Statement, Disclosure Package and the Prospectus are based on or derived from sources that the Company believes, after reasonable inquiry, to be reliable and accurate and, to the extent required, the Company has obtained the written consent to the use of such data from such sources;

(dd) Compliance with ERISA. Except, in each case, for any such matter as would not reasonably be expected to have a Material Adverse Effect, (i) each "employee benefit plan" (within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended, including the regulations and published interpretations thereunder ("**ERISA**")) for which the Company or any member of its "**Controlled Group**" (defined as any organization that is a member of a controlled group of corporations within the meaning of Section 414 of the Internal Revenue Code of 1986, as amended (the "**Code**")) would have liability (each a "**Plan**") is in compliance in all material respects with all applicable statutes, rules and regulations, including ERISA and the Code; (ii) with respect to each Plan subject to Title IV of ERISA (A) no "reportable event" (as defined in Section 4043 of ERISA) has occurred for which the Company or any member of its Controlled Group would have any material liability; and (B) neither the Company nor any member of its Controlled Group has incurred or expects to incur material liability under Title IV of ERISA (other than for contributions to the Plan or premiums payable to the Pension Benefit Guaranty Corporation, in each case in the ordinary course and without default); (iii) no Plan which is subject to Section 412 of the Code or Section 302 of ERISA has failed to satisfy the minimum funding standard within the meaning of such sections of the Code or ERISA; and (iv) each Plan that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, whether by action or by failure to act, which would cause the loss of such qualification.

(ee) Environmental Laws. Except in each case as otherwise disclosed in the Registration Statement, the Disclosure Package and the Prospectus and except in each case as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect: (i) the Company and its subsidiaries have complied with all applicable federal, state, local, foreign and international laws (including the common law), statutes, rules, regulations, orders, judgments, decrees or other legally binding requirements of any court, administrative agency or other governmental authority relating to pollution or to the protection of the environment, natural resources or human health or safety, or to the manufacture, use, generation, treatment, storage, disposal, release or threatened release of hazardous or toxic substances, pollutants, contaminants or wastes, or the arrangement for such activities ("**Environmental Laws**"); (ii) the Company and its subsidiaries have obtained and complied with all permits, licenses, authorizations or other approvals required of them under Environmental Laws to conduct their respective businesses and are not subject to any action to revoke, terminate, cancel, limit or appeal any such permits, licenses, authorizations or approvals; and (iii) none of the Company or any of its subsidiaries has received written notice of or is otherwise subject to any pending or threatened claim, or has any cost or liability under Environmental Laws in respect of its past or present business, operations (including the disposal of hazardous substances at any off-site location), facilities or real property (whether owned, leased or operated) or on account of any predecessor or any person whose liability under any Environmental Laws it has agreed to assume; and the Company is not aware of any facts or conditions that could reasonably be expected to give rise to any such claim, cost or liability. Except in each case as otherwise disclosed in the Registration Statement, the Disclosure Package and the Prospectus, none of the Company or any of its subsidiaries is aware of any facts or issues relating to compliance with Environmental Laws that would reasonably be expected to have a material effect on their capital expenditures, earnings or competitive position or is a party to any judicial or administrative proceeding (including a notice of violation) under any Environmental Laws to which a governmental authority is also a party and which involves potential monetary sanctions, unless it could reasonably be expected that such proceeding will result in monetary sanctions of less than $300,000, or which is otherwise material, and no such proceeding has, to the Company's knowledge, been threatened in writing or is known by the Company to be contemplated.

(ff) Restrictions on Dividends. Except as disclosed in the Registration Statement, the Disclosure Package and the Prospectus, no subsidiary of the Company is prohibited or restricted, directly or indirectly, from paying dividends to the Company or any other subsidiary of the Company, or from making any other distribution with respect to such subsidiary's equity securities or from repaying to the Company or any other subsidiary of the Company any amounts that may from time to time become due under any loans or advances to such subsidiary from the Company or any other subsidiary of the Company or from transferring any property or assets to the Company or to any other subsidiary of the Company.

(gg) Nasdaq Listing. The Company's Common Stock has been registered pursuant to Section 12(b) of the Exchange Act, its outstanding shares of Common Stock have been listed, and an Listing of Additional Shares for the Shares has been submitted to, The Nasdaq Stock Market LLC **("Nasdaq")**, and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or the listing of the Common Stock (including the Shares) on Nasdaq, nor has the Company received any notification that the Commission or Nasdaq is contemplating terminating such registration or listing.

(hh) Certain Relationships and Related Party Transactions. There are no material related-party transactions involving the Company or its subsidiaries or any other person required to be described in the Registration Statement, the Disclosure Package and the Prospectus which have not been described in such documents as required.

(ii) Absence of Labor Dispute. No material labor disturbance by or material dispute with employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is threatened.

(jj) No Finder's Fee. None of the Company or any of its subsidiaries is a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against the Company or any of its subsidiaries or any Manager for a brokerage commission, finder's fee or like payment in connection with the offering and sale of the Shares.

(kk) Absence of Proceedings. Other than as set forth in the Registration Statement, the Disclosure Package and the Prospectus, there are no legal or governmental proceedings pending to which the Company or any of its subsidiaries or, to the Company's knowledge, any officer or director of the Company is a party or of which any property or assets of the Company or any of its subsidiaries or, to the Company's knowledge, any officer or director of the Company is the subject which would individually or in the aggregate reasonably be expected to have a material adverse effect on the current or future financial position, stockholders' equity or results of operations of the Company and its subsidiaries, taken as a whole (a "**Material Adverse Effect**"); and, to the best of the Company's knowledge, no such proceedings are threatened or contemplated by governmental authorities or threatened by others.

(ll) Transfer Taxes. There are no transfer taxes or other similar fees or charges under U.S. federal law or the laws of any state, or any political subdivision thereof, required to be paid in connection with the execution and delivery of this Agreement or the issuance or sale by the Company of the Shares.

(mm) Investment Company Act. The Company is not and, upon the issuance and sale of the Shares and the application of the proceeds thereof as described in the Registration Statement, the Disclosure Package and the Prospectus under the caption "Use of Proceeds," will not be required to be registered as, an "investment company", as such term is defined in the Investment Company Act of 1940, as amended.

(nn) Financial Statements; Non-GAAP Financial Measures. The financial statements, together with related notes and schedules, included in the Registration Statement, the Disclosure Package and the Prospectus, comply in all material respects with the applicable requirements of the Act and present fairly in all material respects the financial position and the results of operations and cash flows of the entities purported to be shown thereby, at the indicated dates and for the indicated periods. Such financial statements and related schedules have been prepared in accordance with GAAP, consistently applied throughout the periods involved, except as disclosed therein, and all adjustments necessary for a fair presentation of results for such periods have been made. The pro forma financial statements, if any, or data included in the Registration Statement or the Prospectus, if any, comply with the applicable requirements of the Act and the Exchange Act, and the assumptions used in the preparation of such pro forma financial statements and data are reasonable, the pro forma adjustments used therein are appropriate to give effect to the transactions or circumstances described therein and the pro forma adjustments have been properly applied to the historical amounts in the compilation of those statements and data; the other financial and statistical data set forth in the Registration Statement, the Disclosure Package or the Prospectus are accurately and fairly presented and prepared on a basis consistent with the financial statements and books and records of the Company. Any non-GAAP financial measure (as such term is defined by the rules and regulations of the Commission), contained in the Registration Statement, the Disclosure Package and the Prospectus has been derived from the accounting records of the Company or its predecessors for accounting purposes, fairly presents in all material respect the information purported to be shown thereby and complies in all material respects with Regulation G of the Exchange Act, and Item 10(e) of Regulation S-K under the Act, to the extent applicable. The Company and its subsidiaries do not have any material liabilities or obligations, direct or contingent, not disclosed in Registration Statement, the Disclosure Package and the Prospectus. There are no financial statements (historical or pro forma) that are required to be included in the Registration Statement, the Disclosure Package or the Prospectus that are not included as required.

(oo) Independent Accountants. The accountants who certified the financial statements and supporting schedules included in the Registration Statement, the Disclosure Package and the Prospectus are independent public accountants as required by the Act, the Exchange Act and the Public Company Accounting Oversight Board.

(pp) Compliance with the Sarbanes-Oxley Act. There is and has been no failure on the part of the Company or any of the Company's directors or officers, in their capacities as such, to comply in all material respects with any applicable provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith, including Section 402 related to loans and Sections 302 and 906 related to certifications.

(qq) Accounting Controls. The Company maintains a system of internal control over financial reporting (as such term is defined in Rule 13a-15(f) under the Exchange Act) that complies with the requirements of the Exchange Act and has been designed by the Company's principal executive officer and principal financial officer, or under their supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. The Company is not aware of any material weaknesses in its internal control over financial reporting. Since the date of the latest audited financial statements included or incorporated by reference in the Disclosure Package, Registration Statement and the Prospectus, there has been no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(rr) Disclosure Controls. The Company maintains disclosure controls and procedures (as such term is defined in Rule 13a-15(e) under the Exchange Act) that comply with the requirements of the Exchange Act; such disclosure controls and procedures have been designed to ensure that material information relating to the Company and its subsidiaries is made known to the Company's principal executive officer and principal financial officer by others within those entities; and such disclosure controls and procedures are effective.

(ss) Foreign Corrupt Practices Act. None of the Company, any of its subsidiaries or, to the knowledge of the Company, any director, officer, employee, agent, affiliate or other person associated with or acting on behalf of the Company or any of its subsidiaries has (A) used any funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (B) made or taken an act in furtherance of an offer, promise or authorization of any direct or indirect unlawful payment or benefit to any foreign or domestic government or regulatory official or employee, including of any government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office; (C) violated or is in violation of any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or committed an offence under the Bribery Act 2010 of the United Kingdom, or any other applicable anti-bribery or anti-corruption laws; or (D) made, offered, agreed, requested or taken an act in furtherance of any unlawful bribe or other unlawful benefit, including, without limitation, any rebate, payoff, influence payment, kickback or other unlawful or improper payment or benefit. The Company and its subsidiaries have instituted, and maintain and enforce, policies and procedures designed to promote and ensure compliance with all applicable anti-bribery and anti-corruption laws.

(tt) Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements, including those of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the applicable money laundering statutes of all jurisdictions where the Company or any of its subsidiaries conducts business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines issued, administered or enforced by any governmental or regulatory agency (collectively, the "**Anti-Money Laundering Laws**") and no action, suit or proceeding by or before any court or governmental or regulatory agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(uu) OFAC. None of the Company, any of its subsidiaries or, to the knowledge of the Company, any director, officer, employee, agent or affiliate of the Company is currently the subject or the target of any sanctions administered or enforced by the U.S. Government, including, without limitation, the Office of Foreign Assets Control of the U.S. Department of the Treasury ("**OFAC**"), or the U.S. Department of State and including, without limitation, the designation as a "specially designated national" or "blocked person", the United Nations Security Council ("**UNSC**"), the European Union, His Majesty's Treasury ("**HMT**"), or other relevant sanctions authority (collectively, "**Sanctions**"), nor is the Company or any of its subsidiaries located, organized or resident in a country or territory that is the subject or the target of Sanctions (each, a "**Sanctioned Country**"); and the Company will not directly or indirectly use the proceeds of the offering of the Shares hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity (i) to fund or facilitate any activities of or business with any person that, at the time of such funding or facilitation, is the subject or the target of Sanctions, (ii) to fund or facilitate any activities of or business in any Sanctioned Country or (iii) in any other manner that will result in a violation by any person (including any person participating in the transaction, whether as sales agent, underwriter, advisor, investor or otherwise) of Sanctions. For the past five years, none of the Company or any of its subsidiaries has knowingly engaged in and are not now knowingly engaged in any dealings or transactions with any person that at the time of the dealing or transaction is or was the subject or the target of Sanctions or with any Sanctioned Country.

(vv) Insurance. Each of the Company and its subsidiaries carry, or are covered by, insurance, from financially sound and reputable insurers, in such amounts and covering such risks as are generally deemed reasonably adequate for the conduct of their respective businesses and the value of their respective properties and as is generally deemed adequate and customary for companies engaged in similar businesses; and the Company has no reason to believe that it or any of its subsidiaries will not be able to renew their existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue their respective businesses at a cost that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(ww) Ownership Structure. (i) the ownership structure (the "**Ownership Structure**") set forth in Annex II of this Agreement complies with all applicable laws, rules and regulations, including those of the People's Republic of China (the "**PRC**"), Hong Kong, the Cayman Islands and the United States, does not violate, breach, contravene or otherwise conflict with any applicable laws, rules and regulations and has not been challenged by any governmental agency; (ii) there are no legal, arbitral, governmental or other proceedings (including, without limitation, governmental investigations or inquiries) pending before or threatened or contemplated by any governmental agency in respect of such Ownership Structure; (iii) all consents, approvals, authorizations, orders, registrations, clearances or qualifications of or with any governmental agency ("**Governmental Authorizations**") in connection with the Ownership Structure have been duly granted, made or unconditionally obtained in writing and are in full force and effect and no such Governmental Authorization has been withdrawn or revoked or is subject to any condition precedent which has not been fulfilled or performed; (iv) in connection with the transactions contemplated by this Agreement, the Ownership Structure will comply with all applicable laws, rules and regulations; (v) all of the Company's subsidiaries incorporated or formed in the PRC and Hong Kong have taken all reasonable steps to comply with any applicable rules and regulations of the PRC State Administration of Foreign Exchange (the "**SAFE Rules and Regulations**"), including, without limitation, requesting each shareholder and option holder that is, or is directly or indirectly owned or controlled by, a PRC resident or citizen to complete any registration and other procedures required under the SAFE Rules and Regulations; and (vi) (A) dividends and other distributions declared with respect to after-tax retained earnings on the share capital of any subsidiary of the Company that is or will be incorporated in the PRC will be permitted under the current laws and regulations of the PRC to be freely transferred out of the PRC and may be paid in U.S. dollars, subject to the successful completion of PRC formalities required for such remittance, and all such dividends and other distributions will not be subject to withholding or other taxes under the laws and regulations of the PRC and are otherwise free and clear of any other tax, withholding or deduction in the PRC, and without the necessity of obtaining any Governmental Authorizations; (B) dividends and other distributions declared and payable on the share capital of any subsidiary of the Company that is or will be incorporated in Hong Kong will be permitted under the current laws and regulations of Hong Kong and the PRC to be paid to the Company, and all such dividends and other distributions will not be subject to withholding or other taxes under the laws and regulations of Hong Kong and the PRC and are otherwise free and clear of any other tax, withholding or deduction in Hong Kong and the PRC and without the necessity of obtaining any Governmental Authorizations of or with any governmental agency in Hong Kong or the PRC and (C) dividends and other distributions declared and payable on the share capital of any subsidiary of the Company that is or will be incorporated in the Cayman Islands will be permitted under the current laws and regulations of the Cayman Islands to be paid to the Company, and all such dividends and other distributions will not be subject to withholding or other taxes under the laws and regulations of the Cayman Islands and are otherwise free and clear of any other tax, withholding or deduction in the Cayman Islands and without the necessity of obtaining any Governmental Authorizations of or with any governmental agency in the Cayman Islands;

(xx) Stabilization. Neither the Company nor, to the Company's knowledge, any of its affiliates, has taken or may take, directly or indirectly, any action designed to cause or result in, or which has constituted or which might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Shares in violation of Regulation M of the Exchange Act.

