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, 2019

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 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, 2019, was approximately $2,463.8 million. Shares of Common Stock held by each executive officer and director and stockholders known by the registrant to own 10% or more of the outstanding stock based on public filings and other information known to the registrant 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, 2020 was 87,999,804.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K incorporate information by reference from the definitive proxy statement for the registrant's 2020 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 on Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report filed on Form 10-K 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 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.

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.

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.

PART I

ITEM 1. BUSINESS

OVERVIEW

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") and connective tissue growth factor ("CTGF") biology to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer.

Roxadustat, our most advanced product, is an inhibitor of HIF prolyl hydroxylase ("HIF-PH") that acts by stimulating the body's natural pathway of erythropoiesis, or red blood cell production.

In August 2019, roxadustat (China tradename: □□□®) received marketing authorization in the People's Republic of China ("China") for the treatment of anemia caused by chronic kidney disease ("CKD") in non-dialysis-dependent patients. Roxadustat was approved in China for the treatment of anemia caused by CKD in dialysis-dependent patients in December 2018.

In September 2019, roxadustat (Evrenzo ®) was approved in Japan for the treatment of anemia associated with CKD in dialysis-dependent patients, and in January 2020, Astellas Pharma Inc. ("Astellas") submitted a supplemental New Drug Application ("NDA") in Japan for the treatment of anemia in non-dialysis CKD patients.

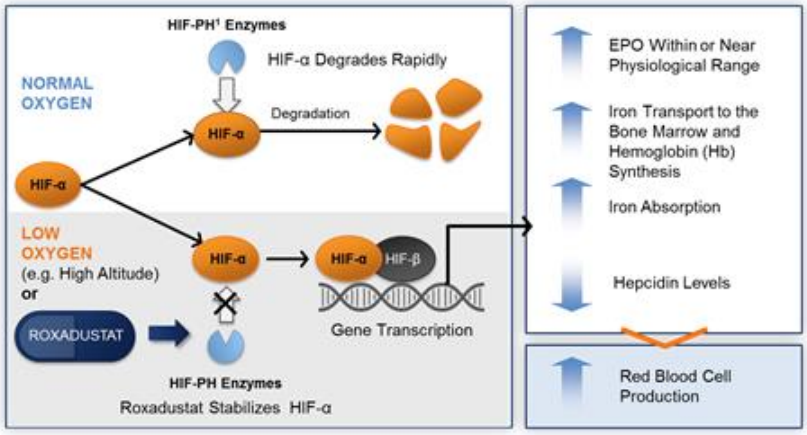
In conjunction with our collaboration partners, AstraZeneca AB ("AstraZeneca") and Astellas, we have completed the Phase 3 trials of roxadustat intended to support our NDA in the United States ("U.S.") and Marketing Authorization Application ("MAA") in the European Union and the United Kingdom ("Europe") for the treatment of anemia in CKD. Our NDA filing for roxadustat for the treatment of anemia in patients with dialysis-dependent CKD and in patients with non-dialysis-dependent CKD was accepted by the U.S. Food and Drug Administration ("FDA") in February, 2020. Astellas is in the process of preparing an MAA for submission to the European Medicines Agency ("EMA") in the second quarter of 2020 for the same indications. In addition, AstraZeneca has submitted applications for marketing approval of roxadustat in CKD anemia in Canada, Mexico, Taiwan, Philippines, and Singapore.

Beyond anemia in CKD, roxadustat is in Phase 3 clinical development in the U.S. and Europe and in Phase 2/3 development in China for anemia associated with myelodysplastic syndromes ("MDS"). We also began a Phase 2 clinical trial of roxadustat in the U.S. in chemotherapy-induced anemia ("CIA") in the third quarter of 2019.

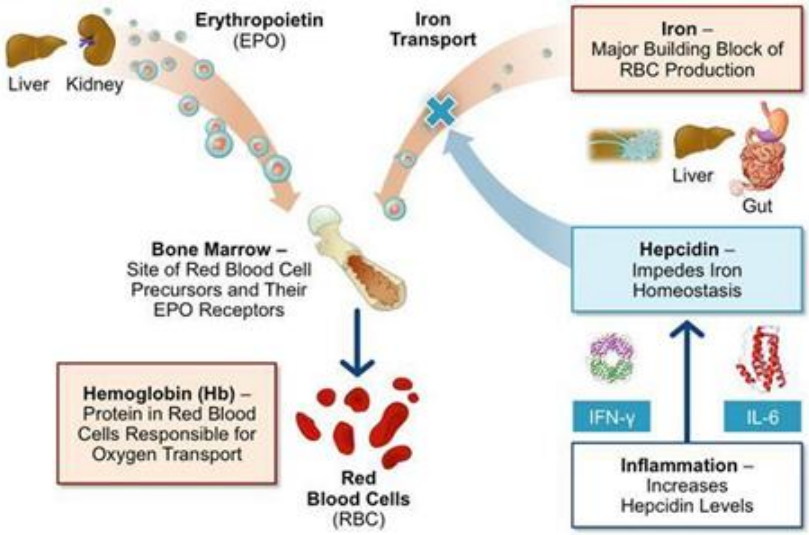
Pamrevlumab is our human monoclonal antibody that inhibits the activity of CTGF, a central mediator and critical common element in the progression of fibrotic and fibro-proliferative diseases. In 2019, we initiated a Phase 3 clinical program for the treatment of idiopathic pulmonary fibrosis ("IPF") and a Phase 3 clinical program for locally advanced unresectable pancreatic cancer. We also plan to initiate a Phase 3 program for the treatment of Duchenne muscular dystrophy ("DMD") in 2020.

ROXADUSTAT FOR THE TREATMENT OF ANEMIA IN CHRONIC KIDNEY DISEASE

Roxadustat is an orally administered small molecule that treats anemia by a mechanism of action that is different from that of erythropoiesis stimulating agents ("ESAs"). Roxadustat, as a HIF-PH inhibitor, relies on the natural mechanism by which the body responds to low oxygen levels. HIF is a transcription factor comprised of a HIF-alpha and a HIF-beta subunit, both of which are required to stimulate erythropoiesis. Under normal oxygen conditions, the HIF-alpha subunit is targeted for rapid degradation through the activity of a family of HIF-PH enzymes. However, under low oxygen conditions, the HIF-PH enzymes cannot function and HIF-alpha accumulates. HIF-alpha then combines with HIF-beta, and the newly formed HIF complex initiates transcription of a number of genes involved in the erythropoietic process, which ultimately leads to increased oxygen delivery to tissues. Roxadustat works by reversibly inhibiting the HIF-PH enzymes, thus mimicking this coordinated natural erythropoietic response through genes encoding the proteins involved in iron absorption, mobilization and transport as well as stimulation of red blood cell progenitors.



The coordinated erythropoiesis activated by roxadustat includes both the stimulation of erythroid maturation, by increasing the body's production of erythropoietin ("EPO"), and an increase in iron availability for hemoglobin synthesis in part through a decrease in hepcidin levels, which is particularly important in patients with inflammation. 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, 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. We believe these high doses of ESAs are a main cause of the significant safety issues that have been attributed to this class of drugs. 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.

In contrast, 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 safer and more effective treatment of anemia, including in the presence of inflammation, which normally limits iron availability.

Background of Anemia in Chronic Kidney Disease

Chronic kidney disease is a progressive disease characterized by gradual loss of kidney function that may eventually lead to kidney failure or end-stage renal disease ("ESRD") 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 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 in CKD 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.

Anemia is a complication of chronic kidney disease and becomes increasingly common as the disease advances. In the U.S., approximately 18 million adults have CKD Stages 3-5. Based on literature and market research, we estimate 25%, 50%, and 55% of CKD non-dialysis patients in Stages 3, 4, and 5, respectively, have anemia. This translates to an estimated 4.9 million CKD non-dialysis anemia patients, and we estimate that up to 50% may be addressable based on our expected label. Additionally, 90% of CKD patients on dialysis in the U.S., or approximately 0.5 million, 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 U.S., while 93% of dialysis patients receive ESAs, in contrast, the percentage of patients who are on one or more ESAs at the time of dialysis initiation declined from 30% in 2006 to 13.6% in 2017, despite the well-recognized health risks of untreated anemia.

In addition to the safety concerns, which may be a greater impediment in the non-dialysis setting, other factors which contribute to the under-treatment of anemia in non-dialysis patients are related to the form of administration and accessibility of ESA products. ESAs are administered by infusion or subcutaneous injections, which is more difficult outside of dialysis centers or nephrology practices where non-dialysis patients are typically treated.

In the dialysis-dependent population, most patients start receiving ESAs when the patient is transitioning to dialysis care. Patients face significant increased risk of death, cardiovascular events and hospitalizations during the first year on dialysis, and concurrently initiating anemia therapy adds complexity and safety risks. In addition, patients at an advanced stage CKD are often affected by chronic inflammation that leads to functional iron deficiency, requiring IV iron, and reduced effectiveness of ESAs.

The Market Opportunity for Roxadustat

We believe there is a significant opportunity for roxadustat, a potentially safer and more effective anemia treatment, to address markets currently served by injectable ESAs. According to IQVIA MIDAS™ reports, global ESA sales in all indications totaled $7.5 billion in 2018, driven primarily by $5.4 billion sold in the U.S. and Europe, mostly for treatment of anemia in CKD. We further believe that the number of patients requiring anemia therapy will grow steadily as the global CKD population and access to dialysis care continue to expand, particularly in China and other emerging markets including the rest of Asia, Latin America, Eastern Europe, the Middle East, and the Commonwealth of Independent States. In addition, obesity, hypertension, and diabetes prevalence continue rising, and the mortality of ESRD patients is declining, particularly in many emerging markets.

Furthermore, we believe there is a significant opportunity for roxadustat to address patient segments that are currently not effectively served by ESAs, such as anemia in non-dialysis CKD due to under-diagnosis of CKD and under-treatment of anemia in this population. Awareness of health consequences and the burden of CKD may also improve the diagnosis rate of CKD, and thus anemia of CKD.

Recently Completed Roxadustat Phase 3 Clinical Program in CKD Anemia

The table below summarizes the basis of our roxadustat U.S. NDA and planned MAA filing in Europe. Our NDA filing was accepted by the FDA in February 2020 for CKD anemia in both dialysis and non-dialysis patients. The FDA has set a Prescription Drug User Fee Act goal date of December 20, 2020. We expect Astellas to submit the MAA in Europe in the second quarter of 2020.

Roxadustat Phase 3 CKD Anemia Clinical Program

Study Sponsor, Number	Comparator	Number of Patients			
		U.S.	Europe	China	Japan
NON-DIALYSIS					
FibroGen - FGCL-4592-060 (ANDES)	Placebo	-------- 922 --------			
Astellas - 1517-CL-0608 (ALPS)	Placebo	-------- 597 --------			
AstraZeneca - D5740C00001 (OLYMPUS)	Placebo	-------- 2,781 --------			
Astellas - 1517-CL-0610	Darbepoetin alfa		616		
FibroGen - FGCL-4592-808	Placebo			151	
Astellas - 1517-CL-0310	Darbepoetin alfa				334
Astellas - 1517-CL-0314	None				99
Non-Dialysis-Dependent CKD Subtotal by Region		4,300	4,916	151	433
STABLE DIALYSIS					
Astellas - 1517-CL-0613 (PYRENEES)	Epoetin alfa or Darbepoetin alfa		838		
FibroGen - FGCL-4592-806	Epoetin alfa			304	
Astellas - 1517-CL-0302	None				56
Astellas - 1517-CL-0307	Darbepoetin alfa				303
Astellas - 1517-CL-0308	None				75
Astellas - 1517-CL-0312	None				164
STABLE AND INCIDENT DIALYSIS					
AstraZeneca - D5740C00002 (ROCKIES)	Epoetin alfa	-------- 2,133 --------			
FibroGen - FGCL-4592-064 (SIERRAS)	Epoetin alfa	-------- 741 --------			
INCIDENT DIALYSIS					
FibroGen - FGCL-4592-063 (HIMALAYAS)	Epoetin alfa	-------- 1,043 --------			
Dialysis-Dependent-CKD Subtotal by Region		3,917	4,755	304	598
Total by Regulatory Approval Region		**8,217**	**9,671**	**455**	**1,031**
Combined Total to Support U.S. and Europe Approvals			**9,671**		

The primary efficacy endpoint was met in each of the pivotal studies for the U.S. NDA and Europe MAA, as shown below:

Summary of Results from Individual Phase 3 Studies of Roxadustat in CKD Anemia

Summary of Roxadustat U.S. and Europe Phase 3 Primary Efficacy Results

Study Sponsor, Number	U.S. Primary Endpoint	Endpoint Met	Europe Primary Endpoint	Endpoint Met
NON-DIALYSIS				
FibroGen - FGCL-4592-060 (ANDES)	Superior to Placebo (p<0.0001)	✓	Superior to Placebo (p<0.0001)	✓
Astellas - 1517-CL-0608 (ALPS)	Superior to Placebo (p<0.001)	✓	Superior to Placebo (p<0.001)	✓
AstraZeneca - D5740C00001 (OLYMPUS)	Statistically-Significant Improvement in Hb Change Compared to Placebo	✓	Statistically-Significant Improvement in Hb Change Compared to Placebo	✓
STABLE DIALYSIS				
Astellas - 1517-CL-0613 (PYRENEES)	Non-Inferior to ESAs	✓	Non-Inferior to ESAs	✓
STABLE AND INCIDENT DIALYSIS				
AstraZeneca - D5740C00002 (ROCKIES)	Statistically-Significant Larger Hb Increase Compared to Epoetin Alfa	✓	Statistically-Significant Larger Hb Increase Compared to Epoetin Alfa	✓
FibroGen - FGCL-4592-064 (SIERRAS)	Superior to Epoetin Alfa (p<0.0001)	✓	Superior to Epoetin Alfa (p<0.0001)	✓
INCIDENT DIALYSIS				
FibroGen - FGCL-4592-063 (HIMALAYAS)	Superior to Epoetin Alfa (p=0.0005)	✓	Non-Inferior to Epoetin Alfa	✓

Pooled Efficacy Results in Non-Dialysis Patients

Superior at Raising Hemoglobin

Roxadustat superiority in efficacy was demonstrated in pooled efficacy analyses across the three Phase 3 dialysis-dependent studies and the three non-dialysis-dependent studies.

In the non-dialysis pool (4,277 patients from OLYMPUS, ANDES, and ALPS), the mean change in hemoglobin (from baseline to the average between Weeks 28-52) in roxadustat patients was also significantly larger than in placebo patients (1.85 g/dL vs. 0.13 g/dL, p<0.001).

Efficacy at Raising Hemoglobin Irrespective of Iron Replete Status

In the non-dialysis pool, roxadustat increased hemoglobin (by 1.94 g/dL) regardless of whether patients were iron-replete (patients shown to have sufficient baseline stores of iron in their body, TSAT ≥20% and Ferritin ≥100 ng/mL) or not iron-replete.

Reduction In Risk of Rescue Therapy and Transfusion

The risk of rescue therapy (blood or red blood cell transfusion, ESA use, or IV iron) was significantly lower in the roxadustat arm (8.9%) than the placebo arm (31.1%) in the pooled non-dialysis patients with a hazard ratio ("HR") = 0.19 (95% confidence interval "95% CI" of 0.16, 0.23), p<0.0001. The percentage of patients receiving red blood cell transfusions during the first year of treatment was also significantly lower in the roxadustat arm (5.2%) as compared to the placebo arm (15.4%) (HR (95% CI) = 0.26 (0.21, 0.32), p<0.0001).

Reduction of Decline in Kidney Function as Measured by eGFR

In a post hoc subgroup analysis of 2,438 non-dialysis patients with baseline eGFR≥15, the one-year decline in estimated glomerular filtration rate ("eGFR," a measure of the filtration function of kidney and renal disease progression) in roxadustat-treated patients (-2.8) was lower than that in placebo treated patients (-4.4), with a treatment difference of 1.6 mL/min/1.73m 2.

Reduction of LDL Cholesterol

In the pooled non-dialysis patients, roxadustat lowered low-density lipoproteins ("LDL"), with a mean change from baseline of -17.06 mg/dL compared to an increase of 1.30 mg/dL for placebo patients, a significant treatment difference of -19.83 mg/dL (p<0.0001).

Improvements in Quality of Life Measures

We have also observed improvements in quality of life. In the pooled analysis from the three non-dialysis studies, we observed statistically significant improvements from baseline to Week 12 in quality of life endpoints, including SF-36 Vitality subscale (p=0.0002), SF-36 Physical Functioning subscale (p=0.0369), FACT-AN Anemia subscale (p=0.0012), FACT-AN Total score (p=0.0056), and EQ-5D-SL VAS score (p=0.0005) when comparing roxadustat to placebo in CKD patients not on dialysis.

Pooled Efficacy Results in Dialysis Patients

Superior at Raising Hemoglobin

In the pooled dialysis studies (3,857 patients from HIMALAYAS, SIERRAS, and ROCKIES) the mean change in hemoglobin (from baseline to the average between Weeks 28-52) in roxadustat patients was significantly larger than in epoetin alfa patients (1.22 g/dL vs. 0.99 g/dL, p<0.001).

Efficacy at Raising Hemoglobin in Patients with Inflammation

In a subgroup of dialysis patients with inflammation (C-reactive protein ("CRP") levels over 4.9 mg/L), the mean change in hemoglobin (from baseline to the average between Weeks 28-52) was significantly higher in roxadustat-treated patients (1.29 g/dL) than epoetin alfa treated patients (0.96 g/dL, p<0.0001).

Lower Intravenous ("IV") Iron Requirements

In the dialysis pool, less mean monthly IV iron supplementation was required at Weeks 28-52 in patients receiving roxadustat versus patients receiving epoetin alfa in pooled analysis, p< 0.0001.

Reduction In Transfusion Risk

In the dialysis pool, during the first year of treatment, patients in the roxadustat arm had a lower transfusion risk (9.5%) as compared to the epoetin alfa arm (12.8%) (HR (95% CI) = 0.82 (0.679, 0.997), p=0.046).

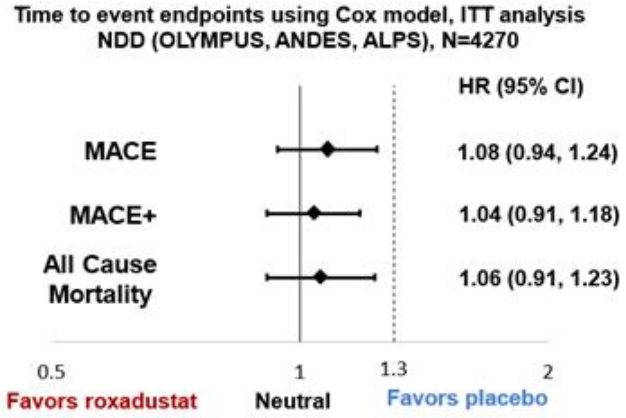
Pooled Cardiovascular Safety Results

In the U.S., the primary safety endpoint is time to first Major Adverse Cardiovascular Event ("MACE"), a composite endpoint of all-cause mortality, stroke and myocardial infarction. In Europe, the primary safety endpoint is the time to first MACE+ ("MACE+") which, in addition to the components in MACE, also includes hospitalization due to heart failure or unstable angina. However, the FDA in the U.S., and the EMA in Europe, will each review MACE, MACE+, and all-cause mortality separately, in addition to other endpoints.

The below cardiovascular safety analyses reflect the pooling strategy and analytical approach we agreed on with the FDA. Similar sets of analyses will be submitted to the EMA to serve as the basis for potential approval in dialysis and non-dialysis in Europe, and additional supportive analyses and sensitivity analyses as well as subgroup analyses were also included in the NDA and will be included in the MAA. However, the FDA and EMA will each conduct their own benefit-risk analysis and may use additional statistical analyses other than those agreed with the FDA or set forth below.

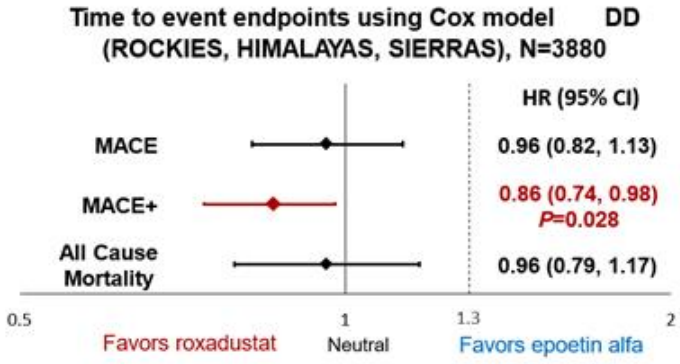
Non-Dialysis - Pooled Cardiovascular Safety Data

In our pre-NDA meeting, the FDA agreed that the intent-to-treat analyses followed for long-term safety results would be our primary cardiovascular safety analysis method for non-dialysis in the U.S. as it uses on-treatment and post treatment long term follow-up (until a common study end date) to account for the higher drop-out rate in the placebo arm. The figure below shows that in the 4,270 pooled non-dialysis patients (OLYMPUS, ANDES, and ALPS), the risk of MACE, MACE+, and all-cause mortality in roxadustat patients were comparable to that in placebo patients based on a reference non-inferiority margin of 1.3.



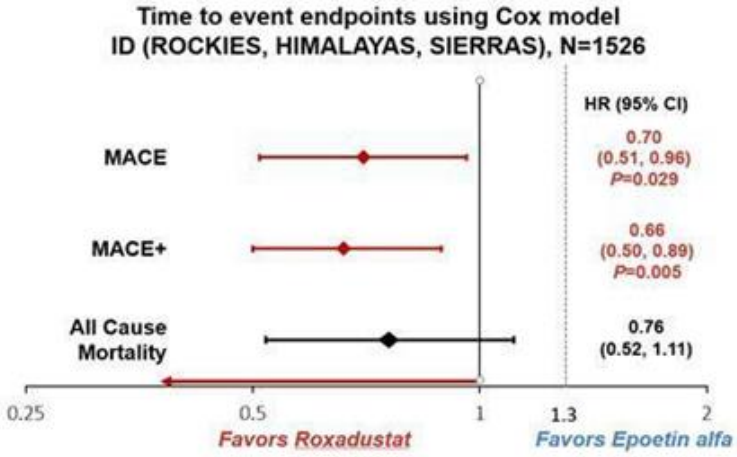
Dialysis - Pooled Cardiovascular Safety Data

In the pooled on-treatment analysis of 3,880 dialysis patients (HIMALAYAS, SIERRAS, and ROCKIES), the risk of MACE and all-cause mortality in roxadustat patients were not increased (based on a reference non-inferiority margin of 1.3), and roxadustat lowered the risk of MACE+ by 14% compared to the active comparator epoetin alfa, based on a hazard ratio of 0.86 and an upper bound of 95% CI under 1.0. The hazard ratios represent a point estimate of relative risk.



Incident Dialysis Subgroup - Pooled Cardiovascular Safety Data

In this program, incident dialysis patients are those who started participation in roxadustat Phase 3 studies within their first four months of dialysis initiation. In this clinically important subgroup of 1,526 incident dialysis patients, roxadustat reduced the risk of MACE by 30% and MACE+ by 34%, with a trend towards lower all-cause mortality. The lower MACE and MACE+ risks (compared to epoetin alfa) are based on hazard ratios of 0.70 and 0.66, respectively, with the upper bound of 95% CI under 1.0 in both. We believe this incident dialysis subpopulation is the appropriate setting for comparison of roxadustat versus epoetin alfa since most incident dialysis patients were ESA-naïve or have had only limited exposure to ESAs prior to study entry. In addition, the initiation of anemia therapy in this incident dialysis subgroup resembles clinical practice as the vast majority of US patients start anemia therapy early in dialysis treatment (during the first four months of treatment).



Non-Dialysis CKD Patients (ANDES) – FibroGen

ANDES is a 922-patient Phase 3, randomized, double-blinded, placebo-controlled trial designed to evaluate the efficacy and safety of roxadustat vs. placebo for the treatment of anemia in patients with later stage CKD (Stages 3, 4 or 5) who are not dialysis-dependent.

U.S. primary efficacy endpoint: roxadustat was superior to placebo in mean hemoglobin change from baseline to the average over Weeks 28 to 52 (2.00 vs. 0.16 g/dL, respectively, p<0.0001).

Europe primary efficacy endpoint: a higher proportion of roxadustat-treated patients (86.0%) achieved a hemoglobin response (defined as achieving a hemoglobin level of at least 11 g/dL on two consecutive visits during the first 24-weeks of treatment and a hemoglobin increase of at least 1.0 g/dL in subjects with baseline hemoglobin >8.0 g/dL, or an increase of at least 2.0 g/dL in subjects with baseline hemoglobin ≤8.0 g/dL), as compared to placebo (6.6%), p<0.0001.

The proportion of subjects who received any rescue therapy (blood/red blood cell transfusion, ESA use, or IV iron) in the first 52 weeks of treatment was 8.9% in the roxadustat arm vs. 28.9% in the placebo arm (HR (95% CI) = 0.19 (0.138, 0.276), p<0.0001). The proportion of subjects who received blood/red blood cell transfusion in the first 52 weeks of treatment was 5.6% in the roxadustat arm vs. 15.4% in the placebo arm (HR (95% CI) = 0.26 (0.165, 0.406), p<0.0001).

The mean change in LDL cholesterol from baseline to average over Weeks 12-28 was -18.48 mg/dL (n=564) in the roxadustat arm vs. 0.22 mg/dL (n=269) in the placebo arm, with a treatment difference of -17.26 mg/dL (p<0.0001).

In this study, roxadustat-treated patients had a sustained reduction in hepcidin whereas placebo patients did not have a reduction in hepcidin. The mean change from baseline to Week 44 was -22.1µg/L in the roxadustat arm vs. 3.88 µg/L in the placebo arm, for a treatment difference between the two arms of -25.71 µg/L (95% CI: -38.523, -12.903).

In this study, subjects in the roxadustat arm had a substantially higher overall study drug exposure compared to subjects in the placebo arm. Study drug discontinuation was higher in the placebo arm compared to roxadustat arm, and the relative difference in discontinuation rates was especially pronounced in the lowest baseline eGFR category. The overall exposure-adjusted safety profile of roxadustat observed during this study was comparable with placebo and consistent with that expected in the CKD study population. The most commonly reported adverse events with roxadustat in this trial were nausea, hyperkalemia, constipation, and hypertension.

Non-Dialysis CKD Patients (ALPS) – Astellas

ALPS is Astellas' Phase 3, randomized, double-blind, placebo-controlled study of the efficacy and safety of roxadustat for the treatment of anemia in CKD in 597 patients not on dialysis. The trial met its primary endpoints by demonstrating superiority in efficacy vs. placebo in terms of hemoglobin change from baseline at Weeks 28 to 52 (1.988 for roxadustat vs 0.406 for placebo, $p<0.001$).

Roxadustat was superior to placebo in its ability to lower LDL from baseline with an LS mean difference of -0.701 mmol/L (95% CI: -0.83, -0.57). Roxadustat was superior to placebo in delaying the need for rescue therapy (HR (95%CI) = 0.238 (0.17, 0.33), $p<0.001$).

The safety profile observed in this study was in line with the expected event profile in non-dialysis patients. Common adverse events in both treatment groups were ESRD, hypertension, peripheral edema, and decreased glomerular filtration rate.

Non-Dialysis CKD Patients (OLYMPUS) – AstraZeneca

OLYMPUS is AstraZeneca's Phase 3, randomized, double-blinded, placebo-controlled trial designed to evaluate the efficacy and safety of roxadustat vs. placebo for the treatment of patients with anemia in CKD Stages 3, 4 or 5 whose disease progression is moderate to severe and who are non-dialysis-dependent. The trial in 2,781 patients met its primary efficacy endpoint by demonstrating a statistically-significant improvement in mean change from baseline in hemoglobin levels averaged over Weeks 28 to 52 (1.75 g/dL) as compared with Placebo (0.40 g/dL).

Roxadustat also improved hemoglobin levels from baseline in a subgroup of patients with inflammation (CRP>5 mg/L), with a statistically significant mean increase of 1.75 g/dL, compared to 0.62g/dL with placebo.

Overall safety findings are generally consistent with the non-dialysis patient population. For all patients, the most commonly reported adverse events in the intent-to-treat analysis set were ESRD, pneumonia, urinary tract infection and hypertension.

Stable Dialysis CKD Patients (PYRENEES) – Astellas

PYRENEES is Astellas' Phase 3, randomized, active-controlled trial designed to assess the efficacy and safety of roxadustat vs. epoetin alfa or darbepoetin alfa, for the treatment of anemia in 838 patients with CKD who are dialysis-dependent. The trial met its primary efficacy endpoint: roxadustat was considered non-inferior to ESAs based on the mean change from baseline in average hemoglobin levels at Weeks 28 to 52 (0.397 vs 0.183; non-inferiority margin = -0.75).

Roxadustat was superior to ESAs in its ability to lower LDL from baseline with an LS mean difference of -0.377 mmol/L (95% CI: -0.451, -0.304). Roxadustat was superior to ESAs in reducing the need for monthly IV iron use (LS mean difference (95%CI) = -31.9 mg (-41.4, -22.4), $p<0.001$).

The safety profile observed in this study was in line with the expected event profile in dialysis patients. There was a greater proportion of deaths in the roxadustat treatment group compared with the ESA group; however, the study was not powered to assess risk of MACE events or death, as compared to the pooled analysis above. Common adverse events in both treatment groups were hypertension, arteriovenous fistula thrombosis, headache, and diarrhea.

Stable and Incident Dialysis CKD Patients (ROCKIES) – AstraZeneca

ROCKIES is AstraZeneca's Phase 3, randomized, open-label, active-controlled trial designed to assess the efficacy and safety of roxadustat vs. epoetin alfa, for the treatment of anemia in patients with CKD who are dialysis-dependent. The trial in 2,133 patients met its primary efficacy endpoint by demonstrating a statistically-significant improvement in mean change from baseline in hemoglobin levels averaged over Weeks 28 to 52 (0.77 g/dL) compared with epoetin alfa (0.68 g/dL).

Roxadustat also improved hemoglobin levels from baseline in a subgroup of patients with inflammation (CRP>5 mg/L, demonstrating a statistically significant improvement with a mean increase of 0.80 g/dL compared to 0.59 g/dL with epoetin alfa. Patients treated with roxadustat used less monthly IV iron (mean = 59mg) compared to those treated with epoetin alfa (mean = 91mg) from Week 36 to the end of the study.

Adverse events with roxadustat were generally similar to those seen in patients treated with epoetin alfa and commonly found in dialysis patients. In roxadustat-treated patients, the most commonly reported adverse events were diarrhea, hypertension, pneumonia, headache, and arteriovenous fistula thrombosis.

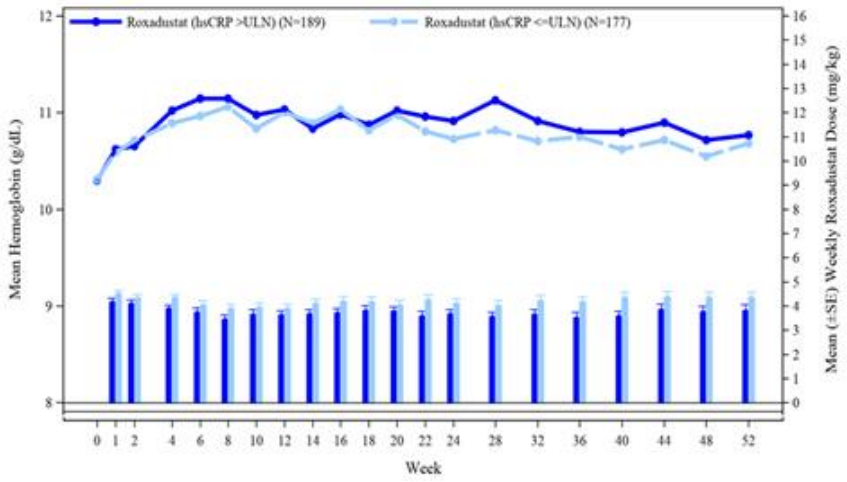
Stable and Incident Dialysis CKD Patients Study (SIERRAS) – FibroGen

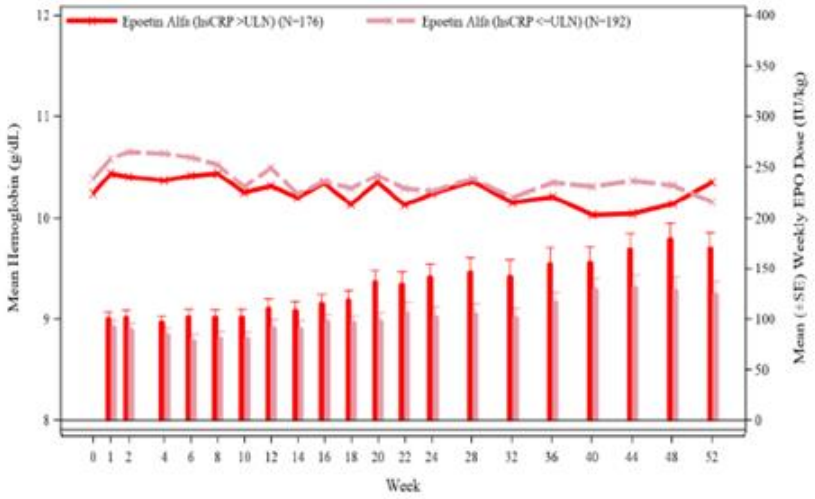
SIERRAS is a 741-patient U.S. Phase 3, randomized, open-label, active-controlled trial to assess the efficacy and safety of roxadustat compared to epoetin alfa for the treatment of anemia in dialysis CKD patients who were receiving stable doses of ESA prior to study participation.