(yy) FINRA Affiliation. To the knowledge of the Company, there are no affiliations or associations between any member of FINRA and any of the officers or directors of the Company or the holders of 5% or greater of the Common Stock, except as described in the Registration Statement, the Disclosure Package and the Prospectus to the extent required to be so described.

(zz) Accuracy of Exhibits. There are no contracts or other documents that are required by the Act to be described in the Prospectus or filed as exhibits to the Registration Statement, or that are required by the Exchange Act to be filed as exhibits to a document incorporated by reference into the Prospectus, that have not been so described in the Prospectus or filed as exhibits to the Registration Statement or such incorporated document.

(aaa) XBRL. The interactive data in the eXtensible Business Reporting Language included as an exhibit to the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.

(bbb) WKSI. (i) At the original effectiveness of the Registration Statement, (ii) at the time of the most recent amendment thereto for the purposes of complying with Section 10(a)(3) of the Act (whether such amendment was by post-effective amendment or incorporated report filed pursuant to Section 13 or 15(d) of the Exchange Act or in the form of a prospectus), (iii) at the time the Company or any person acting on its behalf (within the meaning, for this clause only, of Rule 163(c)) made any offer relating to the Shares in reliance on the exemption of Rule 163, and (iv) as of the Applicable Time, the Company was and is a "well-known seasoned issuer" (as defined in Rule 405 of the Act).

Any certificate signed by any officer of the Company or any of its subsidiaries and delivered to the Managers or to counsel for the Managers in connection with this Agreement or any Terms Agreement shall be deemed a representation and warranty by the Company or such subsidiary of the Company, as applicable, to each Manager as to the matters set forth therein.

The Company acknowledges that the Managers and, for purposes of the opinions to be delivered pursuant to Section 4 hereof, counsel for the Company and counsel for the Managers, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

3. Sale and Delivery of Shares. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company and the Managers agree that the Company may from time to time seek to sell Shares through a Designated Manager, acting as sales agent, or directly to any of the Managers acting as principal, as follows:

(a) The Company may submit to a Designated Manager its orders (including any price, time or size limits or other customary parameters or conditions) to sell Shares on any Trading Day (as defined herein) in a form and manner as mutually agreed to by the Company and such Designated Manager. As used herein, "**Trading Day**" shall mean any trading day on Nasdaq.

(b) Subject to the terms and conditions hereof, each Manager, at any time it is a Designated Manager, shall use its reasonable efforts to execute any Company order submitted to it hereunder to sell Shares and with respect to which such Designated Manager has agreed to act as sales agent. The Company acknowledges and agrees that (i) there can be no assurance that a Designated Manager will be successful in selling the Shares, (ii) a Designated Manager will incur no liability or obligation to the Company or any other person or entity if it does not sell Shares for any reason other than a failure by a Designated Manager to use its reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell such Shares as required under this Agreement and (iii) no Manager shall be under any obligation to purchase Shares on a principal basis pursuant to this Agreement, except as otherwise specifically agreed by Manager and the Company. The Designated Manager may make sales pursuant to each order by any method permitted by law, including without limitation (i) by means of ordinary brokers' transactions (whether or not solicited), (ii) to or through a market maker, (iii) directly on or through any national securities exchange or facility thereof, a trading facility of a national securities association, an alternative trading system, or any other market venue, (iv) in the over-the-counter market, (v) in privately negotiated transactions, or (vi) through a combination of any such methods.

(c) The Company shall not authorize the issuance and sale of, and a Designated Manager shall not sell as sales agent, any Share at a price lower than the minimum price therefor designated from time to time by the Company and notified to a Designated Manager in writing. In addition, the Company or a Designated Manager may upon notice to the other party hereto by telephone (confirmed promptly by email or facsimile), suspend an offering of the Shares with respect to which that Designated Manager is acting as sales agent; *provided*, *however*, that such suspension or termination shall not affect or impair the parties' respective obligations with respect to the Shares sold hereunder prior to the giving of such notice.

(d) The compensation to a Designated Manager for sales of the Shares with respect to which such Designated Manager acts as sales agent hereunder shall be up to 3% of the gross offering proceeds of the Shares sold pursuant to this Agreement as mutually agreed to in writing by such Designated Manager and the Company. The foregoing rate of compensation shall not apply when a Manager, acting as principal, purchases Shares from the Company pursuant to a Terms Agreement. Any compensation or commission due and payable to any Managers hereunder with respect to any sale of Shares shall be paid by the Company to such Managers concurrently with the settlement for sales of the Shares by deduction from the proceeds from sales of the Shares payable to the Company. The remaining proceeds, after further deduction for any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales shall constitute the net proceeds to the Company for such Shares (the "**Net Proceeds**").

(e) Settlement for sales of the Shares pursuant to this Agreement will occur on the second Trading Day following the date on which such sales are made (each such day, a "**Settlement Date**"). On each Settlement Date, the Shares sold through a Designated Manager for settlement on such date shall be issued and delivered by the Company to such Designated Manager against payment of the Net Proceeds from the sale of such Shares. Settlement for all such Shares shall be effected by free delivery of the Shares, in definitive form, by the Company or its transfer agent to such Designated Manager's or its designee's account (*provided* such Designated Manager shall have given the Company written notice of such designee prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto, in return for payments in same day funds delivered to the account designated by the Company. If the Company, or its transfer agent (if applicable) shall default on its obligation to deliver the Shares on any Settlement Date, the Company shall (i) hold each applicable Designated Manager harmless against any loss, claim, damage, or expense (including reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company and (ii) pay each such Designated Manager any commission, discount or other compensation to which it would otherwise be entitled absent such default.

(f) If acting as sales agent hereunder, the Designated Manager shall provide written confirmation (which may be by facsimile or email) to the Company following the close of trading on the Nasdaq each day in which the Shares are sold under this Agreement setting forth (i) the amount of the Shares sold on such day and the gross offering proceeds received from such sale and (ii) the commission payable by the Company to such Designated Manager with respect to such sales.

(g) At each Applicable Time, Settlement Date, Representation Date (as defined in Section 4(k)) and Filing Date (as defined in Section 4(r)), the Company shall be deemed to have affirmed each representation and warranty contained in this Agreement as if such representation and warranty were made as of such date, modified as necessary to relate to the Registration Statement and the Prospectus as amended as of such date. Any obligation of a Designated Manager to use its reasonable efforts to sell the Shares on behalf of the Company as sales agent shall be subject to the continuing accuracy of the representations and warranties of the Company herein (and the completion of any diligence to verify such accuracy by such Designated Manager), to the performance by the Company of its obligations hereunder and to the continuing satisfaction of the additional conditions specified in Section 6 of this Agreement.

(h) Subject to such further limitations on offers and sales of Shares or delivery of instructions to offer and sell Shares as are set forth herein and as may be mutually agreed upon by the Company and a Designated Manager, the Company shall not request the sale of any Shares that would be sold, and no Designated Manager shall be obligated to sell, (i) during any period in which the Company's insider trading policy, as it exists on the date of this Agreement, would prohibit the purchase or sale of any Shares by any of its officers or directors, (ii) any time during the period commencing on the tenth business day prior to the time Company shall issue a press release containing, or shall otherwise publicly announce, its earnings, revenues or other results of operations (each, an "**Earnings Announcement**") through and including the time that is 24 hours after the time that the Company files (a "**Filing Time**") a Quarterly Report on Form 10-Q or an Annual Report on Form 10-K that includes consolidated financial statements as of and for the same period or periods, as the case may be, covered by such Earnings Announcement, or (iii) during any other period in which the Company is, or could be deemed to be, in possession of material non-public information.

(i) If the Company wishes to issue and sell the Shares pursuant to this Agreement directly to any of the Managers acting as principal (each, a "**Placement**"), it will notify the Manager or Managers of the proposed terms of such Placement. If such Manager or Managers, acting as principal, wishes to accept such proposed terms (which a Manager may decline to do for any reason in its sole discretion) or, wishes to accept amended terms proposed by the Company after further discussion, such Manager or Managers and the Company will enter into a Terms Agreement setting forth the terms of such Placement. The terms set forth in a Terms Agreement will not be binding on the Company or such Manager or Managers unless and until the Company and such Manager or Managers have each executed such Terms Agreement accepting all of the terms of such Terms Agreement. In the event of a conflict between the terms of this Agreement and the terms of a Terms Agreement, the terms of such Terms Agreement will control.

(j) Each Placement shall be made in accordance with the terms of this Agreement and, if applicable, a Terms Agreement, which will provide for the sale of such Shares to, and the purchase thereof by, such Manager. A Terms Agreement may also specify certain provisions relating to the reoffering of such Shares by a Manager. The commitment of a Manager to purchase the Shares pursuant to any Terms Agreement shall be deemed to have been made on the basis of the representations and warranties of the Company herein contained and shall be subject to the terms and conditions herein set forth. Each Terms Agreement shall specify the number of the Shares to be purchased by a Manager pursuant thereto, the price to be paid to the Company for such Shares, any provisions relating to rights of, and default by, underwriters acting together with such Manager in the reoffering of the Shares, and the time and date (each such time and date being referred to herein as a "**Time of Delivery**") and place of delivery of and payment for such Shares.

(k) Under no circumstances shall the number and aggregate amount of the Shares sold pursuant to this Agreement and any Terms Agreement exceed (i) the aggregate amount set forth in Section 1, (ii) the number of shares of the Common Stock available for issuance under the currently effective Registration Statement or (iii) the number and aggregate amount of the Shares authorized from time to time to be issued and sold under this Agreement by the board of directors of the Company (the "**Board**"), or a duly authorized committee thereof, and notified to the Managers in writing.

4. Agreements. The Company agrees with each of the Managers that:

(a) During any period when the delivery of a prospectus relating to the Shares is required (including in circumstances where such requirement may be satisfied pursuant to Rule 172 or any similar rule) to be delivered under the Act in connection with the offering or sale of the Shares, the Company will not file any amendment of the Registration Statement or supplement in connection with the offering and sale of the Shares (including the Prospectus or any Interim Prospectus Supplement) to the Base Prospectus, the Disclosure Package or the Prospectus, whether pursuant to the Act, the Exchange Act or otherwise, unless (i) the Company has furnished to the Managers a copy of such amendment or supplement (including, for the avoidance of doubt, reports or other information to be filed by the Company under the Exchange Act that would be incorporated by reference into the Registration Statement and the Prospectus) for its review a reasonable period of time prior to filing (or, in the case of Current Reports on Form 8-K, has used its commercially reasonable efforts to so furnish copies to the Managers prior to filing), and (ii) except for reports or other information required to be filed by the Company under the Exchange Act, the Company will not file any such proposed amendment or supplement to which the Managers reasonably object. The Company prepared the Prospectus, in a form approved by the Existing Manager, and filed such Prospectus, as amended at the Initial Execution Time, with the Commission pursuant to the applicable paragraph of Rule 424(b) promptly after the Initial Execution Time (but in any event within the time period described thereby). The Company will cause any supplement to the Prospectus to be prepared, in a form approved by the Managers, and will file such supplement with the Commission pursuant to the applicable paragraph of Rule 424(b) within the time period prescribed thereby and will notify the Managers of such timely filing, including for the avoidance of doubt, the supplement to the Prospectus filed as of the date hereof. The Company, subject to this Section 4(a) and Section 4(c), will comply with the requirements of Rule 430B. During any period when the delivery of a prospectus relating to the Shares is required (including in circumstances where such requirement may be satisfied pursuant to Rule 172 or any similar rule) to be delivered under the Act in connection with the offering or sale of the Shares, the Company will promptly advise the Managers (A) when the Prospectus, and any supplement thereto, shall have been filed (if required) with the Commission pursuant to Rule 424(b), (B) when, during any period when the delivery of a prospectus (whether physically or through compliance with Rule 172 or any similar rule) is required under the Act in connection with the offering or sale of the Shares, any amendment to the Registration Statement or any new registration statement relating to the Shares shall have been filed or become effective (other than a prospectus supplement relating solely to the offering of securities other than the Shares), (C) of the receipt of any comments from the Commission, (D) of any request by the Commission or its staff for any amendment of the Registration Statement, or for any supplement to the Prospectus or for any additional information related to the Registration Statement or the Prospectus, (E) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or of any notice objecting to its use or any the issuance of any order preventing or suspending the use of the Prospectus or any amendment or supplement thereto, or the institution or threatening of any proceeding for any of such purposes or pursuant to Section 8A of the Act or (F) of the receipt by the Company of any notification with respect to the suspension of the qualification of the Shares for sale in any jurisdiction or the institution or threatening of any proceeding for such purpose. The Company will use its reasonable best efforts to prevent the issuance of any such stop order or the occurrence of any such suspension or objection to the use of the Registration Statement and, upon such issuance, occurrence or notice of objection, to obtain at the earliest possible moment the withdrawal of such stop order or relief from such occurrence or objection, including, if necessary, by filing an amendment to the Registration Statement or a new registration statement and using its reasonable best efforts to have such amendment or new registration statement declared effective as soon as practicable.

(b) If, at any time on or after an Applicable Time but prior to the related Settlement Date or Time of Delivery, any event occurs as a result of which the Disclosure Package would include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein in the light of the circumstances under which they were made or the circumstances then prevailing not misleading, the Company will (i) notify promptly the relevant Manager(s) so that any use of the Disclosure Package may cease until it is amended or supplemented; (ii) amend or supplement the Disclosure Package to correct such statement or omission; and (iii) supply any amendment or supplement to the relevant Manager(s) in such quantities as the Manager(s) may reasonably request.

(c) During any period when the delivery of a prospectus relating to the Shares is required (including in circumstances where such requirement may be satisfied pursuant to Rule 172 or any similar rule) to be delivered under the Act, if any event occurs as a result of which the Prospectus as then supplemented would include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein in the light of the circumstances under which they were made at such time not misleading, or if it shall be necessary to amend the Registration Statement, file a new registration statement or supplement the Prospectus to comply with the Act or the Exchange Act or the respective rules thereunder, including in connection with use or delivery of the Prospectus, the Company promptly will (i) notify the Managers of any such event, (ii) prepare and file with the Commission, subject to the first sentence of paragraph (a) of this Section 4, an amendment or supplement or new registration statement which will correct such statement or omission or effect such compliance, (iii) use its reasonable best efforts to have any amendment to the Registration Statement or new registration statement declared effective as soon as practicable in order to avoid any disruption in use of the Prospectus and (iv) supply any supplemented Prospectus to the Managers in such quantities as the Managers may reasonably request.

(d) As soon as practicable, the Company will make generally available to its security holders and to the Managers an earnings statement or statements of the Company and its subsidiaries which will satisfy the provisions of Section 11(a) of the Act and Rule 158.

(e) The Company will deliver to the Managers and counsel for the Managers, without charge, as such Managers or counsel for the Managers may reasonably request, signed copies of the Registration Statement as originally filed and of each amendment thereto (including exhibits filed therewith or incorporated by reference therein and documents incorporated or deemed to be incorporated by reference therein) and signed copies of all consents and certificates of experts. The Registration Statement and each amendment thereto furnished to the Managers will be identical to any electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T. The Company will pay the expenses of printing or other production of all documents relating to the offering.

(f) The Company will deliver to the Managers and counsel for the Managers, without charge, for so long as delivery of a prospectus by the Managers or dealer may be required by the Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 or any similar rule), as many copies of the Prospectus and each Issuer Free Writing Prospectus and any supplement thereto as the Managers may reasonably request. The Prospectus and any Issuer Free Writing Prospectus and any amendments or supplements thereto furnished to the Managers will be identical to any electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T. The Company will pay the expenses of printing or other production of all documents relating to the offering.

(g) The Company will arrange, if necessary, for the qualification of the Shares for sale under the laws of such jurisdictions as the Managers may designate and will maintain such qualifications in effect so long as required for the distribution of the Shares; *provided* that in no event shall the Company be obligated to qualify to do business in any jurisdiction where it is not now so qualified or to take any action that would subject it to service of process in suits, other than those arising out of the offering or sale of the Shares, in any jurisdiction where it is not now so subject or where it would be subject to taxation as a foreign business.

(h) The Company agrees that, unless it has or shall have obtained the prior written consent of the relevant Designated Manager, and each Manager agrees with the Company that, unless it has or shall have obtained the prior written consent of the Company, as the case may be, it has not made and will not make any offer relating to the Shares that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a "free writing prospectus" (as defined in Rule 405) required to be filed by the Company with the Commission or retained by the Company under Rule 433; *provided* that the prior written consent of the parties hereto shall be deemed to have been given in respect of the Free Writing Prospectuses included in Schedule I hereto. Any such free writing prospectus consented to by the Managers or the Company is hereinafter referred to as a "**Permitted Free Writing Prospectus**." The Company agrees that (i) it has treated and will treat, as the case may be, each Permitted Free Writing Prospectus as an Issuer Free Writing Prospectus and (ii) it has complied and will comply, as the case may be, with the requirements of Rules 164 and 433 applicable to any Permitted Free Writing Prospectus, including in respect of timely filing with the Commission, legending and record keeping.

(i) The Company will not (i) take, directly or indirectly, any action designed to or that might reasonably be expected to cause or result in stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Shares or (ii) sell, bid for, purchase or pay any person (other than as contemplated by this Agreement or any Terms Agreement) any compensation for soliciting purchases of the Shares.

(j) The Company will, at any time during the term of this Agreement, as supplemented from time to time, advise the Managers promptly after it shall have received notice or obtain knowledge thereof, of any information or fact that would materially alter or affect any opinion, certificate, letter and other document provided to the Managers pursuant to Section 6 herein.

(k) Upon commencement of the offering of the Shares under this Agreement (if requested by any Manager) (and upon the recommencement of the offering of the Shares under this Agreement following the termination of a suspension of sales hereunder), and each time that (i) the Registration Statement or the Prospectus shall be amended or supplemented (other than (A) an Interim Prospectus Supplement filed pursuant to Rule 424(b) pursuant to Section 4(r) of this Agreement, (B) a prospectus supplement relating solely to the offering or resale of securities other than the Shares or (C) the filing with the Commission of any report under the Exchange Act except such reports referred to in Section 4(k)(ii)), (ii) there is filed with the Commission any annual report on Form 10-K or quarterly report on Form 10-Q, or any other document that contains financial statements or financial information that is incorporated by reference into the Prospectus, or any amendment thereto, or (iii) the Shares are delivered to one or more Managers as principal at the Time of Delivery pursuant to a Terms Agreement (the date of such commencement (in the case that the above-mentioned request is made by any Manager), the date of each such recommencement and the date of each such event referred to in (i), (ii) and (iii) above, a "**Representation Date**"), the Company shall furnish or cause to be furnished to the Managers forthwith a certificate dated and delivered on such Representation Date, as the case may be, in form satisfactory to the Managers to the effect that the statements contained in the certificate referred to in Section 6(d) of this Agreement which were last furnished to the Managers are true and correct at the time of such Representation Date, as though made at and as of such time (except that such statements shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented to such time) or, in lieu of such certificate, a certificate of the same tenor as the certificate referred to in said Section 6(d), modified as necessary to relate to the Registration Statement, the Disclosure Package and the Prospectus as amended and supplemented to the time of delivery of such certificate. The requirement to provide a certificate under this Section 4(k) shall be waived for any Representation Date occurring at a time when no Company order submitted to any Manager hereunder to sell Shares is pending or a suspension of sales hereunder is in effect, which waiver shall continue until the earlier to occur of the date the Company submits an order to any Manager to sell Shares hereunder (which for such calendar quarter shall be considered a Representation Date) and the next occurring Representation Date. Notwithstanding the foregoing, if the Company subsequently decides to sell Shares following a Representation Date when the Company relied upon the foregoing waiver and therefore did not provide the Managers with a certificate under this Section 4(k), then before the Company submits an order for the sale of Shares or any Manager sells any Shares pursuant to such order, the Company shall provide the Manager with a certificate in conformity with this Section 4(k) dated as of the date that the order for the sale of Shares is submitted to any Manager hereunder, *provided* that for the avoidance of doubt, such date the certificate is delivered pursuant to the foregoing sentence shall also be a Representation Date.

(l) At the Execution Time, and at each Representation Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(k) for which no waiver is applicable, the Company shall furnish or cause to be furnished forthwith to the Managers and to counsel to the Managers (i) a written opinion of Cooley LLP, counsel to the Company ("**Company Counsel**"), or other counsel reasonably satisfactory to the Managers and (ii) a written opinion of the Company's Chief Intellectual Property Officer ("**Intellectual Property Counsel**"), each dated and delivered on such Representation Date and in form and substance satisfactory to the Managers, of the same tenor as the opinion referred to in Section 6(b) of this Agreement, but modified as necessary to relate to the Registration Statement, the Disclosure Package and the Prospectus as amended and supplemented to the time of delivery of such opinion.

(m) At the Execution Time, and at each Representation Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(k) for which no waiver is applicable, Latham & Watkins LLP, counsel to the Managers, shall deliver a written opinion and disclosure letter, dated and delivered on such Representation Date, in form and substance satisfactory to the Managers, of the same tenor as the opinions and disclosure letter referred to in Section 6(c) of this Agreement but modified as necessary to relate to the Registration Statement, the Disclosure Package and the Prospectus as amended and supplemented to the time of delivery of such opinion.

(n) At the Execution Time and each Representation Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(k) for which no waiver is applicable, the Company shall cause Pricewaterhouse Coopers LLP (the "**Accountants**"), or other independent accountants satisfactory to the Managers forthwith, to furnish the Managers a letter, dated and delivered on such Representation Date, in form and substance satisfactory to the Managers of the same tenor as the letter referred to in Section 6(e) of this Agreement but modified to relate to the Registration Statement, the Disclosure Package and the Prospectus, as amended and supplemented to the date of such letter.

(o) At each Representation Date, the Company shall cause to be furnished to the Managers a certificate of its chief financial officer, dated and delivered on such Representation Date, in form and substance satisfactory to the Managers of the same tenor as the certificate referred to in Section 6(f) of this Agreement but modified to relate to the Registration Statement, the Disclosure Package and the Prospectus, as amended and supplemented to the date of such letter.

(p) At each Representation Date, and at such other times as may be reasonably requested by a Manager (which shall be on a monthly basis or otherwise), the Company will conduct a due diligence session, in form and substance satisfactory to the Managers, which shall include representatives of the management of the Company and the independent accountants of the Company. The Company shall cooperate timely with any reasonable due diligence request from or review conducted by the Managers or its agents from time to time in connection with the transactions contemplated by this Agreement, including, without limitation, providing information and available documents and access to appropriate officers and agents of the Company during regular business hours and at the Company's principal offices, and timely furnishing or causing to be furnished such certificates, letters and opinions from the Company, and their officers and agents, as the Managers may reasonably request.

(q) Nothing in this Agreement shall restrict a Manager from trading, and the Company acknowledges that each Manager may trade in the Common Stock for such Manager's own account and for the accounts of its clients before, at the same time as, or after sales of the Shares occur pursuant to this Agreement or pursuant to a Terms Agreement.

(r) The Company will either (i) disclose in its Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, as applicable, with regard to the relevant quarter, the number of the Shares sold by or through the Managers pursuant to this Agreement, the Net Proceeds to the Company and the compensation paid by the Company with respect to such sales of the Shares pursuant to this Agreement, or (ii) on or prior to the earlier of (A) the date on which the Company shall file a Quarterly Report on Form 10-Q or an Annual Report on Form 10-K in respect of any fiscal quarter in which sales of Shares were made by a Manager pursuant to this Agreement and (B) the date on which the Company shall be obligated to file such document referred to in clause (A) in respect of such quarter (each such date, and any date on which an amendment to any such document is filed, a "**Filing Date**"), the Company will file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b), which prospectus supplement will set forth, with regard to such quarter, the number of the Shares sold by or through a Manager pursuant to this Agreement, the Net Proceeds to the Company and the compensation paid by the Company with respect to such sales of the Shares pursuant to this Agreement and deliver such number of copies of each such prospectus supplement to the Nasdaq as are required by such exchange.

(s) If, to the knowledge of the Company, the conditions set forth in Section 6(a) or 6(g) shall not be true and correct on the applicable Settlement Date or Time of Delivery, the Company will offer to any person who has agreed to purchase Shares from the Company as the result of an offer to purchase solicited by a Designated Manager the right to refuse to purchase and pay for such Shares.

(t) Each acceptance by the Company of an offer to purchase the Shares hereunder, and each execution and delivery by the Company of a Terms Agreement, shall be deemed to be an affirmation to the Designated Manager, or the Manager(s) party to a Terms Agreement, as the case may be, that the representations and warranties of the Company contained in or made pursuant to this Agreement are true and correct as of the date of such acceptance or of such Terms Agreement as though made at and as of such date, and an undertaking that such representations and warranties will be true and correct as of the Settlement Date for the Shares relating to such acceptance or as of the Time of Delivery relating to such sale, as the case may be, as though made at and as of such date (except that such representations and warranties shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented relating to such Shares).

(u) The Company will use its commercially reasonable efforts to cause the Shares to be listed for trading on Nasdaq and to maintain such listing.

(v) During any period when the delivery of a prospectus relating to the Shares is required (including in circumstances where such requirement may be satisfied pursuant to Rule 172 or any similar rule) to be delivered under the Act, the Company shall file, on a timely basis, with the Commission and Nasdaq all reports and documents required to be filed under the Exchange Act and the regulations thereunder.

(w) The Company shall cooperate with the Managers and use its reasonable efforts to permit the Shares to be eligible for clearance and settlement through the facilities of DTC.

(x) The Company will apply the Net Proceeds from the sale of the Shares in the manner set forth in the Disclosure Package and the Prospectus.

5. Payment of Expenses. The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations under this Agreement, whether or not the transactions contemplated hereby are consummated, including without limitation (i) all expenses incident to the issuance and delivery of the Shares (including all printing and engraving costs), (ii) all necessary issue, transfer and other stamp taxes in connection with the issuance and sale of the Shares, (iii) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors to the Company, and the reasonable fees and expenses of the Managers' counsel (which shall not be more than one counsel unless otherwise agreed by the Company), (iv) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), each Issuer Free Writing Prospectus and the Prospectus, and all amendments and supplements thereto, and this Agreement, (v) all filing fees, attorneys' fees and expenses incurred by the Company or the Managers in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Shares for offer and sale under the state securities or blue sky laws, and, if requested by the Managers, preparing a "Blue Sky Survey" or memorandum, and any supplements thereto, advising the Managers of such qualifications, registrations and exemptions, (vi) the filing fees incident to the review and approval by FINRA of the terms of the sale of the Shares, (vii) the fees and expenses associated with listing of the Shares on the Nasdaq, (viii) all fees and expenses of the registrar and transfer agent of the Common Stock, (ix) all fees and expenses (including reasonable fees and expenses of counsel) of the Company in connection with approval of the Shares by DTC for "book-entry" transfer, (x) all other fees, costs and expenses referred to in Item 14 of Part II of the Registration Statement and (xi) all other fees, costs and expenses incurred in connection with the performance of its obligations hereunder for which provision is not otherwise made in this Section 5; provided, however, that the amount payable by the Company pursuant to subsection (iii) with respect to the reasonable fees and expenses of Managers' counsel shall not exceed (A) $100,000 arising out of the executing the Original Agreement and the filing of the Registration Statement and the Prospectus and (B) in the amount not to exceed $15,000 per each quarter thereafter (solely for any quarter that includes a Representation Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(k) for which no waiver is applicable). Except as provided in this Section 5 and in Section 7 hereof, the Managers shall pay their own expenses.

6. Conditions to the Obligations of the Managers. The obligations of the Managers under this Agreement and any Terms Agreement shall be subject to (i) the accuracy of the representations and warranties on the part of the Company contained herein as of the Execution Time, each Representation Date, and as of each Applicable Time, Settlement Date and Time of Delivery, (ii) to the performance by the Company of its obligations hereunder and (iii) the following additional conditions:

(a) The Prospectus, and any supplement thereto, required by Rule 424 to be filed with the Commission have been filed in the manner and within the time period required by Rule 424(b) with respect to any sale of Shares; each Interim Prospectus Supplement shall have been filed in the manner required by Rule 424(b) within the time period required by Section 4(r) of this Agreement; any material required to be filed by the Company pursuant to Rule 433(d) under the Act, shall have been filed with the Commission within the applicable time periods prescribed for such filings by Rule 433; and no stop order suspending the effectiveness of the Registration Statement or any notice objecting to its use shall have been issued and no proceedings for that purpose or pursuant to Section 8A of the Act shall have been instituted or threatened.