U.S. primary efficacy endpoint: the mean hemoglobin change from baseline to the average over Weeks 28 to 52 was 0.39 g/dL (roxadustat) vs. -0.09 g/dL (epoetin alfa), a least squares mean treatment difference of 0.48 g/dL (95% CI 0.37, 0.59). Roxadustat met the non-inferiority criteria as the lower bound of 95% CI was well above the non-inferiority margin of -0.75 g/dL. Roxadustat also achieved superiority, p<0.0001.

Europe primary efficacy endpoint: the mean hemoglobin change from baseline to the average over Weeks 28 to 36 was 0.54 g/dL (roxadustat) vs. -0.03 g/dL (epoetin alfa), a least squares mean treatment difference of 0.55 g/dL with a 95% CI (0.40, 0.69). Roxadustat met the non-inferiority criteria as the lower bound of the 95% CI was well above the non-inferiority margin of -0.75 g/dL. Roxadustat also achieved superiority over epoetin alfa, p<0.0001.

As seen in the figures below, in patients with inflammation (CRP>4.9 mg/L), roxadustat doses for maintaining hemoglobin levels were comparable to those with normal CRP and were stable over time as the effect on hemoglobin was durable, whereas epoetin alfa patients required higher mean doses in patients with inflammation (CRP>4.9 mg/L), doses which increased by approximately 50% from baseline after about one year. In these patients with inflammation (CRP>4.9 mg/L) mean change in hemoglobin from baseline to Week 18-24 was 0.61 g/dL in roxadustat vs. -0.03 g/dL in the epoetin alfa group, p<0.0001.





Subjects in the roxadustat group received lower mean IV iron during Weeks 28 to 52 than subjects in the epoetin alfa group (p=0.00091). Roxadustat-treated patients had a greater reduction in hepcidin as compared to ESA-treated patients. Additionally, a lower proportion of subjects on roxadustat received a red blood cell transfusion during treatment than the epoetin alfa group (12.5% and 21.1%, respectively, p=0.0337), with reduction in red blood cell transfusion risk by 33% compared with epoetin alfa; HR (95% CI) = 0.67 (0.466, 0.970), p=0.0337.

Mean LDL cholesterol levels decreased in the roxadustat group from baseline to the average over Weeks 12 to 28 (-13.70 mg/dL) but increased in the epoetin alfa group (1.23 mg/dL) with a treatment difference of -14.67 mg/dL (p<0.0001).

The incidence of treatment emergent adverse events was comparable in the roxadustat and epoetin alfa arms and were generally consistent with those typically expected in study patient population of ESRD on chronic dialysis therapy. The most commonly reported adverse events with roxadustat in this trial were nausea, hypertension, vomiting, and hyperkalemia.

Incident Dialysis CKD Patients Study (HIMALAYAS) – FibroGen

HIMALAYAS is a 1,043-patient Phase 3 randomized, open-label, active-controlled trial to assess the efficacy and safety of roxadustat compared to epoetin alfa, an ESA, for the treatment of anemia in CKD patients who have newly initiated dialysis treatment for ESRD and have had minimal or no exposure to an ESA prior to study participation.

U.S. primary efficacy endpoint: the mean hemoglobin change from baseline to the average over Weeks 28 to 52 was 2.57 g/dL (roxadustat) vs. 2.36 g/dL (epoetin alfa), a least squares mean difference of 0.18 g/dL, with the 95% CI of (0.08, 0.29). The non-inferiority criteria was met as the lower bound of the 95% CI was well above the non-inferiority margin of -0.75 g/dL, and superiority over epoetin alfa was also achieved, p=0.0005. In subgroup analyses, roxadustat was also superior to epoetin alfa in hemoglobin change from baseline regardless of iron repletion and inflammation status.

Europe primary efficacy endpoint: a higher proportion of roxadustat-treated patients (88.2%) achieved a hemoglobin response (defined as achieving a hemoglobin level of at least 11 g/dL on two consecutive visits during the first 24-weeks of treatment and a hemoglobin increase of at least 1.0 g/dL in subjects with baseline hemoglobin >8.0 g/dL, or an increase of at least 2.0 g/dL in subjects with baseline hemoglobin ≤8.0 g/dL), as compared to an 84.4% responder rate in the epoetin alfa arm, with the lower bound of the 95% CI (-0.7%, 7.7%) of the treatment difference in responder rate well above the non-inferiority margin of -15%.

Roxadustat-treated patients had a statistically significant reduction in hepcidin, a key regulator of iron metabolism, as compared to ESA-treated patients. Roxadustat was shown to increase hemoglobin regardless of baseline inflammation status.

The most commonly reported adverse events with roxadustat in this trial were hypertension, diarrhea, and muscle spasms. The safety profile of roxadustat in this study was consistent with results from prior roxadustat studies.

ROXADUSTAT FOR THE TREATMENT OF ANEMIA IN CHRONIC KIDNEY DISEASE IN CHINA

In August 2019, roxadustat (China tradename: □□□®) received marketing authorization in China for the treatment of anemia caused by CKD in non-dialysis-dependent patients. Treatment for anemia caused by CKD in dialysis-dependent patients was approved in 2018.

In July 2019, results from our two China Phase 3 clinical trials were published in the *New England Journal of Medicine*.

In December 2019, roxadustat was included on the updated National Reimbursement Drug List (“NRDL”) released by China’s National Healthcare Security Administration. Roxadustat is included on the NRDL for the treatment of anemia in CKD.

Market Opportunity

The currently available forms of treatment in China for anemia in CKD include ESAs, oral iron, intravenous iron, traditional Chinese medicine, and combinations thereof. ESAs are the largest segment, which we estimate to be approximately $275 million in sales, or approximately 80% of the total ESA market based on data from IQVIA China Hospital Pharmaceutical Audit. With the unique benefits of roxadustat to treat previously unaddressable patient populations, we believe the overall CKD anemia market will increase.

China is experiencing epidemiological changes in metabolic diseases due to economic development, urbanization and an aging population. Diabetes and hypertension are the leading causes of CKD in China, and rates have been growing over past two decades. We believe the increase in diabetes and hypertension prevalence will result in an increase of CKD anemia patients.

Dialysis-Dependent CKD

Based on the latest estimates and published data, we believe there are over 600,000 dialysis patients in China, making it the largest single-country dialysis population in the world. With the substantial growth rate of dialysis patients (over 10% per year from 2011 to 2017), the Ministry of Health and the Chinese Society of Nephrology have publicly recognized the need for further investment in dialysis infrastructure.

The prevalence rate of CKD dialysis patients that have anemia (defined as hemoglobin < 10g/dL) is estimated to be over 90%.

Dialysis treatment is delivered in the form of hemodialysis or peritoneal dialysis. In China, approximately 85% of dialysis patients with CKD are on hemodialysis. Hemodialysis is performed primarily in dialysis clinics within hospitals, most of which are publicly owned. This is in contrast to the U.S. where freestanding dialysis centers located outside of hospitals is common practice. With recent regulatory changes, the number of privately owned dialysis clinics is growing at a rapid pace, a trend that has provided additional capacity to meet the growing demand. The remaining 14-15% of CKD patients (approximately 100,000) are on peritoneal dialysis, which is self-administered at home by patients, a setting roxadustat, with its oral administration, is particularly well-suited for roxadustat. Peritoneal dialysis patients typically visit their nephrologists on a monthly basis at the hospital for monitoring and follow-up.

Non-Dialysis-Dependent CKD

We estimate that there are over 10 million Stage 3-5 non-dialysis CKD patients in China with anemia (defined as hemoglobin < 10g/dL). We believe the addressable population of non-dialysis patients with anemia (anemic patients that have been diagnosed and treated for CKD) is approximately 2-3 million, with 1-2 million in Stages 3 and 4 and 1 million in Stage 5 non-dialysis. This Stage 5 population that is dialysis-eligible but not receiving dialysis is characteristic of developing markets like China, and presents a particular opportunity for roxadustat, as many patients have severe anemia.

Unmet Medical Need and Roxadustat Differentiation in China

We believe there is a particularly significant unmet medical need for the treatment of anemia in CKD in China. Anemia is considered a risk multiplier for CKD patients and is commonly associated with increased rates of cardiovascular events, hospitalizations, CKD progression, and death. Several of the advantages that roxadustat, as an oral therapeutic, potentially offers over ESAs are particularly suited to address the unmet medical need in each of the three categories of CKD patients in China.

We believe there is chronic under-treatment of anemia within the CKD patient population on dialysis in China due in part to under-prescription of IV iron (often necessary for ESA treatment), and lack of efficacy in patients with inflammation. The most recent treatment guidelines published by the Chinese Society of Nephrology in 2018 recommended treatment to hemoglobin 11.0 g/dL to 12.0 g/dL. Even though over 70% of hemodialysis CKD patients, and approximately 60% of peritoneal dialysis CKD patients are treated with ESAs, based on the Chinese Renal Data System in 2015, less than 60% of dialysis patients reached 10.2 g/dL.

In the non-dialysis population and peritoneal dialysis population, only a small percentage of patients receive anemia treatment, and those who do, they receive only a minimal level of treatment, including patients who are eligible for dialysis and who have severe anemia. Roxadustat, as an oral medication, can be easily administered in any setting and stored at room temperature. Injectable drugs like ESAs present a challenge in China because even subcutaneous administration is performed at hospitals and not in the home, in part due to the difficulty in refrigeration and administration of injectable medicines. Frequent hospital visits, for the sole purpose of receiving injectable ESA treatment (as well as IV iron, which is often necessary with ESA treatment), can present a substantial logistical and financial burden to patients.

In the context of the rapidly growing China pharmaceutical market, we believe that the demand for anemia therapy will continue to grow as a result of an expanding CKD population, as well as the central government’s mandate to make dialysis more available through government reimbursement and build-out of dialysis facilities. In addition, as the standard of living improves in China, the demand for access to innovative drugs increases. In this context, we believe that roxadustat is a particularly promising product for this market.

Commercialization

AstraZeneca is our commercialization partner for roxadustat in China. Under our collaboration agreement, AstraZeneca will lead commercialization activities and has responsibility for sales and marketing, and market access. FibroGen has responsibility for medical affairs, manufacturing (as the Marketing Authorization Holder), executing sales to distributors, and pharmacovigilance. FibroGen and AstraZeneca will work together to manage distribution.

Pricing and Reimbursement

In December 2019, roxadustat was included for the treatment of anemia in CKD on the updated NRDL released by China's National Healthcare Security Administration. The list is effective for a standard two-year period from January 1, 2020 to December 31, 2021. The negotiated price for a roxadustat 50 mg capsule is RMB 95. Roxadustat will be subject to price re-negotiation at the end of 2021.

We believe reimbursement is one of the two most critical market access factors for commercialization success in China, with the other being hospital listings. China is mostly a single-payor market with near universal healthcare provided by the government. Over 95% of the population receives healthcare coverage under one government-funded medical reimbursement plan or another, each with different levels of reimbursement. Commercial health insurance is available but is minimally adopted, and is seen as a supplement above and beyond government reimbursement.

Reimbursement for roxadustat will differ based on multiple factors including the CKD patient population (dialysis vs. non-dialysis), location, patient employment status, and if roxadustat is qualified into the "Critical Disease" or "Chronic Disease" insurance programs for such locations. We expect roxadustat reimbursement rates will be largely consistent with those ESAs listed on the NRDL. We believe in the next few years and in many parts of the country, dialysis patients will generally be reimbursed for 80-90% of their costs for roxadustat and non-dialysis patients in the 50-70% range.

Hospital Listing

Before roxadustat can be prescribed at a government hospital, which is 90% of the market in China, it has to be carried in the hospital formulary. The process of entry into the formulary is commonly referred to as "hospital listing". Decisions are made on a hospital-by-hospital basis, where hospital listing committees meet anywhere from every six months to every five years. Temporary listings can be used in the interim, where the head of the department could place an ad-hoc order with the formulary for a single or handful of patients for small quantities of roxadustat. These market access constraints impact all drugs, not just roxadustat. Consistent with the experience of other product launches in China, significant market uptake is usually seen a few years after launch, although in the case of roxadustat, it could be sooner given the inclusion in NRDL within 12 months of market approval.

Tendering

Tendering is a provincial level procedure. For drugs with multiple brands, it is a collective tender process for purchases by government hospitals of a medicine included in provincial or local medicine procurement catalogs. In the case of roxadustat, it is a more administrative process than for most drugs as roxadustat is currently the only drug of its class (HIF-PHI) available on the market. The tendering process of roxadustat is substantially complete in all 31 provinces in China.

ROXADUSTAT FOR THE TREATMENT OF ANEMIA IN CHRONIC KIDNEY DISEASE IN JAPAN

In September 2019, roxadustat (Evrenzo®) was approved in Japan for the treatment of anemia associated with CKD in dialysis patients. Our collaboration partner Astellas launched Evrenzo in November 2019, targeting healthcare providers that care for approximately 330,000 dialysis patients across Japan.

In January 2020, Astellas submitted a supplemental NDA in Japan for the treatment of anemia in non-dialysis CKD patients, supported by three clinical studies in more than 500 Japanese non-dialysis patients with anemia associated with CKD.

ROXADUSTAT FOR THE TREATMENT OF CHEMOTHERAPY-INDUCED ANEMIA AND ANEMIA ASSOCIATED WITH MYELODYSPLASTIC SYNDROMES

Based on roxadustat's mechanism of action and safety and efficacy profile to date, we believe it has the potential to treat anemia associated with many other conditions, including CIA and MDS.

Background of 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 1.7 million in the U.S. and 3.2 million in China. Eighty percent of those patients in developed countries and 40% of patients in China develop CIA. 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 600,000 in the U.S. and 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 box warnings for ESAs in cancer populations in 2007, followed by the ESA Risk Evaluation and Mitigation Strategy (“REMS”) program.

Market Opportunity for Roxadustat in Chemotherapy-Induced Anemia

ESA sales for CIA dropped significantly in the U.S. since the reported safety risks of ESA use in cancer patients in 2006, from estimated $2.5 billion in 2006 to less than $0.5 billion in 2019. During the same period, the prevalence of diagnosed CIA remained at similar levels, and is expected to grow slightly as a marginal decline of chemotherapy use is offset by an aging population.

We believe that if our clinical program shows an acceptable safety and efficacy profile, roxadustat would have the potential to address anemia in this population of patients undergoing chemotherapy, including, potentially, those patients with concomitant inflammation.

Clinical Development of Roxadustat in Chemotherapy-Induced Anemia

We began a Phase 2 proof of concept clinical trial of roxadustat in the U.S. in CIA in the third quarter of 2019. This is a single-arm open label study investigating the efficacy and safety of roxadustat for the treatment of anemia in patients receiving myelosuppressive chemotherapy treatment for non-myeloid malignancies, with treatment duration of 16 weeks, and will enroll up to 100 patients.

Background of Anemia in Myelodysplastic Syndromes

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

Incidence and prevalence of MDS are not yet well understood, and may be greatly underestimated. MDS diagnosis became reportable under the World Health Organization oncology classification system only in 2001, and since then cases of MDS have been tracked by cancer registries.

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. We estimate that currently, approximately 70,000 patients are diagnosed with MDS in the United States.

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 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 we may be able to replicate this result in MDS anemia patients, where it is not uncommon for patients to present with autoimmune and inflammatory conditions.

Clinical Development of Roxadustat in Myelodysplastic Syndromes

We are conducting a Phase 3 placebo controlled, double-blind clinical trial to evaluate the safety and efficacy of roxadustat for treatment of anemia in MDS in the U.S. and Europe. We continue to enroll this 160-patient randomized, double-blind, placebo-controlled Phase 3 clinical study of roxadustat in 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 by 28 weeks with secondary endpoints and safety evaluated at 52 weeks.

In the open-label dose-finding component of this study, 24 lower-risk, transfusion dependent MDS patients with anemia were enrolled in three sequential starting dose cohorts (1.5 mg/kg, 2.0 mg/kg, and 2.5 mg/kg), with roxadustat doses adjusted every eight weeks per a pre-defined algorithm based on hemoglobin response. Best supporting care including red blood cell transfusion was allowed, as needed, per investigator's discretion. Patients treated with roxadustat achieved a greater than or equal to 8-week transfusion independence rate of 38% in the first 28 weeks and 54% of patients had greater than or equal to 50% reduction in red blood cell transfusion over any eight weeks, from baseline. Roxadustat was generally well tolerated in each dose cohort. The dose level of 2.5 mg/kg was selected as the starting dose for the double-blind component of the study.

In China, we continue to enroll the open-label portion of our Phase 2/3 clinical trial to evaluate the safety and efficacy of roxadustat in non-transfusion dependent, lower-risk MDS patients with anemia. After the open-label portion we expect to begin the 135-patient double-blind, placebo-controlled Phase 3 portion of the study, in which subjects will be randomized 2:1 to receive roxadustat or placebo three-times weekly for 26 weeks. The primary endpoint for this study is percentage of patients achieving a hemoglobin response.

Research at FibroGen

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. The HIF-PH enzymes regulate the stability of the HIF transcription factor, which not only has therapeutic relevance for the treatment of anemia as exemplified by roxadustat, but also has implications for other diseases where activation of the HIF pathway would be expected to have beneficial effects. 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 world leader in inhibition of enzymes belonging to this family, and. our internal medicinal chemistry efforts have generated a large library of novel compounds designed to target the 2OG-dependent oxygenase family.

PAMREVLUMAB FOR THE TREATMENT OF FIBROSIS AND CANCER

We were founded to discover and develop therapeutics for fibrosis and began studying CTGF shortly after its discovery. Our accumulated discovery research efforts 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. We believe that pamrevlumab blocks CTGF and inhibits its central role 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 are currently conducting Phase 3 studies in pancreatic cancer and IPF and a Phase 2 trial in DMD. In the U.S., the FDA has granted Orphan Drug Designation to pamrevlumab for the treatment of IPF, locally advanced unresectable pancreatic cancer, and DMD. In addition, the EMA has granted Orphan Medicinal Product Designation to pamrevlumab for the treatment of DMD. Pamrevlumab has also received Fast Track designation from the FDA for the treatment of both IPF and locally advanced unresectable pancreatic cancer.

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 biological agents and pathways have been implicated in the fibrotic process, many of which converge on CTGF, a central mediator of fibrosis. In the case of cancer, the sustained tumor-associated fibrotic tissue promotes 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 believe that targeting CTGF to block or inhibit its activity could 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 have generated data in human and animal studies that lung fibrosis progression can be slowed, arrested, or possibly reversed in some instances upon treatment with pamrevlumab.

Clinical Development of Pamrevlumab — Overview

We have performed clinical trials of pamrevlumab in IPF, pancreatic cancer, liver fibrosis and diabetic kidney disease. In eleven Phase 1 and Phase 2 clinical studies involving pamrevlumab to date, including more than 600 patients who were treated with pamrevlumab (about half of patients 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.

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 unregulated cycles of injury, 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.

The U.S. prevalence and incidence of IPF are estimated to be 44,000 to 135,000 cases, and 21,000 new cases per year, respectively, based on Raghu et al. (Am J Respir Crit Care Med (2006)) and on data from the United Nations Population Division. 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 therapies approved to treat IPF in Europe and the U.S., pirfenidone and nintedanib. The approvals and subsequent launches of pirfenidone and nintedanib have clearly shown the commercial potential in IPF. Hoffmann-La Roche (“Roche”) reported worldwide sales of approximately $1 billion for 2018 and $1.15 billion for 2019 for Esbriet® (pirfenidone). Similarly, Boehringer Ingelheim Pharma GmbH & Co. KG (“Boehringer Ingelheim”) reported total sales of approximately $1 billion for Ofev® (nintedanib) in 2017, and approximately $1.2 billion in 2018.

Phase 3 Clinical Development – Randomized, Double-Blind, Placebo-Controlled Trials of Pamrevlumab in IPF

We continue to enroll ZEPHYRUS, our double-blind, placebo-controlled Phase 3 trial of pamrevlumab in IPF patients. In 2020, we will initiate a second IPF study similar in design to ZEPHYRUS. Each study will target approximately 340 patients. The primary U.S. efficacy endpoint for each study is change from baseline in forced vital capacity (“FVC”). The primary efficacy endpoint in Europe for each study is disease progression (defined by a decline in FVC percent predicted of greater than or equal to 10% or death). Secondary endpoints will include clinical outcomes of disease progression, patient reported outcomes, and quantitative changes in lung fibrosis volume from baseline.

PRAISE – Study 067 – Randomized, Double-Blind, Placebo-Controlled Phase 2 Trial of Pamrevlumab in IPF

In September 2019, positive results from PRAISE, our randomized, double-blind, placebo-controlled Phase 2 clinical trial (Study 067), were published in *The Lancet Respiratory Medicine.* 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 were performed at baseline and on 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 2.85 in the pamrevlumab arm (n=50) as compared to an average decline of 7.17 in the placebo arm (n=51), a statistically significant difference of 4.33 (p=0.0331, using a linear slope analysis in intent-to-treat population).

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). The percentage of pamrevlumab patients who experienced disease progression and discontinued therapy was less than 15% of that in the placebo arm.

In this study, we measured change in quantitative lung fibrosis 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 quantitative lung fibrosis ("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.

As in our previous open label Phase 2 study, a correlation between FVC percent predicted and quantitative lung fibrosis was confirmed at both Week 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 (SGRQ) vs. a reduction in quality of life seen in placebo patients over the 48 weeks of treatment. The SGRQ quality of life measurement has been validated in chronic obstructive pulmonary disease. In the 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.

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.

The double-blind, active-controlled combination sub-studies were designed to assess the safety of combining pamrevlumab with standard of care medication in IPF patients. Study subjects were on stable doses of pirfenidone or nintedanib for at least three months and were randomized 2:1 to receive 30 mg/kg of pamrevlumab or placebo every three weeks for 24 weeks. Thirty-six patients were enrolled in the pirfenidone sub-study and 21 patients were enrolled in the nintedanib sub-study. Pamrevlumab appeared to be well-tolerated when given in combination with either pirfenidone or nintedanib.

Study 049 – Open-Label Phase 2 Trial of Pamrevlumab in IPF

We completed an 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. During the initial one-year treatment period, pamrevlumab was administered at a dose of 15 mg/kg in Cohort 1 (53 patients) and 30 mg/kg in Cohort 2 (36 patients) by IV infusion every three weeks for 45 weeks. After 45 weeks of dosing, subjects whose FVC declined less than predicted were allowed to continue dosing in an extension study until they had disease progression. Nineteen patients from Cohort 1 (35.8%) and 18 patients from Cohort 2 (50.0%) entered the extension study. Efficacy endpoints were pulmonary function assessments, extent of pulmonary fibrosis as measured by quantitative imaging and measures of health-related quality of life. 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. Some of the 37 patients who enrolled in the extension study were treated with pamrevlumab for up to five years. Trends regarding improved or stable pulmonary function and stable fibrosis observed during the initial one-year study were also observed in the extension study.

In Cohort 1, we enrolled patients with a wide range of disease severity to assess safety and efficacy. Baseline FVC percent predicted for Cohort 1 was 43% to 90%, with a mean of 62.8%. In contrast, other IPF clinical trials, such as those for pirfenidone and nintedanib, have enrolled patients who on average had mild to moderate disease (mean FVC percent predicted 73.1% to 85.5%). Fourteen patients in Cohort 1 withdrew, and ten of the 14 had severe disease.

In order to enroll IPF patients similar to those in other IPF trials, we amended the protocol for Cohort 2 to include only patients with mild to moderate disease (FVC ≥ 55% predicted). Baseline FVC percent predicted for Cohort 2 was 53% to 112%, with a mean of 72.7%. Based on this definition of disease severity, 37 patients in Cohort 1 and 32 patients in Cohort 2 had mild to moderate disease.

The table below provides a summary of the observed quantitative change in fibrosis for mild to moderate patients in Cohorts 1 and 2 as measured by quantitative HRCT. Twenty-four percent of these patients had improved fibrosis at Week 48. We believe that this is the first trial to demonstrate a reversal of fibrosis (as measured by HRCT) in a subset of IPF patients. Stable fibrosis has been considered the only achievable favorable outcome in IPF. The table below sets forth the number of patients who showed stable or improved fibrosis at Weeks 24 and 48 compared to the amount of fibrosis at the start of the trial.

Changes in Fibrosis in Patients with Mild to Moderate IPF Treated with Pamrevlumab in FGCL-3019-049

	Stable or Improved Compared to Baseline		Improved Compared to Baseline		Improved Compared to Week 24
	Week 24	Week 48	Week 24	Week 48	Week 48
Cohort 1	21/45 (47%)	14/38 (37%)	12/45 (27%)	12/38 (32%)	8/38 (21%)
Cohort 2	12/29 (41%)	9/28 (32%)	5/29 (17%)	4/28 (14%)	8/26 (31%)
Combined	33/75 (44%)	23/66 (35%)	17/74 (23%)	16/66 (24%)	16/64 (25%)

Eighty-nine patients had at least one adverse event. The most common reported events were cough, fatigue, shortness of breath, upper respiratory tract infection, sore throat, bronchitis, nausea, dizziness, and urinary tract infection. Including the open-label extension, there were 45 serious adverse events in 31 patients, four of which were considered possibly related by the principal investigator to the investigational drug. After investigation, it is our belief that there is no causal relationship between pamrevlumab and the serious adverse events deemed possibly related by the principal investigator. During the first year of treatment there were 38 treatment-emergent serious adverse events in 24 patients. Adverse events observed to date are consistent with typical conditions observed in this patient population.

Pancreatic Cancer

Understanding Pancreatic Cancer and the Limitations of 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 European Commission's European Cancer Information System, there were 100,005 new cases of pancreatic cancer and 95,373 deaths from pancreatic cancer in the Europe projected for 2018. The National Cancer Center of Japan estimated that there were 36,239 new cases of pancreatic cancer in 2014, increased from 24,442 cases in 2004. In its report of December 2017, Decision Resources Group estimated that the major market sales (U.S., Europe and Japan) of pancreatic cancer drugs will grow from $1.3 billion in 2016 to approximately $3.7 billion in 2026. According to the U.S. National Cancer Institute, there were an estimated 57,000 new cases of pancreatic cancer in the U.S. in 2019. Fifty percent of new cases are metastatic. Another 15-20% have localized resectable tumors. The remaining 30-35% have localized but unresectable tumors.

For those with non-resectable tumors, median survival is eight to 12 months post-diagnosis, and about 8% realize five years of survival; similar to metastatic cases. For those with resectable tumors, 50% survive 17 to 27 months post-diagnosis and ~20% report five-year survival.

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 Development – Randomized, Double-Blind, Placebo-Controlled Trial of Pamrevlumab in Locally Advanced, Unresectable Pancreatic Cancer

We continue to enroll LAPIS, our double-blind placebo controlled Phase 3 trial of pamrevlumab as a neoadjuvant therapy for locally advanced unresectable pancreatic cancer. We intend to enroll approximately 260 patients, randomized 1:1 to receive either pamrevlumab, in combination with gemcitabine and nab-paclitaxel, or placebo with gemcitabine and nab-paclitaxel. After completion of the 6-month treatment period, if the results show an improved resection rate in the pamrevlumab arm, we may request a meeting with the FDA to discuss the adequacy of these results to support a marketing application under the provisions of accelerated approval. After this interim assessment of resection rates, the study will continue to collect data on overall survival, the primary endpoint.

Study 069 – Randomized, Open-Label, Active-Controlled Phase 1/2 Trial of Pamrevlumab in Locally Advanced Pancreatic Cancer

We continue to follow patients in our ongoing 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 locally advanced pancreatic cancer 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 is 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 ongoing 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 6 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 who 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). All of the patients on study at the time of the results reported in June 2018 continue to remain on study. No increase in serious adverse events was observed in the pamrevlumab arm and no delay in wound healing was observed post-surgery.

Patients with locally advanced unresectable pancreatic cancer have 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 locally advanced pancreatic cancer patients.

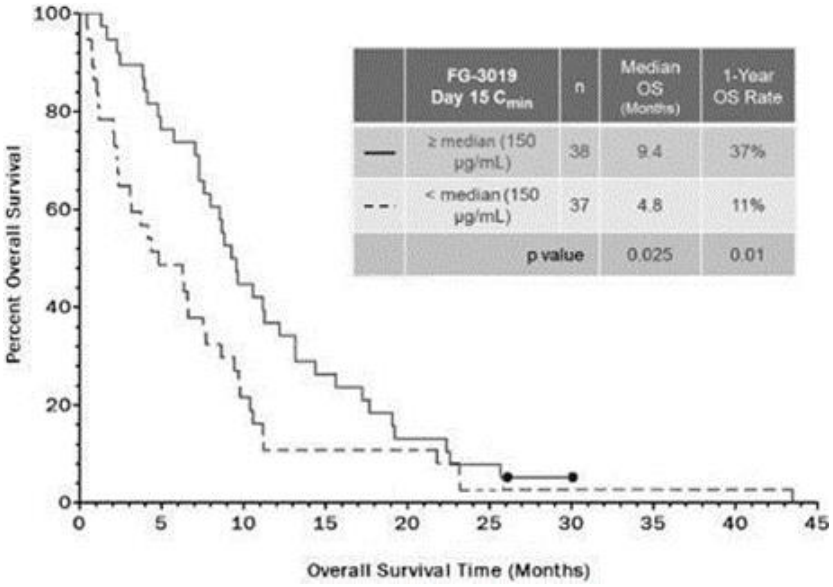
Completed Clinical Trials of Pamrevlumab in Pancreatic Cancer

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 dose-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), as illustrated below. 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.

Increased Pancreatic Cancer Survival Associated with Increased Plasma Levels of Pamrevlumab



The Kaplan-Meier plot provides a representation of survival of all patients in the clinical trial. Each vertical drop in the curve represents a recorded event (death) of one or more patients. When a patient's event cannot be determined either because he or she has withdrawn from the study or because the analysis is completed before the event has occurred, that patient is "censored" and denoted by a symbol (●) on the curve at the time of the last reliable assessment of that patient.

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 is our belief 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.

Pamrevlumab for Duchenne Muscular Dystrophy

Understanding DMD and the Limitations of 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 muscle loss, 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.

Clinical Development of Pamrevlumab for Duchenne Muscular Dystrophy

Based on the FDA review of one year data from our Phase 2 administrative analysis, we intend to begin a Phase 3 study of pamrevlumab in non-ambulatory DMD patients in the second half of 2020.

All 21 non-ambulatory patients from our fully enrolled Phase 2 open-label single-arm trial have completed over one year of treatment with pamrevlumab. 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, we are encouraged by the data obtained so far. Pamrevlumab was well tolerated in this study.

In June 2019 at the Parent Project Muscular Dystrophy meeting, we reported topline results from our one-year administrative analysis comparing our Phase 2 data to recent published natural disease history studies of DMD patients.

In pulmonary function tests, the results from our study indicate a potential reduction in the 1-year decline in FVC percent predicted from baseline for our 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 the 2019 Ricotti study, the DMD patients were treated with steroids only. Similarly, all of the patients in our Phase 2 pamrevlumab trial were on steroids. 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.

Our data showed an increase in cardiac function, measured by mean change of left ventricular ejection fraction (“LVEF”), of 0.29% from baseline for our pamrevlumab-treated patients. Whereas, data published in 2018 by McDonald of DMD patients only on steroids showed a mean LVEF decline of 0.82% from baseline in one year.