(b) The Company shall have requested and caused Company Counsel and Intellectual Property Counsel to furnish to the Managers, on every date specified in Section 4(l) of this Agreement, opinions in form and substance satisfactory to the Managers.

(c) The Managers shall have received from Latham & Watkins LLP, counsel for the Managers, on every date specified in Section 4(m) of this Agreement, such opinion or opinions and disclosure letter or letters, dated as of such date and addressed to the Managers, with respect to the issuance and sale of the Shares, the Registration Statement, the Disclosure Package, the Prospectus (together with any supplement thereto) and other related matters as the Managers may reasonably require, and the Company shall have furnished to such counsel such documents as they reasonably request for the purpose of enabling them to pass upon such matters.

(d) The Company shall have furnished or caused to be furnished to the Managers, on every date specified in Section 4(k) of this Agreement, a certificate of the Company, signed by the chief executive officer or the President of the Company, and of the chief financial or chief accounting officer of the Company, dated as of such date, to the effect that the signers of such certificate have carefully examined the Registration Statement, the Disclosure Package and the Prospectus and any supplements or amendments thereto and this Agreement and that:

(i) the Company has received no stop order suspending the effectiveness of the Registration Statement, and no proceedings for such purpose or pursuant to Section 8A of the Act have been instituted or, to the Company's knowledge, threatened by the Commission;

(ii) since the date of the most recent financial statements included in the Prospectus and the Disclosure Package, there has been no event or condition of a type described in Section 2(l) hereof (a "**Material Adverse Change**"), except as set forth in or contemplated in the Disclosure Package and the Prospectus;

(iii) the representations, warranties and covenants set forth in Section 2 of this Agreement are true and correct with the same force and effect as though expressly made on and as of such date; and

(iv) the Company and its subsidiaries have complied with all the agreements hereunder and satisfied all the conditions on its part to be performed or satisfied hereunder at or prior to such date.

(e) The Company shall have requested and caused the Accountants to have furnished to the Managers, on every date specified in Section 4(n) hereof and to the extent requested by the Managers in connection with any offering of the Shares, letters (which may refer to letters previously delivered to the Managers), dated as of such date, in form and substance satisfactory to the Managers, which letters shall cover, without limitation, the various financial statements and disclosures contained in the Registration Statement, the Disclosure Package and the Prospectus and other matters ordinarily covered by accountants' "comfort letters" to underwriters in connection with registered public offerings as contemplated in the Statement on Auditing Standards No. 72, as well as confirming that they have performed a review of any unaudited interim financial information of the Company included in the Registration Statement, the Disclosure Package and the Prospectus in accordance with Statement on Auditing Standards No. 100.

References to the Prospectus in this paragraph (e) include any supplement thereto at the date of the letter.

(f) The Company shall have furnished or caused to be furnished to the Managers, on every date specified in Section 4(o) of this Agreement, a certificate of the chief financial officer of the Company, dated as of such date, in form and substance to the Managers and agreed upon prior to the date hereof, covering certain financial matters of the Company.

(g) Since the respective dates as of which information is disclosed in the Registration Statement, the Disclosure Package and the Prospectus, except as otherwise stated therein, there shall not have been (i) any change specified in the letter or letters referred to in paragraph (e) of this Section 6 or (ii) Material Adverse Change, except as set forth in or contemplated in the Disclosure Package (exclusive of any amendment or supplement thereto) the effect of which, in any case referred to in clause (i) or (ii) above, is, in the sole judgment of the Managers, so material and adverse as to make it impractical or inadvisable to proceed with the offering or delivery of the Shares as contemplated by the Registration Statement (exclusive of any amendment thereof), the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(h) FINRA shall not have raised any objection with respect to the fairness and reasonableness of the terms and arrangements under this Agreement.

(i) Nasdaq shall not have objected to the listing of the Shares for trading on Nasdaq.

(j) Prior to each Settlement Date and Time of Delivery, as applicable, the Company shall have furnished to the Designated Manager such further information, certificates and documents as the Designated Manager may reasonably request.

If any of the conditions specified in this Section 6 shall not have been fulfilled when and as provided in this Agreement, or if any of the opinions and certificates mentioned above or elsewhere in this Agreement shall not be reasonably satisfactory in form and substance to the Managers and counsel for the Managers, this Agreement and all obligations of the applicable Manager hereunder may be canceled at, or at any time prior to, any Settlement Date or Time of Delivery, as applicable, by such Manager with respect to itself only. Notice of such cancellation shall be given to the Company in writing or by telephone or facsimile confirmed in writing.

The documents required to be delivered by this Section 6 shall be delivered remotely via electronic exchange, on each such date as provided in this Agreement.

7. Indemnification and Contribution.

(a) The Company agrees to indemnify and hold harmless each Manager, its affiliates, as such term is defined in Rule 501(b) under the Act (each, an "**Affiliate**"), the directors, officers, employees and agents of each Manager, any broker-dealer affiliate of a Manager through which Shares are sold, and each person who controls a Manager within the meaning of either the Act or the Exchange Act and against any loss, claim, damage, liability or expense, as incurred, to which they or any of them may become subject under the Act, the Exchange Act or other federal or state statutory law or regulation, at common law or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of the Company or otherwise permitted by paragraph (d) below), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based (i) upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto) or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) upon any untrue statement or alleged untrue statement of a material fact contained in any Issuer Free Writing Prospectus or any "issuer information" filed or required to be filed pursuant to Rule 433(d) under the Act, the Base Prospectus, the Prospectus or any Interim Prospectus Supplement (or any amendment or supplement thereto) or the omission or alleged omission therefrom of a material fact, in each case, necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; or (iii) in whole or in part upon any inaccuracy in the representations and warranties of the Company contained herein; or (iv) in whole or in part upon any failure of the Company to perform its obligations hereunder or under law and agrees to reimburse each such indemnified party, for any and all expenses (including the reasonable fees and disbursements of counsel chosen by the indemnified party) as such expenses are reasonably incurred by them in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action; *provided*, *however*, that the foregoing indemnity agreement shall not apply to any loss, claim, damage, liability or expense to the extent, but only to the extent, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by any Manager expressly for use in the Registration Statement (or any amendment thereto), any Issuer Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto). This indemnity agreement will be in addition to any liabilities that the Company may otherwise have.

(b) Each Manager agrees, severally and not jointly, to indemnify and hold harmless the Company, each of its directors, each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of the Act or the Exchange Act, against any loss, claim, damage, liability or expense, as incurred, to which the Company or any such director, officer or controlling person may become subject, under the Act, the Exchange Act, or other federal or state statutory law or regulation, or at common law or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of such Manager or otherwise permitted by paragraph (d) below), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based (i) upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto) or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) upon any untrue statement or alleged untrue statement of a material fact contained in any Issuer Free Writing Prospectus or any "issuer information" filed or required to be filed pursuant to Rule 433(d) under the Act, the Base Prospectus, the Prospectus or any Interim Prospectus Supplement (or any amendment or supplement thereto) or the omission or alleged omission therefrom of a material fact, in each case, necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement, the Base Prospectus, any Issuer Free Writing Prospectus, any Prospectus or any Interim Prospectus Supplement (or any amendment or supplement thereto), in reliance upon and in conformity with written information furnished to the Company by any Manager expressly for use therein; and to reimburse the Company, or any such director, officer or controlling person for any legal and other expense reasonably incurred by the Company, or any such director, officer or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. The indemnity agreement set forth in this Section 7(b) shall be in addition to any liabilities that each Manager may otherwise have. The Company acknowledges that with respect to each Manager, the name of such Manager constitutes the only information furnished in writing by or on behalf of such Manager for inclusion in the Registration Statement, the Base Prospectus, any Issuer Free Writing Prospectus, any prospectus supplement or any Interim Prospectus Supplement (or any amendment or supplement thereto).

(c) Promptly after receipt by an indemnified party under this Section 7 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against the indemnifying party under this Section 7, notify the indemnifying party in writing of the commencement thereof; but the omission to so notify the indemnifying party will not relieve it from any liability which it may have to any indemnified party for contribution or otherwise than under the indemnity agreement contained in paragraph (a) or (b) above or to the extent it is not prejudiced (through the forfeiture of substantive rights or defenses) as a proximate result of such failure. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it shall elect, jointly with all other indemnifying parties similarly notified, by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; *provided*, *however*, if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that a conflict may arise between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of such indemnifying party's election to assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 7 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed separate counsel in accordance with the proviso to the next preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the expenses of more than one separate counsel (together with local counsel), approved by the indemnifying party (the Managers in the case of Section 7(b) and Section 7(e)), representing the indemnified parties who are parties to such action), (ii) the indemnifying party shall not have employed counsel reasonably satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of the action, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying party or (iii) the indemnifying party shall authorize the indemnified party to employ separate counsel at the expense of the indemnifying party.

(d) The indemnifying party under this Section 7 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for reasonable and documented fees and expenses of counsel as contemplated by Section 7(c) hereof, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 60 days after receipt by such indemnifying party of the aforesaid request and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent (i) includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act, by or on behalf of any indemnified party.

(e) If the indemnification provided for in this Section 7 is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount paid or payable by such indemnified party, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and each Manager, on the other hand, from the offering of the Shares pursuant to this Agreement, or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and each Manager, on the other hand, in connection with the statements or omissions or inaccuracies in the representations and warranties herein which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company shall be deemed to be equal to the total net proceeds from the offering (before deducting expenses) received by them, and benefits received by each Manager shall be deemed to be equal to the total compensation received by such Manager under Section 3(c) of this Agreement, in each case as determined by this Agreement or any applicable Terms Agreement. The relative fault of the Company, on the one hand, and each Manager, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact or any such inaccurate or alleged inaccurate representation or warranty relates to information supplied by the Company, on the one hand, or such Manager, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Section 7(c), any legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in Section 7(c) with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this Section 7(e); *provided*, *however*, that no additional notice shall be required with respect to any action for which notice has been given under Section 7(c) for purposes of indemnification.

The Company and the Managers agree that it would not be just and equitable if contribution pursuant to this Section 7(e) were determined by pro rata allocation (even if the Managers were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to in this Section 7(e).

Notwithstanding the provisions of this Section 7(e), no Manager shall be required to contribute any amount in excess of the discounts and commissions received by such Manager in connection with the Shares sold by it pursuant to this Agreement and any applicable Terms Agreement in the specific transaction or transactions giving rise to the contribution obligation. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Managers' obligations to contribute pursuant to this Section 7(e) are several, and not joint. For purposes of this Section 7(e), each Affiliate, director, officer, employee and agent of a Manager, each person, if any, who controls a Manager within the meaning of the Act and the Exchange Act and any broker-dealer affiliate of a Manager through which Shares are sold shall have the same rights to contribution as such Manager, and each director of the Company or each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Act and the Exchange Act shall have the same rights to contribution as the Company.

8. Termination.

(a) The Company shall have the right, by giving written notice as hereinafter specified, to terminate the provisions of this Agreement relating to the solicitation of offers to purchase the Shares in its sole discretion at any time. Any such termination shall be without liability of any party to any other party except that (i) if Shares have been sold through a Manager for the Company, then Section 4(t) shall remain in full force and effect with respect to such Manager and the Company, (ii) with respect to any pending sale, through the Designated Manager for the Company, the obligations of the Company, including in respect of compensation of the Designated Manager, shall remain in full force and effect notwithstanding the termination and (iii) the provisions of Sections 2, 5, 7, 9, 10, 12 and 14 of this Agreement shall remain in full force and effect notwithstanding such termination.

(b) Each Manager shall have the right, by giving written notice as hereinafter specified, to terminate the provisions of this Agreement relating to the solicitation of offers to purchase the Shares in its sole discretion at any time, with respect to such Manager only. Any such termination shall be without liability of any party to any other party except that the provisions of Sections 2, 5, 7, 9, 10, 12 and 14 of this Agreement shall remain in full force and effect with respect to such Manager notwithstanding such termination. Following any such termination by a Manager, this Agreement shall remain in effect as to each other Manager that has not exercised its right to terminate the provisions of this Agreement pursuant to this Section 8(b) and any obligations and rights of the Managers under this Agreement shall be satisfied by or afforded to, as applicable, only such other Managers.

(c) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 8(a) or (b) above or otherwise by mutual agreement of the parties; *provided* that any such termination by mutual agreement shall in all cases be deemed to provide that Sections 2, 5, 7 and 9 shall remain in full force and effect.

(d) Any termination of this Agreement shall be effective on the date specified in such notice of termination; *provided* that such termination shall not be effective until the close of business on the date of receipt of such notice by a Manager or the Company, as the case may be. If such termination shall occur prior to the Settlement Date or Time of Delivery for any sale of the Shares, such sale shall, subject to Section 6 hereof, settle in accordance with the provisions of Section 3(e) of this Agreement.

(e) In the case of any purchase of Shares by a Manager pursuant to a Terms Agreement, the obligations of such Manager pursuant to such Terms Agreement shall be subject to termination, in the absolute discretion of such Manager, by notice given to the Company prior to the Time of Delivery relating to such Shares, if at any time prior to such delivery and payment (i) trading or quotation in any of the Company's securities shall have been suspended or limited by the Commission or by Nasdaq, or trading in securities generally on either Nasdaq or the New York Stock Exchange shall have been suspended or limited, or minimum or maximum prices shall have been generally established on any of such stock exchanges by the Commission or FINRA; (ii) a general banking moratorium shall have been declared by any of federal or New York authorities; (iii) there shall have occurred any outbreak or escalation of national or international hostilities or any crisis or calamity involving the United States, or any change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States' or international political, financial or economic conditions, as in the judgment of such Manager is material and adverse and makes it impracticable or inadvisable to proceed with the offering or delivery of the Shares in the manner and on the terms described in the Disclosure Package and the Prospectus or to enforce contracts for the sale of securities; (iv) in the judgment of such Manager there shall have occurred any Material Adverse Change or (v) there shall have occurred a material disruption in commercial banking or securities settlement or clearance services in the United States.

9. Representations and Indemnities to Survive. The respective agreements, representations, warranties, indemnities and other statements of the Company, the officers of the Company and of each Manager set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by a Manager or the Company or any of the officers, directors, employees, agents or controlling persons referred to in Section 7 hereof, and will survive delivery of and payment for the Shares.

10. Notices. All communications hereunder will be in writing and effective only on receipt, and:

If sent to Goldman, will be mailed, delivered or telefaxed to:

Goldman Sachs & Co. LLC
200 West Street
New York, New York 10282
Facsimile: (212) 902-9316
Attention: Registration Department

If sent to BofA Securities, Inc., will be mailed, delivered or telefaxed to

BofA Securities, Inc.