In muscle function tests, the majority of the results of this Phase 2 study showed the mean change from baseline in our pamrevlumab-treated patients were more favorable than previously published data. Our results showed a positive 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. In the performance of the upper limb (“PUL”) test specifically developed for DMD patients, our pamrevlumab-treated patients had a mean change from baseline of -1.53. In the 2019 study by Ricotti of DMD patients taking either nothing or only steroids, the annual mean change in the PUL test was -4.13. Furthermore, in our study a strong correlation between change in biceps brachii T2-mapping and change in PUL score was observed, demonstrating stabilization and even possible improvement in the muscle fibrosis burden.

Commercialization Strategy for Pamrevlumab

Our goal, if pamrevlumab is successful, is to be a leader in the development and commercialization of novel approaches for inhibiting fibrosis and treating some forms of cancer and muscular dystrophy diseases. To date, we have retained exclusive worldwide rights for pamrevlumab.

COLLABORATIONS

Collaboration Partnerships for Roxadustat

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 share equally 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 own 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.

The Astellas agreements will continue in effect until terminated. Either party may terminate the agreements for certain material breaches by the other party. In addition, Astellas will have the right to terminate the agreements for certain specified technical product failures, upon generic sales reaching a particular threshold, upon certain regulatory actions, or upon our entering into a settlement admitting the invalidity or unenforceability of our licensed patents. Astellas may also terminate the agreements for convenience upon advance written notice to us. In the event of any termination of the agreements, Astellas will transfer and assign to us the regulatory filings for roxadustat and will assign or license us the relevant trademarks used with the products in the Astellas territories. Under certain terminations, Astellas is also obligated to pay us a termination fee.

Consideration under these agreements includes a total of $360.1 million in upfront and non-contingent payments, and milestone payments totaling $557.5 million, of which $542.5 million are development and regulatory milestones, and $15.0 million are commercial-based milestones. Total consideration, excluding development cost reimbursement and product sales-related payments, could reach $917.6 million.

Additionally, under these agreements, Astellas pays 100% of the commercialization costs in their territories. Astellas will pay us a transfer price for our manufacture and delivery of roxadustat based on net sales of roxadustat in the low 20% range.

AstraZeneca

We also have two agreements with AstraZeneca for the development and commercialization of roxadustat for anemia, one for China (the “China Agreement”), and one for the U.S. and all other countries not previously licensed to Astellas (the “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.

In 2015, we reached the $116.5 million cap on our initial funding obligations (under which we shared 50% of the initial development costs), therefore all future development and commercialization costs for roxadustat for the treatment of anemia in CKD in the U.S., Europe, Japan and all other markets outside of China will be paid by Astellas and AstraZeneca.

In China, our subsidiary FibroGen Beijing will conduct the development work for CKD anemia and will hold all of the regulatory licenses issued by China regulatory authorities and be primarily responsible for regulatory, clinical and manufacturing. China development costs are shared 50/50. AstraZeneca is also responsible for 100% of development expenses in all other licensed territories outside of China. We are responsible, through our contract manufacturers, for the manufacture and supply of all quantities of roxadustat to be used in development and commercialization under the agreements.

Under the AstraZeneca agreements, we receive upfront and subsequent non-contingent payments totaling $402.2 million. Potential milestone payments under the agreements total $1.2 billion, of which $571.0 million are development and regulatory milestones, and $652.5 million are commercial-based milestones. Total consideration under the agreements, excluding development cost reimbursement, transfer price payments, royalties and profit share, could reach $1.6 billion.

Payments under these agreements include over $500 million in upfront, non-contingent and other payments received or expected to be received prior to the first U.S. approval, excluding development expense reimbursement.

Under the U.S./RoW Agreement, AstraZeneca will pay for all commercialization costs in the U.S. and RoW, AstraZeneca will be responsible for the U.S. commercialization of roxadustat, with FibroGen undertaking specified promotional activities in the ESRD segment in the U.S. In addition, we will receive a transfer price for delivery of commercial product based on a percentage of net sales in the low- to mid-single digit range and AstraZeneca will pay us a tiered royalty on net sales of roxadustat in the low 20% range.

Under the China Agreement, which is conducted through FibroGen China Anemia Holdings, Ltd. ("FibroGen China"), the commercial collaboration is structured as a 50/50 profit share. AstraZeneca will conduct sales and marketing activities in China for roxadustat and will fund roxadustat launch costs in China until FibroGen Beijing has achieved profitability. At that time, AstraZeneca will recoup 50% of their historical launch costs out of initial roxadustat profits in China.

AstraZeneca may terminate the U.S./RoW Agreement upon specified events, including our bankruptcy or insolvency, our uncured material breach, technical product failure, or upon 180 days prior written notice at will. If AstraZeneca terminates the U.S/RoW Agreement at will, in addition to any unpaid non-contingent payments, it will be responsible to pay for a substantial portion of the post-termination development costs under the agreed development plan until regulatory approval.

AstraZeneca may terminate the China Agreement upon specified events, including our bankruptcy or insolvency, our uncured material breach, technical product failure, or upon advance prior written notice at will. If AstraZeneca terminates our China Agreement at will, it will be responsible to pay for transition costs as well as make a specified payment to FibroGen China.

In the event of any termination of the agreements, but subject to modification upon termination for technical product failure, AstraZeneca will transfer and assign to us any regulatory filings and approvals for roxadustat in the affected territories that they may hold under our agreements, grant us licenses and conduct certain transition activities.

Additional Information Related to Collaboration Agreements

Additional information related to collaboration agreements is set forth in Item 7 of this Annual Report on Form 10-K. 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 14 to our consolidated financial statements under Item 8 of this Annual Report.

COMPETITION

The pharmaceutical and biotechnology industries are highly competitive, particularly in some of the indications we are 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 on the basis of, 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 following indications:

Roxadustat — Anemia in CKD

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 ("Vifor"), 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 20 years, serving a significant majority of dialysis patients. While non-dialysis CKD 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 patients under nephrology 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.

We may also face competition from potential new anemia therapies currently in clinical development, including in those patient segments not currently 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"), Japan Tobacco, and Zydus Cadila. Akebia is currently conducting Phase 3 studies in CKD patients on dialysis and not on dialysis, as well as a Phase 2 study evaluating pharmacokinetics and pharmacodynamics in dialysis-dependent patients with three-times weekly versus once-a-day dosing. Akebia expects to complete these studies by August 2020. In Japan, Mitsubishi Tanabe Pharmaceutical Corporation, Akebia's collaboration partner, submitted an NDA for treatment of anemia in dialysis and non-dialysis CKD patients in July 2019, and is awaiting an approval decision later in 2020. GSK is also conducting global Phase 3 studies in CKD patients on dialysis and not on dialysis, and expects to complete those studies by March 2022. GSK and Kyowa Hakko Kirin announced in November 2018 that the two companies signed a strategic commercialization deal in Japan for daprodustat. GSK submitted a Japan NDA for treatment of anemia in dialysis and non-dialysis in August 2019 and is awaiting approval later in 2020. Bayer has completed global Phase 2 studies and its HIF-PH inhibitor is now in Phase 3 development in CKD populations on dialysis and not on dialysis in Japan. Japan Tobacco submitted an NDA for treatment of anemia associated with CKD in Japan in November 2019, supported by the six Phase 3 studies conducted in CKD patients on dialysis and not on dialysis in Japan, and its partner JW Pharmaceuticals started a Phase 3 study in dialysis patients in Korea. Zydus Cadila (India) started Phase 3 studies in dialysis and non-dialysis CKD patients in India in 2019.

In addition, there are other companies developing biologic therapies for the treatment of other anemia indications that we may also seek to pursue in the future, including anemia of MDS. For example, Acceleron Pharma, Inc., in partnership with Celgene Corporation, a Bristol-Myers Squibb company ("Celgene"), developed Reblozyl® (luspatercept), a protein therapeutic, which was approved in November 2019 by the FDA for anemia treatment in patients with ß-thalassemia. Its Biologics License Application ("BLA") under review by the FDA, for treatment of adult patients with very low to intermediate MDS associated anemia who have ring sideroblast and require red blood cell transfusions, has a Prescription Drug User Fee Act date of April 4, 2020. Acceleron expects an EMA decision on the MAA in the second half of 2020. In Japan, Celgene started a luspatercept Phase 2 study in May 2019. 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 if and when it is commercialized.

In China, biosimilars of epoetin alfa are offered by Chinese pharmaceutical companies such as EPIAO marketed by 3SBio Inc. as well as more than 15 other local manufacturers. We may also face competition by HIF-PH inhibitors from other companies such as Akebia, Bayer, and GSK, which was authorized by the National Medical Products Administration ("NMPA") to conduct trials in China to support its ex-China regulatory filings. Two domestic companies, Jiangsu Hengrui Medicine Co., Ltd. and Guandong Sunshine Health Investment Co., Ltd, have been permitted by the NMPA to conduct clinical trials for CKD anemia patients both on dialysis and not on dialysis, and 3SBio Inc. has submitted a clinical trial application to the NMPA to initiate trials for their HIF-PH inhibitor. Another domestic company, China Medical System, in-licensed desidustat, a compound which is currently in Phase 3 trials in India, from Zydus Candila for greater China in January 2020. Akebia announced in December 2015 that it had entered into a development and commercialization partnership with Mitsubishi Tanabe Pharmaceutical Corporation for its HIF-PH inhibitor vadadustat in Japan, Taiwan, South Korea, India and certain other countries in Asia, and announced in April 2017 an expansion of their U.S. collaboration with Otsuka to add markets, including China. 3SBio Inc. announced in 2016 its plan to begin a Phase 1 clinical trial of a HIF-PH inhibitor for the China market.

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 ESRD bundle. The patents for Amgen's EPOGEN® (epoetin alfa) expired in 2004 in the 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 the 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 BLA in the U.S.

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 anemia therapies are administered as part of the visit. Two of the largest operators of dialysis clinics in the U.S., DaVita Healthcare Partners Inc. ("DaVita"), and Fresenius Medical Care AG & Co. KGaA ("Fresenius"), collectively provide dialysis care to more than 80% of U.S. dialysis patients, and therefore have historically won long-term contracts including rebate terms with Amgen. DaVita has a six-year sourcing and supply agreement with Amgen effective through 2022. Fresenius' contract with Amgen expired in 2015, following which Fresenius is providing Roche's ESA Mircera® to a significant portion of its U.S. dialysis patients. Successful penetration in this market may require a significant agreement with Fresenius or DaVita, on favorable terms and on a timely basis.

Pamrevlumab

We are currently in Phase 2 development of pamrevlumab to treat DMD and Phase 3 development of pamrevlumab in IPF and pancreatic cancer. 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 co-development 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). We believe that if pamrevlumab can be shown to safely stabilize or reverse lung fibrosis, and thus stabilize or improve lung function in IPF patients, it can compete with pirfenidone and nintedanib for market share in IPF. However, it may be difficult to encourage treatment providers and patients to switch to pamrevlumab from a product they are already familiar with. We may also face competition from potential new IPF therapies in recruitment and enrollment in our clinical trials and potentially in commercialization.

Pamrevlumab is an injectable protein, which may be more expensive and less convenient than small molecules such as nintedanib and pirfenidone. Other potential competitive product candidates in various stages of development for IPF include Galapagos NV's GLPG1690 and GLPG1205, Kadmon Holdings, Inc.'s KD025, Liminal BioSciences' PBI-4050, and Roche/Promedior, Inc.'s PRM-151. In particular, GLPG1690 is in a Phase 3 program consisting of two clinical trials with 750 subjects each, intended to support both the U.S. NDA and MAA in Europe.

Pancreatic Cancer

We are developing pamrevlumab to be used in combination with Abraxane® (nab-paclitaxel) and gemcitabine in pancreatic cancer. Celgene's Abraxane was launched in the U.S. and Europe in 2013 and 2014, respectively, and was the first drug approved in this disease in nearly a decade. In 2015, Merrimack Pharmaceuticals Inc. ("Merrimack") received FDA approval for the use of ONIVYDE (irinotecan liposome injection, now licensed to Ipsen) 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 products seeking approval in conjunction with gemcitabine and Abraxane including FOLFRINOX, a combination chemotherapy regimen of folic acid, 5-fluouracil, oxaliplatin and irinotecan, 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., EU, and Japan.

On September 19, 2016, the FDA approved Sarepta Therapeutics Inc.'s ("Sarepta") Exondys 51™ (eteplirsen). This was the first drug approved to treat DMD. Exondys 51 is approved 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 has reported a full year Exondys 51 revenue of $380 million in 2019. Sarepta's Vyondys 53™ (golodirsen) was also approved by the FDA in December 2019 for patients with a confirmed genetic mutation that is amenable to exon 53 skipping, which accounts for 8% of the DMD population.

PTC Therapeutics' product Translarna ™ 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 complete response letter 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 Catabasis Pharmaceuticals ("Catabasis"), Santhera Pharmaceuticals ("Santhera") and Sarepta. Catabasis' edasalonexent was reported to have preserved muscle function and slowed the progression of DMD compared to rates of change in the control period prior to treatment with edasalonexent in a Phase 2 study, and is currently undergoing Phase 3 development. Santhera's Puldysa® (idebenone) MAA for treatment of DMD was filed with the EMA, and the opinion from the Committee for Medicinal Products for Human Use is expected in the second quarter of 2020. The FDA requested additional clinical data from the idebenone Phase 3 trial currently ongoing in the U.S. and Europe. Santhera offers compassionate use of idebenone in patients with DMD in U.S. and UK. Sarepta's SRP-9001 is an investigational gene therapy for DMD. Sarepta announced in December 2019 the licensing agreement with Roche that grants Roche the commercial rights to SRP-9001 outside the U.S.

MANUFACTURE AND SUPPLY

We have historically and in the future plan to continue to enter into contractual arrangements with qualified third-party manufacturers to manufacture and package our products and product candidates. We believe that 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. Outside of China, we plan to continue to use, Shanghai SynTheAll Pharmaceutical Co., Ltd. ("WuXi STA") and Catalent, Inc. ("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 China. 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 China. Catalent has passed several regulatory inspections, including by the FDA, and manufactures commercial products for other clients.

To date, we believe that roxadustat has been manufactured under cGMP and in compliance with applicable regulatory requirements for the manufacture of drug substance and drug product used in clinical trials and we and Astellas have performed audits of the existing roxadustat manufacturers. The intended commercial manufacturing route outside of China has been successfully scaled up to multiple hundred kilogram scale and produced several metric tons of roxadustat drug substance. We are in discussions with multiple parties regarding longer term commercial supply arrangements.

In China, our Beijing facility received the Good Manufacturing Practice ("GMP") license for API and drug product. We are manufacturing drug product at our FibroGen Beijing manufacturing facility for commercial supply. We are manufacturing API at our Cangzhou manufacturing facility, which has been fully qualified and licensed. We may also qualify a third party manufacturer to produce commercial API under the Marketing Authorization Holder System program.

Irix Pharmaceuticals, Inc.

In July 2002, we and IRIX Pharmaceuticals, Inc. (“IRIX”), a third party manufacturer, entered into a Letter of Agreement for IRIX Pharmaceuticals Single Source Manufacturing Agreement (the “Letter of Agreement”), in connection with a contract manufacturing arrangement for clinical supplies of HIF-PH inhibitors, including roxadustat. The Letter of Agreement contained a service agreement that included terms and schedule for the delivery of clinical materials, and also included a term sheet for a single source agreement for the cGMP manufacture of HIF-PH inhibitors, including roxadustat. Specifically, pursuant to the Letter of Agreement, we and IRIX agreed to negotiate a single source manufacturing agreement that included a first right to negotiate a manufacturing contract for HIF-PH inhibitors, including roxadustat, provided that IRIX is able to match any third party bids within 5%, and the exclusive right to manufacture extends for five years after approval of an NDA. Any agreement would provide that no minimum amounts would be specified until appropriate by forecast, that we and our commercialization partner would have the rights to contract with independent third parties that exceed IRIX’s internal capabilities or in the event that we or our commercialization partner determines for reasons of continuity and security that such a need exists, provided that IRIX would supply a majority of the product if it is able to meet the requirements and the schedule required by us and our partner. Subsequent to the Letter of Agreement, we and IRIX have entered into several additional service agreements. IRIX has requested in writing that we honor the Letter of Agreement with respect to the single source manufacturing agreement. To date, we have offered to IRIX opportunities to bid for the manufacture of HIF-PH inhibitors, including roxadustat. In 2015, Patheon Pharmaceuticals Inc., a business unit of DPx Holdings B.V. (“Patheon”), acquired IRIX, and in 2017 ThermoFisher Scientific Inc. acquired Patheon.

Pamrevlumab

To date, pamrevlumab has been manufactured using specialized biopharmaceutical process techniques under an agreement with a qualified third party contract manufacturer, Boehringer Ingelheim. Our contract manufacturer is the sole source for the current clinical supply of the drug substance and drug product for pamrevlumab. Our contract manufacturer is only obligated to supply the amounts of pamrevlumab as agreed on pursuant to work orders that are executed from time to time under our agreement as we determine need for clinical material, and we are not required to make fixed or minimum annual purchases. Our existing agreement allows us to transfer the cell line manufacturing process to another third party manufacturer at our expense, and our contractor is obligated to provide reasonable technology transfer assistance in the event of such a transfer.

GOVERNMENT REGULATION

The clinical testing, manufacturing, labeling, storage, distribution, record keeping, advertising, promotion, import, export and marketing, among other things, of our product candidates are subject to extensive regulation by governmental authorities in the U.S. 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. 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. Pharmaceutical products are also subject to regulation by other governmental agencies, such as the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services, the Consumer Product Safety Commission and the Environmental Protection Agency. The clinical testing, manufacturing, labeling, storage, distribution, record keeping, advertising, promotion, import, export and marketing, among other things, of our product candidates are subject to extensive regulation by governmental authorities in the U.S. and other countries. The steps required before a drug or biologic may be approved for marketing in the U.S. generally include:

- Preclinical laboratory tests and animal tests conducted under Good Laboratory Practices.
- The submission to the FDA of an IND for human clinical testing, which must become effective before each human clinical trial commence.
- Adequate and well-controlled human clinical trials to establish the safety and efficacy of the product and conducted in accordance with Good Clinical Practices.

- The submission to the FDA of an NDA, in the case of a small molecule drug product, or a BLA, in the case of a biologic product.
- FDA acceptance, review and approval of the NDA or BLA, as applicable.
- Satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made to assess compliance with cGMPs.

The testing and approval process requires substantial time, effort and financial resources, and the receipt and timing of any approval is uncertain. The FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to a potentially unacceptable health risk.

Preclinical studies include laboratory evaluations of the product candidate, as well as animal studies to assess the potential safety and efficacy of the product candidate. Preclinical studies must be conducted in compliance with FDA regulations regarding GLPs. 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 the results of preclinical testing and a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase or phases of the clinical trial lends themselves to an efficacy determination. 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. The IND must become effective before clinical trials may be commenced.

Clinical trials involve the administration of the product candidates to healthy volunteers, or subjects, or patients with the disease to be treated under the supervision of a qualified principal investigator. Clinical trials must be conducted under the supervision of one or more qualified principal investigators in accordance with GCPs and in accordance with protocols detailing the objectives of the applicable phase of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Progress reports detailing the status of clinical trials must be submitted to the FDA annually. Sponsors must also timely report to the FDA serious and unexpected adverse events, any clinically important increase in the rate of a serious suspected adverse event over that listed in the protocol or investigator's brochure, or any findings from other studies or tests that suggest a significant risk in humans exposed to the product candidate. Further, the protocol for each clinical trial must be reviewed and approved by an independent institutional review board ("IRB"), either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, ethical factors, and the safety of human subjects and the possible liability of the institution.

Clinical trials are typically conducted in three sequential phases prior to approval, but the phases may overlap and different trials may be initiated with the same drug candidate within the same phase of development in similar or different patient populations. These phases generally include the following:

Phase 1. Phase 1 clinical trials represent the initial introduction of a product candidate into human subjects, frequently healthy volunteers. In Phase 1, the product candidate is usually tested for pharmacodynamic and pharmacokinetic properties such as safety, including adverse effects, dosage tolerance, absorption, distribution, metabolism and excretion.

Phase 2. Phase 2 clinical trials usually involve studies in a limited patient population to (1) evaluate the efficacy of the product candidate for specific indications, (2) determine dosage tolerance and optimal dosage and (3) identify possible adverse effects and safety risks.

Phase 3. If a product candidate is found to be potentially effective and to have an acceptable safety profile in Phase 2 studies, the clinical trial program will be expanded to Phase 3 clinical trials to further evaluate clinical efficacy, optimal dosage and safety within an expanded patient population at geographically dispersed clinical study sites.

Phase 4. Phase 4 clinical trials are conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations, or when otherwise requested by the FDA in the form of post-market requirements or commitments. Failure to promptly conduct any required Phase 4 clinical trials could result in withdrawal of approval.

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 has been 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. This is typically 12 months from the date of submission. The review process is often extended by FDA requests for additional information or clarification. 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 being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA or BLA, the FDA may inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facility complies with cGMPs and will also inspect clinical trial sites for integrity of data supporting safety and efficacy. During the approval process, the FDA also will determine whether a REMS, is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the application must submit a proposed REMS; the FDA will not approve the application without an approved REMS, if required. A REMS can substantially increase the costs of obtaining approval. The FDA may also convene an advisory committee of external experts to provide input on certain review issues relating to risk, benefit and interpretation of clinical trial data. The FDA may delay approval of an NDA if applicable regulatory criteria are not satisfied and/or the FDA requires additional testing or information. 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 complete response letter detailing the deficiencies and information required in order for reconsideration of the application.

Pediatric Exclusivity and Pediatric Use

Under the Best Pharmaceuticals for Children Act, certain drugs or biologics may obtain an additional six months of exclusivity in an indication, if the sponsor submits information requested in writing by the FDA ("Written Request"), relating to the use of the active moiety of the drug or biologic in children. The FDA may not issue a Written Request for studies on unapproved or approved indications or where it determines that information relating to the use of a drug or biologic in a pediatric population, or part of the pediatric population, may not produce health benefits in that population.

We have not received a Written Request for such pediatric studies with respect to our product candidates, although we may ask the FDA to issue a Written Request for studies in the future. To receive the six-month pediatric market exclusivity, we would have to receive a Written Request from the FDA, conduct the requested studies in accordance with a written agreement with the FDA or, if there is no written agreement, in accordance with commonly accepted scientific principles, and submit reports of the studies. A Written Request may include studies for indications that are not currently in the labeling if the FDA determines that such information will benefit the public health. The FDA will accept the reports upon its determination that the studies were conducted in accordance with and are responsive to the original Written Request, agreement, or commonly accepted scientific principles, as appropriate, and that the reports comply with the FDA's filing requirements.

In addition, the Pediatric Research Equity Act ("PREA") requires a sponsor to conduct pediatric studies for most drugs and biologicals, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs, BLAs and supplements thereto must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must include the evaluation of the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA, on its own initiative or at the request of the sponsor, may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted by FDA if they believe that additional safety or effectiveness data in the adult population needs to be collected before the pediatric studies begin. After April 2013, the FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

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. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

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. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may also result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- Restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls.
- Fines, warning letters or holds on post-approval clinical trials.
- Refusal of the FDA to approve pending NDAs or BLAs or supplements to approved NDAs or BLAs, or suspension or revocation of product license approvals.
- Product seizure or detention, or refusal to permit the import or export of products.
- Injunctions or the imposition of civil or criminal penalties.

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 that is found to have improperly promoted off-label uses may be subject to significant liability.

Prescription Drug Marketing Act

The distribution of pharmaceutical products is subject to the Prescription Drug Marketing Act (“PDMA”), which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors at the state level. Under the PDMA and state law, states require the registration of manufacturers and distributors who provide pharmaceuticals in that state, including in certain states manufacturers and distributors who ship pharmaceuticals into the state even if such manufacturers or distributors have no place of business within the state. The PDMA and state laws impose requirements and limitations upon drug sampling to ensure accountability in the distribution of samples. The PDMA sets forth civil and criminal penalties for violations of these and other provisions.

Federal and State Fraud and Abuse and Data Privacy and Security 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. The term "remuneration" has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other. 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, and our practices may not in all cases meet all of the criteria for a statutory exception or safe harbor protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. 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). Further, civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal false claims laws 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. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses. 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 data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates — independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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 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. Some states require the posting of information relating to clinical studies. In addition, California requires pharmaceutical companies to implement a comprehensive compliance program that includes a limit on expenditures for, or payments to, individual medical or health professionals. 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.

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. Sales of our products will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by third-party payors. These 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. The market for our products and product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

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. Because coverage and reimbursement determinations are made on a payor-by-payor basis, obtaining acceptable coverage and reimbursement from one payor does not guarantee that we will obtain similar acceptable coverage or reimbursement from another payor. 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 Europe 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. For example, the Europe provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of a company placing the medicinal product on the market. 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, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations as we begin to directly commercialize our products. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state level that seek to reduce healthcare costs. If a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). The MMA imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval. However, any negotiated prices for our future products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain from non-governmental payors. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from Medicare Part D may result in a similar reduction in payments from non-governmental payors.

Moreover, on November 27, 2013, the federal Drug Supply Chain Security Act was signed into law, which imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new federal legislation, manufacturers will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Furthermore, political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental change. Initiatives to reduce the federal budget and debt and to reform healthcare coverage are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative healthcare benefits, controls on healthcare spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups, price controls on pharmaceuticals and other fundamental changes to the healthcare delivery system. Any proposed or actual changes could limit or eliminate our spending on development projects and affect our ultimate profitability. In March 2010, PPACA was signed into law. PPACA has the potential to substantially change the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, 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. In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit the prices we are able to charge for our products, or the amounts of reimbursement available for our products. If future legislation were to impose direct governmental price controls and access restrictions, it could have a significant adverse impact on our business. Managed care organizations, as well as Medicaid and other government agencies, continue to seek price discounts. Some states have implemented, and other states are considering, price controls or patient access constraints under the Medicaid program, and some states are considering price-control regimes that would apply to broader segments of their populations that are not Medicaid-eligible. Due to the volatility in the current economic and market dynamics, we are unable to predict the impact of any unforeseen or unknown legislative, regulatory, payor or policy actions, which may include cost containment and healthcare reform measures. Such policy actions could have a material adverse impact on our profitability.

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.

Our roxadustat NDA for treatment of CKD anemia was submitted by FibroGen Beijing as a domestic entity under the Domestic Class 1 designation, which refers to a new drug which has never been marketed in any country.

Our NDA package in China contained information similar to what is necessary for a U.S. NDA, including preclinical data, clinical data, technical data on API and drug product, and related stability data.

The NDA package was found acceptable to the NMPA, and FibroGen Beijing was granted a New Drug License confirming the drug as suitable for marketing in December 2018. In addition, FibroGen Beijing was granted a Manufacturing License which lists the Drug Approval Code as well as the name and address of the Manufacturing License holder.

Shortly before NDA approval, FibroGen Beijing conducted a three-batch validation campaign, one of which was observed onsite by the NMPA. Following the successful completion of the validation campaign and associated inspection, FibroGen Beijing was granted a cGMP certification for the commercial production of roxadustat at our Beijing manufacturing facility. We are using our FibroGen Beijing manufacturing facility for commercial supply of drug product. Our Cangzhou manufacturing facility has been fully qualified and licensed for manufacture of roxadustat API for the China market, and we will continue to use this facility for commercial supply. We may also qualify a third party manufacturer to produce commercial API under the Marketing Authorization Holder System program.

Pricing, Reimbursement, Hospital Listing, and Tendering

Please see the discussion above in the section "*Roxadustat for the Treatment of Anemia in Chronic Kidney Disease in China.*"

Foreign Regulation Outside of China

We have received marketing authorization for roxadustat in Japan for anemia of CKD in dialysis patients, and in China for dialysis and non-dialysis patients. Astellas has submitted a supplemental NDA for non-dialysis patients in Japan and intends on submitting an MAA for Europe in the first half of 2020. Our partners also intend to submit for marketing authorization in other countries and we may file for marketing authorization for pamrevlumab or roxadustat in other indications and in other countries in the future. 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 ("CTA"), much like an IND prior to the commencement of human clinical trials. A CTA must be submitted to each national health authority and an independent ethics committee.

For other countries outside of the Europe, 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. The time required to obtain approval in other countries and jurisdictions might differ from or be longer than that required to obtain FDA approval. 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 FDCA 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 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, locally advanced unresectable pancreatic cancer, 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 drug 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 the Europe has similar but not identical benefits in that jurisdiction.

Products receiving orphan designation in the 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 the 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

The Europe also provides opportunities for additional market exclusivity. For example, in the Europe, upon receiving marketing authorization, an NCE generally receives eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the 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 Provisions for Drug Registration, 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 addition, if an approved drug manufactured in China qualifies as an innovative drug, such as Domestic Class 1, and the NMPA determines that it is appropriate to protect public health with respect to the safety and efficacy of the approved drug, the NMPA may elect to monitor such drug for up to five years. During this post-marketing observation period, the NMPA will not grant approval to another company to produce, change dosage form of or import the drug while the innovative drug is under observation. 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 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 administrative proceedings with respect to our patents and patent applications and may, as a result of our extensive portfolio, be involved in such proceedings in the future. Additionally, in the future, we may claim that a third party infringes our intellectual property or a third party may claim that we infringe its intellectual property. In any of the administrative proceedings or in litigation, we may incur 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 roxadustat composition-of-matter, for pharmaceutical compositions containing roxadustat, and for methods for treating anemia using roxadustat or its analogs. Exclusive of any patent term extension, the granted U.S. patents relating to the composition-of-matter of roxadustat are due to expire in 2024 or 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.

Oppositions were filed against our European Patent No. 2872488 (the "`488 Patent"), which claims a crystalline form of roxadustat. Final resolution of the opposition proceedings will take time, and we cannot be assured of the breadth of the claims that will remain in the '488 Patent or that the patent will not be revoked in its entirety.

We believe that, if roxadustat is approved, a full five-year patent term extension under the Hatch-Waxman act will be available for a granted U.S. patent relating to roxadustat, which extension would expire in 2029 or 2030, depending on the patent extended. *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 manufacturing processes, formulations, and methods for use of roxadustat.

Roxadustat China Patent Portfolio

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

We believe that roxadustat, as a new chemical entity, would be eligible for six years of data exclusivity in China. Furthermore, upon approval as a new drug, roxadustat may receive up to five years of market exclusivity under a NMPA-imposed new drug monitoring period. *Refer to "Government Regulation — Regulatory Exclusivity for Approved Products — Foreign Country Data Exclusivity."*

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.

This portfolio reflects a series of discoveries we made from the initial days of our HIF program through the present time. Our research efforts have resulted in progressive innovation, and the corresponding patents and patent applications reflect the success of our HIF program. Such discoveries include the ability of HIF-PH inhibitors:

- To induce endogenous EPO in CKD patients with anemia.
- To increase efficacy of EPO signaling.
- To enhance EPO responsiveness of the bone marrow, for example, by increasing EPO receptor expression.
- To overcome the suppressive and inhibitory effects of inflammatory cytokines, such as members of the interleukin-1 and IL-6 cytokine families, on EPO production and responsiveness.
- To increase effective metabolism of iron.
- To increase iron absorption and bioavailability, as measured using clinical parameters such as percent TSAT%.
- To overcome iron deficiency through effects on iron regulatory factors such as ferroportin and hepcidin.
- To provide coordinated erythropoiesis resulting in increased CHr and increased mean corpuscular volume.
- To improve kidney function.

The table below sets forth representative granted U.S. patents relating to these and other inventions, including the projected expiration dates of these patents.

PATENT NO.	TITLE	DUE TO EXPIRE
6,855,510	Pharmaceuticals and Methods for Treating Hypoxia and Screening Methods Therefor	July 2022
8,466,172	Stabilization of Hypoxia Inducible Factor (HIF) Alpha	December 2022
8,629,131	Enhanced Erythropoiesis and Iron Metabolism	June 2024
8,604,012	Enhanced Erythropoiesis and Iron Metabolism	June 2024
8,609,646	Enhanced Erythropoiesis and Iron Metabolism	June 2024
8,604,013	Enhanced Erythropoiesis and Iron Metabolism	June 2024
8,614,204	Enhanced Erythropoiesis and Iron Metabolism	June 2026
7,713,986	Compounds and Methods for Treatment of Chemotherapy-Induced Anemia	June 2026
8,318,703	Methods for Improving Kidney Function	February 2027

In addition to the U.S. patents listed above, our HIF anemia-related technologies portfolio includes corresponding foreign patents granted and patent applications pending in various territories worldwide.