One Bryant Park
New York, NY 10036
Attention: ATM Execution Team
Email: dg.atm_execution@bofa.com

with a copy to:

Latham & Watkins LLP
505 Montgomery Street, Suite 2000
San Francisco, California 94111
Attention: Phillip Stoup
E-mail: phillip.stoup@lw.com

If sent to the Company, will be mailed, delivered or telefaxed to:

FibroGen, Inc.
409 Illinois Street
San Francisco, CA 84158
Attention: Chief Legal Officer

with a copy to:

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94304
Facsimile: (650) 843-7400
Attention: Nancy Wojtas

Any party hereto may change the address for receipt of communications by giving written notice to the others.

11. Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto and their respective successors and the officers, directors, employees, agents and controlling persons referred to in Section 7 hereof, and no other person will have any right or obligation hereunder.

12. No Fiduciary Duty. The Company hereby acknowledges that (a) the purchase and sale of the Shares pursuant to this Agreement is an arm's-length commercial transaction between the Company, on the one hand, and the Manager and any affiliate through which it may be acting, on the other, (b) each Manager is acting solely as sales agent and/or principal in connection with the purchase and sale of the Company's securities and not as a fiduciary of the Company and (c) the Company's engagement of each Manager in connection with the offering and the process leading up to the offering is as independent contractors and not in any other capacity. Furthermore, the Company agrees that it is solely responsible for making its own judgments in connection with the offering (irrespective of whether a Manager has advised or is currently advising it on related or other matters). The Company agrees that it will not claim that a Manager has rendered advisory services of any nature or respect, or owe an agency, fiduciary or similar duty to the Company, in connection with the transactions contemplated by this Agreement or the process leading thereto.

13. Integration. This Agreement and any Terms Agreement supersede all prior agreements and understandings (whether written or oral) between the Company and the Managers with respect to the subject matter hereof.

14. Applicable Law. This Agreement and any Terms Agreement will be governed by and construed in accordance with the laws of the State of New York applicable to contracts made and to be performed within the State of New York.

15. Waiver of Jury Trial. The Company hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement, any Terms Agreement or the transactions contemplated hereby or thereby.

16. Counterparts. This Agreement and any Terms Agreement may be signed in one or more counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement.

17. Headings. The section headings used in this Agreement and any Terms Agreement are for convenience only and shall not affect the construction hereof.

18. Recognition of the U.S. Special Resolution Regimes.

(a) In the event that any Manager that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Manager of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(b) In the event that any Manager that is a Covered Entity or a BHC Act Affiliate of such Manager becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Manager are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

As used in this Section 18:

"**BHC Act Affiliate**" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k).

"**Covered Entity**" means any of the following:

(i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b);

(ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or

(iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b).

"**Default Right**" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable.

"**U.S. Special Resolution Regime**" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

19. Definitions. The terms that follow, when used in this Agreement and any Terms Agreement, shall have the meanings indicated.

"**Act**" shall mean the Securities Act of 1933, as amended, and the rules and regulations of the Commission promulgated thereunder.

"**Applicable Time**" shall mean, with respect to any Shares, the time of sale of such Shares pursuant to this Agreement or any relevant Terms Agreement.

"**Base Prospectus**" shall mean the base prospectus referred to in Section 2(a) above contained in the Registration Statement at the Initial Execution Time.

"**Business Day**" shall mean any day other than a Saturday, a Sunday or a legal holiday or a day on which banking institutions or trust companies are authorized or obligated by law to close in New York City.

"**Commission**" shall mean the Securities and Exchange Commission.

"**Designated Manager**" shall mean, as of any given time, a Manager that the Company has designated as sales agent to sell Shares pursuant to the terms of this Agreement.

"**Disclosure Package**" shall mean (i) the Base Prospectus, (ii) the Prospectus, (iii) the most recently filed Interim Prospectus Supplement, if any, (iv) the Issuer Free Writing Prospectuses, if any, identified in Schedule I hereto, (v) the public offering price of Shares sold at the relevant Applicable Time as specified in a Terms Agreement and (vi) any other Free Writing Prospectus that the parties hereto shall hereafter expressly agree in writing to treat as part of the Disclosure Package.

"**Effective Date**" shall mean each date and time that the Registration Statement and any post-effective amendment or amendments thereto became or becomes effective.

"**Execution Time**" shall mean the date and time that this Agreement is executed and delivered by the parties hereto.

"**Exchange Act**" shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission promulgated thereunder.

"**Free Writing Prospectus**" shall mean a free writing prospectus, as defined in Rule 405.

"**Initial Execution Time**" shall mean the date and time that the Original Agreement was executed and delivered by the parties thereto.

"**Interim Prospectus Supplement**" shall mean the prospectus supplement relating to the Shares prepared and filed pursuant to Rule 424(b) from time to time as provided by Section 4(r) of this Agreement.

"**Issuer Free Writing Prospectus**" shall mean an issuer free writing prospectus, as defined in Rule 433.

"**Prospectus**" shall mean the Prospectus included in the Registration Statement relating to the Shares and the most recently filed Interim Prospectus Supplement (if any).

"**Registration Statement**" shall mean the registration statement referred to in Section 2(a) above, including exhibits and financial statements and any prospectus supplement relating to the Shares that is filed with the Commission pursuant to Rule 424(b) and deemed part of such registration statement pursuant to Rule 430B, as amended on each Effective Date and, in the event any post-effective amendment thereto becomes effective, shall also mean such registration statement as so amended.

"**Rule 158**," "**Rule 163**," "**Rule 164**," "**Rule 172**," "**Rule 405**," "**Rule 415**," "**Rule 424**," "**Rule 430B**" and "**Rule 433**" refer to such rules under the Act.

[Signature Page Follows]

If the foregoing is in accordance with your understanding of our agreement, please sign and return to us the enclosed duplicate hereof, whereupon this letter and your acceptance shall represent a binding agreement among the Company and the Managers.

Very truly yours,

FIBROGEN, INC.

By:	/s/ Juan Graham
Name:	Juan Graham
Title:	Senior Vice President and Chief Financial Officer

CONFIRMED AND ACCEPTED,
as of the date first written above:

Goldman Sachs & Co. LLC

By:	/s/ Emily West
Name:	Emily West
Title:	Managing Director

BofA Securities, Inc.

By:	/s/ Aamir Mecklai
Name:	Aamir Mecklai
Title:	Managing Director

SCHEDULE I

Schedule of Free Writing Prospectuses included in the Disclosure Package

None

[Form of Terms Agreement] **ANNEX I**

FIBROGEN, INC.
Common Stock ($0.01 par value)

TERMS AGREEMENT

_____, 20___

[name/address of designated manager]

Dear Sirs:

FibroGen, Inc., a Delaware corporation (the "Company") proposes, subject to the terms and conditions stated herein and in the Amended and Restated Equity Distribution Agreement, dated February 27, 2023 (the "Equity Distribution Agreement"), among the Company, Goldman Sachs & Co. LLC, and BofA Securities, Inc., to issue and sell to Goldman Sachs & Co. LLC and BofA Securities, Inc., the securities specified in the Schedule I hereto the "Purchased Shares") [, and solely for the purpose of covering over-allotments, to grant to [name of designated manager] (the "Designated Manager") the option to purchase the additional securities specified in the Schedule I hereto (the "Additional Shares")] [**Include only if the Designated Manager has an over-allotment option**].

[The Designated Manager shall have the right to purchase from the Company all or a portion of the Additional Shares as may be necessary to cover over-allotments made in connection with the offering of the Purchased Shares, at the same purchase price per share to be paid by the Designated Manager to the Company for the Purchased Shares. This option may be exercised by the Designated Manager at any time (but not more than once) on or before the thirtieth day following the date hereof, by written notice to the Company. Such notice shall set forth the aggregate number of shares of Additional Shares as to which the option is being exercised, and the date and time when the Additional Shares are to be delivered (such date and time being herein referred to as the "Option Closing Date"); provided, however, that the Option Closing Date shall not be earlier than the Time of Delivery (as set forth in the Schedule I hereto) nor earlier than the second business day after the date on which the option shall have been exercised nor later than the fifth business day after the date on which the option shall have been exercised. Payment of the purchase price for the Additional Shares shall be made at the Option Closing Date in the same manner and at the same office as the payment for the Purchased Shares.] [Include only if the Designated Manager has an over-allotment option]

Each of the provisions of the Equity Distribution Agreement not specifically related to the solicitation by the Designated Manager, as agent of the Company, of offers to purchase securities is incorporated herein by reference in its entirety, and shall be deemed to be part of this Terms Agreement to the same extent as if such provisions had been set forth in full herein. Each of the representations and warranties set forth therein shall be deemed to have been made at and as of the date of this Terms Agreement [and] [,] the Time of Delivery [and any Option Closing Date] **[Include only if the Designated Manager has an over-allotment option]**, except that each representation and warranty in Section 2 of the Equity Distribution Agreement which makes reference to the Prospectus (as therein defined) shall be deemed to be a representation and warranty as of the date of the Equity Distribution Agreement in relation to the Prospectus, and also a representation and warranty as of the date of this Terms Agreement [and] [,] the Time of Delivery [and any Option Closing Date] **[Include only if the Designated Manager has an over-allotment option]** in relation to the Prospectus as amended and supplemented to relate to the Purchased Shares.

An amendment to the Registration Statement (as defined in the Equity Distribution Agreement), or a supplement to the Prospectus, as the case may be, relating to the Purchased Shares [and the Additional Shares] **[Include only if the Designated Manager has an over-allotment option]**, in the form heretofore delivered to the Manager is now proposed to be filed with the Securities and Exchange Commission.

Subject to the terms and conditions set forth herein and in the Equity Distribution Agreement which are incorporated herein by reference, the Company agrees to issue and sell to the Designated Manager and the latter agrees to purchase from the Company the number of shares of the Purchased Shares at the time and place and at the purchase price set forth in the Schedule I hereto.

If the foregoing is in accordance with your understanding, please sign and return to us a counterpart hereof, whereupon this Terms Agreement, including those provisions of the Equity Distribution Agreement incorporated herein by reference, shall constitute a binding agreement between the Managers and the Company.

FIBROGEN, INC.

By: _____

Name:

Title:

ACCEPTED as of the date first written above.

[DESIGNATED MANAGER]

By: _____

Name:

Title:

[Form of Terms Agreement] **Schedule I to the Terms Agreement**

Title of Purchased Shares [and Additional Shares]:

Common Stock

Number of Shares of Purchased Shares:

[Number of Shares of Additional Shares:]

[Price to Public:]

Purchase Price by [Goldman Sachs & Co. LLC] [BofA Securities, Inc.]:

Method of and Specified Funds for Payment of Purchase Price:

By wire transfer to a bank account specified by the Company in same day funds.

Method of Delivery:

Free delivery of the Shares to the Manager's account at The Depository Trust Company in return for payment of the purchase price.

Time of Delivery:

Closing Location:

Documents to be Delivered:

The following documents referred to in the Equity Distribution Agreement shall be delivered as a condition to the closing at the Time of Delivery [and on any Option Closing Date]:

(1) The opinion referred to in Section 4(l).

(2) The opinion referred to in Section 4(m).

(3) The accountants' letter referred to in Section 4(n).

(4) The officers' certificate referred to in Section 4(k).

(5) Such other documents as the Manager shall reasonably request.

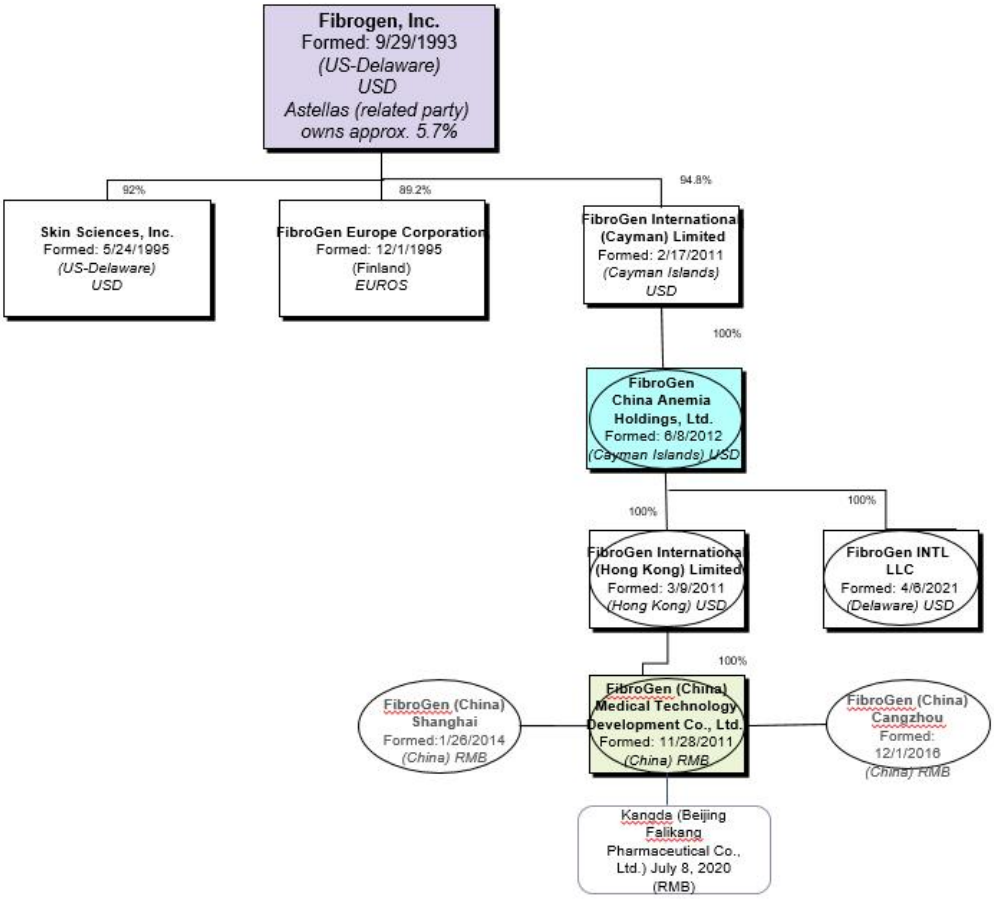
Annex II

Organizational Chart

of

FibroGen, Inc.

And its Cayman, Hong Kong and China Subsidiaries



[*] = 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 10.45

SAMSUNG BIOLOGICS CO., LTD.
AMENDMENT NO 1 TO PRODUCT SPECIFIC AGREEMENT – CLINICAL PRODUCT DRUG SUBSTANCE

This Amendment No. 1 to the Product Specific Agreement – Clinical Product Drug Substance (this "**Amendment No. 1**") is made effective as of the date of last signature below (the "**Amendment No. 1 Effective Date**") by and between FibroGen, Inc., a Delaware corporation having its principal place of business at 409 Illinois Street, San Francisco, California, USA 94158 ("**Client**") and Samsung Biologics Co., Ltd., a Korean corporation having its principal place of business at [*] ("**SBL**"). Client and SBL are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

WHEREAS, Client and SBL entered into a Master Services Agreement effective October 30, 2020 (the "**MSA**") and a Product Specific Agreement – Clinical Product Drug Substance effective October 30, 2020 (the "**PSA**"). In accordance with the terms of the MSA, SBL and Client wish to amend the PSA with effect from and as of the Amendment No. 1 Effective Date, as provided in this Amendment No. 1. All capitalized terms not defined in this Amendment No. 1 will have the meanings given to them in the MSA and PSA.

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

1. **Amendments to the PSA.**

a. Section 5.c. of the PSA shall be deleted in their entirety and replaced with the following:

"c. Product Purchase Commitment.

i. Notwithstanding anything to the contrary, during [*] (each a "Binding Year"), Client shall order from SBL on a [*], and SBL commits to Manufacture, the number of Batches of Product set forth in the table below on the terms and conditions set forth herein and in the MSA (the "Product Purchase Commitment"). The Product Purchase Commitment [*].

[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]

ii. Within [*], Client shall update, issue and/or re-issue a binding Purchase Order for [*] for the [*].

iii. Notwithstanding anything to the contrary, [*] shall not apply to the PSA as amended by this Amendment No. 1."

[*] = 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.

2. **Effect on the PSA**. Except as specifically amended by this Amendment No. 1, the PSA shall remain in full force and effect, and the PSA, as amended by this Amendment No. 1, is hereby ratified and affirmed in all respects. Each reference in the PSA "to this PSA", "herein," "hereunder" or words of similar import shall mean and be a reference to the PSA as amended by this Amendment No. 1. All other applicable provisions of the MSA and PSA shall apply to this Amendment No. 1, *mutatis mutandis*.

3. **Entire Agreement**. This Amendment No. 1, together with the MSA and the PSA constitute the entire agreement between the Parties relating to the subject matter hereof and supersede all previous oral and written communications between the Parties with respect to such subject matter.

4. **Counterparts**. This Amendment No. 1 shall become binding following signatures of each of the Parties hereto. This Amendment No. 1 may be executed in two or more counterparts, each of which shall be deemed an original as against the Party whose signature appears thereon, but all of which taken together shall constitute but one and the same instrument.

Signature Page Follows.

The Parties have entered into this Amendment No. 1 as of the Amendment No. 1 Effective Date by their respective duly authorized representatives.

SAMSUNG BIOLOGICS CO., LTD.		**FIBROGEN, INC.**	
By:	/s/ [*]	By:	/s/ [*]
Name:	[*]	Name:	[*]
Title:	[*]	Title:	[*]
Date:	Oct 24, 2022	Date:	10/25/2022

[ ] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

[*] = 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 10.46

REVENUE INTEREST FINANCING AGREEMENT

This Revenue Interest Financing Agreement (this "***Agreement***") is entered into as of November 4, 2022 (the "***Effective Date***"), between FibroGen, Inc., a Delaware corporation having an address of 409 Illinois Street, San Francisco, CA 94158 ("***Company***") and NQ Project Phoebus, L.P., a Delaware limited partnership having an address of 4208 Six Forks Road, Suite 920 Raleigh, NC 27609 ("***NovaQuest***"). Company and NovaQuest are each referred to herein by name or, individually, as a "***Party***" or, collectively, as "***Parties***."

INTRODUCTION

A. Company researches, develops, and commercializes products for the treatment of human diseases, disorders, and conditions.

B. Company has previously entered into certain agreements with Astellas (as defined below), pursuant to which, among other things, Company granted Astellas a license to commercialize the Product (as defined below) in the Territory (as defined below) and Company receives certain payments from Astellas in connection therewith.

C. In consideration of the Investment Amount (defined below), NovaQuest and Company desire for NovaQuest to be granted an undivided percentage interest in Company's revenue received under the Astellas Agreements (defined below) and for Company to make certain payments to NovaQuest as set forth herein, all subject to the terms and conditions of this Agreement.

D. As a material inducement for NovaQuest's entry into this Agreement, the Company has agreed to grant to NovaQuest a security interest in the Collateral, as set forth in this Agreement.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE I

DEFINITIONS

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

"***2022 Royalty Dates***" has the meaning set forth in Section 4.1.

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

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

[*].

[*] = 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.

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

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

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

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

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

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

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

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

"***Astellas Agreement***" means each or any of the Astellas EMEA Agreement or the Astellas Japan Agreement. "***Astellas Agreements***" means both of the foregoing, collectively.

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

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

"***Astellas Japan Agreement***" means that certain Collaboration Agreement by and between Astellas Pharma Inc. and FibroGen, Inc. dated June 1, 2005, as amended January 1, 2013, attached hereto as Exhibit C, and as may be further amended from time to time in accordance with this Agreement.

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

"***Astellas Other Revenue***" means [*].

"***Astellas Revenue***" means, collectively, the Astellas EMEA Revenue, the Astellas Japan Revenue and the Astellas Other Revenue.

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

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

[*] = 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.

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

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

"***Collateral***" means the Revenue Interest Collateral and the Product IP Rights.

"***Collateral Revenue Interests***" means, in each case, as further described in Section 4.1(a) (i) twenty-two and one-half percent (22.5%) of each of the Astellas EMEA Revenue, Astellas Japan Revenue and Replacement Net Sales Revenue, (ii) from the Effective Date and through Fiscal Year 2027, ten percent (10%) of Astellas Other Revenue, (iii) for Fiscal Year 2028 and all Fiscal Years thereafter, twenty percent (20%) of Astellas Other Revenue , (iv) for Fiscal Years prior to 2028, ten percent (10%) of Replacement Other Revenue, and (v) for Fiscal Year 2028 and all Fiscal Years thereafter, twenty percent (20%) of Replacement Other Revenue.

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

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

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

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

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

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

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

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

"***Data Room***" has the meaning set forth in Section 5.4.

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

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

"***Diligence Expenses***" means NovaQuest's reasonable and documented out-of-pocket legal fees, due diligence expenses, and other reasonable and documented out-of-pocket expenses relating to the Transaction Documents that have been incurred up to and on the Effective Date, up to [*].

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

[*] = 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.

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

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

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

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

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

"***Event of Default***" means each or any of: (a) any Bankruptcy Event of Default; (b) the breach by Company of any material payment obligations under Section 4.1 of this Agreement, which failure to pay continues for more than [*] after receipt by Company of written notice from NovaQuest; (c) except as set forth in clause (b) of this definition, the breach by Company of any of its obligations under this Agreement, where written notice of such breach has been provided by NovaQuest to Company and Company has not cured such breach within [*] following receipt of such notice and where such breach, if not cured, would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect; (d) breach by Company of any of its respective obligations under any Astellas Agreement, and which breach, if curable, is not cured within [*] following receipt by Company of written notice of such breach and where such breach, if not cured, would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect; and (e)(i) [*].

"***Event of Default Fee***" means [*].

"***Event of Default Payment Date***" has the meaning set forth in Section 8.3(a).

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

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

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

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

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

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

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

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

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

"***Indemnified Party***" has the meaning set forth in Section 10.2(a).

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

"***Investor Return Payment***" means each or any of the Revenue Interest Payments, True-Up Payments, or Event of Default Fee. "***Investor Return Payments***" means all of the foregoing, collectively.

"***Investor Return Payment Satisfaction***" has the meaning set forth in Section 4.1(e).

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

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

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

"***License***" means a grant of any Product IP Rights or Regulatory Approvals for making, developing, Commercializing or otherwise exploiting the Product in the Territory. For the avoidance of doubt: (a) the Astellas EMEA Agreement is a License; (b) the Astellas Japan Agreement is a License; and (c) any Replacement Agreement shall be a License.

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

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

[*] = 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.

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

"***Material Adverse Effect***" means any material adverse effect on: (a) the ability of the Company to make the Revenue Interest Payments required to be made by this Agreement; (b) the Commercialization of the Product in the Territory; (c) for the purpose of Section 7.1 only, any of the Product IP Rights, including Company's rights in or to any Product IP Rights; (d) for the purpose of Section 7.1 only, any Regulatory Approval granted prior to the Effective Date for the Product in the Territory; (e) for the purpose of Section 7.1 only, the legality, validity, or enforceability of any Astellas Agreement or Transaction Document; (f) the ability of Company to perform any of its material obligations under any Astellas Agreement or Transaction Document, or to consummate the transactions contemplated hereby or thereby; or (g) the rights or remedies of NovaQuest under any Transaction Document.

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

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

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

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

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

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

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

"***Payment Cap***" means: (a) with respect to a date of determination that is on or before December 31, 2028, One Hundred Million Dollars ($100,000,000); (b) with respect to a date of determination that is on or after January 1, 2029, but on or before December 31, 2029, One Hundred Twelve Million, Five Hundred Thousand Dollars ($112,500,000); or (c) with respect to a date of determination that is after January 1, 2030, One Hundred Twenty-Five Million Dollars ($125,000,000).

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

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

"***Permitted Encumbrance***" means

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

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

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

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

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

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

(g) [*];

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

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

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

"***Prepayment***" has the meaning set forth in Section 4.1(d).

"***Prepayment Amount***" means, as of the date of determination: (a) the amount that is in the column labeled "Prepayment Amount" and in the row with the then-current "Fiscal Year" in the table set forth below this definition; minus (b) the sum of any Revenue Interest Payments paid to NovaQuest prior to such date.

Fiscal Year During Which Prepayment Amount is Received by NovaQuest	Prepayment Amount
[*]	$80,000,000
[*]	[*]
[*]	[*]
[*]	[*]
2028	$100,000,000
2029	$112,500,000
2030	$125,000,000

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

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

[*] = 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.

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

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

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

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

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

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

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

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

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

[*] = 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.

"***Replacement Net Sales Revenue***" means any payments based on sales of the Product in the Territory received by Company or any of its Affiliates under or pursuant to a Replacement Agreement. For the avoidance of doubt, Replacement Net Sales Revenue excludes Astellas EMEA Revenue, Astellas Japan Revenue, and Astellas Other Revenue.

"***Replacement Other Revenue***" means any revenue, other than Replacement Net Sales Revenue, recognized by Company or any of its Affiliates under or pursuant to a Replacement Agreement attributable to payments for the Product in the Territory. For the avoidance of doubt, Replacement Net Sales Revenue excludes Astellas EMEA Revenue, Astellas Japan Revenue, and Astellas Other Revenue.

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

"***Revenue Interest Collateral***" means the [*].

"***Revenue Interests***" means [*].

"***Revenue Interest Payment***" has the meaning set forth in Section 4.1(a). "***Revenue Interest Payments***" means the Revenue Interest Payment, collectively.

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

[*].

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

[*].

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

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

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

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

"***Third-Party Claim***" has the meaning set forth in Section 10.1.

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

"***True-Up Payment***" means each or any of True-Up Payment One or True-Up Payment Two. "***True-Up Payments***" means both of the foregoing, collectively.

"***True-Up Payment One***" has the meaning set forth in Section 4.1(c)(i).

"***True-Up Payment Two***" has the meaning set forth in Section 4.1(c)(ii).

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

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

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

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

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

ARTICLE II

SCOPE OF AGREEMENT

2.1 General Agreement. Subject to the terms and conditions hereof, NovaQuest shall pay the Investment Amount to Company, in accordance with Section 3.1(a), in exchange for payments from Company as set forth in ARTICLE IV and as limited in Section 4.1(e), and Company's other commitments as set forth herein.

2.2 Diligence Expenses. Without limiting NovaQuest's right to offset its Diligence Expenses against the Investment Amount in accordance with Section 3.1(a), Company shall pay NovaQuest's Diligence Expenses [*]. Company shall deliver such payment in Dollars by electronic wire transfer in immediately available funds to the bank account designated by NovaQuest for the Diligence Expenses, unless and to the extent such amount is offset by NovaQuest in accordance with Section 3.1(a).

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

[*] = 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.

ARTICLE III

NOVAQUEST FUNDING; COMMERCIALIZATION

3.1 NovaQuest's Funding Obligation.

(a) Investment Amount. Within [*] after the Effective Date, NovaQuest shall pay Company an amount equal to Fifty Million Dollars ($50,000,000) (the "***Investment Amount***"). NovaQuest may elect, in its sole discretion, to offset any unreimbursed Diligence Expenses from the Investment Amount. Such offset, however, shall not be construed to reduce the amount that NovaQuest has been deemed to have paid to Company under this Section 3.1(a).

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

(c) Miscellaneous. The Investment Amount will be paid in Dollars by electronic wire transfer in immediately available funds to the bank account set forth in Exhibit E or such other account designated by Company in writing. Notwithstanding anything to the contrary herein, NovaQuest's aggregate payment obligations under this Section 3.1 shall not exceed the Investment Amount.

3.2 Diligence. During the Term, Company shall use [*] to ensure that a Permitted Company is Commercializing the Product in the Territory in each country where the Product has received Regulatory Approval.

ARTICLE IV

PAYMENTS TO NOVAQUEST

4.1 Payments and Reports.

(a) Revenue Interest Payments. Commencing on the Effective Date and continuing with respect to each Fiscal Year until the achievement of Investor Return Payment Satisfaction as outlined in Section 4.1(e), Company shall pay to NovaQuest a payment (each such payment, a "***Revenue Interest Payment***") in an amount equal to:

(i) twenty-two and one-half percent (22.5%) of Astellas EMEA Revenue recognized during such Fiscal Year; plus

(ii) twenty-two and one-half percent (22.5%) of Astellas Japan Revenue recognized during such Fiscal Year; plus

(iii) twenty-two and one-half percent (22.5%) of any Replacement Net Sales Revenue recognized during such Fiscal Year; plus

(iv) a percentage of Astellas Other Revenue recognized during such Fiscal Year, which percentage shall be (1) from the Effective Date and through Fiscal Year 2027, ten percent (10%), or (2) for Fiscal Year 2028 and all Fiscal Years thereafter, twenty percent (20%); plus

(v) a percentage of Replacement Other Revenue recognized during such Fiscal Year, which percentage shall be (1) for Fiscal Years prior to 2028, ten percent (10%), or (2) for Fiscal Year 2028 and all Fiscal Years thereafter, twenty percent (20%).

[*].

[*] = 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.

Each Revenue Interest Payment shall be due and payable [*].