Akebia and others have filed oppositions against certain European patents within our HIF anemia-related technologies patent portfolio. In three of these proceedings, for FibroGen European Patent Nos. 1463823, 1633333, and 2322155, the European Patent Office has handed down decisions unfavorable to FibroGen. In the fourth of these proceedings, the European Patent Office issued a decision favorable to FibroGen, maintaining FibroGen European Patent No. 2322153 in amended form. All of these decisions are currently under appeal, and these four patents are valid and enforceable pending resolution of the appeals. The ultimate outcomes of such proceedings remain uncertain, and ultimate resolution of such may take considerable time.

In addition, Akebia has filed oppositions against FibroGen European Patent Nos. 2289531 and 2298301. Akebia and GSK have also initiated invalidation actions in the United Kingdom against the United Kingdom counterparts of each of these European patents, and GSK has filed for a declaration of non-infringement of certain United Kingdom patents (corresponding to FibroGen European Patent Nos. 2322153 and 2322155) with respect to its daprodustat product. Akebia is also pursuing invalidation actions against corresponding patents in Canada and in Japan, and invalidation actions against corresponding patents in the United Kingdom have been initiated by GSK and by Akebia, although FibroGen has reached an agreement with GSK that will lead to dismissal of the UK court actions and the proceedings filed by GSK against the patents in the EPO. Astellas' proceedings brought against GSK on a *quia timet* basis have also been dismissed as a result of the settlement agreement. While we believe the ultimate outcome of all proceedings will be that these FibroGen patents will be upheld in relevant part, we note that narrowing or even revocation of any of these patents would not affect our exclusivity for roxadustat or our freedom-to-operate with respect to use of roxadustat for the treatment of anemia.

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, U.S. patents relating to pamrevlumab composition-of-matter are due to expire in 2024 or 2025. Corresponding foreign patents are due to expire, exclusive of any patent term extension, in 2024.

We believe that, if pamrevlumab is approved, a full five-year patent term extension under the Hatch-Waxman act will be available for a granted patent relating to pamrevlumab, which extension would expire in 2029 or 2030, depending on the patent extended . In addition, we believe that pamrevlumab, if approved under a BLA, should qualify for the 12-year period of exclusivity currently permitted by the BPCIA. Refer to *"Government Regulation — Regulatory Exclusivity for Approved Products."*

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

Dana-Farber Cancer Institute

Effective March 2006, we entered into a license agreement with the Dana-Farber Cancer Institute ("DFCI"), under which we obtained an exclusive license to certain patent applications, patents and biological materials for all uses. The patent rights relate to inhibition of prolyl hydroxylation of the alpha subunit of hypoxia-inducible factor (HIFα), and include granted U.S. and foreign patents due to expire in 2022, exclusive of possible patent term extension. The licensed patents relate to use of HIF-PH inhibitors such as roxadustat.

Under the DFCI agreement, we are obligated to pay DFCI for past and ongoing patent prosecution expenses for the licensed patents. We are also obligated to pay DFCI annual maintenance fees, development milestone payments of up to $425,000, sales milestone payments of up to $3 million, and a sub-single-digit royalty on net sales by us or our affiliates or sublicensees of products that are covered by the licensed patents or incorporate the licensed biological materials. In addition, each sublicense we grant is subject to a one-time fixed amount payment to DFCI.

Unless earlier terminated, the agreement will continue in effect, on a country-by-country basis, until the expiration of all licensed patents in a country or, if there is no patent covering a licensed product incorporating the licensed biological materials, until 20 years after the effective date of the agreement. DFCI may terminate the agreement for our uncured material breach, if we cease to carry on our business and development activities with respect to all licensed products, if we fail to comply with our insurance obligations, or if we are convicted of a felony related to the manufacture, use, sale or importation of licensed products. We may terminate the agreement at any time on prior written notice to DFCI.

University of Miami

In May 1997, we entered into a license agreement with the University of Miami (the "University"), amended in July 1999, under which we obtained an exclusive, worldwide license to certain patent applications and patents for all uses. The current patent rights consist of a U.S. patent that relates to antibodies that specifically bind to biologically active fragments of CTGF, and is due to expire in 2022, exclusive of any patent term extension or adjustment that may be available. The licensed patent relates to pamrevlumab and related products.

Under the University agreement, we are obligated to pay for all ongoing patent expenses for the licensed patent. We were also obligated to pay an upfront licensing fee of $21,500, all of which has been paid, and development milestone payments of up to $450,000, of which $150,000 has been paid, as well as an additional milestone payment, in the low hundreds of thousands of dollars, for each new indication for which we obtain approval for a licensed product, and a single digit royalty, subject to certain reductions, on net sales of licensed products by us or our affiliates or sublicensees.

Unless earlier terminated, the agreement will continue in effect, on a country-by-country basis, until the expiration of all licensed patents in a country. The University may terminate the agreement for our uncured material breach or bankruptcy. We may terminate the agreement for the University's uncured material breach or at any time on prior written notice to the University.

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.

Third Party Filings

Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in granted patents that use of our product candidates or proprietary technologies may infringe.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including but not limited to, litigation expenses, substantial damages, attorney fees, injunction, royalty payments, cross-licensing of our patents, redesign of our products, or processes and related fees and costs.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our products, product candidates, and/or proprietary technologies infringe their intellectual property rights. If one of these patents were to be found to cover our products, product candidates, proprietary technologies, or their uses, we could be required to pay damages and could be restricted from commercializing our products, product candidates or using our proprietary technologies unless we obtain a license to the patent. A license may not be available to us on acceptable terms, if at all. In addition, during litigation, the patent holder might obtain a preliminary injunction or other equitable right, which could prohibit us from making, using or selling our products, technologies, or methods.

EMPLOYEES

As of January 31, 2020, we had 531 full-time employees, 136 of whom held Ph.D. or M.D. degrees, 279 of whom were engaged in research and development and 252 of whom were engaged in manufacturing, sales and marketing, business development, finance, information systems, facilities, human resources or administrative support. 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 consider our employee relations to be good.

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 35,000 square feet subleased. The lease for our San Francisco headquarters expires in 2023. We also lease approximately 67,000 square feet of office and manufacturing space in Beijing, China. Our lease in China expires in 2021. 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.

LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

FINANCIAL INFORMATION

Information regarding our revenues, net loss and total assets is contained in our consolidated financial statements under Item 8 of this Annual Report, which information is incorporated by reference here. For the specifics of our segment and geographic revenue, refer to Note 14 to our consolidated financial statements.

Research and development expenses for fiscal years ended December 31, 2019, 2018 and 2017 were $209.3 million, $235.8 million, and $196.5 million, respectively. We expect our research and development expenses to continue to increase in the future as we advance our product candidates through clinical trials and expand our product candidate portfolio.

Our revenue to date has been generated primarily from our collaboration agreements with Astellas and AstraZeneca for the development and commercialization of roxadustat. For fiscal years ended December 31, 2019, 2018 and 2017, substantially all of our revenue was related to our collaboration agreements.

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. Our website and information included in or linked to our website are not part of 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 (the “Exchange Act”), 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 (“SEC”). Additionally the SEC 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

We were incorporated in 1993 in Delaware. 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. 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 subsidiaries consist of the following: 1) FibroGen Europe Oy ("FibroGen Europe"), 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; and 6) FibroGen (China) Medical Technology Development Co., Ltd., a majority owned entity incorporated in China in 2011.

"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, 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 Our Financial Condition and History of Operating Losses

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 financings in order to fund our operations.

We are a biopharmaceutical company with two lead product candidates in clinical development, roxadustat in anemia in chronic kidney disease ("CKD"), myelodysplastic syndromes ("MDS"), and chemotherapy-induced anemia, and pamrevlumab in idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer, and Duchenne muscular dystrophy ("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 year ended December 31, 2019, 2018 and 2017 were $77.0 million, $86.4 million and $120.9 million, respectively. As of December 31, 2019, we had an accumulated deficit of $784.7 million. As of December 31, 2019, we had capital resources consisting of cash, cash equivalents and short-term investments of $533.8 million plus $61.1 million of long-term investments classified as available for sale securities. Despite contractual development and cost coverage commitments from our collaboration partners, AstraZeneca AB ("AstraZeneca") and Astellas Pharma Inc. ("Astellas"), and the potential to receive milestone and other payments from these partners, and despite commercialization efforts in the People's Republic of China ("China") and Japan 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 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 late-stage clinical development of roxadustat, grow our operations in China, expand our clinical development efforts on pamrevlumab, continue to seek regulatory approval, launch commercialization 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 ourselves and our partners. 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 the net proceeds from our 2017 public offerings, our existing cash and cash equivalents, short-term and long-term investments and accounts receivable, and expected third-party collaboration revenues will allow us to fund our operating plans through at least the next 12 months. 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 financings or other sources, such as royalty monetization or other structured financings. Such financings 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.

Additional funds may not be available when we require them, or on terms that are acceptable to us. 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.

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 commercialization of roxadustat for the treatment of anemia caused by CKD, or we may require additional partnering in order to help fund such development and commercialization. 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.

Risks Related to the Development and Commercialization of Our Product Candidates

We are substantially dependent on the success of our lead product, roxadustat, and our second compound in development, pamrevlumab.

To date, we have invested a substantial portion of our efforts and financial resources in the research and development of roxadustat and pamrevlumab. While we have received approval of our New Drug Applications ("NDA") for roxadustat in China for CKD anemia for patients on dialysis and not on dialysis, and for roxadustat in Japan for CKD anemia in dialysis patients, we will need to make substantial additional investments in both the development and commercialization of roxadustat worldwide and in various indications. Our near-term prospects, including maintaining our existing collaborations with Astellas and AstraZeneca, will depend heavily on successful development and commercialization of roxadustat, including obtaining regulatory approvals for the commercialization of roxadustat for anemia associated with CKD.

Our other lead product candidate, pamrevlumab, is currently in clinical development for IPF, pancreatic cancer and DMD. Pamrevlumab requires substantial further development and investment and we do not have a collaboration partner for support of this compound. In addition, pamrevlumab is a monoclonal antibody, which may require greater financial resources than for our small molecule, roxadustat.

The clinical and commercial success of roxadustat and pamrevlumab will depend on a number of factors, many of which are beyond our control, and we may be unable to complete the development or commercialization of roxadustat or pamrevlumab.

The clinical and commercial success of roxadustat and pamrevlumab will depend on a number of factors, including the following:

- the timely initiation and completion of our clinical trials;
- our ability to demonstrate the safety and efficacy of our product candidates to the satisfaction of the relevant regulatory authorities;
- the ultimate approval criteria (which may include non-inferiority margins and statistical analyses methods), indications, patient populations, and ultimate benefit-risk analysis used by regulatory authorities in their approval processes;
- whether we are required by the United States ("U.S.") Food and Drug Administration ("FDA") or other regulatory authorities to conduct additional clinical trials, and the scope and nature of such clinical trials, prior to approval to market our products;
- the clinical indications for which the product is approved and the labeling required by regulatory authorities for use with the product, including any warnings that may be required in the labeling;
- the receipt or timely receipt of marketing approvals from the FDA and foreign regulatory authorities, including pricing and reimbursement determinations;
- the ability to successfully commercialize, market, sell and distribute our product candidates, if approved, for marketing and sale by the FDA or foreign regulatory authorities, whether alone or in collaboration with others;
- whether we or our partners are able to recruit and retain adequate numbers of effective sales and marketing personnel for the sale of our products;
- whether we will maintain sufficient funding to cover the costs and expenses associated with creating and sustaining a capable sales and marketing organization and related commercial infrastructure;
- whether we can compete successfully as a new entrant in the treatment of anemia caused by CKD;
- our ability and the ability of our third-party manufacturing partners to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability;

- our success in educating health care providers, patients and the healthcare community about the benefits, risks, administration and use of our product candidates, if approved;
- acceptance of our product candidates, if approved, as safe and effective by patients and the healthcare community;
- the success of efforts to enter into relationships with large dialysis organizations involving the administration of roxadustat to dialysis patients;
- the achievement and maintenance of compliance with all regulatory requirements applicable to us and our product candidates;
- the maintenance of an acceptable safety profile of our products following any approval;
- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competitive treatments;
- the restrictions on the use of our products together with other medications, if any;
- our ability to negotiate, obtain and sustain an adequate level of pricing or reimbursement for our products by third-party payors;
- the availability of adequate coverage and reimbursement or pricing by third-party payors and government authorities;
- our ability to enforce successfully our intellectual property rights for our product candidates and against the products of potential competitors;
- our ability to avoid or succeed in third-party patent interference or patent infringement claims; and
- sufficient stability data for launch and market supply.

Many of these factors are beyond our control. Successful commercialization of our products will require significant resources and time, and there is a risk that we may not successfully commercialize them. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our products and generate revenues, which would deprive us from additional working capital and would materially harm our ability to achieve profitability through the sale of or royalties from our product candidates.

As a company, we have limited commercialization experience, and the time and resources to develop such experience are significant. If we fail to achieve and sustain commercial success for roxadustat, either directly or with our collaboration partners, our business would be harmed.

We do not have a sales or marketing infrastructure and have no experience in the sales, marketing or distribution of pharmaceutical products in any country. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish sales and marketing capabilities or make and maintain our existing arrangements with third parties to perform these services at a level sufficient to support our commercialization efforts.

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 sales and marketing 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 sales and marketing organization.

With respect to roxadustat, we are dependent on the commercialization capabilities of our collaboration partners, AstraZeneca and 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 or little 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 our products, if any, effectively. If they are not successful in commercializing our product candidates, our business and financial condition would suffer.

Commercializing roxadustat requires us to establish commercialization systems, including but not limited to, medical affairs, sales, pharmacovigilance, supply-chain, and distribution capabilities to perform our portion of the collaborative efforts. These efforts require resources and time. If we, along with Astellas and AstraZeneca, are not successful in setting our marketing, pricing and reimbursement strategy, facilitating adoption by hospitals, recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing roxadustat, which would adversely affect our business and financial condition.

Although regulatory approval has been obtained for roxadustat in China and Japan, we may be unable to obtain regulatory approval for our product candidates in other countries, or such approval may be delayed or limited, due to a number of factors, many of which are beyond our control.

The clinical trials and the manufacturing of our product candidates are and will continue to be, and the marketing of our product candidates will 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 regulatory review and approval process is expensive and requires substantial resources and time, and in general very few product candidates that enter development 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 roxadustat or pamrevlumab or any of our other product candidates in one or more indications and jurisdictions.

Moreover, for any Phase 3 clinical trial to support an NDA 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 enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs, trial sites, principal investigators or other third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable. Accordingly, the FDA or other regulatory authorities may require us to exclude the use of patient data from these unreliable clinical trials, or perform additional clinical trials before approving our marketing applications. The FDA or other regulatory authorities may even reject our application for approval or refuse to accept our future applications.

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 that roxadustat is safe and effective in treating anemia in CKD or that pamrevlumab is safe and effective in treating IPF, pancreatic cancer or DMD;
- our failure to demonstrate that a 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 roxadustat or pamrevlumab, or that ongoing clinical trials need to be modified in design, size, conduct or implementation;
- our product candidates may exhibit an unacceptable safety signal as they advance through clinical trials, in particular controlled Phase 3 trials;

- the clinical research organizations ("CROs") that conduct clinical trials on our behalf may take actions outside of our control that materially adversely impact our clinical trials;
- 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 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. In addition, if our product candidates produce undesirable side effects or safety issues, the FDA may require the establishment of REMS (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.

Preclinical, Phase 1 and Phase 2 clinical trial results may not be indicative of the results that may be obtained in larger, controlled Phase 3 clinical trials required for approval.

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 or terminated for a variety of reasons, including delay or failure to:

- address any physician or patient safety concerns that arise during the course of the trial;
- obtain required regulatory or institutional review board approval or guidance;
- reach timely agreement on acceptable terms with prospective CROs and clinical trial sites;
- recruit, enroll and retain patients through the completion of the trial;
- maintain clinical sites in compliance with clinical trial protocols;
- initiate or add a sufficient number of clinical trial sites; and
- manufacture sufficient quantities of product candidate for use in clinical trials.

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

- severity of the disease under investigation;
- availability of alternative treatments;
- size and nature of the patient population;
- eligibility criteria for and design of the study in question;
- perceived risks and benefits of the product candidate under study;
- ongoing clinical trials of competitive agents;

- physicians' and patients' perceptions of the potential advantages of our product candidates being studied in relation to available therapies or other products under development;
- our CRO's and our trial sites' efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients and collect patient data adequately during and after treatment.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate on-going or planned clinical trials.

In addition, we could encounter delays if a clinical trial is 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. A suspension or termination of clinical trials may result from any number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, changes in laws or regulations, or a principal investigator's determination that a serious adverse event could be related to our product candidates. 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 and 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 Phase 3 clinical trial development plan becoming longer and more extensive;
- 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. Refer to "*Business — Roxadustat for the Treatment of Anemia in Chronic Kidney Disease*" and "*Business — Pamrevlumab for the Treatment of Fibrosis and Cancer*" for a discussion of the adverse events and serious adverse events that have emerged in clinical trials of roxadustat and pamrevlumab.

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. 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 our most advanced product candidate 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 we or third-party manufacturers and other service providers on which we rely cannot manufacture sufficient quantities of our product candidates, or at sufficient quality, or perform other services we require, we may experience delays in development, regulatory approval, launch or successful commercialization.

Completion of our clinical trials and commercialization of our product candidates 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 the manufacture of some of our drug candidates, active pharmaceutical ingredients, intermediates or raw materials, 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.

We have 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 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.

We have a limited amount of roxadustat and pamrevlumab in storage, limited capacity reserved at our third-party manufacturers, and there are long lead times required to manufacture and scale-up the manufacture of additional supply, as required for both late-stage clinical trials, post-approval trials, and commercial supply. 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. 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 clinical trials must be conducted with product produced under applicable cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. 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;
- 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;
- quality control and quality assurance;
- 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; and
- natural disasters, such as floods, storms, earthquakes, tsunamis, and droughts, or accidents such as fire, that affect facilities, possibly limit or postpone production, and increase costs.

The FDA and European Medicines Agency will do their own benefit risk analysis and may reach a different conclusion than we or our partners have internally, 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 subpopulations, or using certain statistical methods of analysis, the FDA and European Medicines Agency 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, and regulatory authorities may change their approvability criteria based on their internal analyses and discussions with expert advisors. Regulatory authorities may approve roxadustat 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 will present to regulatory authorities certain pre-specified and not pre-specified sub-populations and sub-group analyses (for example, incident dialysis), multiple secondary endpoints, and multiple 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, such as incident dialysis, estimated glomerular filtration rate, hepcidin, or quality of life measures, regulatory authorities may not include such claims on any approved labeling for roxadustat, which may limit the commercialization or market opportunity for roxadustat. The failure to obtain regulatory approval, or any label, population or other approval limitations in any jurisdiction, may significantly limit 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 “Black Box” warnings on their labels. The safety concerns relating to ESAs may result in labeling for roxadustat containing similar warnings even if our Phase 3 clinical trials do not suggest that roxadustat has similar safety issues. Even if the label for roxadustat does not contain all of the warnings contained in the “Black Box” warning for ESAs, the 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 lack of clarity regarding the safety issues associated with ESAs, even if our Phase 3 clinical trials do not themselves raise safety concerns.

We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.

The development and commercialization of new pharmaceutical products is highly competitive. Our future success depends on our ability 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, market-leading products of companies that have large, established commercial organizations.

If roxadustat is approved and launched commercially, competing drugs 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 Hoffmann-La Roche (“Roche”) outside of 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 20 years, serving a significant majority of dialysis-dependent CKD patients. While non-dialysis-dependent CKD 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 patients under nephrology 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.

We may also face competition from potential new anemia therapies currently in clinical development, including in those patient segments not currently 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"), Japan Tobacco, and Zydus Cadila. Akebia is currently conducting Phase 3 studies in CKD patients on dialysis and not on dialysis, as well as a Phase 2 study evaluating pharmacokinetics and pharmacodynamics in dialysis-dependent patients with three-times weekly versus once-a-day dosing. Akebia expects to complete these studies by August 2020. In Japan, Mitsubishi Tanabe Pharmaceutical Corporation, Akebia's collaboration partner, submitted an NDA for treatment of anemia in dialysis and non-dialysis CKD patients in July 2019, and is awaiting an approval decision later in 2020. GSK is also conducting global Phase 3 studies in CKD patients on dialysis and not on dialysis, and expects to complete those studies by March 2022. GSK and Kyowa Hakko Kirin announced in November 2018 that the two companies signed a strategic commercialization deal in Japan for daprodustat. GSK submitted a Japan NDA for treatment of anemia in dialysis and non-dialysis in August 2019 and is awaiting approval later in 2020. Bayer has completed global Phase 2 studies and its HIF-PH inhibitor is now in Phase 3 development in CKD populations on dialysis and not on dialysis in Japan. Japan Tobacco submitted an NDA for treatment of anemia associated with CKD in Japan in November 2019, supported by the six Phase 3 studies conducted in CKD patients on dialysis and not on dialysis in Japan, and its partner JW Pharmaceuticals started a Phase 3 study in dialysis patients in Korea. Zydus Cadila (India) started Phase 3 studies in dialysis and non-dialysis CKD patients in India in 2019.

In addition, there are other companies developing biologic therapies for the treatment of other anemia indications that we may also seek to pursue in the future, including anemia of MDS. For example, Acceleron Pharma, Inc., in partnership with Celgene Corporation, a Bristol-Myers Squibb company ("Celgene"), developed Reblozyl® (luspatercept), a protein therapeutic, which was approved in November 2019 by the FDA for anemia treatment in patients with ß-thalassemia. Its Biologics License Application ("BLA") under review by the FDA, for treatment of adult patients with very low to intermediate MDS associated anemia who have ring sideroblast and require red blood cell transfusions, has a Prescription Drug User Fee Act date of April 4, 2020. Acceleron expects an EMA decision on the MAA in the second half of 2020. In Japan, Celgene started a luspatercept Phase 2 study in May 2019. 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 if and when it is commercialized.

In China, biosimilars of epoetin alfa are offered by Chinese pharmaceutical companies such as EPIAO marketed by 3SBio Inc. as well as more than 15 other local manufacturers. We may also face competition by HIF-PH inhibitors from other companies such as Akebia, Bayer, and GSK, which was authorized by the National Medical Products Administration ("NMPA") to conduct trials in China to support its ex-China regulatory filings. Two domestic companies, Jiangsu Hengrui Medicine Co., Ltd. and Guandong Sunshine Health Investment Co., Ltd, have been permitted by the NMPA to conduct clinical trials for CKD anemia patients both on dialysis and not on dialysis, and 3SBio Inc. has submitted a clinical trial application to the NMPA to initiate trials for their HIF-PH inhibitor. Another domestic company, China Medical System, in-licensed desidustat, a compound which is currently in Phase 3 trials in India, from Zydus Candila for greater China in January 2020. Akebia announced in December 2015 that it had entered into a development and commercialization partnership with Mitsubishi Tanabe Pharmaceutical Corporation for its HIF-PH inhibitor vadadustat in Japan, Taiwan, South Korea, India and certain other countries in Asia, and announced in April 2017 an expansion of their U.S. collaboration with Otsuka to add markets, including China. 3SBio Inc. announced in 2016 its plan to begin a Phase 1 clinical trial of a HIF-PH inhibitor for the China market.

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 ESRD bundle. The patents for Amgen's EPOGEN® (epoetin alfa) expired in 2004 in the 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 the 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 BLA in the U.S.

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 anemia therapies are administered as part of the visit. Two of the largest operators of dialysis clinics in the U.S., DaVita Healthcare Partners Inc. ("DaVita"), and Fresenius Medical Care AG & Co. KGaA ("Fresenius"), collectively provide dialysis care to more than 80% of U.S. dialysis patients, and therefore have historically won long-term contracts including rebate terms with Amgen. DaVita has a six-year sourcing and supply agreement with Amgen effective through 2022. Fresenius' contract with Amgen expired in 2015, following which Fresenius is providing Roche's ESA Mircera® to a significant portion of its U.S. dialysis patients. Successful penetration in this market may require a significant agreement with Fresenius or DaVita, on favorable terms and on a timely basis.

If approved and launched commercially to treat IPF, pamrevlumab is expected to compete with Roche's Esbriet® (pirfenidone), and Boehringer Ingelheim's Ofev® (nintedanib). We believe that if pamrevlumab can be shown to safely stabilize or reverse lung fibrosis, and thus stabilize or improve lung function in IPF patients, it can compete with pirfenidone and nintedanib for market share in IPF. However, it may be difficult to encourage treatment providers and patients to switch to pamrevlumab from a product they are already familiar with. We may also face competition from potential new IPF therapies in recruitment and enrollment in our clinical trials and potentially in commercialization.

Pamrevlumab is an injectable protein, which may be more expensive and less convenient than small molecules such as nintedanib and pirfenidone. Other potential competitive product candidates in various stages of development for IPF include Galapagos NV's GLPG1690 and GLPG1205, Kadmon Holdings, Inc.'s KD025, Liminal BioSciences' PBI-4050, and Roche/Promedior, Inc.'s PRM-151. In particular, GLPG1690 is in a Phase 3 program consisting of two clinical trials with 750 subjects each, intended to support both the U.S. NDA and MAA in Europe.

If pamrevlumab is approved and launched commercially to treat locally advanced pancreatic cancer patients who are not candidates for surgical resection, pamrevlumab may face competition from other products seeking approval in combination with gemcitibine and nab-paclitaxel, including FOLFRINOX, a combination chemotherapy regimen of folic acid, 5-fluouracil, oxaliplatin and irinotecan, and from companies such as Rafael Pharma's defactinib/CPI-613 and Merrimack's istiratumab. Gemcitabine and/or nab-paclitaxel are the current standard of care in the first-line treatment of metastatic pancreatic cancer. Celgene Corporation's Abraxane® (nab-paclitaxel) was launched in the U.S. and Europe in 2013 and 2014, and was the first drug approved in this disease in nearly a decade.

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., EU, and Japan. On September 19, 2016, the FDA approved Sarepta Therapeutics Inc.'s ("Sarepta") Exondys 51™ (eteplirsen). This was the first drug approved to treat DMD. Exondys 51 is approved 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 has reported a full year Exondys 51 revenue of $380 million in 2019. Sarepta's Vyondys 53™ (golodirsen) was also approved by the FDA in December 2019 for patients with a confirmed genetic mutation that is amenable to exon 53 skipping, which accounts for 8% of the DMD population.

PTC Therapeutics' product Translarna ™ 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 complete response letter 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 Catabasis Pharmaceuticals ("Catabasis"), Santhera Pharmaceuticals ("Santhera") and Sarepta. Catabasis' edasalonexent was reported to have preserved muscle function and slowed the progression of DMD compared to rates of change in the control period prior to treatment with edasalonexent in a Phase 2 study, and is currently undergoing Phase 3 development. Santhera's Puldysa® (idebenone) MAA for treatment of DMD was filed with the EMA, and the opinion from the Committee for Medicinal Products for Human Use is expected in the second quarter of 2020. The FDA requested additional clinical data from the idebenone Phase 3 trial currently ongoing in the U.S. and Europe. Santhera offers compassionate use of idebenone in patients with DMD in U.S. and UK. Sarepta's SRP-9001 is an investigational gene therapy for DMD. Sarepta announced in December 2019 the licensing agreement with Roche that grants Roche the commercial rights to SRP-9001 outside the U.S.

The success of any or all of these potential competitive products may negatively impact the development and potential for success of pamrevlumab. In addition, any competitive products that are on the market or in development may compete with pamrevlumab for patient recruitment and enrollment for clinical trials or may force us to change our clinical trial design, including, in order to compare pamrevlumab against another drug, which may be the new standard of care.

Moreover, many of our competitors have significantly greater resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients, manufacturing pharmaceutical products, and commercialization. In the potential anemia market for roxadustat, for example, large and established companies such as Amgen and Roche, among others, compete aggressively to maintain their market shares. In particular, the currently marketed ESA products are supported by large pharmaceutical companies that have greater experience and expertise in commercialization in the anemia market, including in securing reimbursement, government contracts and relationships with key opinion leaders; conducting testing and clinical trials; obtaining and maintaining regulatory approvals and distribution relationships to market products; and marketing approved products. These companies also have significantly greater scale, research and marketing capabilities than we do and may also have products that have been approved or are in later stages of development and have collaboration agreements in our target markets with leading dialysis companies and research institutions. These competitors have in the past successfully prevented new and competing products from entering the anemia market, and we expect that their resources will represent challenges for us and our collaboration partners, AstraZeneca and Astellas. If we and our collaboration partners are not able to compete effectively against existing and potential competitors, our business and financial condition may be materially and adversely affected.

No or limited reimbursement or insurance coverage of our approved products, if any, 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 its 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 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, third-party payors may not establish adequate reimbursement amounts, which may reduce the demand for, or the price of, our products. For example, the initial roxadustat reimbursement prices set by the Ministry of Health, Labour and Welfare in Japan in November 2019 did not reflect innovation premium over the current ESA therapy, despite roxadustat's advantages observed in our clinical programs. We believe the Japanese authority's decision was primarily based on the comparability of roxadustat shown in the Japan Phase 3 studies which supported the Japan NDA, that was not designed to evaluate the outcome and additional efficacy and safety data observed in the large global Phase 3 programs that included over 8,000 patients. We have no control over whether the agency will revisit the pricing once they review the comprehensive data from the global Phase 3 program including the MACE/MACE+ outcomes. If reimbursement is not available or is available only to limited levels or only in subsets of the dialysis and non-dialysis populations, we may not be able to successfully commercialize certain of our products, or in particular jurisdictions.

Price controls may limit the price at which products such as roxadustat, if approved, are sold. For example, 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, we or our partner 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, we or our partner 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 with our collaboration partners Astellas or AstraZeneca were terminated, if Astellas or AstraZeneca were to prioritize other initiatives over their collaborations with us, whether as a result of a change of control or otherwise, if conflicts arise between us and Astellas or AstraZeneca, or if Astellas or AstraZeneca becomes our competitor in the future, 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 our collaboration partners 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. 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. In addition, each of those agreements provides our respective partners the right to terminate any of those agreements upon written notice for convenience. 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 addition, some of our collaborations are exclusive and preclude us from entering into additional collaboration agreements with other parties in the area or field of exclusivity.

If we fail to 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 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 is approved, we will remain substantially dependent on the commercialization strategy and efforts of our collaboration partners, and neither of our collaboration partners has experience in commercialization of a novel drug such as roxadustat in the dialysis market.

With respect to our collaboration agreements for roxadustat, there are additional complexities in that we and our collaboration partners, Astellas and AstraZeneca, must reach consensus on our regulatory activities, including for the NDA in the U.S. and the Marketing Authorization Application in Europe. 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 may negatively impact the timing or success of our regulatory approval applications.

We intend to 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. 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.

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.

We rely on third parties for the conduct of most of our preclinical and clinical trials for our product candidates, and if our third-party contractors do not properly and successfully perform their obligations under our agreements with them, 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, including those for roxadustat. 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, including our Phase 3 development program for roxadustat. 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.

Moreover, while our reliance on these third parties for certain development and management activities will reduce our control over these activities, it will not relieve us of our responsibilities. For example, the FDA and foreign regulatory authorities require compliance with regulations and standards, including GCP requirements for designing, conducting, monitoring, recording, analyzing and reporting the results of clinical trials to ensure that the data and results from trials are credible and accurate and 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 enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites.

If any of our CROs, trial sites, principal investigators or other third parties fail to comply with applicable GCP requirements, other regulations, trial protocol or other requirements under their agreements with us, the quality or accuracy of the data they obtain may be compromised or unreliable, and the trials of our product candidates may not meet regulatory requirements. If trials do not meet regulatory requirements or if these third parties need to be replaced, the development of our product candidates may be delayed, suspended or terminated, regulatory authorities may require us to exclude the use of patient data from our approval applications or perform additional clinical trials before approving our marketing applications. Regulatory authorities may even reject our application for approval or refuse to accept our future applications for an extended time period. We cannot assure that upon inspection by a regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements or that our results may be used in support of our regulatory submissions. If any of these events occur, we may not be able to obtain 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 not perform satisfactorily.

We do not have operating manufacturing facilities at this time other than our roxadustat manufacturing facility in China, and our current commercial manufacturing facility plans 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 also rely entirely on third parties for 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;
- 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 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.

The facilities used by our contract manufacturers to manufacture our product candidates must pass inspections by the FDA and other regulatory authorities. Although, except for China, we do not control the manufacturing operations of, and expect to remain completely dependent on, our contract manufacturers for manufacture of drug substance and finished drug product, we are ultimately responsible for ensuring that our product candidates are manufactured in compliance with cGMP requirements. If our contract manufacturers cannot successfully manufacture material that conforms to our or our collaboration partners' specifications, or the regulatory requirements of the FDA or other regulatory authorities, we may not be able to secure and/or maintain regulatory approval for our product candidates and our development or commercialization plans may be delayed. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. In addition, although our longer-term agreements are expected to provide for requirements to meet our quantity and quality requirements to manufacture our products candidates for clinical studies and commercial sale, we will have minimal direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel and we expect to rely on our audit rights to ensure that those qualifications are maintained to meet our requirements. If our contract manufacturers' facilities do not pass inspection by regulatory authorities, or if regulatory authorities do not approve these facilities for the manufacture of our products, or withdraw any such approval in the future, 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 sanctions being imposed on us or adverse regulatory consequences, including clinical holds, warnings or untitled letters, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which would be expected to significantly and adversely affect supplies of our products to us and our collaboration partners.

Other than for Catalent, our commercial third-party supplier of roxadustat drug product in the U.S. and Europe, most of our other third-party manufacturers may terminate their engagement with us at any time and we have not yet entered into any commercial supply agreements for the manufacture of drug substance or active pharmaceutical ingredient ("API") or drug products. With respect to roxadustat, AstraZeneca and Astellas have certain rights to assume manufacturing of roxadustat and the existence of those rights may limit our ability to enter into favorable long-term supply agreements, if at all, with other third-party manufacturers. 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 have a letter agreement with IRIX Pharmaceuticals, Inc. ("IRIX"), a third-party manufacturer that we have used in the past, pursuant to which we agreed to negotiate a single source manufacturing agreement that included a right of first negotiation for the cGMP manufacture of HIF-PH inhibitors, including roxadustat, provided that IRIX is able to match any third-party bids within 5%. The exclusive right to manufacture extends for five years after approval of an NDA for those compounds, and any agreement would provide that no minimum amounts would be specified until appropriate by forecast and that we and a commercialization partner would have the rights to contract with independent third parties that exceed IRIX's internal manufacturing capabilities or in the event that we or our commercialization partner determines for reasons of continuity of supply and security that such a need exists, provided that IRIX would supply no less than 65% of the product if it is able to provide this level of supply. Subsequent to the letter agreement, we and IRIX have entered into several additional service agreements. IRIX has requested in writing that we honor the letter agreement with respect to the single source manufacturing agreement, and if we were to enter into any such exclusive manufacturing agreement, there can be no assurance that IRIX will not assert a claim for right to manufacture roxadustat or that IRIX could manufacture roxadustat successfully and in accordance with applicable regulations for a commercial product and the specifications of our collaboration partners. In 2015, Patheon Pharmaceuticals Inc., a business unit of DPx Holdings B.V. ("Patheon"), acquired IRIX, and in 2017 ThermoFisher Scientific Inc. acquired Patheon.

If any third-party manufacturer terminates its engagement with us or fails to perform as agreed, we may be required to find replacement manufacturers, which would result in significant cost and delay to our development programs. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur significant delays and added costs in identifying, qualifying and contracting with any such third party or potential second source manufacturer. In any event, with any third-party manufacturer we expect to enter into technical transfer agreements and share our know-how with the third-party manufacturer, which can be time-consuming and may result in delays. These delays could result in a suspension or delay of marketing roxadustat.

Certain of the components of our product candidates are acquired from single-source suppliers and have been purchased without long-term supply agreements. The loss of any of these suppliers, or their failure to supply us with supplies of sufficient quantity and quality to complete our drug substance or finished drug product of acceptable quality and an acceptable price, would materially and adversely affect our business.

We do not have an alternative supplier of certain components of our product candidates. We may be unable to enter into long-term commercial supply arrangements for some of our products, or do so on commercially reasonable terms, which could have a material adverse impact upon our business. In addition, we currently rely on our contract manufacturers to purchase from third-party suppliers some of the materials necessary to produce our product candidates. We do not have direct control over the acquisition of those materials by our contract manufacturers.

The logistics of our supply chain, which include shipment of materials and intermediates from countries such as China and India add additional time and risk (including risk of loss) to the manufacture of our product candidates. While we have in the past maintained sufficient inventory of materials, API, and drug product to meet our and our collaboration partners' needs for roxadustat 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 by preventing unauthorized use by third parties to the extent that our patents, trade secrets, and contractual position allow us to do so. Any disclosure to or misappropriation by third parties of our trade secrets or confidential information could compromise our competitive position. Moreover, we are involved in, have in the past been involved in, and may in the future be involved in legal or administrative proceedings involving our intellectual property initiated by third parties, and which proceedings can result in significant costs and commitment of management time and attention. As our product candidates continue in development, third parties may attempt to challenge the validity and enforceability of our patents and proprietary information and technologies.

We also are involved in, have in the past been involved in, 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 relating to the API are generally considered to be 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 that we own or license may fail to result in 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 we or our licensors were the first to make the inventions claimed in our owned and licensed patents or patent applications, or that we or our licensors 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 may 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 all of our employees to assign their inventions to us, and we require all of our employees, consultants, advisors and any 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 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 are unable to prevent unauthorized disclosure of our intellectual property related to our product candidates and technology to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business and operations.

Intellectual property disputes with third parties and competitors may be costly and 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. Pharmaceutical and biotechnology intellectual property disputes are characterized by complex, lengthy and expensive litigation over patents and other intellectual property rights. We may initiate or become party to or be threatened with future litigation or other proceedings regarding intellectual property rights with respect to our product candidates and competing products.

As our product candidates progress toward commercialization, we or our collaboration partners 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.

We intend, if necessary, to vigorously enforce our intellectual property in order to protect the proprietary position of our product candidates, including roxadustat and pamrevlumab. In addition, our collaboration partners who have been granted licenses to our patents may also have rights related to enforcement of those patents. Active efforts to enforce our patents by us or by our partners may include litigation, administrative proceedings, or both, depending on the potential benefits that might be available from those actions and the costs associated with undertaking those efforts against third parties. We carefully review and monitor publicly available information regarding products that may be competitive with our product candidates and assert our intellectual property rights where appropriate. For example, we previously prevailed in an administrative challenge initiated by a major biopharmaceutical company regarding our intellectual property rights, maintaining our intellectual property in all relevant scope, and will continue to protect and enforce our intellectual property rights. In addition, our partner Astellas initiated *quia timet* infringement actions against Akebia and GSK based on our specific patents in the United Kingdom in response to actions taken by Akebia and GSK against those patents, as further detailed below.

Third parties may also challenge our patents and patent applications, through interference, reexamination, *inter partes* review, and post-grant review proceedings before the U.S. Patent and Trademark Office ("USPTO") or through comparable proceedings in other territories. For example, Akebia and others have filed oppositions against certain European patents within our HIF anemia-related technologies patent portfolio. In three of these proceedings, for FibroGen European Patent Nos. 1463823, 1633333, and 2322155, the European Patent Office has handed down decisions unfavorable to FibroGen. In a fourth of these proceedings, the European Patent Office issued a decision favorable to FibroGen, maintaining FibroGen European Patent No. 2322153 in amended form. All of these decisions are currently under appeal, and these four patents are valid and enforceable pending resolution of the appeals. The ultimate outcomes of such proceedings remain uncertain, and ultimate resolution of the appeals may take considerable time. In addition, Akebia has filed oppositions against FibroGen European Patent Nos. 2289531 and 2298301. As mentioned above, Akebia and GSK initiated invalidation actions in the United Kingdom against the United Kingdom counterparts of each of these European patents, and GSK has filed for a declaration of non-infringement of certain United Kingdom patents (corresponding to FibroGen European Patent Nos. 2322153 and 2322155) with respect to its daprodustat product. We have reached a settlement agreement with GSK to resolve the actions to which GSK is/was a party, resulting in dismissal of the UK court actions as well as the proceedings filed by GSK against the patents in the EPO. Astellas' proceedings brought against GSK on a *quia timet* basis have also been dismissed as a result of the settlement agreement. Akebia is also pursuing invalidation actions against corresponding patents in Canada and in Japan. While we believe the ultimate outcome of all proceedings will be that these FibroGen patents will be upheld in relevant part, we note that narrowing or even revocation of any of these patents would not affect our exclusivity for roxadustat or our freedom-to-operate with respect to use of roxadustat for the treatment of anemia.

Oppositions have also recently been filed against our European Patent No. 2872488, which claims a crystalline form of roxadustat. Final resolution of the opposition proceedings will take considerable time, and we cannot be assured of the breadth of the claims that will remain in the '488 Patent or that the patent will not be revoked in its entirety.

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 in place with our collaboration partners. 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.

We have an extensive worldwide patent portfolio. The cost of maintaining our patent protection is high and maintaining our patent protection requires continuous review and compliance in order to maintain worldwide patent protection. We may not be able to effectively maintain our intellectual property position throughout the major markets of the world.

The USPTO 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, particularly certain developing countries such as China, 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 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.
- We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- The prosecution of our pending patent applications may not result in granted patents.
- Granted patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- 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 the commercialization of 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. Except for roxadustat in China for patients on dialysis and not on dialysis, and Japan for patients on dialysis, we have not obtained regulatory approval for any product candidate, and it is possible that neither roxadustat nor pamrevlumab, nor any future product candidates we may discover, in-license or acquire and seek to develop in the future, will obtain regulatory approval in additional countries.

Our product candidates could fail to receive regulatory approval from the FDA or other regulatory authorities for many reasons, including:

- disagreement over the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement over our interpretation of data from preclinical studies or clinical trials;
- disagreement over whether to accept efficacy results from clinical trial sites outside the U.S. where the standard of care is potentially different from that in the U.S.;
- the insufficiency of data collected from clinical trials of our present or future product candidates to support the submission and filing of an NDA or other submission or to obtain regulatory approval;
- disapproval of the manufacturing processes or facilities of either our manufacturing plant or third party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or other regulatory authorities may require more information, including additional preclinical or clinical data to support approval, or different analyses, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program altogether. 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 REMS 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.

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. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. We may not be able to file for regulatory approvals and even if we file we may not receive the necessary approvals to commercialize our product candidates in any market.

Our relationships with customers, physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

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 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, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act (“PPACA”), which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare and Medicaid Services (“CMS”), information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;

- foreign and state law equivalents of each of the above federal laws, such as the U.S. Foreign Corrupt Practices Act ("FCPA"), anti-kickback and false claims 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, many of which differ from each other in significant ways, thus complicating compliance efforts; and
- the Trade Agreements Act ("TAA"), which requires that drugs sold to the U.S. Government must be manufactured in the U.S. or in TAA approved and designated countries. Drugs manufactured in countries not approved under the TAA, may not be sold to the U.S. without specific regulatory approval. We have little experience with this regulation and there is a risk that drugs made from Chinese-made API may not be sold to an entity of the U.S. such as the Veterans Health Administration ("VA") due to our inability to obtain regulatory approval. While there have been recent VA policy changes that appear to allow for sale of drugs from non-TAA approved countries, this policy may change or there may be additional policies or legislation that affect our ability to sell drug to the U.S. Government.

The scope of these laws and our lack of experience in establishing the compliance programs necessary to comply with this complex and evolving regulatory environment increases the risks that we may unknowingly violate the applicable laws and regulations. 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 penalties, including civil and criminal penalties, damages, fines, 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. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have a material adverse effect on our ability to compete in the marketplace.

We are subject to laws and regulations governing corruption, which will require us to develop, maintain, and implement 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 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.

Anti-bribery laws prohibit us, our employees, and some of our agents or representatives from offering or providing any personal benefit to covered government officials to influence their performance of their duties or induce them to serve interests other than the missions of the public organizations in which they serve. Certain commercial bribery rules also prohibit offering or providing any personal benefit to employees and representatives of commercial companies to influence their performance of their duties or induce them to serve interests other than their employers. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

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, affiliates, 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.

As we expand our operations in China and other jurisdictions internationally, we will need to increase the scope of our compliance programs to address the risks relating to the potential for violations of the FCPA and other anti-bribery and anti-corruption laws. Our compliance programs will need to include policies addressing not only the FCPA, but also the provisions of a variety of anti-bribery and anti-corruption laws in multiple foreign jurisdictions, including China, provisions relating to books and records that apply to us as a public company, and include effective training for our personnel throughout our organization. The creation and implementation 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.

The impact of recent U.S. healthcare reform, its potential partial or full repeal, and other changes in the healthcare industry and in healthcare spending is currently unknown, and may adversely affect our business model.

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.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") altered Medicare coverage and payments for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. The MMA also provided authority for limiting the number of drugs that will be covered in any therapeutic class and as a result, we expect that there will be additional pressure to reduce costs. For example, the CMS in implementing the MMA has enacted regulations that reduced capitated payments to dialysis providers. These cost reduction initiatives and other provisions of the MMA could decrease the scope of coverage and the price that may be received for any approved dialysis products and could seriously harm our business and financial condition. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may cause a similar reduction in payments from private payors. Similar regulations or reimbursement policies have been enacted in many international markets which could similarly impact the commercial potential for our products.

Under the Medicare Improvements for Patients and Providers Act ("MIPPA"), a basic case-mix adjusted composite, or bundled, payment system commenced in January 2011 and transitioned fully by January 2014 to a single reimbursement rate for drugs and all services furnished by renal dialysis centers for Medicare beneficiaries with end-stage renal disease. Specifically, under MIPPA the bundle now covers drugs, services, lab tests and supplies under a single treatment base rate for reimbursement by the CMS based on the average cost per treatment, including the cost of ESAs and IV iron doses, typically without adjustment for usage. It is unknown whether roxadustat, if approved in the U.S., will be included in the payment bundle. Under MIPPA, agents that have no IV equivalent in the bundle are currently expected to be excluded from the bundle until 2025. If roxadustat were included in the bundle, it may reduce the price that could be charged for roxadustat, and therefore potentially limit our profitability. Based on roxadustat's differentiated mechanism of action and therapeutic effects, and discussions with our collaboration partner, we currently believe that roxadustat might not be included in the bundle. If roxadustat is reimbursed outside of the bundle, it may potentially limit or delay market penetration of roxadustat.

In March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, (collectively, the "PPACA"), was passed, which substantially changed the way healthcare is financed by both governmental and private payors in the U.S. There remain judicial and Congressional challenges to certain aspects of the PPACA as well as efforts by the Trump administration to repeal or replace certain aspects of the PPACA. For example, the Tax Cuts and Jobs Act of 2017, (the "Tax Act"), was enacted, which includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Additionally, on December 15, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA and our business.

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 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. At the federal level, the Trump administration's budget proposals for fiscal year 2020 contains further drug price control measures that could be enacted during the budget process or in other future legislation. In addition, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services has solicited feedback on some of these measures and has implemented others under its existing authority. While some of these measures may require additional authorization to become effective, the U.S. Congress and the Trump administration have indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented 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 U.S. healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for any future products or additional pricing pressures.

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

Roxadustat is considered a Class 2 substance on the World Anti-Doping Agency ("WADA") 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. This is particularly the case in China where we will not be able to sell roxadustat in private pharmacies due to the WADA classification. While private pharmacies only represent approximately 10% of the market in China, this will negatively affect sales and therefore the profitability of roxadustat and the Company as a whole.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could result in significant liability for us and 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 privacy laws protecting personal information;
- 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 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. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could harm our business, results of operations, financial condition and cash flows, including through the imposition of significant fines or other sanctions.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

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

We expect to be subject to a number of risks related with our international operations, many of which may be beyond our control. These risks include:

- different regulatory requirements for drug approvals in different countries;
- different standards of care in various countries that could complicate the evaluation of our product candidates;
- different U.S. and foreign drug import and export rules;
- reduced protection for intellectual property rights in certain countries;

- changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems and different competitive drugs indicated to treat the indications for which our product candidates are being developed;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- compliance with the FCPA, and other anti-corruption and anti-bribery laws;
- U.S. and foreign taxes, including withholding of payroll taxes;
- 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.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- a reliance on CROs, clinical trial sites, principal investigators and other third parties that may be less experienced with clinical trials or have different methods of performing such clinical trials than we are used to in the U.S.;
- potential liability resulting from development work conducted by foreign distributors; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

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. Refer to "*Business — Government Regulation — Regulation in China*" for a discussion of the regulatory requirements that are applicable to our current and planned business activities in China. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. For example, the Chinese government has implemented regulations that impact distribution of pharmaceutical products in China. These regulations generally require that at most two invoices may be issued throughout the distribution chain. Failure to comply with the "Two-Invoices" regulations would prevent us from accessing the market in China. As a result of the "Two-Invoices" regulation, we, rather than AstraZeneca, have been directly engaging distributors and a third-party logistics provider, and we are planning on modifying the distribution responsibilities under the China Agreement such that both companies will work together to manage the distribution network. FibroGen China Anemia Holdings, Ltd ("FibroGen China") has never managed distribution of pharmaceutical products, and this new distribution structure may impose higher costs or limit or delay our ability to sell products to our principal customers, and may limit the near term sales of our products. Any other such changes or amendments may result in increased compliance costs on 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.

We plan to use our own manufacturing facilities in China to produce roxadustat API and roxadustat drug product. As an organization, we have limited experience in the construction, licensure, and operation of a manufacturing plant, and accordingly we cannot assure you we will be able to meet regulatory requirements to operate our plant and to sell our products.

We have two manufacturing facilities in China, with one located in Beijing and the other in Cangzhou, Hebei. However, as an organization, we have limited experience licensing and operating commercial manufacturing facilities.

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, we and our product suppliers must continually spend time, money and effort in production, record-keeping and quality assurance and appropriate controls in order to ensure that any products manufactured in 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 NMPA and other regulatory authorities. We expect to depend on these facilities for our product candidates and business operations in China. Natural disasters or other unanticipated catastrophic events, including power interruptions, water shortages, storms, fires, pandemics, earthquakes, terrorist attacks, government appropriation of our facilities, and wars, could significantly impair our ability to operate our manufacturing facilities. Certain equipment, records and other materials located in these facilities would be difficult to replace or would require substantial replacement lead time that would impact our ability to successfully commercialize our product candidates in China. The occurrence of any such event could materially and adversely affect our business, financial condition, results of operations, cash flows and prospects.

In addition to manufacturing, we are responsible for pharmacovigilance, medical affairs, and management of the third-party distribution logistics for roxadustat in China. We have no experience in these areas as a company, and accordingly we cannot assure you we will be able to meet regulatory requirements or operate in these capacities successfully.

We are responsible for commercial manufacturing, pharmacovigilance, medical affairs, and management of the third-party distribution logistics for roxadustat commercial activities in China. While we have been increasing our staffing in these areas, as a company, we have no experience managing or operating these functions for a commercial product and there can be no guarantee that we will do so efficiently or effectively. Mistakes or delays in these areas could limit our ability to successfully commercialize roxadustat in China, could limit our eventual market penetration, sales and profitability, and could subject us to significant liability in China.

Our business could be adversely affected by the effects of health epidemics in regions where we have significant manufacturing facilities, concentrations of customers, or other business operations. We have significant operations in China and depend on China manufacturing operations for various stages of our worldwide supply chain for roxadustat. We do not yet know the full extent of the impact on our roxadustat global supply chain or China operations from the disease caused by the 2019 novel coronavirus ("COVID-19"). In addition, if COVID-19 becomes a worldwide pandemic, it could materially affect our operations globally, including at our headquarters in San Francisco, California, and our clinical trials that are taking place predominantly in the U.S., Europe and China.

Our business could be adversely affected by health epidemics in regions where we have significant manufacturing facilities, concentrations of customers, or other business operations.

We have taken measures to minimize the health risks of COVID-19 as the safety and well-being of our staff is our top priority. While we have resumed manufacturing operations in China, we currently expect many of our employees to continue transitioning from working from home to returning to our offices following the closure of our offices in Beijing, Shanghai, and Canghzou in February 2020. Our collaboration partner AstraZeneca is also in the process of resuming operations. In addition, many governments, including the Chinese government, have taken measures to restrict travel to reduce the spread of COVID-19, which may limit our operational capabilities.

Due to these and potentially additional business disruptions, there may be delays to our roxadustat supply chain, problems with our distribution or warehousing vendors, or delays to our (and our partners') commercialization and launch activities in China (including efforts to list roxadustat in hospitals), all of which could have a material impact on our revenue.

If the COVID-19 outbreak continues to spread, particularly outside of China, we may need to limit operations again in China or implement limitations, including work from home policies, in the U.S. There is a risk that other countries or regions may be less effective at containing COVID-19, or it may be more difficult to contain if the outbreak reaches a larger population or broader geography, in which case the risks described herein could be elevated significantly.

In particular, while we and our Chinese manufacturing partner WuXi STA have resumed manufacturing operations, we only have a limited stockpile of roxadustat API and Drug Product, and therefore, if there is a greater impact from the COVID-19 outbreak than currently expected, or if operations are halted again, we could face shortages in our China and global supply chains.

In addition, current and upcoming clinical trials run in China by us and our partner AstraZeneca may be affected by the COVID-19 outbreak. Site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 outbreak, but the extent of these potential delays is unknown at this time. If COVID-19 becomes a worldwide pandemic, it may delay enrollment in our global clinical trials, including here in the U.S., and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our clinical results and ultimate commercialization of our product candidates affected.

The COVID-19 outbreak has already impacted China's economy and the global economy, and China's healthcare system as a whole has been disrupted since the beginning of 2020. It is unknown how long this disruption will continue and how it will affect the government healthcare budget and pharmaceutical sales as patient visits to hospitals and physician engagement and medical affairs efforts have been greatly affected due to the outbreak. The effect on the government budget in China could lead to increased pressure on drug prices which could affect future reimbursement or our ability to obtain hospital listings for roxadustat.

For roxadustat specifically, while the effect on our sales may be more limited than for more established drugs as we have only recently been added to the National Reimbursement Drug List and are still in the process of securing hospital listings, we do expect some delay in our launch-progress, including with respect to increasing sales and obtaining more hospital listings.

The ultimate impact of the COVID-19 outbreak is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, healthcare systems, or the global economy as a whole. However, these effects could have a material impact on our operations and revenue and we will continue to monitor the COVID-19 situation closely.

We and our collaboration partner in China, AstraZeneca, may experience difficulties in successfully generating sales of roxadustat in China.

We and AstraZeneca have a profit sharing arrangement with respect to roxadustat in China and any difficulties we may experience in generating sales will affect our bottom line. Difficulties may be related to our ability to maintain reasonable pricing and reimbursement, obtain hospital listing, or other difficulties related to distribution, marketing, and sales efforts in China. For example, our current National Reimbursement Drug List reimbursement pricing is effective for a standard two-year period (between January 1, 2020 to December 31, 2021), after which time we will have to renegotiate a new price for roxadustat, which may be lower. Sales of roxadustat in China may 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 hospital listing process is critical to roxadustat's near-term commercial success in China and may take many years to obtain the majority of hospital listings.

The retail prices of any product candidates that we develop may be subject to control, including periodic downward adjustment, by Chinese government authorities.

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.

If our planned business activities in China fall within a restricted category under the China Catalog for Guidance for Foreign Investment, we will need to operate in China through a variable interest entity ("VIE") structure.

The China Catalog for Guidance for Foreign Investment sets forth the industries and sectors that the Chinese government encourages and restricts with respect to foreign investment and participation. The Catalog for Guidance for Foreign Investment is subject to revision from time to time by the China Ministry of Commerce. While we currently do not believe the development and marketing of roxadustat falls within a restricted category under the Catalog for Guidance for Foreign Investment, if roxadustat does fall under such a restricted category, we will need to operate in China through a VIE structure. A VIE structure involves a wholly foreign-owned enterprise that would control and receive the economic benefits of a domestic Chinese company through various contractual relationships. Such a structure would subject us to a number of risks that may have an adverse effect on our business, including that the Chinese government may determine that such contractual arrangements do not comply with applicable regulations, Chinese tax authorities may require us to pay additional taxes, shareholders of our VIEs may have potential conflicts of interest with us, and we may lose the ability to use and enjoy assets held by our VIEs that are important to the operations of our business if such entities go bankrupt or become subject to dissolution or liquidation proceedings. VIE structures in China have come under increasing scrutiny from accounting firms and the Securities and Exchange Commission ("SEC") staff. If we do attempt to use a VIE structure and are unsuccessful in structuring it so as to qualify as a VIE, we would not be able to consolidate the financial statements of the VIE with our financial statements, which could have a material adverse effect on our operating results and financial condition.

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 and FibroGen Beijing. We may 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 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, 2019, approximately $7.0 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 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, which could adversely affect our financial performance.

Most of our product sales will occur in local Chinese 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 value of the Renminbi against the U.S. dollar, Euro and other currencies is affected by, among other things, changes in China's political and economic conditions. Currently, the Renminbi is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. 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 ("SAFE") by complying with certain procedural requirements. However, approval from SAFE 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.

In addition, we and our foreign subsidiaries 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 U.S. enacted the Tax Act that instituted fundamental changes to the taxation of multinational corporations. The Tax Act includes changes to the taxation of foreign earnings by implementing a dividend exemption system, expansion of the current anti-deferral rules, a minimum tax on low-taxed foreign earnings and new measures to deter base erosion. There have been developing interpretations of the provisions of the Tax Act, including changes and issuance of new U.S. Treasury regulations, administrative interpretations, or court decisions since its inception. As regulations and guidance evolve with respect to the Tax Act, we continue to examine the impact to our business, which could have a material adverse effect on our business, results of operations or financial condition.

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 could have a material adverse effect on us.

The legal system of China is a civil law system primarily based on written statutes. 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. Navigating the uncertainty and change in the China legal system will require the devotion of significant resources and time, and there can be no assurance that our contractual and other rights will ultimately be enforced.

Changes in China's economic, political or social conditions or government policies could have a material adverse effect on our business and operations.

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. 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.

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.

Developments relating to the United Kingdom's referendum vote in favor of leaving the European Union could adversely affect us.

Effective January 31, 2020, the United Kingdom commenced an exit from the European Union, commonly referred to as "Brexit." During a transition period (set to expire on December 31, 2020), the British government will continue to negotiate the terms of the United Kingdom's future relationship with the European Union. The outcome of these negotiations is uncertain, and we do not know to what extent Brexit will ultimately impact the business and regulatory environment in the United Kingdom, the rest of Europe, or other countries. The effects of the United Kingdom's withdrawal from the European Union, and the perceptions as to its impact, are expected to be far-reaching and may adversely affect business activity and economic conditions in Europe and globally and could continue to contribute to instability in global financial markets, including foreign exchange markets. The United Kingdom's withdrawal from the European Union could also have the effect of disrupting the free movement of goods, services and people between the United Kingdom and Europe and could also lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which European laws to replace or replicate, including laws that could impact our ability, or our collaborator's ability in the case of roxadustat, to obtain approval of our products or sell our products in the United Kingdom. Changes impacting our ability to conduct business in the United Kingdom or other European countries, or changes to the regulatory regime applicable to our operations in those countries (such as with respect to the approval of our product candidates), may materially and adversely impact our business, prospects, operating results, and financial condition.

Risks Related to the Operation of Our Business

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 and we continue to undertake the efforts and expense to operate as a public reporting company, we expect that we will need to increase the responsibilities on members of management in order to manage any future growth effectively. 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, including the recent passing of our founder, chairman and chief executive officer, could adversely affect our ability to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

We are highly dependent on members of our senior management team. In August 2019, Thomas B. Neff, our founder, chairman and chief executive officer, passed away, and subsequently James Schoeneck, a longtime member of our Board of Directors, was appointed as interim chief executive officer. On January 6, 2020, we announced the appointment of Enrique Conterno as chief executive officer, with Mr. Schoeneck stepping down from the interim role. The loss of Mr. Neff and his knowledge of the Company's programs may be disruptive to our operations and could negatively impact the development and commercialization of our product candidates, our existing collaborative relationships, and our ability to successfully implement our business strategy, as could changes in our executive team in the future.

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.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

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, 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 the implementation of 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 2017, 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.

We depend on sophisticated information technology systems to operate our business and a cyber-attack or other breach of these systems could have a material adverse effect on our business.

We rely on information technology systems to process, transmit and store electronic information in our day-to-day operations. The size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption. While we have recently upgraded our disaster data recovery program, a successful attack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyber-attacks are becoming more sophisticated and frequent. We have invested in our systems and the protection and recoverability of our data to reduce the risk of an intrusion or interruption, and we monitor and test our systems on an ongoing basis for any current or potential threats. There can be no assurance that these measures and efforts will prevent future interruptions or breakdowns. If we fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to these systems, we could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating costs and expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows.

Our headquarters are located near known earthquake fault zones. The occurrence of an earthquake, fire or any other catastrophic event could disrupt our operations or the operations of third parties who provide vital support functions to us, which could have a material adverse effect on our business, results of operations and financial condition.

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.

We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations, 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, 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 we have in place are unlikely to provide adequate protection in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

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

Risks Related to Our Common Stock

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

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. This type of litigation could result in substantial costs and divert our management's attention and resources and could also require us to make substantial payments to satisfy judgments or to settle litigation.

If securities or industry analysts do not continue to publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of January 31, 2020, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 27.60% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after such date and shares issuable upon settlement of restricted stock units that will vest within 60 days after such date. This percentage is based upon information supplied by officers, directors and principal stockholders and Schedules 13D and 13G, if any, filed with the SEC, which information may not be accurate as of January 31, 2020. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. The interests of this group may differ from those of other stockholders and they may vote their shares in a way that is contrary to the way other stockholders vote their shares. This concentration of ownership could have the effect of entrenching our management and/or the board of directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

We may engage in future acquisitions that could disrupt our business, cause dilution to our stockholders and harm our business, results of operations, financial condition and cash flows and future prospects.

While we currently have no specific plans to acquire any other businesses, 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, even if an acquisition would be beneficial to our stockholders, 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, 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 may have exposure to additional non-income tax liabilities, which could have an adverse effect on our results of operations and financial condition.

In addition, our judgment in providing for the possible impact of the Tax Act remains subject to developing interpretations of the provisions of the Tax Act. As regulations and guidance evolve with respect to the Tax Act, we continue to examine the impact to our tax provision or exposure to additional tax liabilities, which could have a material adverse effect on our business, results of operations or financial condition.

Tariffs imposed by the U.S. and those imposed in response by other countries, as well as rapidly changing trade relations, could have a material adverse effect on our business and results of operations.

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 amended and restated certificate of incorporation designates the state or federal courts located in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, 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 state and federal courts located in the State of Delaware will be the sole and exclusive forum for (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. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. 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. Alternatively, 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.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain and you may never receive a return on your investment.

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.

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 35,000 square feet subleased. The lease for our San Francisco headquarters expires in 2023. We also lease approximately 67,000 square feet of office and manufacturing space in Beijing, China. Our lease in China expires in 2021. 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 PROCEEEDINGS

We are not currently a party to any material legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

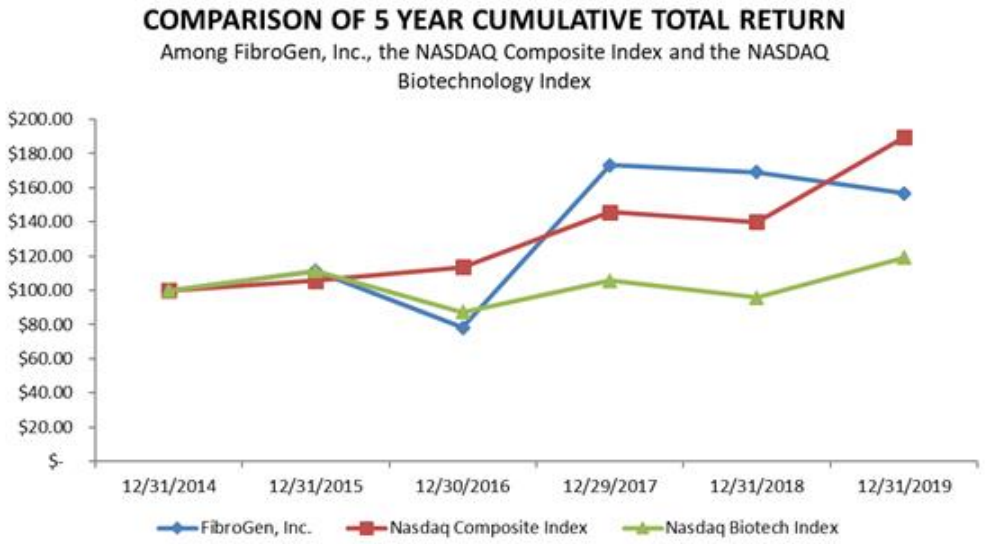
ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

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, 2014 to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes an initial investment of $100 on December 31, 2014, 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, 2020, there were 136 registered stockholders of record for our common stock. This number of registered stockholders does not include stockholders whose shares are held in street name 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.