(b) Minimum Revenue Interest Payment. If, at any time during the Term commencing on or after January 1, 2028, the Product is not Commercialized by a Permitted Company for any consecutive twelve (12)-month period, then notwithstanding Section 4.1(a), the Revenue Interest Payment owed by Company to NovaQuest for each Fiscal Year ending after the expiration of such twelve (12)-month period shall instead be the greater of: [*] or (ii) Ten Million Dollars ($10,000,000). For the avoidance of doubt, any payments made hereunder shall be considered a Revenue Interest Payment for the purposes of calculating Investor Return Payment Satisfaction. Notwithstanding the foregoing, with respect to any Fiscal Year during the Term in which a Permitted Company is Commercializing the Product such that NovaQuest would receive a Revenue Interest Payment greater than Zero Dollars ($0) under Section 4.1(a), then this Section 4.1(b) shall not be applicable to such Revenue Interest Payment.

(c) True-Up Payments.

(i) If, by no later than December 31, 2028, the sum of all Investor Return Payments paid to NovaQuest hereunder does not equal or exceed Sixty-Two Million, Five Hundred Thousand Dollars ($62,500,000), then Company shall become immediately and irrevocably obligated to pay NovaQuest True-Up Payment One and shall make such payment by no later than March 1, 2029. "***True-Up Payment One***" means an amount equal to the difference between: (A) Sixty-Two Million Five Hundred Thousand Dollars ($62,500,000) and (B) the sum of all Investor Return Payments paid to NovaQuest on or before December 31, 2028; provided that in no event may True-Up Payment One be a negative number.

(ii) If, by no later than December 31, 2030, the sum of all Investor Return Payments paid to NovaQuest hereunder does not equal or exceed One Hundred Twenty-Five Million Dollars ($125,000,000), then Company shall become immediately and irrevocably obligated to pay NovaQuest True-Up Payment Two and shall make such payment by no later than March 1, 2031. "***True-Up Payment Two***" means an amount equal to the difference between: (A) One Hundred Twenty-Five Million Dollars ($125,000,000) and (B) the sum of all Investor Return Payments paid to NovaQuest on or before December 31, 2030; provided that in no event may True-Up Payment One be a negative number.

(d) Prepayment. Notwithstanding any other provision of this Agreement, Company may prepay its obligations to NovaQuest in full at any time during the Term of this Agreement, without penalty. Company may exercise such prepayment option by paying NovaQuest the then-current Prepayment Amount and providing NovaQuest with written notice designating such payment as a prepayment pursuant to this Section 4.1(d) (such payment, a "***Prepayment***"). Company and NovaQuest agree that any Prepayment shall be deemed to be due and payable to NovaQuest upon its receipt, as consideration for NovaQuest's provision of funding hereunder.

(e) Satisfaction of Investor Return Payment Obligations; Payment Cap. Notwithstanding anything to the contrary herein, Company's obligation to make any Investor Return Payments to NovaQuest will terminate upon the earliest to occur of the following (such occurrence, "***Investor Return Payment Satisfaction***"): (i) such time as the sum of all Investor Return Payments paid to NovaQuest as of a particular date of determination equals the Payment Cap in effect for such date of determination; or (ii) such time as NovaQuest has received a Prepayment in accordance with Section 4.1(d). For clarity, upon the achievement of Investor Return Payment Satisfaction, this Agreement will terminate in accordance with Section 9.2(b).

[*] = 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.

(f) Payment Reports. Commencing with the Fiscal Year during which the Effective Date occurs and continuing for each Fiscal Year until the achievement of Investor Return Payment Satisfaction, Company shall, simultaneously with its delivery of a Revenue Interest Payment pursuant to Section 4.1(a) or, if no Revenue Interest Payment is due, within [*] of the end of the applicable Fiscal Year, prepare and deliver a written report to NovaQuest that includes (to the extent received from a Responsible Party or otherwise reasonably available to the Company) reasonably detailed information regarding the total monthly sales of the Product on a country-by-country basis in such Fiscal Year, including the amounts of gross sales of the Product per country in the Territory, and a calculation of the respective portions of Astellas EMEA Revenue, Astellas Japan Revenue, Astellas Other Revenue, and the applicable Revenue Interest Payment payable to NovaQuest which are attributable to each country for such Fiscal Year (including any foreign exchange rates employed) (such written report, a "***Payment Report***"); provided that, notwithstanding the foregoing, the Royalty Report for the 2022 Royalty Dates shall be deferred and provided to NovaQuest with the Payment Report for Fiscal Year 2023. For the avoidance of doubt for each other Fiscal Year during the Term, Company shall provide NovaQuest with a Payment Report pursuant to this Section 4.1(f) even if no Revenue Interest Payment is owed for a given Fiscal Year.

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

4.3 Taxes; Withholding.

(a) If any Governmental Authority requires Company to deduct or withhold any amount from, or NovaQuest to pay any present or future Tax, assessment, or other governmental charge on, any payment by Company to NovaQuest (a "***Withholding Payment***"), then Company shall, in addition to paying NovaQuest the amount reduced by such Withholding Payment, simultaneously pay NovaQuest an additional amount such that NovaQuest receives the full contractual amount of the applicable payment as if no such Withholding Payment had occurred (such additional amount, the "***Gross-Up Amount***").

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

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

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

(e) For Tax purposes, Company and NovaQuest shall treat the transaction contemplated by this Agreement as indebtedness subject to the rules applicable to contingent payment debt instruments under Treasury Regulation Section 1.1275-4(b). Company shall prepare and provide NovaQuest with the "project payment schedule" in accordance with the requirements of Treasury Regulation Section 1.1275-4(b) and Company will reasonably consider any feedback with respect to the "projected payment schedule" from NovaQuest. If there is an inquiry by any Governmental Authority of Company or NovaQuest related to this Section 4.3(e), the Parties shall cooperate with each other in responding to such inquiry in a commercially reasonable manner consistent with this Section 4.3(e).

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

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

4.5 Grant of Security Interest.

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

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

(c) Following the termination of this Agreement, upon the Company's request, NovaQuest shall (i) file a UCC-3 termination statement terminating the security interest granted in this Section 4.5 and terminate any intellectual property security agreements filed with the with the United States Patent and Trademark Office, and (ii) execute and deliver such documents, and take any other actions, to evidence the payment in full of all obligations under this Agreement and the other Transaction Documents and the termination (and notice of termination) of all security interests granted under this Agreement or any other Transaction Document. [*].

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

(i) [*];

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

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

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

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

[*] = 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.

ARTICLE V

INFORMATION RIGHTS; RECORD KEEPING

5.1 Information Rights.

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

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

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

(iii) material Regulatory Filings, including any NDA;

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

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

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

(vii) receipt of Regulatory Approvals; and

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

Notwithstanding the foregoing, Company may, at its election, deliver the information contemplated herein and therein via disclosures made pursuant to Company's public reporting requirements, by delivery of summaries, reports, or presentations to NovaQuest, or by providing excerpts of materials presented to the Company's board of directors or executive leadership team, provided that upon NovaQuest's reasonable request, Company promptly shall provide reasonable access to any material information and documents encompassing the information provided by Company pursuant to this Section 5.1(a).

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

[*] = 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.

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

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

(a) Records. Company shall, and shall ensure that the Responsible Parties shall, consistent with GAAP or IFRS, as applicable, keep and maintain for a period of at least [*] from the end of any Fiscal Quarter (except as otherwise provided herein) accounts and records of all data reasonably required to verify:

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

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

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

(b) Audit. From the Effective Date until the expiration of the Recordkeeping Period, upon prior written notice to Company: (i) NovaQuest shall have the right to review and audit, through an independent certified public accountant selected by NovaQuest and reasonably satisfactory to Company, those accounts and records of Company as NovaQuest determines is reasonably necessary to verify Company's and Responsible Parties' compliance with this Agreement; and (ii) Company shall, upon the reasonable request of NovaQuest, [*] review and audit each Responsible Party, through an independent certified public accountant reasonably approved by NovaQuest, those accounts and records of each such Responsible Party as NovaQuest determines is reasonably necessary to verify such Responsible Party's compliance with this Agreement. Such review and audits shall occur during normal business hours and no more than once per Fiscal Year, provided that NovaQuest shall be entitled to conduct a reasonable number of follow-up reviews and audits if NovaQuest finds that Company or a Responsible Party is not in material compliance with this Agreement. In addition, Company shall, upon reasonable request by NovaQuest (which request NovaQuest shall be permitted to make one time every [*], promptly exercise its audit rights pursuant to Section 10.5 of the Astellas Japan Agreement or the Section of the Astellas EMEA Agreement titled "Reporting and Audit Rights," in each case to the extent necessary to verify the calculations of Astellas Japan Revenue, Astellas EMEA Revenue, or Astellas Other Revenue, and shall furnish the results of such audit to NovaQuest. With respect to any Replacement Agreement entered into by Company that would reasonably be expected to generate Replacement Net Sales Revenue or Replacement Other Revenue, Company shall use reasonable efforts to ensure that such Replacement Agreement grants Company audit rights which are substantially similar in all material respects to Company's audit rights pursuant to section 10.5 of the Astellas Japan Agreement or the section of the Astellas EMEA Agreement titled "Reporting and Audit Rights." With respect to any such Replacement Agreement described in the foregoing sentence, Company shall, upon request by NovaQuest (which request NovaQuest shall be permitted to make one time every [*], promptly exercise its audit rights to the extent necessary to verify the calculations of Replacement Net Sales Revenue or Replacement Other Revenue and shall furnish the results of such audit to NovaQuest. NovaQuest shall be solely responsible for all of the expenses of any audit conducted pursuant to this Section 5.2(b), unless the independent certified public accountant's report shows, in respect of any Fiscal Year then being reviewed, an underpayment of amounts due to NovaQuest hereunder for such Fiscal Year by more than [*], in which case Company shall be responsible for the reasonable expenses incurred by NovaQuest for the independent certified public accountant's services. If the report shows an underpayment of amounts due to NovaQuest hereunder, then Company will pay NovaQuest an amount equal to such underpayment, plus interest on such amounts in accordance with Section 4.4, within [*] after receipt of notice of such underpayment and copy of the relevant portion of the audit report.

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

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

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

(c) the occurrence of any Material Adverse Effect;

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

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

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

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

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

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

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

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

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

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

5.4 ESG Questionnaires. The Company will provide, to the Knowledge of Company and solely as permitted by Applicable Law, true and complete responses to any ESG Questionnaires submitted to Company by NovaQuest no more than once per each Fiscal Year during the Term. For the purposes of this Section 5.4 and this Agreement, "***ESG Questionnaires***" means any questionnaire, survey, request for information, or other similar inquiry, relating to environmental, social, or governance issues and Company's policies and practices in connection therewith.

5.5 Data Room. Within [*] after the Effective Date, Company shall deliver to NovaQuest an electronic copy of all the documents and information contained in the virtual online data room hosted on behalf of Company by [*] in the online workspace captioned [*] as of the Effective Date (the "***Data Room***").

ARTICLE VI

CONFIDENTIAL INFORMATION

6.1 Definition of Confidential Information.

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

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

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

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

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

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

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

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

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

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

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

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

[*] = 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.

6.3 Permitted Disclosures.

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

(i) its Affiliates and its and its Affiliates' limited partners, members, managers, directors and individuals or bodies responsible for governance of receiving Party (including, with respect to NovaQuest, NovaQuest's investment committee and limited partner advisory committee), banks and other actual or potential financing sources, and actual or potential permitted assignees, purchasers, transferees, or successors-in-interest under Sections 8.2, 8.3, or 11.6 or its or their employees, agents, consultants, attorneys or accountants, in each case, who need to know such Confidential Information (including to provide financing to receiving Party, to assist receiving Party in evaluating or monitoring receiving Party's interests in the transactions contemplated hereby, or in fulfilling its obligations or exploiting its rights hereunder (or to determine their interest in providing such financing or assistance)) and who are, prior to receiving such disclosure, bound by customary contractual or professional confidentiality and non-use obligations;

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

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

[*].

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

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

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

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

ARTICLE VII

REPRESENTATIONS AND WARRANTIES; LIMITATION OF LIABILITY

7.1 Company's Representations and Warranties. Except as set forth in the applicable Schedules attached hereto, Company represents and warrants to NovaQuest as of the Effective Date as follows:

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

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

[*] = 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.

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

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

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

(f) Litigation. Except as set forth in Schedule 7.1(f), there is no action, suit, claim, proceeding, interference, reexamination, opposition, *inter partes* or post-grant review, or investigation pending or, to the Knowledge of Company, threatened against Company, any other Responsible Party, or any of its or their licensors, at law or in equity, in an arbitration proceeding to which Company, any other Responsible Party, or any of its or their licensors is a party, or Governmental Authority inquiry pending or, to the Knowledge of Company, threatened against Company, any other Responsible Party, or any of its or their licensors, that, in each case, if adversely determined, would: (i) question or defeat the validity or enforceability of any Product IP Rights; (ii) prevent, interfere with, or delay the consummation of the transactions contemplated by this Agreement; (iii) otherwise adversely affect any Product IP Rights or NovaQuest's rights under this Agreement; or (iv) have, or reasonably be expected to result in, a Material Adverse Effect.

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

[*] = 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.

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

(i) Certain Regulatory Matters.

(i) To the Company's Knowledge, a Responsible Party holds all or is seeking the applicable approvals and authorizations from Governmental Authorities necessary for Company or, to the Knowledge of Company, such Responsible Party to conduct its business in the manner in which such business is being conducted and as contemplated hereunder with respect to the Product in the Territory, including the manufacture, testing, and Commercialization of the Product. To the Knowledge of the Company, the countries in which a Responsible Party holds an applicable approval and authorization for the Product in the Territory is as set forth on Schedule 7.1(i) and all such issued approvals and authorizations are in good standing and in full force and effect. Company or, to the Knowledge of Company, a Responsible Party has not received any written notice or any other communication from any Governmental Authority regarding any actual or possible revocation, withdrawal, suspension, cancellation, termination, or material modification of any such issued or pending approvals or authorizations for the Product in the Territory.

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

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

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

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

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

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

(l) Lien Representations and Warranties. The Company's exact legal name is, and has been since its incorporation, "FibroGen, Inc." The Company is, and has been since its incorporation, incorporated in the State of Delaware.

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

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

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

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

(q) Full Disclosure. With respect to the Product in the Territory, the Data Room contains true and complete copies of all agreements, contracts, documents, or other information referred to in this Agreement or that have been requested by NovaQuest, in each case, that has not been publicly disclosed by the Company. No representation or warranty or other statement made by Company in this Agreement, the Exhibits, the Schedules, any supplements, attachments, or annexes to the Exhibits or Schedules, or any certificates delivered in connection with the transactions contemplated in this Agreement contains any untrue statement or omits to state a material fact necessary to make any of them, in light of the circumstances in which it was made, not misleading. To the Knowledge of Company, there is no fact, event, or condition that has specific application to Company and that materially adversely affects the Product that has not been set forth in this Agreement, the Exhibits, and the Schedules hereto.