Use of Proceeds from Initial Public Offering of Common Stock

On November 13, 2014, our Registration Statement on Form S-1, as amended (Reg. Nos. 333-199069 and 333-200189) was declared effective in connection with the initial public offering of our common stock. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on November 14, 2014.

Recent Sales of Unregistered Securities

During the year ended December 31, 2019, a warrant to purchase 4,430 shares of our common stock was exercised at a per share price of $15.00.

These shares issued pursuant to the warrant were not registered under the Securities Act of 1933, as amended, in reliance upon the exemption set forth in Section 4(a)(2) of such Act for transactions not involving a public offering.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated results of operations data for the years ended December 31, 2019, 2018 and 2017, and the consolidated balance sheet data as of December 31, 2019 and 2018 should be read together with Part II, Item 7 *"Management's Discussion and Analysis of Financial Condition and Results of Operations"* and in conjunction with the consolidated financial statements, related notes, and other financial information included elsewhere in this Annual Report. The selected consolidated results of operations data for the year ended December 31, 2016 and 2015 and the consolidated balance sheet data as of December 31, 2017, 2016 and 2015 have been derived from audited financial statements not included herein. Our historical results are not necessarily indicative of the results to be expected in the future.

	Years Ended December 31,				
	2019	2018	2017	2016	2015
	(in thousands, except for per share data)				
Result of Operations					
Revenue:					
License revenue	$ 177,086	$ 22,269	$ 9,933	$ 50,607	$ 89,401
Development and other revenue	114,115	125,913	121,063	132,582	82,985
Product revenue	(34,624)	64,776	—	—	—
Total revenue	256,577	212,958	130,996	183,189	172,386
Operating expenses:					
Cost of goods sold	1,147	—	—	—	—
Research and development	209,265	235,839	196,517	187,206	214,089
Selling, general and administrative	135,479	63,812	51,760	46,025	44,364
Total operating expenses	345,891	299,651	248,277	233,231	258,453
Net loss	$ (76,970)	$ (86,420)	$ (120,875)	$ (58,068)	$ (94,221)
Net loss per share - basic and diluted	$ (0.89)	$ (1.03)	$ (1.66)	$ (0.93)	$ (1.56)

	December 31,				
	2019	2018	2017	2016	2015
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$ 126,266	$ 89,258	$ 673,658	$ 173,782	$ 153,324
Short-term and long-term investments	468,609	587,964	72,566	150,407	159,567
Working capital	599,745	600,982	663,010	192,806	131,468
Total assets	857,397	880,598	898,650	469,552	470,574
Deferred revenue	99,939	149,880	154,911	154,737	141,511
Accumulated deficit	(784,720)	(715,827)	(630,657)	(509,782)	(451,714)
Total stockholders' equity	516,135	509,199	528,467	115,798	133,902

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 15 of this Annual Report on Form 10-K. 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 "Risk Factors" section 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.

BUSINESS OVERVIEW

We were incorporated in 1993 in Delaware and 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 developing and commercializing a pipeline of first-in-class therapeutics. We apply our pioneering expertise in hypoxia-inducible factor ("HIF"), connective tissue growth factor ("CTGF") biology, and clinical development to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer. Roxadustat, our most advanced product, is an oral small molecule inhibitor of HIF prolyl hydroxylase ("HIF-PH") activity that has received marketing authorization in China for the treatment of anemia caused by chronic kidney disease ("CKD") in dialysis and non-dialysis patients. In September 2019, roxadustat (Evrenzo®) was approved in Japan for the treatment of anemia associated with CKD in dialysis-dependent patients. In January 2020, Astellas Pharma Inc. ("Astellas") submitted a supplemental New Drug Application ("NDA") in Japan for the treatment of anemia in non-dialysis CKD patients. Our NDA filing for roxadustat for the treatment of anemia patients with dialysis-dependent CKD and non-dialysis-dependent CKD was accepted for review by the United States ("U.S.") Food and Drug Administration ("FDA") in February 2020, and Astellas is in the process of preparing a Marketing Authorization Application ("MAA") for submission to the European Medicines Agency ("EMA") in the second quarter of 2020 for the same indications. Roxadustat is in Phase 3 clinical development in the U.S. and Europe and in Phase 2/3 development in China for anemia associated with myelodysplastic syndromes ("MDS"). Roxadustat is in Phase 2 clinical development for chemotherapy-induced anemia. Pamrevlumab, an anti-CTGF human monoclonal antibody, is in Phase 3 clinical development for the treatment of both idiopathic pulmonary fibrosis ("IPF") and pancreatic cancer. Pamrevlumab is also currently in a Phase 2 trial for Duchenne muscular dystrophy ("DMD").

Financial Highlights

	Years Ended December 31,		
	2019	2018	2017
	(in thousands, except for per share data)		
Result of Operations			
Revenue	$ 256,577	$ 212,958	$ 130,996
Operating costs and expenses	345,891	299,651	248,277
Net loss	(76,970)	(86,420)	(120,875)
Net loss per share - basic and diluted	$ (0.89)	$ (1.03)	$ (1.66)

	December 31, 2019	December 31, 2018
	(in thousands)	
Balance Sheet		
Cash and cash equivalents	$ 126,266	$ 89,258
Short-term and long-term investments	$ 468,609	$ 587,964
Accounts receivable	$ 28,455	$ 63,684

Our revenue for the year ended December 31, 2019 included the revenues recognized related to the following:

- Two regulatory milestones totaling $130.0 million associated with the planned MAA submission to the EMA under the collaboration agreement with Astellas for roxadustat as a treatment for dialysis and non-dialysis CKD patients;
- A $50.0 million regulatory milestone associated with the NDA submission to the FDA under the collaboration agreement with AstraZeneca for roxadustat as a treatment for dialysis and non-dialysis CKD patients;
- Three regulatory milestones totaling $22.0 million associated with roxadustat being included on the updated National Reimbursement Drug List ("NRDL") released by China's National Healthcare Security Administration ("NHSA"); and
- A regulatory milestone of $12.5 million associated with the NDA approval in Japan.

Meanwhile, our overall revenue for the year ended December 31, 2019 was reduced by $36.3 million of a change in estimated variable consideration related to the API product revenue that was recognized in 2018 discussed below, which reflected the total difference between estimated and actual listed price and yield from the manufacture of bulk product tablets.

As comparison, our revenue for the year ended December 31, 2018 included the revenues recognized related to the following:

- A $64.8 million product revenue for API delivered during 2018, under the amendment to the collaboration agreement with Astellas for roxadustat for the treatment of anemia in Japan ("Japan Agreement"), to conduct commercial scale manufacturing validation for roxadustat drug product in anticipation of commercial launch in Japan;
- A regulatory milestone of $15.0 million associated with an NDA submission during 2018 in Japan;
- A $6.0 million milestone under the collaboration agreements with AstraZeneca upon our receipt of marketing authorization from the NMPA for roxadustat, a first-in-class HIF-PH inhibitor, for the treatment of anemia caused by CKD in patients on dialysis; and
- A $6.0 million milestone payable under the collaboration agreement with AstraZeneca upon our receipt of First Manufacturing Approval for a Product in the Field in the Territory, which allows production for Phase 4 clinical studies, patients' early experience programs, donation programs, as well as to supply products for testing and assessments required prior to launch.

Operating expenses increased for the year ended December 31, 2019 compared to the prior year primarily due to the following:

- Higher outside service expenses related to co-promotional activities and scientific contract expenses;
- Higher stock-based compensation related to the cumulative impact of stock option grant activities;
- Amortization of finance lease ROU assets and higher depreciation expenses related to the adoption of lease accounting guidance under ASC 842;
- Higher legal expenses mainly associated with patent-related and international activities; and
- Higher employee-related expenses resulting from higher average compensation level.

The increases were partially offset by:

- Lower clinical trial expenses related to lower activities for roxadustat offset by higher activities for pamrevlumab; and
- Lower drug development expenses associated with drug substance manufacturing activities related to pamrevlumab, and capitalization of inventory manufacturing costs.

Our research and development expenses were $209.3 million, $235.8 million and $196.5 million for the years ended December 31, 2019, 2018 and 2017, respectively. Since inception and through December 31, 2019, we have incurred a total of approximately $2 billion in research and development expenses, a majority of which relates to the development of roxadustat, pamrevlumab and other HIF-PH inhibitors. We expect to continue to incur significant expenses and operating losses over at least the next several years and we expect our research and development expenses to increase in the future as we advance our product candidates through clinical trials and expand 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.

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 "*Risk Factors*."

During the year ended December 31, 2019, we had a net loss of $77.0 million, or net loss per basic and diluted share of $0.89, as compared to a net loss of $86.4 million, or net loss per basic and diluted share of $1.03 for the prior year, primarily due to an increase in revenue, partially offset by an increase in operating expenses.

Cash and cash equivalents, investments and accounts receivable totaled $623.3 million at December 31, 2019, a decrease of $117.6 million from December 31, 2018, primarily due to cash used in operations.

Programs

Roxadustat, our most advanced product, is an oral small molecule inhibitor of HIF-PH activity that has received marketing authorization in China for the treatment of anemia caused by CKD in non-dialysis-dependent patients (adding the non-dialysis indication to the label for dialysis-dependent patients, which was approved in December 2018). In September 2019, roxadustat (Evrenzo®) was approved in Japan for the treatment of anemia associated with CKD in dialysis-dependent patients. In January 2020, Astellas submitted a supplemental NDA in Japan for the treatment of anemia in non-dialysis CKD patients. Our U.S. NDA filing for roxadustat for the treatment of anemia patients with dialysis-dependent CKD and non-dialysis-dependent CKD was accepted for review by the FDA in February 2020, and Astellas is in the process of preparing an MAA for submission to the EMA in the second quarter of 2020 for the same indications. Roxadustat is in Phase 3 clinical development in the U.S. and Europe and in Phase 2/3 development in China for anemia associated with MDS. Roxadustat is in Phase 2 clinical development for chemotherapy-induced anemia.

Pamrevlumab, an anti-CTGF human monoclonal antibody, is in Phase 3 clinical development for the treatment of both IPF and pancreatic cancer. Pamrevlumab is also currently in a Phase 2 trial for DMD.

Collaboration Partnerships for Roxadustat

Our current and future research, development, manufacturing and commercialization efforts with respect to roxadustat and our other product candidates currently in development depend on funds from our collaboration agreements with Astellas and AstraZeneca as described below.

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 (“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. Under these agreements, we provide Astellas the right to develop and commercialize roxadustat for anemia indications in these territories.

We share responsibility with Astellas for clinical development activities required for the U.S. and the Europe regulatory approval of roxadustat and share equally 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 own 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.

The Astellas agreements will continue in effect until terminated. Either party may terminate the agreements for certain material breaches by the other party. In addition, Astellas will have the right to terminate the agreements for certain specified technical product failures, upon generic sales reaching a particular threshold, upon certain regulatory actions, or upon our entering into a settlement admitting the invalidity or unenforceability of our licensed patents. Astellas may also terminate the agreements for convenience upon advance written notice to us. In the event of any termination of the agreements, Astellas will transfer and assign to us the regulatory filings for roxadustat and will assign or license to us the relevant trademarks used with the products in the Astellas territories. Under certain terminations, Astellas is also obligated to pay us a termination fee.

Consideration under these agreements includes a total of $360.1 million in upfront and non-contingent payments, and milestone payments totaling $557.5 million, of which $542.5 million are development and regulatory milestones and $15.0 million are commercial-based milestones. Total consideration, excluding development cost reimbursement and product sales-related payments, could reach $917.6 million. The aggregate amount of such consideration received, through December 31, 2019 totals $500.1 million. Additionally, under these agreements, Astellas pays 100% of the commercialization costs in its territories. Astellas will pay FibroGen a transfer price, based on net sales, in the low 20% range for our manufacture and delivery of roxadustat.

In September 2019, Japan’s Ministry of Health, Labour and Welfare approved roxadustat for the treatment of anemia associated with dialysis CKD patients. Accordingly, the consideration of $12.5 million associated with this milestone was included in the transaction price and allocated to performance obligations under the Japan Agreement in the third quarter of 2019. This milestone payment was received in October 2019.

During the second quarter of 2019, we received positive topline results from analyses of pooled major adverse cardiac event ("MACE") and MACE+ data from its Phase 3 trials evaluating roxadustat as a treatment for dialysis and non-dialysis CKD patients, enabling Astellas to prepare for an MAA submission to the EMA in the second quarter of 2020, following our NDA submission to the FDA in 2019 and acceptance for review in February 2020. We evaluated the two regulatory milestone payments associated with the planned MAA submission and concluded that these milestones became probable of being achieved in the second quarter of 2019. Accordingly, the total consideration of $130.0 million associated with these milestones was included in the transaction price and allocated to performance obligations under the Europe Agreement in the second quarter of 2019.

During the second quarter of 2018, Astellas reported positive results from the final Phase 3 CKD-dialysis trial of roxadustat in Japan, indicating that Astellas was ready to make an NDA submission for the treatment of anemia with roxadustat in CKD-dialysis patients in 2018. We evaluated the regulatory milestone payment associated with NDA submission in Japan based on variable consideration requirements under the current revenue standards and concluded that this milestone became probable of being achieved in the second quarter of 2018. Accordingly, the consideration of $15.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the Japan Agreement, substantially all of which was recognized as revenue in 2018.

On November 30, 2018, FibroGen and Astellas entered into an amendment to the Japan Agreement that will allow Astellas to manufacture roxadustat drug product for commercialization in Japan (the "Japan Amendment"). Under this amendment, FibroGen would continue to manufacture and deliver to Astellas roxadustat API. The commercial terms of the 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. This amendment obligated Astellas to purchase a total of $64.7 million API from FibroGen, all of which was delivered to Astellas in 2018. In 2019, a change in estimated variable consideration resulted in a $36.3 million reduction to revenue, at the time the listed price for roxadustat was issued by the Japanese Ministry of Health, Labour and Welfare, which reflected the total difference between estimated and actual listed price and yield from the manufacture of bulk product tablets.

In the fourth quarter of 2018, we were engaged in the final stages of review with our partners over the proposed development of roxadustat for the treatment of chemotherapy-induced anemia. AstraZeneca and Astellas approved the program in December 2018 and January 2019, respectively. Costs associated with the development of this indication are shared 50-50 between our two partners. For revenue recognition purposes, we concluded that this new indication represents a modification to the Europe agreements and will be accounted for separately, meaning the development costs associated with the new indications are distinct from the original development costs. The development service period for roxadustat for the treatment of CIA under the Europe Agreement is estimated to continue through the end of 2023 to allow for development of this indication.

In addition, as of December 31, 2019, Astellas had separate investments of $80.5 million in the equity of FibroGen, Inc.

AstraZeneca

In July 2013, we entered into the U.S./RoW Agreement a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in the U.S. and all territories not previously licensed to Astellas, except China. In July 2013, through our China subsidiary and related affiliates, we entered into the China Agreement a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in China. Under these agreements we provide 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.

In 2015, we reached the $116.5 million cap on our initial funding obligations (during which time we shared 50% of the joint initial development costs), therefore all development and commercialization costs for roxadustat for the treatment of anemia in CKD in the U.S., Europe, Japan and all other markets outside of China have been paid by Astellas and AstraZeneca since reaching the cap.

In China, FibroGen (China) Medical Technology Development Co., Ltd. ("FibroGen Beijing") will conduct the development work for CKD anemia, will hold all of the regulatory licenses issued by China regulatory authorities, and will be primarily responsible for regulatory, clinical and manufacturing. China development costs are shared 50/50. AstraZeneca is also responsible for 100% of development expenses in all other licensed territories outside of China. We are responsible, through our contract manufacturers, for the manufacture and supply of all quantities of roxadustat to be used in development and commercialization under the AstraZeneca agreements.

Under the AstraZeneca agreements, we will receive upfront and subsequent non-contingent payments totaling $402.2 million. Potential milestone payments under the agreements total $1.2 billion, of which $571.0 million are development and regulatory milestones and $652.5 million are commercial-based milestones. Total consideration under the agreements, excluding development cost reimbursement, transfer price payments, royalties and profit share, could reach $1.6 billion. The aggregate amount of such consideration received through December 31, 2019 totals $444.2 million.

Under the U.S./RoW Agreement, AstraZeneca will pay for all commercialization costs in the U.S. and RoW and AstraZeneca will be responsible for the U.S. commercialization of roxadustat, with FibroGen undertaking specified promotional activities in the end stage renal disease segment in the U.S. In addition, we will receive a transfer price for delivery of commercial product based on a percentage of net sales in the low- to mid-single digit range and AstraZeneca will pay us a tiered royalty on net sales of roxadustat in the low 20% range.

Under the China Agreement, which is conducted through FibroGen China Anemia Holdings, Ltd. ("FibroGen China"), the commercial collaboration is structured as a 50/50 profit share. AstraZeneca will conduct sales and marketing activities in China and fund roxadustat launch costs in China until FibroGen Beijing has achieved profitability. At that time, AstraZeneca will recoup 50% of their historical launch costs out of initial roxadustat profits in China. As of December 31, 2019, we accrued $53.1 million of co-promotional expenses related to the estimated amount payable to AstraZeneca for such sales and marketing efforts. The payment for such amount is not expected to occur within the next year.

Payments under these agreements include over $500.0 million in upfront, non-contingent and other payments received or expected to be received prior to the first U.S. approval, excluding development expense reimbursement.

AstraZeneca may terminate the U.S./RoW Agreement upon specified events, including our bankruptcy or insolvency, our uncured material breach, technical product failure, or upon 180 days prior written notice at will. If AstraZeneca terminates the U.S./RoW Agreement at will, in addition to any unpaid non-contingent payments, it will be responsible for paying for a substantial portion of the post-termination development costs under the agreed development plan until regulatory approval.

AstraZeneca may terminate the China Agreement upon specified events, including our bankruptcy or insolvency, our uncured material breach, technical product failure, or upon advance prior written notice at will. If AstraZeneca terminates our China Agreement at will, it will be responsible for paying for transition costs as well as make a specified payment to FibroGen China.

In the event of any termination of the agreements, but subject to modification upon termination for technical product failure, AstraZeneca will transfer and assign to us any regulatory filings and approvals for roxadustat in the affected territories that they may hold under our agreements, grant us licenses and conduct certain transition activities.

In December 2019, roxadustat has been included on the updated NRDL released by China's NHSA for the treatment of anemia in CKD, covering patients who are non-dialysis-dependent as well as those who are dialysis-dependent. The inclusion on the NRDL triggered a total of $22.0 million milestones payable to us by AstraZeneca. Accordingly, the total consideration of $22.0 million associated with these milestones was included in the transaction price and allocated to performance obligations under the U.S./ RoW Agreement in the fourth quarter of 2019.

As mentioned above, during the second quarter of 2019, we received positive topline results from analyses of pooled MACE and MACE+ data from its Phase 3 trials for roxadustat, enabling our U.S. NDA submission to the FDA. We evaluated the regulatory milestone payment associated with this NDA submission and concluded that this milestone became probable of being achieved in the second quarter of 2019. Accordingly, the consideration of $50.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the U.S./ RoW Agreement in the second quarter of 2019. We submitted our NDA to the FDA in December 2019, which was accepted for review in February 2020.

On December 17, 2018, FibroGen Beijing, received marketing authorization from the NMPA for roxadustat, a first-in-class HIF-PH inhibitor, for the treatment of anemia caused by CKD in patients on dialysis. This approval triggered a $6.0 million milestone payable to us by AstraZeneca. On December 29, 2018, FibroGen Beijing received First Manufacturing Approval for a Product in the Field in the Territory, which allows production for Phase 4 clinical studies, patients' early experience programs, donation programs, as well as to supply products for testing and assessments required prior to launch. This approval triggered a $6.0 million milestone payable to us by AstraZeneca.

As mentioned above, in the fourth quarter of 2018, we were engaged in the final stages of review with our partners over the proposed development of roxadustat for the treatment of CIA. AstraZeneca and Astellas approved the program in December 2018 and January 2019, respectively. Costs associated with the development of this indication are expected to be shared 50-50 between our two partners. In addition to CIA, in December 2018, anemia of chronic inflammation ("ACI") and multiple myeloma ("MM") have been approved for development by AstraZeneca and is expected to be fully funded by them. For revenue recognition purposes, we concluded that the approval of additional research and development services for these new indications represent modifications to our collaboration agreements in the periods in which approval was received. The research and development services associated with the new indications are distinct from other promises in our collaboration agreements, and will be accounted for separately. The development service period for roxadustat for the treatment of CIA, ACI and MM under the AstraZeneca agreements is estimated to continue through the end of 2024, to allow for development of these additional indications.

Additional Information Related to Collaboration Agreements

Of the $1.1 billion in development and regulatory milestones payable in the aggregate under our Astellas and AstraZeneca collaboration agreements, $425.0 million is payable upon achievement of milestones relating to the submission and approval of roxadustat in dialysis-dependent CKD and non-dialysis-dependent CKD in the U.S. and Europe.

For more detailed discussions on the accounting for these agreements, refer to Note 3 to the consolidated financial statements. In addition, refer to "*Business — Collaborations*" for a more detailed description of our collaboration agreements.

Total cash consideration received through December 31, 2019 and potential cash consideration, other than development cost reimbursement, transfer price payments, royalties and profit share, pursuant to our existing collaboration agreements are as follows:

	Cash Received Through December 31, 2019	Additional Potential Cash Payments	Total Potential Cash Payments
		(in thousands)	
Astellas--related-party:			
Japan Agreement	$ 90,093	$ 82,500	$ 172,593
Europe Agreement	410,000	335,000	745,000
Total Astellas	500,093	417,500	917,593
AstraZeneca:			
U.S. / RoW Agreement	389,000	860,000	1,249,000
China Agreement	55,200	321,500	376,700
Total AstraZeneca	444,200	1,181,500	1,625,700
Total revenue	$ 944,293	$ 1,599,000	$ 2,543,293

These collaboration agreements also provide for reimbursement of certain fully burdened research and development costs as well as direct out of pocket expenses.

RESULTS OF OPERATIONS

Revenue

	Years Ended December 31,			Change 2019 vs. 2018	
	2019	2018	2017	$	%
		(dollars in thousands)			
Revenue:					
License revenue	$ 177,086	$ 22,269	$ 9,933	$ 154,817	695 %
Development and other revenue	114,115	125,913	121,063	(11,798)	(9) %
Product revenue	(34,624)	64,776	—	(99,400)	(153) %
Total revenue	$ 256,577	$ 212,958	$ 130,996	$ 43,619	20 %

Our revenue to date has been generated substantially from our collaboration agreements with Astellas and AstraZeneca.

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 periods. This revenue is generally recognized as deliverables are met and services are performed. License revenues represented 69%, 11% and 8% of total revenues for the years ended December 31, 2019, 2018 and 2017, respectively.

Development and other revenue includes co-development and other development related services. Co-development services are recognized as revenue in the period in which they are billed to our partners, excluding China. For China co-development services, revenue is deferred until the end of the development period once all performance obligations have been satisfied. Other development related services are recognized as revenue over the non-contingent development period based on a proportional performance method. As of December 31, 2019, the future non-contingent development periods range from 12 to 60 months. Other revenues consist of sales of research and development material and have been included with Development and other revenue in the consolidated statements of operations, as they have not been material for any of the periods presented. Development and other revenues represented 44%, 59% and 92% of total revenues for the years ended December 31, 2019, 2018 and 2017, respectively.

In the third quarter of 2019, we started generating net product revenue from commercial sales of roxadustat drug product in China. In addition, product revenue for 2019 included a change in estimated variable consideration related to the product revenue recognized in 2018 associated with commercial-grade API sales to Astellas. Product revenue is recognized 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 (13)% and 30% of total revenue for the year ended December 31, 2019 and 2018. There was no product revenue for the year ended December 31, 2017.

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 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 increased $43.6 million, or 20% for the year ended December 31, 2019 compared to the year ended December 31, 2018 for the reasons discussed in the sections below.

License Revenue

	Years Ended December 31,			Change 2019 vs. 2018	
	2019	2018	2017	$	%
	(dollars in thousands)				
License revenue:					
Astellas	$ 129,405	$ 14,323	$ —	$ 115,082	803 %
AstraZeneca	47,681	7,946	9,933	39,735	500 %
Total license revenue	$ 177,086	$ 22,269	$ 9,933	$ 154,817	695 %

License revenue increased $154.8 million, or 695% for the year ended December 31, 2019 compared to the year ended December 31, 2018.

License revenue recognized under our collaboration agreements with Astellas increased $115.1 million, or 803% for the year ended December 31, 2019 compared to the year ended December 31, 2018. License revenue recognized under our collaboration agreements with Astellas for the year ended December 31, 2019 represented the allocated revenue of $117.5 million related to two regulatory milestones totaling $130.0 million associated with the planned MAA submission in Europe that were included in the transaction price during the second quarter of 2019 when these milestones became probable of being achieved; and the allocated revenue of $11.9 million related to a regulatory milestone of $12.5 million associated with the NDA approval in Japan achieved during the third quarter of 2019. License revenue recognized under our collaboration agreements with Astellas for the year ended December 31, 2018 represented the allocated revenue related to a $15.0 million regulatory milestone associated with Astellas' expected NDA submission in Japan that was included in the transaction price during the second quarter of 2018 when this milestone became probable of being achieved.

License revenue recognized under our collaboration agreements with AstraZeneca increased $39.7 million, or 500% for the year ended December 31, 2019 compared to the year ended December 31, 2018. License revenue recognized under our collaboration agreements with AstraZeneca for the year ended December 31, 2019 represented the allocated revenue of $33.1 million related to a regulatory milestone of $50.0 million associated with the NDA submission in the U.S. that was included in the transaction price during the second quarter of 2019 when this milestone became probable of being achieved; and the allocated revenue of $14.6 million related to three regulatory milestones totaling $22.0 million associated with roxadustat being included on the updated NRDL released by China's NHSA during the fourth quarter of 2019. License revenue recognized under our collaboration agreements with AstraZeneca for the year ended December 31, 2018 represented the allocated revenue related to a $6.0 million milestone associated with FibroGen Beijing's receipt of marketing authorization from the NMPA for roxadustat, and a $6.0 million milestone associated with FibroGen Beijing's receipt of First Manufacturing Approval for a Product in the Field in the Territory.

Development and Other Revenue

	Years Ended December 31,			Change 2019 vs. 2018	
	2019	2018	2017	$	%
	(dollars in thousands)				
Development revenue:					
Astellas	$ 29,394	$ 20,903	$ 20,111	$ 8,491	41 %
AstraZeneca	84,719	104,970	100,928	(20,251)	(19) %
Total development revenue	114,113	125,873	121,039	(11,760)	(9) %
Other revenue	2	40	24	(38)	(95) %
Total development and other revenue	$ 114,115	$ 125,913	$ 121,063	$ (11,798)	(9) %

Development revenue decreased $11.8 million, or 9% for the year ended December 31, 2019 compared to the year ended December 31, 2018.

Development revenue recognized under our collaboration agreements with Astellas increased $8.5 million, or 41% for the year ended December 31, 2019 compared to the year ended December 31, 2018. Development revenue recognized under our collaboration agreements with Astellas for the year ended December 31, 2019 included the allocated revenue of $11.4 million related to the above-mentioned $130.0 million associated with the regulatory milestones of the planned MAA submission in Europe, and the allocated revenue of $0.5 million related to the above-mentioned $12.5 million associated with the NDA approval in Japan. Development revenue recognized under our collaboration agreements with Astellas for the year ended December 31, 2018 included the allocated revenue related to the above-mentioned $15.0 million associated with the regulatory milestone of NDA submission in Japan. The increase for the year ended December 31, 2019 was partially offset by a decrease in co-development billings related to the development of roxadustat as a result of the substantial completion of Phase 3 trials for roxadustat.

Development revenue recognized under our collaboration agreements with AstraZeneca decreased $20.3 million, or 19% for the year ended December 31, 2019 compared to the year ended December 31, 2018, primarily due to a decrease in co-development billings related to the development of roxadustat as a result of the substantial completion of Phase 3 trials for roxadustat. The decrease was partially offset by the allocated revenue of $9.3 million related to the above-mentioned $50.0 million associated with the regulatory milestone of the NDA submission in the U.S., and the allocated revenue of $4.1 million related to the above-mentioned regulatory milestones totaling $22.0 million associated with roxadustat being included on the updated NRDL released by China's NHSA.

Product Revenue

	Years Ended December 31,		Change 2019 vs. 2018	
	2019	2018	$	%
	(dollars in thousands)			
Product revenue, net:				
API product	$ (36,324)	$ 64,776	$ (101,100)	(156) %
Drug product				
Gross revenue	2,803	—	2,803	— %
Price adjustment	(936)	—	(936)	— %
Sales rebates and other discounts	(167)	—	(167)	— %
Drug product revenue, net	1,700	—	1,700	— %
Total product revenue, net	$ (34,624)	$ 64,776	$ (99,400)	(153) %

Product revenue of $64.8 million for the year ended December 31, 2018 represented the sales of commercial-grade API to Astellas to conduct commercial scale manufacturing validation for roxadustat drug product in anticipation of commercial launch in Japan. The product revenue was recorded in 2018 based on an estimated transaction price after we evaluated the latest available facts and circumstances, and was subject to potential future adjustments. A change in estimated variable consideration resulted in a $36.3 million reduction to revenue, at the time the listed price for roxadustat was issued by the Japanese Ministry of Health, Labour and Welfare, which reflected the total difference between estimated and actual listed price and yield from the manufacture of bulk product tablets.

In addition, we started commercial sales of roxadustat drug product in China in the third quarter of 2019. Drug product revenue is recognized in an amount that reflects the consideration to which we expect to be entitled in exchange for those products, net of price adjustment, contractual sales rebate and other discounts. For the year ended December 31, 2019, upon roxadustat being included on the NRDL in December 2019, we recorded $0.9 million of price adjustment based on government-listed price guidance and estimated channel inventory levels. The contractual sales rebate and other discounts were immaterial for the year ended December 31, 2019.

Operating Expenses

	Years Ended December 31,			Change 2019 vs. 2018	
	2019	2018	2017	$	%
			(dollars in thousands)		
Operating costs and expenses					
Cost of goods sold	$ 1,147	$ —	$ —	$ 1,147	100 %
Research and development	209,265	235,839	196,517	(26,574)	(11) %
Selling, general and administrative	135,479	63,812	51,760	71,667	112 %
Total operating costs and expenses	$ 345,891	$ 299,651	$ 248,277	$ 46,240	15 %

Total operating expenses increased $46.2 million, or 15%, for the year ended December 31, 2019 compared to the year ended December 31, 2018, for the reasons discussed in the sections below.

Cost of goods sold

We started commercial sales of roxadustat drug product in China in the third quarter of 2019. The associated cost of goods sold was $1.1 million for the year ended December 31, 2019.

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 costs 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. Research and development costs are expensed as incurred. Costs for certain development activities are recognized 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.

The following table summarizes our research and development expenses incurred during the years ended December 31, 2019, 2018 and 2017:

Product Candidate	Phase of Development	Years Ended December 31, 2019	2018	2017
			(in thousands)	
Roxadustat	Phase 3	$ 125,429	$ 139,876	$ 125,144
Pamrevlumab	Phase 2/3	58,750	72,063	52,260
FG-5200	Preclinical	5,323	5,122	4,628
Other research and development expenses		19,763	18,778	14,485
Total research and development expenses		$ 209,265	$ 235,839	$ 196,517

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. We expect our research and development expenses to increase in the future as we advance our product candidates through clinical trials and expand our product candidate portfolio. We expect development expenses to increase as we continue Phase 3 trials for pamrevlumab.

Research and development expenses decreased $26.6 million, or 11%, for the year ended December 31, 2019 compared to the year ended December 31, 2018. The decrease was primarily due to decreases in drug development expenses of $29.8 million, clinical trials costs of $20.7 million, and $6.8 million of capitalization of inventory manufacturing costs. The decreases were partially offset by increases in allocated facility related expense of $11.9 million, stock-based compensation expense of $10.5 million, outside services of $7.3 million, and licenses and permits fees of $2.9 million.

Drug development expenses decreased primarily due to lower drug substance manufacturing activities related to pamrevlumab, partially offset by higher activities for roxadustat in its global program. Clinical trial costs decreased as a result of the substantial completion of Phase 3 trials for roxadustat, partially offset by the increases resulted from Phase 3 trials for pamrevlumab and preparation work related to NDA submission in the U.S. Facility related expenses, as part of the allocated overhead costs, was higher due to increase in depreciation expenses related to China facilities, the amortization of finance lease ROU assets related to the adoption of ASC 842, and higher depreciation expenses primarily related to the change estimated useful life for our leasehold improvements, from the building life to the shorter of the building life and remaining lease term, as a result of the adoption of ASC 842. Stock-based compensation expense increased due to the cumulative impact of stock option grant activities. Outside services costs increased due to higher scientific contract work related to roxadustat submission activities, higher medical affairs expenses for roxadustat in China and higher consulting expenses related to pamrevlumab. Licenses and permits fees increased related to the Prescription Drug User Fee incurred for NDA submission to the FDA.

Selling, General and Administrative Expenses

We started to incur sales and marketing expenses in the first quarter of 2019 in China to prepare for commercial operations. 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, recruiting fees and expenses associated with obtaining and maintaining patents.

We anticipate that our SG&A expenses will increase in the future as we increase co-promotional expenses for roxadustat and our headcount to support potential commercialization of our product candidates. We also anticipate increased expenses, including exchange listing and SEC requirements, director and officer insurance premiums, legal, audit and tax fees, and regulatory compliance programs associated with being a public company. Additionally, we anticipate an increase in payroll and related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

SG&A expenses increased $71.1 million, or 112%, for the year ended December 31, 2019 compared to the year ended December 31, 2018, primarily due to increases in outside service expenses of $54.1 million, employee-related costs of $5.1 million, legal expense of $4.7 million, stock-based compensation expense of $3.6 million, and facility related expenses of $2.9 million,

Outside service expenses increased due to the recognition of our share of co-promotional expenses incurred with AstraZeneca sales and marketing efforts related to the commercial launch of roxadustat in China, and licensing agreement fees associated with pamrevlumab. Employee-related costs increased due to higher headcount primarily in the sales and marketing functions in China. Legal expenses increased mainly associated with patent-related and international activities. Stock-based compensation expense increased due to cumulative impact of stock option grant activities, partially offset by the cancellation of our founding chief executive officer's unvested options upon his passing during the year. Facility related expenses, as part of the allocated overhead costs, was higher due to the amortization of finance lease ROU assets related to the adoption of ASC 842, and higher depreciation expenses primarily related to the change estimated useful life for our leasehold improvements, from the building life to the shorter of the building life and remaining lease term, as a result of the adoption of ASC 842.

Interest and Other, Net

	Years Ended December 31,			Change 2019 vs. 2018	
	2019	2018	2017	$	%
	(dollars in thousands)				
Interest and other, net:					
Interest expense	$ (2,876)	$ (10,991)	$ (9,706)	$ 8,115	(74) %
Interest income and other, net	15,548	11,568	6,433	3,980	34 %
Total interest and other, net	$ 12,672	$ 577	$ (3,273)	$ 12,095	2,096 %

Interest Expense

Before December 31, 2018, interest expense included payments made for imputed interest related to the facility lease financing obligations for our leased facilities in San Francisco and China. After adoption of ASC 842 as of January 1, 2019, the 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 decreased $8.1 million, or 74%, for the year ended December 31, 2019 compared to the year ended December 31, 2018 due to the different method of interest computation of interest expense under the old and new lease accounting rules.

Interest Income and Other, Net

Interest income and other, 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.

Interest income and other, net increased $4.0 million, or 34%, for the year ended December 31, 2019 compared to the year ended December 31, 2018, primarily due to $3.9 million higher interest earned on our cash, cash equivalents and investments associated with the higher average balances and $1.2 million higher net unrealized gain on our marketable equity investments, partially offset by $1.2 million related to a one-time realized foreign currency gain during the prior year.

Provision for Income Taxes

	Years Ended December 31,		
	2019	2018	2017
	(dollars in thousands)		
Loss before income taxes	$ (76,642)	$ (86,116)	$ (120,554)
Provision for income taxes	328	304	321
Effective tax rate	(0.4)%	(0.4)%	(0.3)%

The provisions for income taxes for the years end December 31, 2019 and 2018 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 will continue to maintain a full valuation allowance on our net deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of this allowance.

SELECTED QUARTERLY FINANCIAL DATA

The following tables present unaudited quarterly results for 2019 and 2018. These tables include all adjustments, consisting only of normal recurring adjustments that we consider for the fair statement of our consolidated financial position and operating results for the quarters presented. Payments from our collaboration partners have caused, and are likely to continue to cause, fluctuations in our quarterly results. These unaudited quarterly results of operations should be read in conjunction with the consolidated financial statements and notes included in Item 8 of this Annual Report on Form 10-K. We have prepared the unaudited information on the same basis as our audited consolidated financial statements. Our operating results for any quarter are not necessarily indicative of results for any future quarters or for a full year.

	2019			
	Fourth Quarter	Third Quarter	Second Quarter	First Quarter
	(in thousands, except for per share data)			
Revenue (1)	$ 7,974	$ 33,174	$ 191,566	$ 23,863
Operating expenses (2)	108,410	86,028	78,747	72,706
Net income (loss)	(98,123)	(49,439)	116,003	(45,411)
Net income (loss) per share (4):				
Basic	(1.12)	(0.57)	1.34	(0.53)
Diluted	$ (1.12)	$ (0.57)	$ 1.26	$ (0.53)

	2018			
	Fourth Quarter	Third Quarter	Second Quarter	First Quarter
	(in thousands, except for per share data)			
Revenue (3)	$ 108,054	$ 29,027	$ 43,952	$ 31,925
Operating expenses	88,135	71,799	67,193	72,524
Net income (loss)	20,952	(42,556)	(23,420)	(41,396)
Net income (loss) per share (4):				
Basic	0.25	(0.50)	(0.28)	(0.50)
Diluted	$ 0.23	$ (0.50)	$ (0.28)	$ (0.50)

(1) Revenue for the second quarter of 2019 was significantly higher compared to other quarters primarily due to the revenue recognized related to three milestone payments. Revenue for the fourth quarter of 2019 was significantly lower compared to other quarters primarily due to the change in estimated variable consideration related to the API product revenue.

(2) Operating expenses for the fourth quarter of 2019 was significantly higher compared to other quarters primarily due to the recognition of our share of co-promotional expenses incurred with AstraZeneca for sales and marketing efforts related to the commercial launch of roxadustat in China, and permit fees for NDA filing to the FDA.

(3) Revenue for the fourth quarter of 2018 was significantly higher compared to other quarters due to the API product revenue recognized, and revenue recognized on two milestone payments.

(4) Basic and diluted net income (loss) per share is computed independently for each of the quarters presented. Therefore, the sum of quarterly basic and diluted net income (loss) per share may not equal annual basic and diluted net income (loss) per share.

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, 2019, we had cash and cash equivalents of $126.3 million. Cash is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting of available-for-sale debt investments, marketable equity investments, term deposit and certificate of deposit, and stated at fair value, are also available as a source of liquidity. As of December 31, 2019 we had short-term and long-term investments of $407.5 million and $61.1 million, respectively. As of December 31, 2019, a total of $11.9 million of our cash and cash equivalents was held outside of the U.S. in our foreign subsidiaries to be used primarily for our China operations.

Operating Capital Requirements

In the third quarter of 2019, we started generating revenue from commercial sales of roxadustat drug product in China. Even with the expectation of increases in revenue from drug product sales, we anticipate that we will continue to generate losses for the foreseeable future. We expect increase in our operating expenses as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. To date, we have funded certain portions of our research and development and manufacturing efforts in China and Europe through outside parties. There is no guarantee that sufficient funds will be available to continue to fund these development efforts through commercialization or otherwise. Although our share of expenses for roxadustat will decrease as a result of AstraZeneca funding all non-China collaboration expenses not reimbursed by Astellas, we expect our research and development expenses to continue to increase as we invest in our other programs. We are 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. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We may not be able to secure additional financing to meet our operating requirements on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, the ownership of our existing stockholders will be diluted. If we raise additional financing by the incurrence of indebtedness, we will be subject to increased fixed payment obligations and could also be subject to restrictive covenants, such as limitations on our ability to incur additional debt, and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to obtain needed additional funds, we will have to reduce our operating costs and expenses, which would impair our growth prospects and could otherwise negatively impact our business.

We believe that our existing cash and cash equivalents, short-term and long-term investments and accounts receivable will be sufficient to meet our anticipated cash requirements for at least the next 12 months from the filing date of this Annual Report on Form 10-K. However, our liquidity assumptions may change over time, and we could utilize our available financial resources sooner than we currently expect. In addition, we may elect to raise additional funds at any time through equity, equity-linked or debt financing arrangements. 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. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. 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 Fact*ors” in this Annual Report on Form 10-K. We may not be able to secure additional financing to meet our operating requirements on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, the ownership of our existing stockholders will be diluted. If we raise additional financing by the incurrence of indebtedness, we will be subject to increased fixed payment obligations and could also be subject to restrictive covenants, such as limitations on our ability to incur additional debt, and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to obtain needed additional funds, we will have to reduce our operating costs and expenses, which would impair our growth prospects and could otherwise negatively impact our business.

Cash Sources and Uses

The following table summarizes the primary sources and uses of cash for the years ended December 31, 2019, 2018 and 2017:

	Years Ended December 31,		
	2019	2018	2017
	(in thousands)		
Net cash provided by (used in):			
Operating activities	$ (78,705)	$ (76,144)	$ (66,513)
Investing activities	120,018	(522,123)	69,866
Financing activities	(4,300)	13,875	496,472
Effect of exchange rate changes on cash and cash equivalents	(5)	(8)	51
Net increase (decrease) in cash and cash equivalents	$ 37,008	$ (584,400)	$ 499,876

Operating Activities

Net cash used in operating activities was $78.7 million for the year ended December 31, 2019 and consisted primarily of net loss of $77.0 million adjusted for non-cash items of $83.9 million and a net decrease in operating assets and liabilities of $85.7 million. The significant non-cash items included stock-based compensation expense of $66.3 million, depreciation expense of $11.1 million, amortization of finance lease ROU of $10.3 million, and net amortization of premium and discount on investments of $3.7 million. The significant items in the changes in operating assets and liabilities included decreases resulting from prepaid expenses and other current assets of $128.6 million, deferred revenue of $49.9 million, inventories of $6.9 million, other assets of $3.3 million, and accounts payable of $3.1 million, partially offset by increases resulting from other long-term liabilities of $52.4 million, accounts receivable of $35.2 million, and accrued and other liabilities of $18.3 million. The changes in prepaid expenses and other current assets and deferred revenue were primarily driven by a $130.0 million unbilled contract asset related to regulatory milestones under the Europe Agreement with Astellas associated with the planned MAA submission in Europe and a $50.0 million contract asset related to a regulatory milestone under the U.S./RoW Agreement with AstraZeneca associated with the NDA submission in the U.S., which were not billable to Astellas or AstraZeneca as of December 31, 2019, net of the associated deferred revenues of $4.8 million and $50.0 million, respectively. The change in deferred revenue was also related to the recognition of revenues under our collaboration agreements with Astellas and AstraZeneca. The change in inventories was due to the capitalization of inventory costs starting in June 2019 when FibroGen Beijing began productions of roxadustat for commercial sales purposes. The change in other assets was primarily related to the net accumulation of input value added tax by FibroGen Beijing. The changes in accounts payable, and accrued and other liabilities were primarily driven by the timing of invoicing and payments. The change in accrued and other liabilities was also driven by accrued $36.3 million related to the change in estimated variable consideration associated with the roxadustat API. The change in other long-term liabilities was primarily due to the accrual of co-promotional expenses with AstraZeneca for sales and marketing efforts related to the commercial launch of roxadustat in China that are not expected to be paid in the next year. The change in accounts receivable was primarily related to the collection of $43.9 million from Astellas for the API delivery in December 2018 under the Japan Amendment, as well as the timing of the receipt of upfront payments and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca.

Net cash used in operating activities was $76.1 million for the year ended December 31, 2018 and consisted primarily of net loss of $86.4 million adjusted for non-cash items of $58.7 million and a net decrease in operating assets and liabilities of $48.4 million. The significant non-cash items included stock-based compensation expense of $52.1 million, depreciation expense of $6.6 million, unrealized loss on our marketable equity investments of $1.1 million and realized foreign currency gain of $1.1 million. The significant items in the changes in operating assets and liabilities included decreases resulting from accounts receivable of $55.2 million and deferred revenue of $5.0 million, partially offset by increases resulting from accrued liabilities of $5.6 million, accounts payable of $3.6 million, other long-term liabilities of $1.6 million and other assets of $1.1 million. The change in accounts receivable was primarily related to the delivery of $43.9 million roxadustat API to Astellas in December 2018 under the Japan Amendment, as well as the timing of the receipt of payments and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca. The change in deferred revenue was related to the recognition of revenues under our collaboration agreements with Astellas and AstraZeneca. The changes in accrued liabilities, accounts payable and other long-term liabilities were primarily driven by the timing of invoicing and payments. The change in other assets was primarily related to a cash refund for value added tax received by FibroGen Beijing during the third quarter of 2018.

Investing Activities

Investing activities primarily consist of purchases of property and equipment, purchases of investments, and proceeds from the maturity and sale of investments.

Net cash provided by investing activities was $120.0 million for the year ended December 31, 2019 and consisted of proceeds from maturities of investments of $537.1 million, partially offset by cash used in purchases of available-for-sale securities and term deposit of $411.3 million, and purchases of property and equipment of $5.8 million.

Net cash used in investing activities was $522.1 million for the year ended December 31, 2018 and consisted of cash used in purchases of available-for-sale securities and term deposit of $576.9 million, and purchases of property and equipment of $8.0 million, partially offset by proceeds from maturities of investments of $54.4 million and sales of available-for-sale securities of $8.2 million.

Financing Activities

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

Net cash used in financing activities was $4.3 million for the year ended December 31, 2019 and consisted primarily of $12.8 million of cash paid for payroll taxes on restricted stock unit releases, $11.9 million of repayments of finance lease liabilities, and $0.4 million of repayments on our lease obligations, partially offset by $20.8 million of proceeds from the issuance of common stock upon exercise of stock options and purchases under ESPP.

Net cash provided by financing activities was $13.9 million for the year ended December 31, 2018 and consisted primarily of $29.8 million of proceeds from the issuance of common stock upon exercise of stock options and purchases under ESPP, partially offset by $15.6 million of cash paid for payroll taxes on restricted stock unit releases, and $0.4 million of repayments on our lease liability.

Off-Balance Sheet Arrangements

During the year ended December 31, 2019, 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

In the ordinary course of business, we provide indemnifications of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters, including, but not limited to, losses arising out of breach of such agreements, solutions to be provided by us or from intellectual property infringement claims made by third parties. In addition, we have entered into indemnification agreements with directors and certain officers and employees that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors, officers or employees.

Contractual Obligations and Commitments

Contractual Obligations

At December 31, 2019, our contractual obligations were as follows:

	Payments Due In				
	Less Than 1 Year	1 - 3 Years	3 - 5 Years	More Than 5 Years	Total
	(in thousands)				
Operating lease liabilities	$ 1,043	$ 975	$ —	$ —	$ 2,018
Finance lease liabilities	14,078	27,554	12,523	—	54,155
Total contractual obligations	$ 15,121	$ 28,529	$ 12,523	$ —	$ 56,173

The contractual obligations table excludes uncertain tax benefits of approximately $31.8 million that are disclosed in Note 12 to the consolidated financial statements because these uncertain tax positions, if recognized, would be an adjustment to the deferred tax assets.

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. Future milestone payments for research and pre-clinical stage development programs consisted of up to $11.0 million in total potential future milestone payments under our license agreements with Dana-Farber Cancer Institute, University of Miami and Medarex, Inc. These milestone payments generally become due and payable only upon the achievement of certain developmental, clinical, regulatory and/or commercial milestones. These contingent payments have not been included in the above table as the event triggering such payment or obligation has not yet occurred.

Clinical Trials

As of December 31, 2019, 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 cancellable, we have historically not cancelled such contracts.

Product Development Obligations

As of December 31, 2019, our FibroGen Europe Oy (“FibroGen Europe”) subsidiary had $10.6 million of principal outstanding and $6.2 million of interest accrued related to the TEKES loans, respectively, which have been included as product development obligations on our consolidated balance sheet.

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 for at least the next five years. 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.

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 currently active legal action in our consolidated balance sheets as of December 31, 2019 and 2018, as we could not predict the ultimate outcome of these matters, or reasonably estimate the potential exposure.

Recently Issued and Adopted Accounting Guidance

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). Under this guidance, an entity is required to recognize ROU assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. This guidance offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements* ("ASU 2018-11"), which provides entities the option to initially apply ASU 2016-02 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. We adopted the above guidance under ASC 842 as of January 1, 2019, using the modified retrospective transition method, through a cumulative-effect adjustment at the beginning of the first quarter of 2019. We elected the optional transition method under the guidance, which allowed it to continue applying previous lease guidance (ASC 840) for the comparative prior year periods presentation in the year of adoption. Accordingly, we recognized a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. In addition, we elected the package of transitional practical expedients permitted under the transition guidance under ASC 842, which among other things allows us to carry forward its historical lease classification, and not to reassess initial direct costs for any existing leases. Meanwhile, we did not elect the hindsight practical expedient because it has limited number of leases, lease terms are straightforward, and most of its lease renewals are undefined until negotiated. In addition, we have elected the short term accounting policy practical expedient and does not apply the balance sheet recognition requirements for short-term leases (excluding expenses relating to leases with a lease term of one month or less), by class of underlying asset to which the right of use relates. We have not elected the non-lease components practical expedient, and therefore accounts for each lease component separately from the non-lease components. Upon adoption of ASC 842, we classified our existing building leases that were previously accounted for as build-to-suit arrangements as finance leases, and applied the transition guidance. Accordingly, we derecognized the assets and liabilities previously recognized under ASC 840 build-to-suit guidance. In addition, as a result of applying the transition guidance, we also recorded an adjustment to the accumulated depreciation of related leasehold improvements to reflect a change in estimated useful life from the building life to the shorter of the building life and remaining lease term. Differences between the assets and liabilities derecognized were recorded to the opening balance of retained earnings. The adoption of ASC 842 resulted in a recognition of approximately $50.3 million in right-of-use assets and approximately $62.0 million in lease liabilities, respectively, upon adoption of this guidance, for our operating leases and finance leases. The adoption of this guidance did not have a material impact to our consolidated statement of operations or consolidated statement of cash flows for the year ended December 31, 2019. Refer to Note 2 to the consolidated financial statements for details.

In February 2018, the FASB issued ASU 2018-02, *Income Statement - Reporting Comprehensive Income: Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*. This guidance allows for the reclassification from accumulated other comprehensive income to retained earnings for the stranded tax effects arising from the reduction of the U.S. federal statutory income tax rate from 35% to 21%. This guidance was effective for annual reporting periods beginning after December 15, 2018, including interim periods. We adopted this guidance on January 1, 2019 using the modified retrospective approach, which resulted in a reclassification of $0.6 million, based on the aggregate portfolio approach, from accumulated other comprehensive loss to opening accumulated deficit. The adoption of this guidance had no impact to our consolidated statement of operations or consolidated statement of cash flows for the year ended December 31, 2019. Refer to Note 2 to the consolidated financial statements for details.

In June 2018, the FASB issued ASU 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.* This guidance expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance also specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. This guidance is effective for annual reporting period beginning after December 15, 2018, including interim periods. We adopted this guidance on January 1, 2019 and the adoption of this guidance had no impact to our 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

Substantially all of our revenues to date have been generated from our 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 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 our 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 details in Note 3 “Collaboration Agreements” to our consolidated financial statements.

For revenue recognition purposes, we determine that the term of our collaboration agreements begin on the effective date and ends 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 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 unless in exceptionally rare situations.

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; 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 our 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. Determining the amount of variable consideration from co-development billings requires 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. Milestone payments 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, we have not recognized any royalty revenue resulting from our collaboration arrangements.

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 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 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 is recognized over time based on progress toward complete satisfaction of the performance obligation. We use an input method to measure progress toward the satisfaction of co-development services and certain other related performance obligations, 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. We believe this measure of progress provides a faithful depiction of the transfer of services because other measures do not measure as accurately how we transfer our performance obligations to our collaboration partners.

During 2019, we started selling roxadustat in China through a number of pharmaceutical distributors located in China. 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. Product revenue is recognized when control of the promised good is transferred to the customer in an amount that reflects the consideration to which we expect to be entitled in exchange for the product.

The period between the transfer control of promised goods and when we receive payment is based on a general 60-day payment term. As such, product revenue is not adjusted for the effects of a significant financing component. We establish a bad debt allowance based on our judgment to consider factors such as the age of the receivables. Bad debt expense is included in selling, general and administrative expenses on the consolidated statements of operations. There was no bad debt allowance provided as of December 31, 2019.

Product drug revenue is recorded at the net sales prices (transaction price) which includes the following estimates of variable consideration:

- Price adjustment: In December 2019, China's NHSA released price guidance for roxadustat under NRDL, effective January 1, 2020. Any channel inventories as of January 1, 2020 that had not been sold to hospitals by distributors, or to patients by hospitals, were eligible for a price adjustment under the price protection. The price adjustment is calculated based on estimated channel inventory levels at January 1, 2020. If price guidance changes in the future, the price adjustment will be calculated in the same manner;
- 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 accrued at the point of sale to the distributor, and applied to future sales orders made by the distributor under our discretion;
- Key account hospital sales rebate: An additional sales rebate is provided to a distributor for product sold to key account hospitals as a percentage of gross sales made by the distributor to eligible hospitals. This additional rebate is accrued at the point of sale to the distributor and applied to future sales orders made by the distributor under our discretion;
- Transfer fee discount: The transfer fee discount is offered to a distributor who has its downstream distributors supply to eligible hospitals. This discount is calculated based on a percentage of gross sales made to the downstream distributors, and accrued at the point of sale to the distributor;

- Sales return: Distributors can request to return product to us only due to quality issues and for product within one year of its expiration date. We, at our sole discretion, decide whether to accept such return request. The sales return allowance provided as of December 31, 2019 was immaterial; and
- 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 meets the sales volume and timing requirements. The non-key account hospital listing award is accrued when the distributor meets eligibility requirements, and applied against future sales orders made by the distributor. We consider this particular award to be a material right within the definitions of ASC 606 and therefore have treated it as a separate performance obligation.

The above allowances are recorded as reductions of the gross accounts receivable from the distributor in the same period that the related revenue is recorded, with the exception of the non-key account hospital listing award, which is accrued when the distributor meets the eligibility requirements. The calculation of such allowances are 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 substantial degree of judgment.

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. The functional currency of our FibroGen Europe Oy subsidiary is the local currency. Most of our revenue from collaboration agreements are denominated in U.S. dollars, and therefore our revenue is not currently subject to significant foreign currency risk. Our operating expenses are denominated in the currencies of the countries in which our operations are located, which are primarily in the United States, China, and Europe. Our consolidated results of operations and cash flows are, therefore, 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, 2019, our financial assets and liabilities denominated in foreign currencies primarily included CNY14.3 million in cash and cash equivalent, CNY48.7 million in other current and long-term assets, and CNY434.1 million and EUR1.4 million in accounts payable, accrued liabilities and other long-term liabilities. These balances are subject to fluctuation in the exchange rate with the U.S. dollar. The effect of a hypothetical 10% change in foreign currency exchange rates would have resulted in a net gain or loss on foreign currency of approximately $5.5 million for the year ended December 31, 2019.

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 U.S. government treasury bills and notes. A portion of our investments is also invested in certificates of deposit and demand deposits with high quality and established banking institutions. Given the nature of our investments as of December 31, 2019, 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

The supplementary financial information required by this Item 8 is included in Item 7 under the caption “Quarterly Results of Operations”.

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, 2019 and 2018, and the related consolidated statements of operations, of comprehensive loss, of changes in stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 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, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

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.

Revenue Recognition - Estimated Variable Consideration Associated With Milestones Related to the United States New Drug Application (NDA) and the European Marketing Authorization Application (MAA) Submissions

As described in Notes 2 and 3 to the consolidated financial statements, milestone payments are considered variable consideration, which requires management to make estimates of when achievement of a particular milestone becomes probable. Milestone payments are included in the transaction price when it becomes probable that such inclusion would not result in a significant revenue reversal. Management evaluated the two regulatory milestone payments associated with the planned European MAA submission and the regulatory milestone payment associated with the acceptance by the United States Food and Drug Administration (FDA) of the NDA submission and concluded that these milestones became probable of being achieved in the second quarter of 2019. Accordingly, the total consideration of $180.0 million associated with these milestones was included in the transaction price and allocated to performance obligations under the related agreements, of which $171.2 million was recognized as revenue during the year ended December 31, 2019 from performance obligations satisfied or partially satisfied as of December 31, 2019.

The principal consideration for our determination that performing procedures relating to revenue recognition – estimated variable consideration associated with milestones related to the United States NDA submission and European MAA submission is a critical audit matter is there was significant judgment by management in determining that these milestones became probable of being achieved. This in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating audit evidence related to the judgments made by management.

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 the revenue recognition process, including the control over the milestone probability assessment performed by management. These procedures also included, among others, reading the collaboration agreements and testing management’s process for determining the acceptance of the United States NDA submission and the European MAA submission were probable.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 2, 2020

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

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

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 126,266	$ 89,258
Short-term investments	407,491	532,144
Accounts receivable, net ($4,845 and $47,210 from a related party)	28,455	63,684
Inventories	6,887	—
Prepaid expenses and other current assets ($125,210 and $0 from a related party)	133,391	4,929
Total current assets	702,490	690,015
Restricted time deposits	2,072	4,145
Long-term investments	61,118	55,820
Property and equipment, net	42,743	127,198
Finance lease right-of-use assets	39,602	—
Other assets	9,372	3,420
Total assets	$ 857,397	$ 880,598
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 6,088	$ 9,139
Accrued and other current liabilities ($36,883 and $444 to a related party)	83,816	66,123
Deferred revenue	490	13,771
Finance lease liabilities, current	12,351	—
Total current liabilities	102,745	89,033
Long-term portion of lease obligations	1,141	97,157
Product development obligations	16,780	16,798
Deferred rent	—	3,038
Deferred revenue, net of current	99,449	136,109
Finance lease liabilities, non-current	37,610	—
Other long-term liabilities	64,266	9,993
Total liabilities	321,991	352,128
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 125,000 shares authorized; no shares issued and outstanding at December 31, 2019 and December 31, 2018	—	—
Common stock, $0.01 par value; 225,000 shares authorized at December 31, 2019 and December 31, 2018; 87,657 and 85,432 shares issued and outstanding at December 31, 2019 and December 31, 2018	877	854
Additional paid-in capital	1,300,725	1,226,453
Accumulated other comprehensive loss	(747)	(2,281)
Accumulated deficit	(784,720)	(715,827)
Total stockholders' equity	516,135	509,199
Non-controlling interests	19,271	19,271
Total equity	535,406	528,470
Total liabilities, stockholders' equity and non-controlling interests	$ 857,397	$ 880,598

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,		
	2019	**2018**	**2017**
Revenue:			
License revenue (includes $129,405, $14,323 and $0 from a related party)	$ 177,086	$ 22,269	$ 9,933
Development and other revenue (includes $29,393, $20,903 and $20,111 from a related party)	114,115	125,913	121,063
Product revenue, net (includes $(36,324), $64,776 and $0 from a related party)	(34,624)	64,776	—
Total revenue	256,577	212,958	130,996
Operating costs and expenses:			
Cost of goods sold	1,147	—	—
Research and development	209,265	235,839	196,517
Selling, general and administrative	135,479	63,812	51,760
Total operating costs and expenses	345,891	299,651	248,277
Loss from operations	(89,314)	(86,693)	(117,281)
Interest and other, net			
Interest expense	(2,876)	(10,991)	(9,706)
Interest income and other, net	15,548	11,568	6,433
Total interest and other, net	12,672	577	(3,273)
Loss before income taxes	(76,642)	(86,116)	(120,554)
Provision for income taxes	328	304	321
Net loss	$ (76,970)	$ (86,420)	$ (120,875)
Net loss per share - basic and diluted	$ (0.89)	$ (1.03)	$ (1.66)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	86,633	84,062	72,987

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,		
	2019	2018	2017
Net loss	$ (76,970)	$ (86,420)	$ (120,875)
Other comprehensive income (loss):			
Foreign currency translation adjustments	331	771	(2,022)
Available-for-sale investments:			
Unrealized gain (loss) on investments, net of tax effect	592	(7)	1,259
Reclassification from accumulated other comprehensive loss	—	—	(72)
Net change in unrealized gain on available-for-sale investments	592	(7)	1,187
Other comprehensive income (loss), net of taxes	923	764	(835)
Comprehensive loss	$ (76,047)	$ (85,656)	$ (121,710)

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

FIBROGEN, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands, except share data)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Non Controlling	
	Shares	Amount	Capital	Loss	Deficit (Note 2)	Interests	Total
Balance at December 31, 2016	63,665,284	$ 637	$ 625,903	$ (960)	$ (509,782)	$ 19,271	$ 135,069
Net loss	—	—	—	—	(120,875)	—	(120,875)
Change in unrealized gain or loss on investments	—	—	—	1,187	—	—	1,187
Foreign currency translation adjustments	—	—	—	(2,022)	—	—	(2,022)
Follow-on Offerings, net of underwriting discounts, commission and issuance costs	14,428,750	144	470,082	—	—	—	470,226
Shares issued from stock plans, net of payroll taxes paid	4,404,094	44	26,570	—	—	—	26,614
Stock-based compensation	—	—	37,539	—	—	—	37,539
Balance at December 31, 2017	82,498,128	825	1,160,094	(1,795)	(630,657)	19,271	547,738
Impact of change in accounting principle upon adoption of ASU 2016-01 **(Note 2)**	—	—	—	(1,250)	1,250	—	—
Net loss	—	—	—	—	(86,420)	—	(86,420)
Change in unrealized gain or loss on investments	—	—	—	(7)	—	—	(7)
Foreign currency translation adjustments	—	—	—	771	—	—	771
Adjustment to issuance costs for Follow-on Offerings	—	—	11	—	—	—	11
Shares issued from stock plans, net of payroll taxes paid	2,933,974	29	14,206	—	—	—	14,235
Stock-based compensation	—	—	52,142	—	—	—	52,142
Balance at December 31, 2018	85,432,102	854	1,226,453	(2,281)	(715,827)	19,271	528,470
Impact of adoption of ASC 842 **(Note 2)**	—	—	—	—	8,688	—	8,688
Impact of change in accounting principle upon adoption of ASU 2018-02 **(Note 2)**	—	—	—	611	(611)	—	—
Net loss	—	—	—	—	(76,970)	—	(76,970)
Change in unrealized gain or loss on investments	—	—	—	592	—	—	592
Foreign currency translation adjustments	—	—	—	331	—	—	331
Shares issued from stock plans, net of payroll taxes paid	2,220,957	23	7,939	—	—	—	7,962
Warrants exercised	4,430	—	66	—	—	—	66
Stock-based compensation	—	—	66,267	—	—	—	66,267
Balance at December 31, 2019	87,657,489	$ 877	$ 1,300,725	$ (747)	$ (784,720)	$ 19,271	$ 535,406

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,		
	2019	2018	2017
Operating activities			
Net loss	$ (76,970)	$ (86,420)	$ (120,875)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	11,147	6,562	6,099
Amortization of finance lease right-of-use assets	10,307	—	—
Net amortization (accretion) of premium (discount) on investments	(3,667)	(42)	1,844
Unrealized loss (gain) on cash equivalents and short-term equity investments	(88)	1,120	2
Loss (gain) on disposal of property and equipment	(42)	53	3
Stock-based compensation	66,267	52,142	37,539
Realized foreign currency gain	—	(1,074)	—
Realized gain on sales of available-for-sale securities	—	(87)	(143)
Changes in operating assets and liabilities:			
Accounts receivable, net ($42,365, $(43,486) and $98 from a related party)	35,229	(55,232)	1,996
Inventories	(6,887)	—	—
Prepaid expenses and other current assets ($(125,210), $0 and $0 from a related party)	(128,598)	(129)	(1,911)
Other assets	(3,253)	1,090	(2,365)
Accounts payable	(3,051)	3,630	(714)
Accrued and other liabilities ($36,439, $172 and $(1,343) from a related party)	18,288	5,606	9,196
Deferred revenue	(49,941)	(5,031)	174
Lease obligations	—	32	1,023
Accrued interest for finance lease liabilities	194	—	—
Other long-term liabilities	52,360	1,636	1,619
Net cash used in operating activities	(78,705)	(76,144)	(66,513)
Investing activities			
Purchases of property and equipment	(5,762)	(8,020)	(8,500)
Proceeds from sale of property and equipment	7	184	5
Purchases of available-for-sale securities and term deposit	(411,299)	(576,880)	(169)
Proceeds from sales of available-for-sale securities	—	8,167	21,109
Proceeds from maturities of investments	537,072	54,426	57,421
Net cash provided by (used in) investing activities	120,018	(522,123)	69,866
Financing activities			
Borrowings under capital lease obligations	—	49	—
Repayments of capital lease obligations	—	(6)	—
Repayments of finance lease liabilities	(11,925)	—	—
Repayments of lease obligations	(403)	(403)	(403)
Proceeds from follow-on offerings, net of underwriting discounts and commission costs	—	—	471,205
Cash paid for payroll taxes on restricted stock unit releases	(12,750)	(15,612)	(8,296)
Proceeds from issuance of common stock	20,778	29,847	34,910
Payments of deferred offering costs	—	—	(944)
Net cash provided by (used in) financing activities	(4,300)	13,875	496,472
Effect of exchange rate change on cash and cash equivalents	(5)	(8)	51
Net increase (decrease) in cash and cash equivalents	37,008	(584,400)	499,876
Total cash and cash equivalents at beginning of period	89,258	673,658	173,782
Total cash and cash equivalents at end of period	$ 126,266	$ 89,258	$ 673,658
Supplemental cash flow information:			
Interest payments	$ 174	$ 218	$ 255
Balance in accounts payable and accrued liabilities related to purchases of property and equipment	460	276	3,781
Deferred offering costs recorded in accounts payable and accrued liabilities	$ —	$ 24	$ 35

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

1. The Company

FibroGen, Inc. ("FibroGen" or the "Company") was incorporated in 1993 in Delaware and are 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"), connective tissue growth factor ("CTGF") biology, and clinical development to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer. Roxadustat, FibroGen's most advanced product, is an oral small molecule inhibitor of HIF prolyl hydroxylase ("HIF-PH") activity that has received marketing authorization in China for the treatment of anemia caused by chronic kidney disease ("CKD") in dialysis and non-dialysis patients. In September 2019, roxadustat (Evrenzo®) was approved in Japan for the treatment of anemia associated with CKD in dialysis-dependent patients. In January 2020, Astellas Pharma Inc. ("Astellas") submitted a supplemental New Drug Application ("NDA") in Japan for the treatment of anemia in non-dialysis CKD patients. The Company's U.S. NDA filing for roxadustat for the treatment of anemia patients with dialysis-dependent CKD and non-dialysis-dependent CKD was accepted by the U.S. Food and Drug Administration ("FDA") in February, 2020, and Astellas is in the process of preparing a Marketing Authorization Application ("MAA") for submission to the European Medicines Agency ("EMA") in the second quarter of 2020 for the same indications. Roxadustat is in Phase 3 clinical development in the U.S. and Europe and in Phase 2/3 development in China for anemia associated with myelodysplastic syndromes ("MDS"). Roxadustat is in Phase 2 clinical development for chemotherapy-induced anemia. Pamrevlumab, an anti-CTGF human monoclonal antibody, is in Phase 3 clinical development for the treatment of both idiopathic pulmonary fibrosis ("IPF") and pancreatic cancer. Pamrevlumab is also currently in a Phase 2 trial for Duchenne muscular dystrophy ("DMD").