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

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

[*] = 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.

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

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

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

(e) Litigation. There is no action, suit, claim, proceeding, or investigation pending or, to the knowledge of NovaQuest, which, for the purpose of this Section 7.2(e) means the actual knowledge of Jacob Comer, threatened against NovaQuest or any of its Affiliates, at law or in equity, in an arbitration proceeding to which NovaQuest or any of its Affiliates is a party, or pursuant to the procedures of a Governmental Authority having jurisdiction over NovaQuest or its Affiliates, that, if adversely determined, would: (i) prevent the consummation of the transactions contemplated by this Agreement; or (ii) otherwise materially adversely affect Company's rights under this Agreement.

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

7.3 [*****].

ARTICLE VIII

COVENANTS

8.1 Notifications.

(a) Defaults, Termination and Litigation.

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

[*] = 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.

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

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

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

8.3 Event of Default.

(a) The Company shall notify NovaQuest in writing as soon as possible, and in any event within [*] following the occurrence of any Default or Event of Default during the Term, identifying the nature of such Default or Event of Default and whether or not such Default or Event of Default is in respect of, or is, a Bankruptcy Event of Default. [*] Company shall pay to NovaQuest, by wire transfer of immediately available funds in Dollars, [*].

(b) Subject to the terms and conditions of [*], if an Event of Default has occurred and is continuing, NovaQuest may, without further notice to Company, exercise all remedies available at law or in equity in respect of the Collateral, including directing Company and its Affiliates to assemble and deliver the Collateral as directed by NovaQuest, notifying any Third Party holding such Collateral (or portion thereof) of NovaQuest's rights in such Collateral (or portion) and directing such Third Party to transfer such Collateral or make payments in respect thereof to NovaQuest (and Company hereby consents to such transfer or payment).

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

[*] = 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.

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

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

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

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

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

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

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

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

8.6 Additional Covenants and Agreements of Company.

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

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

(c) Material Contracts and Licenses. Company shall comply with all terms and conditions of, and fulfill all of its obligations under, all of the Material Contracts, except for such noncompliance that would not reasonably be expected to result in a Material Adverse Effect. Company shall use [*] to enforce against the other party(ies) to each Material Contract all material terms and conditions thereunder, except where the failure of the other party(ies) to perform would not reasonably be expected to have a Material Adverse Effect. Company shall ensure that all Licenses contain provisions that require the Licensees to notify Company of any Material Adverse Effect and that allow Company to share information pertaining to the Commercialization of the Product to NovaQuest as contemplated by this Agreement. [*].

(d) Astellas Agreements.

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

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

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

(iv) Company shall, at NovaQuest's request and expense, make available its relevant records and personnel to NovaQuest in connection with any prosecution of litigation by Company or NovaQuest against any party to the Astellas Agreements to enforce any of Company's rights under the Astellas Agreements, and provide reasonable assistance and authority to file and bring such litigation, including, if required to bring such litigation, being joined as a party or plaintiff. All reasonable and documented out-of-pocket Third-Party expenses of Company (including reasonable and documented attorneys' fees) incurred pursuant to this Section 8.6(d)(iv) shall be reimbursed by NovaQuest.

ARTICLE IX

TERM AND TERMINATION

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

9.2 Termination.

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

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

(c) Termination for Material Breach. NovaQuest may terminate this Agreement in the event of an Event of Default or material breach of this Agreement by Company, provided that Company has received written notice from NovaQuest of such breach, specifying in reasonable detail the particulars of the alleged breach and such breach has not been cured within [*] after the date of the relevant notice. NovaQuest will have the right to pursue remedies it may have at law or equity for such breach, including the right to seek damages from Company. For the avoidance of doubt, a material breach of this Agreement by Company will include (but not be limited to) the occurrence of any of the following events, actions or omissions:

(i) Company materially breaches any representation or warranty under this Agreement or under any other agreement between the Parties contemplated by this Agreement;

[*] = 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.

(ii) Company materially breaches any agreement, covenant, or obligation in this Agreement or under any other agreement between the Parties contemplated by this Agreement, or a Responsible Party other than Company materially breaches any agreement, covenant, or obligation in this Agreement applicable to Responsible Parties.

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

9.3 Effects of Termination. Expiration or termination of this Agreement for any reason will not release either Party from any obligation or liability which, at the time of such expiration or termination, has already accrued to the other Party or which is attributable to a period prior to such expiration or termination.

9.4 Survival. Notwithstanding anything to the contrary contained in this Agreement, ARTICLE IV (to the extent payment of any Investor Return Payments are contemplated following such termination), Section 5.2 (for the duration of the Recordkeeping Period), ARTICLE VI, ARTICLE VII, Section 9.3, this Section 9.4, ARTICLE X, and ARTICLE XI shall survive the termination of this Agreement for any reason.

ARTICLE X

INDEMNIFICATION

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

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

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

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

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

[*] = 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.

10.2 Procedures.

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

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

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

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

(e) Cooperation. With respect to the defense of any Third-Party Claim for which indemnification is sought and for which NovaQuest elects the defense thereof to be assumed by Company, the Indemnified Party shall reasonably cooperate in the defense or prosecution thereof, and Company shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith. In the event NovaQuest elects not to have Company assume the defense of any Third-Party Claim for which indemnification is sought, then Company shall cooperate with the Indemnified Party in the defense or prosecution thereof, including by furnishing such records, information, and testimony, providing such witnesses and attending such conferences, discovery proceedings, hearings, trials, and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnified Party to, and reasonable retention by Company of, records and information that are reasonably relevant to such Third-Party Claim, and making Company employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder.

[*] = 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.

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

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

ARTICLE XI

MISCELLANEOUS

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

11.2 Dispute Resolution.

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

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

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

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

[*] = 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.

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

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

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

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

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

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

[*] = 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.

11.4 Expenses. Except as expressly set forth herein, each Party shall be responsible for and bear all of its own costs and expenses (including any legal fees, any accountants' fees, and any brokers', finders', or investment banking fees or any prior commitment in respect thereof) with regard to the negotiation and consummation of the transactions contemplated by this Agreement. Notwithstanding the foregoing, each Party represents and warrants to the other that the other Party will not be liable for any brokerage commission, finder's fee, or other like payment in connection with the transactions contemplated hereby because of any action taken by, or agreement or understanding reached by, that Party. If, after the Effective Date, Company requests an amendment of this Agreement in connection with any restructuring, reorganization, or similar transaction to which Company or any Affiliate of Company is a party, [*].

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

11.6 Successors and Assigns. Neither this Agreement nor any rights or obligations hereunder may be assigned in whole or in part by either Party, by operation of law or otherwise, without the prior written consent of the other Party (not to be unreasonably withheld, conditioned or delayed), provided that, notwithstanding the foregoing: (a) subject to the terms of any [*], NovaQuest may, upon delivery of reasonable written notice to Company, (i) assign, sell, or otherwise transfer this Agreement to an Affiliate of NovaQuest, and (ii) assign, sell, pledge, contribute, or otherwise transfer, in whole or in part, its rights to receive any payments under this Agreement, its rights to enforce such payment rights, and its rights to conduct or request audits or receive information and audit findings under ARTICLE V to any Person that is not a Company Competitor, and such Person may assign, sell, pledge, contribute, or otherwise transfer such rights to another Person that is not a Company Competitor; and (b) Company may assign, sell, pledge, contribute or otherwise transfer its rights or obligations hereunder in accordance with Section 8.2, Section 8.3, and Section 8.4. This Agreement shall be binding upon, and subject to the terms of this Section 11.6, inure to the benefit of the Parties hereto, their permitted successors, legal representatives and assigns, provided that [*]. Any assignment or attempted assignment not in accordance with this Section 11.6 shall be null and void. Company shall maintain at one of its offices a register for the recordation of the names and addresses of the Parties and the commitments of, and principal amounts (and stated interest) under the Agreement owing to, each Party pursuant to the terms hereof from time to time (the "***Register***"). The entries in the Register shall be conclusive absent manifest error, and the Parties shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as a Party hereunder for all purposes of this Agreement. The Register shall be available for inspection by the Parties, at any reasonable time and from time to time upon reasonable prior notice. The Parties agree that the foregoing is intended to ensure that the Agreement is in "registered form" within the meaning of Treasury Regulation Section 5f.103-1(c) and shall be interpreted consistently therewith. For avoidance of doubt, Company may assign, assign, sell, pledge, contribute or otherwise transfer its rights or obligations under such portions of Astellas Revenue that are not part of the Revenue Interest Payments due and payable to NovaQuest.

[*] = 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.

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

If to Company:

FibroGen, Inc.
409 Illinois Street
San Francisco, CA 94158
[*]

with a copy to:

Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
[*]

If to NovaQuest:

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

with a copy to:

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

or to such other address or addresses as NovaQuest or Company may from time to time designate by notice as provided herein. Any such notice shall be deemed given: (a) when actually received when so delivered personally or by overnight courier; (b) if mailed, other than during a period of general discontinuance or disruption of postal service due to strike, lockout or otherwise, on the [*] after its postmarked date thereof; or (c) if sent by e-mail with acknowledgement of receipt, transmission on the date sent if such day is a Business Day or the next following Business Day if such day is not a Business Day.

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

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

11.10 Entire Agreement. This Agreement, [*], including any Exhibits or Schedules to any the foregoing, set forth all of the covenants, promises, agreements, warranties, representations, conditions, and understandings between the

[*] = 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.

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

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

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

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

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

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

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

[*] = 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.

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

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

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

[Signature page follows]

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

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

FIBROGEN, INC.

By:	/s/ [*]
Name:	[*]
Title:	[*]

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

NQ PROJECT PHOEBUS, L.P.

By:	NQ POF V GP, Ltd, its general partner
By:	/s/ [*]
Name:	[*]
Title:	[*]

Exhibit A

Reserved

Exhibit B

Astellas EMEA Agreement

[Attached]

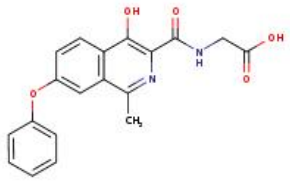
Exhibit C

Astellas Japan Agreement

[Attached]

Exhibit D

Compound



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

Exhibit E

Company Bank Account Information

[*]

Schedule 7.1(e)

Product Patents

[*].

Schedule 7.1(f)

Litigation

[*].

Schedule 7.1(h)

Material Contracts

[*].

Schedule 7.1(i)

Certain Regulatory Matters

- [*]

EXECUTION VERSION

[*] = 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 10.47

LETTER AGREEMENT

THIS LETTER AGREEMENT ("**Letter Agreement**") is effective as of **NOVEMBER 4, 2022** ("**Effective Date**") by and among **ASTELLAS PHARMA INC.** ("**Astellas**"), **Astellas Pharma Europe Ltd. ("APEL**"), and **FibroGen, Inc.** ("**FibroGen**"). This Letter Amendment amends both the Anemia License and Collaboration Agreement entered into by and between Astellas and FibroGen on April 28, 2006, as previously amended (the "**EU LCA**") and the Astellas EU Supply Agreement entered into by and between APEL and FibroGen effective as of January 1, 2021, as amended (the "**EU CSA**"). Astellas, APEL, and FibroGen shall be referred to individually herein as a "**Party**" and collectively as the "**Parties**".

WHEREAS, under the EU LCA, Astellas and FibroGen have agreed to collaborate on the development and commercialization of certain small molecule prolyl hydroxylase inhibitors as therapeutics, including Roxadustat, in the Astellas Territory; and under the EU CSA, FibroGen has agreed to supply to APEL bulk product of Roxadustat for commercialization in such Astellas Territory; and

WHEREAS, subject to the terms and conditions of this Letter Amendment, the Parties agree to (1) extend the date in which FibroGen shall be obligated to maintain two (2) separate, validated manufacturing sites, as contemplated by the Manufacturing & Supply terms and conditions under the EU LCA and (2) [*] in the EU CSA, in each case of (1) and (2), [*].

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

1) Unless otherwise defined herein, all capitalized terms and phrases used in this Letter Agreement shall have the meaning ascribed to them in the EU LCA and the EU CSA.

2) Astellas and FibroGen hereby agree to extend the date by which FibroGen shall be obligated to maintain two (2) separate validated manufacturing sites for the manufacture of Bulk Product, pursuant to the EU LCA's Manufacturing & Supply section (first paragraph, page 19) (the "**Alternative Site Validation Obligations**"), [*], provided that in any event the Alternative Site Validation Obligations shall be fulfilled by FibroGen [*].

3) Astellas and FibroGen intend for FibroGen to become obligated to maintain two (2) separate validated manufacturing sites for Bulk Product within the time frames noted in paragraph 2 above (the "**Purpose**"). Notwithstanding anything to the contrary pursuant to the definition of "**Marketing Approval Application**" or "**MAA**" in Section 1.51 of the EU LCA, the Parties agree that the definition of "Marketing Approval Application" or "MAA" shall be and is hereby limited to the approval of a new drug application by the U.S. Food and Drug Administration, and the regulations promulgated thereunder, for the purpose of enabling the Purpose of this Letter Agreement only.

4) [*].

5) The EU LCA and EU CSA, each as amended hereby, contains the entire understanding of the Parties with respect to the subject matter hereof.

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

[*] = 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.

7) This Letter Agreement may be executed in counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Counterparts may be signed and delivered by facsimile and/or via portable document format (.pdf), each of which shall be binding when sent.

In Witness Whereof, the Parties have executed this Letter Agreement as of the Effective Date.

Astellas Pharma Europe Ltd.

By:	/s/ [*]
Name:	[*]
Title:	[*]
Date:	4 November 2022

Astellas Pharma Inc.

By:	/s/ [*]
Name:	[*]
Title:	[*]
Date:	Nov 4th, 2022

FibroGen, Inc.

By:	/s/ [*]
Name:	[*]
Title:	[*]
Date:	11/4/2022

[*] = 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-3 (No. 333-236844 and 333-266663) and Form S-8 (No. 333-200348, No. 333-213816, No. 333-216369, No. 333-233204, No. 333-258655, and No. 333-266667) of FibroGen, Inc. of our report dated February 27, 2023 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 27, 2023

Exhibit 31.1

CERTIFICATION

I, Enrique Conterno, 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 27, 2023

/s/ Enrique Conterno

Enrique Conterno
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 27, 2023

/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), Enrique Conterno, 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, 2022 (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 27th day of February 2023.

/s/ Enrique Conterno	/s/ Juan Graham
Enrique Conterno Chief Executive Officer	Juan Graham 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.