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 United States of America ("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 China"). All inter-company transactions and balances have been eliminated in consolidation.

The Company operates in one segment — the discovery, development and commercialization of novel therapeutics to treat serious unmet medical needs.

Foreign Currency Translation

The reporting currency of the Company and its subsidiaries is the United States ("U.S.") dollar. The functional currency of FibroGen Europe is the Euro. The assets and liabilities of FibroGen Europe 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.

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. 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 and Other Risks and Uncertainties

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 US treasury instruments. Any remaining cash is deposited with major financial institutions in the U.S., Finland, 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,	
	2019	2018
Astellas Pharma Inc. (“Astellas”)—Related party	17%	74%
AstraZeneca AB (“AstraZeneca”)	81%	26%

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, rapid technological change, the results of clinical trials and the achievement of milestones, market acceptance of the Company’s product candidates, competition from other products and larger companies, protection of proprietary technology, strategic relationships and dependence on key individuals.

Cash, Cash Equivalents and Restricted Time Deposits

The Company considers all highly liquid investments with maturities of three months or less and that are used in the Company’s cash management activities 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 as of December 31, 2019 and 2018 totaled $2.1 million and $4.1 million, respectively. As of December 31, 2019 and 2018, a total of $11.9 million and $21.9 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, 2019, the Company’s investments consist of US treasuries, diversified bond funds, marketable equity investments, a term deposit and a certificate of deposit. 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) 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.

Fair Value of Financial Instruments

Carrying amounts of certain of the Company’s financial instruments including cash equivalents, investments, receivables, accounts payable and accrued liabilities approximate fair value (refer to Note 4).

Inventories

Inventories are stated at the lower of cost or net realizable value. The cost of inventories is determined using full absorption and standard costing, which approximates cost based on a first-in, first-out 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 inventories includes direct material cost, direct labor and manufacturing overhead. 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 reserve is recorded through a charge to cost of goods sold on the Company's consolidated statements of operations. The establishment of inventory valuation reserves, together with the calculation of the amount of such reserves, requires 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.

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.

The Company's building leases previously accounted for as build-to-suit arrangements prior to the adoption of Accounting Standards Codification ("ASC") 842 - *Leases* ("ASC 842") are accounted for as finance leases under the requirements of ASC 842.
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.

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 other assets, accrued and other current liabilities, and other long-term liabilities 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 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.

Revenue Recognition

Revenues under collaboration agreements

Substantially all of the Company's revenues to date have been generated from its 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." 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 details in Note 3 "Collaboration Agreements."

For revenue recognition purposes, the Company determines that the term of its collaboration agreements begin on the effective date and ends 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 unless in exceptionally rare situations.

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"); 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. Determining the amount of variable consideration from co-development billings requires the Company 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 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. Milestone payments 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, the Company has not recognized any royalty revenue resulting from its collaboration arrangements.

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."

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 is 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 co-development services and certain other related performance obligations, 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. The Company believes this measure of progress provides a faithful depiction of the transfer of services because other measures do not measure as accurately how the Company transfers its performance obligations to its collaboration partners.

API product revenue

Product revenue in 2018 consisted of sales of commercial-grade API used in support of pre-commercial validation work. In 2018, the Company recorded revenue from commercial-grade API sales to Astellas based on a transaction price that was subject to potential future adjustments, which represented a form of variable consideration. The Company evaluated the latest available facts and circumstances in 2018, including listed prices of comparable drug products in Japan and historical bulk drug product manufacturing yields and costs, to determine whether any adjustments to the estimated transaction price was necessary. As of December 31, 2018, no new facts or circumstances were available to warrant an adjustment to the estimated transaction price. With respect to these sales in 2018, a change in estimated variable consideration occurred in 2019 at the time the actual listed price for roxadustat was issued by the Japanese Ministry of Health, Labour and Welfare, which resulted in a total difference of $36.3 million between the estimated and the actual listed price and yield from the manufacture of bulk product tablets.

Drug product revenue, net

During 2019, the Company started selling roxadustat in China through a number of pharmaceutical distributors located in China. 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 to which the Company expects to be entitled in exchange for the product.

The period between the transfer control of promised goods and when the Company receives payment is based on a general 60-day payment term. As such, product revenue is not adjusted for the effects of a significant financing component. The Company established a bad debt allowance based on its judgment to consider factors such as the age of the receivables. Bad debt expense is included in selling, general and administrative expenses on the consolidated statements of operations. There was no bad debt allowance provided as of December 31, 2019.

Product drug revenue is recorded at the net sales prices (transaction price) which includes the following estimates of variable consideration:

- Price adjustment: In December 2019, China's NHSA released price guidance for roxadustat under NRDL, effective January 1, 2020. Any channel inventories as of January 1, 2020 that had not been sold to hospitals by distributors, or to patients by hospitals, were eligible for a price adjustment under the price protection. The price adjustment is calculated based on estimated channel inventory levels at January 1, 2020. If price guidance changes in the future, the price adjustment will be calculated in the same manner;
- 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 accrued at the point of sale to the distributor, and applied to future sales orders made by the distributor under the Company's discretion;
- Key account hospital sales rebate: An additional sales rebate is provided to a distributor for product sold to key account hospitals as a percentage of gross sales made by the distributor to eligible hospitals. This additional rebate is accrued at the point of sale to the distributor and applied to future sales orders made by the distributor under the Company's discretion;
- Transfer fee discount: The transfer fee discount is offered to a distributor who has its downstream distributors supply to eligible hospitals. This discount is calculated based on a percentage of gross sales made to the downstream distributors, and accrued at the point of sale to the distributor;
- Sales return: Distributors can request to return product to the Company only due to quality issues and for product within one year of its expiration date. The Company, at its sole discretion, decides whether to accept such return request. The sales return allowance provided as of December 31, 2019 was immaterial; and
- 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 meets the sales volume and timing requirements. The non-key account hospital listing award is accrued when the distributor meets eligibility requirements, and applied against future sales orders made by the distributor. The Company considers this particular award to be a material right within the definitions of ASC 606 and therefore have treated it as a separate performance obligation.

The above allowances are recorded as reductions of gross accounts receivable from the distributor in the same period that the related revenue is recorded, with the exception of the non-key account hospital listing award, which is accrued when the distributor meets the eligibility requirements. The calculation of such allowances are 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 substantial degree of judgment.

Research and Development Expenses

Research and development expenses consist of independent research and development costs and the gross amount of costs associated with work performed under collaboration agreements. Research and development costs include employee-related expenses, expenses incurred under agreements with clinical research organizations ("CROs"), 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, 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 also for deferred tax assets and liabilities, and any valuation allowances recorded against the Company's deferred tax assets. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent the Company believes that recovery is not likely, the Company must establish a valuation allowance.

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

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

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

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

Stock-Based Compensation

The Company maintains equity incentive plans under which incentive and nonqualified stock options are granted to employees and non-employee consultants. Compensation expense relating to non-employee stock options has not been material for all the periods presented.

The Company measures and recognizes compensation expense for all stock options and restricted stock units ("RSUs") 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 fair value is recognized as expense, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award, on a straight-line basis. 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. As such, the fair value of the unvested portion of the options granted to non-employees is re-measured each period. The resulting increase in value, if any, is recognized as expense during the period the related services are rendered on a straight-line basis. The determination of the grant date fair value of options using an option pricing 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.

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

ASC 842

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). Under this guidance, an entity is required to recognize ROU assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. This guidance offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements* ("ASU 2018-11"), which provides entities the option to initially apply ASU 2016-02 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption.

The Company adopted the above guidance under ASC 842 as of January 1, 2019, using the modified retrospective transition method, through a cumulative-effect adjustment at the beginning of the first quarter of 2019. The Company elected the optional transition method under the guidance, which allowed it to continue applying previous lease guidance (ASC 840) for the comparative prior year periods presentation in the year of adoption. Accordingly, the Company recognized a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption.

In addition, the Company elected the package of transitional practical expedients permitted under the transition guidance under ASC 842, which among other things allows the Company to carry forward its historical lease classification, and not to reassess initial direct costs for any existing leases. Meanwhile, the Company did not elect the hindsight practical expedient because it has a limited number of leases, lease terms are straightforward, and most of its lease renewals are undefined until negotiated.

In addition, the Company has elected the short-term accounting policy practical expedient and does not apply the balance sheet recognition requirements for short-term leases (excluding expenses relating to leases with a lease term of one month or less), by class of underlying asset to which the right of use relates. The Company has not elected the non-lease components practical expedient, and therefore accounts for each lease component separately from the non-lease components.

Upon adoption of ASC 842, the Company classified its existing building leases that were previously accounted for as build-to-suit arrangements as finance leases and applied the transition guidance. Accordingly, the Company derecognized the assets and liabilities previously recognized under ASC 840 build-to-suit guidance. In addition, as a result of applying the transition guidance, the Company also recorded an adjustment to the accumulated depreciation of related leasehold improvements to reflect a change in estimated useful life from the building life to the shorter of the building life and remaining lease term. Differences between the assets and liabilities derecognized were recorded to the opening balance of retained earnings.

The impacts to the select line items from the Company's consolidated balance sheet upon adoption of the ASC 842 guidance are as follows (in thousands):

Balance Sheet Line Item	Nature of Adjustment	New Lease Guidance Adoption Adjustment
Assets		
Property and equipment, net	Derecognition - build-to-suit lease assets - building shell, cost	$ (53,880)
	Derecognition - build-to-suit lease assets - building shell, accumulated depreciation	13,476
	Change of useful life - leasehold improvements, accumulated depreciation	(38,877)
Finance lease right-of-use assets	Recognition - finance lease ROU assets	49,597
Other assets	Recognition - operating lease ROU assets	730
Liabilities		
Accrued and other current liabilities	Derecognition - deferred rent, current	(619)
	Derecognition - build-to-suit lease liabilities, current	(545)
	Recognition - operating lease liabilities, current	404
Finance lease liabilities, current	Recognition - finance lease liabilities, current	11,499
Long-term portion of lease obligations	Derecognition - build-to-suit lease liabilities, non-current	(95,613)
Deferred rent	Derecognition - deferred rent, non-current	(3,038)
Finance lease liabilities, non-current	Recognition - finance lease liabilities, non-current	49,884
Other long-term liabilities	Recognition - operating lease liabilities, non-current	250
Stockholders' equity		
Accumulated deficit	Cumulative decrease to accumulated deficit	$ 8,688

The adoption of this guidance did not have a material impact to the Company's consolidated statement of operations or consolidated statement of cash flows for the year ended December 31, 2019.

ASU 2018-02

In February 2018, the FASB issued ASU 2018-02, *Income Statement - Reporting Comprehensive Income: Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*. This guidance allows for the reclassification from accumulated other comprehensive income to retained earnings for the stranded tax effects arising from the reduction of the U.S. federal statutory income tax rate from 35% to 21%. This guidance was effective for annual reporting periods beginning after December 15, 2018, including interim periods. The Company adopted this guidance on January 1, 2019 using the modified retrospective approach. The impacts, based on the aggregate portfolio approach, to the Company's accumulated other comprehensive loss and accumulated deficit upon adoption of this guidance are as follows (in thousands):

	Accumulated Other Comprehensive Loss	Accumulated Deficit
Balance at December 31, 2018	$ (2,281)	$ (715,827)
Impact of change in accounting principle upon adoption of ASU 2018-02	611	(611)
Opening balance as of January 1, 2019	$ (1,670)	$ (716,438)

The adoption of this guidance had no impact to the Company's consolidated statement of operations or consolidated statement of cash flows for the year ended December 31, 2019.

ASU 2018-07

In June 2018, the FASB issued ASU 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.* This guidance expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance also specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. This guidance was effective for annual reporting periods beginning after December 15, 2018, including interim periods. The Company adopted this guidance on January 1, 2019, and the adoption of this guidance had no impact to the Company's consolidated financial statements.

ASU 2016-01

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments-Overall (Subtopic 825-10)*. The Company adopted this guidance as of January 1, 2018 using the modified retrospective approach. The impacts to the Company's accumulated other comprehensive loss and accumulated deficit upon adoption of this guidance are as follows (in thousands):

	Accumulated Other Comprehensive Loss	Accumulated Deficit
Balance at December 31, 2017	$ (1,795)	$ (630,657)
Impact of change in accounting principle upon adoption of ASU 2016-01	(1,250)	1,250
Opening balance as of January 1, 2018	$ (3,045)	$ (629,407)

The adoption of this guidance had no impact to the Company's consolidated statement of cash flows for the year ended December 31, 2018.

Recently Issued Accounting Guidance Not Yet Adopted

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. This guidance simplifies the accounting for income taxes by clarifying and amending existing guidance related to the recognition of franchise tax, the evaluation of a step up in the tax basis of goodwill, and the effects of enacted changes in tax laws or rates in the effective tax rate computation, among other clarifications. This guidance is effective for annual reporting periods beginning after December 15, 2020 including interim periods, with early adoption permitted. The Company does not plan to early adopt this guidance and does not anticipate a material impact to its consolidated financial statements upon adoption of this guidance.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.* This guidance requires capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). This guidance should be applied either retrospectively or prospectively, and is effective for annual reporting periods beginning after December 15, 2019 including interim periods, with early adoption permitted. The Company will adopt this guidance on January 1, 2020 and does not anticipate a material impact to its consolidated financial statements upon adoption of this guidance.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. This guidance is intended to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. This guidance requires the measurement of financial assets with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. This guidance requires an impairment model, known as the current expected credit loss model, which is based on expected losses rather than incurred losses. Entities are required to carry an allowance for expected credit losses for financial assets, including most debt instruments (except those carried at fair value) and trade receivables. Available-for-sale debt securities are scoped out of this guidance. This guidance is effective for annual reporting periods beginning after December 15, 2019 including interim periods. The Company's investment portfolio primarily consists of U.S. Treasury bills and notes carried at fair value. Further, the Company's trade receivables do not have abnormally long terms and the Company has never written off trade receivables. Accordingly, the Company has concluded that the adoption of this guidance on January 1, 2020 will not have a material impact on the Company's consolidated financial statements.

3. Collaboration Agreements and Revenues

Astellas Agreements

Japan Agreement

In June 2005, the Company entered into a collaboration agreement with Astellas Pharma Inc. ("Astellas") for the development and commercialization (but not manufacture) of roxadustat for the treatment of anemia in Japan ("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 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 Japan Agreement also provides for tiered payments based on net sales of product (as defined) in the low 20% range after commercial launch. The aggregate amount of such consideration received through December 31, 2019 totals $90.1 million.

In September 2019, Japan's Ministry of Health, Labour and Welfare approved Evrenzo® (generic name: roxadustat; tradename Evrenzo® in Japan) for the treatment of anemia associated with CKD in dialysis patients. This approval triggered a $12.5 million milestone payable to the Company by Astellas under the Japan Agreement. Accordingly, the consideration of $12.5 million associated with this milestone was included in the transaction price and allocated to performance obligations under the Japan Agreement in the third quarter of 2019, substantially all of which was recognized as revenue during the year ended December 31, 2019 from performance obligations satisfied or partially satisfied.

During the second quarter of 2018, Astellas reported positive results from the final phase 3 CKD-dialysis trial of roxadustat in Japan, indicating that Astellas was ready to make an NDA submission for the treatment of anemia with roxadustat in CKD-dialysis patients in 2018. The Company evaluated the regulatory milestone payment associated with NDA submission in Japan based on variable consideration requirements under the current revenue standards and concluded that this milestone became probable of being achieved in the second quarter of 2018. Accordingly, the consideration of $15.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the Japan Agreement in the second quarter of 2018, substantially all of which was recognized as revenue during the year ended December 31, 2018 from performance obligations satisfied or partially satisfied.

On November 30, 2018, FibroGen and Astellas entered into an amendment to the Japan Agreement that will allow Astellas to manufacture roxadustat drug product for commercialization in Japan (the "Japan Amendment"). Under this amendment, FibroGen would continue to manufacture and deliver to Astellas roxadustat API. The commercial terms of the 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. This amendment obligates Astellas to purchase API from the Company, of which $20.9 million was delivered to Astellas in the second quarter of 2018 under a material transfer agreement to conduct commercial scale manufacturing validation for roxadustat drug product in anticipation of commercial launch in Japan. The remaining $43.9 million of API was delivered to Astellas in December 2018. The transaction price of such API product was adjusted in 2019 at the time the listed price for roxadustat was issued by the Japanese Ministry of Health, Labour and Welfare to reflect a total difference of $36.3 million between estimated and actual listed price and yield from the manufacture of bulk product tablets.

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 ("Europe Agreement"). Under the terms of the Europe Agreement, Astellas paid license fees and other upfront consideration totaling $320.0 million (such amounts were fully received as of February 2009). The 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), (ii) up to $335.0 million in milestone payments upon achievement of specified regulatory milestone events. Under the Europe Agreement, Astellas committed to fund 50% of joint development costs for Europe and North America, and all territory-specific costs. The Europe Agreement also provides for tiered payments based on net sales of product (as defined) in the low 20% range. The aggregate amount of such consideration received through December 31, 2019 totals $410.0 million.

During the second quarter of 2019, the Company received positive topline results from analyses of pooled major adverse cardiac event ("MACE") and MACE+ data from its Phase 3 trials evaluating roxadustat as a treatment for dialysis and non-dialysis CKD patients, enabling Astellas to prepare for an MAA submission to the EMA in the second quarter of 2020, following the Company's NDA submission to the FDA that was accepted for review in February 2020. The Company evaluated the two regulatory milestone payments associated with the planned MAA submission and concluded that these milestones became probable of being achieved in the second quarter of 2019. Accordingly, the total consideration of $130.0 million associated with these milestones was included in the transaction price and allocated to performance obligations under the Europe Agreement in the second quarter of 2019, of which $128.8 million was recognized as revenue during the year ended December 31, 2019 from performance obligations satisfied or partially satisfied. According to the Europe Agreement, these milestone payments are not billable to Astellas until the submission of an MAA, therefore this $130.0 million remained as an unbilled contract asset as of December 31, 2019.

In the fourth quarter of 2018, the Company's was engaged in the final stages of review with its partners over the proposed development of roxadustat for the treatment of chemotherapy induced anemia ("CIA"). AstraZeneca and Astellas approved the program in December 2018 and January 2019, respectively. Costs associated with the development of this indication are expected to be shared 50-50 between the Company's two partners. For revenue recognition purposes, the Company concluded that this new indication represents a modification to the Europe agreements and will be accounted for separately, meaning the development costs associated with the new indications are distinct from the original development costs. The development service period for roxadustat for the treatment of CIA under the Europe Agreement is estimated to continue through the end of 2023 to allow for development of this indication.

AstraZeneca Agreements

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 ("U.S./RoW Agreement"). It also excludes China, which is covered by a separate agreement with AstraZeneca described below. Under the terms of the 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 U.S./RoW Agreement, the Company is also eligible to receive from AstraZeneca 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, $15.0 million of which was received in 2015 as a result of the finalization of its two audited pre-clinical carcinogenicity study reports, (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. The aggregate amount of such consideration received through December 31, 2019 totals $389.0 million.

Under the U.S./RoW Agreement, the Company and AstraZeneca will share equally 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 delivery 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.

As mentioned above, during the second quarter of 2019, the Company received positive topline results from analyses of pooled MACE and MACE+ data from its Phase 3 trials for roxadustat, enabling the Company's NDA submission to the FDA. The Company evaluated the regulatory milestone payment associated with this planned NDA submission and concluded that this milestone became probable of being achieved in the second quarter of 2019. Accordingly, the consideration of $50.0 million associated with this milestone was included in the transaction price and allocated to performance obligations under the U.S./ RoW Agreement in the second quarter of 2019, of which $42.4 million was recognized as revenue during the year ended December 31, 2019 from performance obligations satisfied or partially satisfied. On December 23, 2019, the Company submitted such NDA, which was accepted by FDA in February 2020. According to the U.S/RoW Agreement, this milestone payment is not billable to AstraZeneca until the NDA is accepted by the FDA, therefore this $50.0 million remained as an unbilled contract asset as of December 31, 2019, and will be billed during the first quarter of 2020.

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 ("China Agreement"). Under the terms of the China Agreement, AstraZeneca agreed to pay upfront consideration totaling $28.2 million (such amounts were fully received in 2014). Under the 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 China Agreement is structured as a 50/50 profit or loss share (as defined) 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. The aggregate amount of such consideration received through December 31, 2019 totals $55.2 million.

In December 2019, roxadustat has been included on the updated NRDL released by China's NHSA for the treatment of anemia in CKD, covering patients who are non-dialysis dependent as well as those who are dialysis-dependent. The inclusion on the NRDL triggered a total of $22.0 million milestones payable to the Company by AstraZeneca. Accordingly, the total consideration of $22.0 million associated with these milestones was included in the transaction price and allocated to performance obligations under the China Agreement, of which $18.7 million was recognized as revenue during the year ended December 31, 2019 from performance obligations satisfied or partially satisfied.

As mentioned above, in the fourth quarter of 2018, the Company was engaged in the final stages of review with its partners over the proposed development of roxadustat for the treatment of CIA. AstraZeneca and Astellas approved the program in December 2018 and January 2019, respectively. Costs associated with the development of this indication are expected to be shared 50-50 between the Company's two partners. In addition to CIA, in December 2018, anemia of chronic inflammation ("ACI") and multiple myeloma ("MM") have been approved for development by AstraZeneca and is expected to be fully funded by them. For revenue recognition purposes, the Company concluded that the addition of these new indications represents a modification to the collaboration agreements and will be accounted for separately, meaning the development costs associated with the new indications are distinct from the original development costs. The development service period for roxadustat for the treatment of CIA, ACI and MM under the AstraZeneca agreements is estimated to continue through the end of 2024, to allow for development of these additional indications.

On December 17, 2018, FibroGen (China) Medical Technology Development Co., Ltd. ("FibroGen China"), received marketing authorization from the NMPA for roxadustat, a first-in-class hypoxia-inducible factor prolyl hydroxylase inhibitor, for the treatment of anemia caused by CKD in patients on dialysis. This approval triggered a $6.0 million milestone payable to the Company by AstraZeneca. On December 29, 2018, FibroGen China received First Manufacturing Approval for a Product in the Field in the Territory , which allows production for Phase 4 clinical studies, patients' early experience programs, donation programs, as well as to supply products for testing and assessments required prior to launch. This approval triggered a $6.0 million milestone payable to the Company by AstraZeneca. Approximately $9.9 million of the total $12.0 million milestone payables was recognized as revenue during the year ended December 31, 2018 from performance obligations satisfied or partially satisfied.

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, 2019, the transaction price for the Japan Agreement included $40.1 million of non-contingent upfront payments, $50.0 million of variable consideration related to payments for milestones considered probable of being achieved, and $11.4 million of variable consideration related to co-development billings. The transaction price for the Europe Agreement included $320.0 million of non-contingent upfront payments, $220.0 million of variable consideration related to payments for milestones considered probable of being achieved, and $229.2 million of variable consideration related to co-development billings.

For revenue recognition purposes, the Company determined that the term of each collaboration agreement with Astellas begins on the effective date and ends upon the completion of all performance obligations contained in the 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 requirement to continue funding development for a substantive period of time and loss of product rights, along with non-refundable upfront payments already remitted by Astellas, create significant disincentive for Astellas to exercise its right to terminate the agreements.

For the Astellas 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 allocated entirely to co-development services performance obligations.

For the technology license under the Japan Agreement and 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 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 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 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 is recognized as revenue in its entirety at the point in time the license transfers to Astellas.

(2) *Co-development services (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, and such an allocation is consistent with the allocation objective. Revenue is 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 and out-of-pocket expenses incurred relative to total expected costs to be incurred. The measure of progress is updated each reporting period. Co-development services are expected to continue over the development period that is currently estimated to continue through the end of 2019. In addition, the Company concluded that the new indication related to CIA approved in January 2019 represents a modification to the Europe agreements at that time and will be accounted for separately, for which the development service period is estimated to continue through the end of 2023. There was no provision for co-development services in the 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 (3)-(5) are bundled into a single performance obligation which 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. Revenue is 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. The measure of progress is updated 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. To date, no such revenue has been recognized.

In 2018, the Company recorded revenue from commercial-grade API sales to Astellas to conduct commercial scale manufacturing validation based on a transaction price that was subject to potential future adjustments. This represents a form of variable consideration. The Company evaluated the latest available facts and circumstances in 2018, including listed prices of comparable drug products in Japan and historical bulk drug product manufacturing yields and costs, to determine whether any adjustments to the estimated transaction price was necessary. As of December 31, 2018, no new facts or circumstances were available to warrant an adjustment to the transaction price. The transaction price was later adjusted in 2019 at the time the listed price for roxadustat was issued by the Japanese Ministry of Health, Labour and Welfare to reflect the difference between estimated and actual listed price and yield from the manufacture of bulk product tablets.

Accounting for the AstraZeneca Agreements

The Company evaluated whether the U.S./RoW Agreement and 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 U.S./RoW Agreement and 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, 2019, the transaction price for the U.S./RoW Agreement and China Agreement 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, and $598.8 million of variable consideration related to co-development billings.

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. Co-development billings under the U.S./RoW Agreement were allocated entirely to the U.S./RoW co-development services performance obligation, and co-development billings under the China Agreement were allocated entirely to the combined performance obligation under the China Agreement.

For revenue recognition purposes, the Company determined that the term of its collaboration agreements with AstraZeneca begin on the effective date and ends 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%.

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 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 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. Revenue is 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. Co-development services are expected to continue over the development period that is currently estimated to continue through the end of 2020. In addition, the Company concluded that the addition of the new indications related to CIA, ACI and MM approved during the fourth quarter of 2018 represents a modification to the collaboration agreements and will be accounted for separately, for which the joint development service period is estimated to continue through the end of 2024.

(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 (3)-(4) are bundled into a single performance obligation which 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. Revenue is 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. The measure of progress is updated 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. Payments received for commercial supplies of products represent sales-based royalties related predominately to the license of intellectual property under the agreement. Revenue is recognized as supplies are shipped for commercial use during the commercialization period. To date, no such revenue has been recognized.

China Agreement:

The performance obligation that were analyzed, along with their general timing of satisfaction and recognition as revenue, are 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 China Agreement with AstraZeneca 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 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 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. Due to certain regulatory restrictions in China, manufacturing services of commercial drug product in China are not readily available to AstraZeneca or any other parties. Therefore, AstraZeneca cannot benefit from the license on its own or together with other readily available resources. Accordingly, all the promises identified, including co-development services, under the 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. Upon commencement of the transfer of control to commercial drug product, revenue would be recognized in a pattern consistent with estimated deliveries of the commercial drug product.

Summary of revenue recognized under the collaboration agreements

The table below summarizes the accounting treatment for the various performance obligations pursuant to each of the Astellas and AstraZeneca 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 revenue under the Japan Agreement with Astellas were as follows (in thousands):

		Years Ended December 31,		
Agreement	**Performance Obligation**	**2019**	**2018**	**2017**
Japan	License revenue	$ 11,935	$ 14,323	$ —
	Development revenue	$ 1,222	$ 2,400	$ 1,588

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

Japan Agreement	**Cumulative Revenue Through December 31, 2019**	**Deferred Revenue at December 31, 2019**	**Total Consideration Through December 31, 2019**
License	$ 86,024	$ —	$ 86,024
Development revenue	15,130	375	15,505
Total license and development revenue	$ 101,154	$ 375	$ 101,529

The revenue recognized under the Japan Agreement for the year ended December 31, 2019 included an increase of $12.1 million resulting from changes to estimated variable consideration in the current year relating to performance obligations satisfied or partially satisfied in previous periods. The remainder of the transaction price related to the Japan Agreement includes no further variable consideration from estimated future co-development billing.

Amounts recognized as revenue under the Europe Agreement with Astellas were as follows (in thousands):

		Years Ended December 31,		
Agreement	**Performance Obligation**	**2019**	**2018**	**2017**
Europe	License revenue	$ 117,470	$ —	$ —
	Development revenue	$ 28,172	$ 18,503	$ 18,523

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

Europe Agreement	Cumulative Revenue Through December 31, 2019	Deferred Revenue at December 31, 2019		Total Consideration Through December 31, 2019
License	$ 487,951	$ —		$ 487,951
Development revenue	231,008	4,790		235,798
Total license and development revenue	$ 718,959	$ 4,790	*	$ 723,749

* Contract assets and liabilities related to rights and obligations in the same contract are recorded net on the condensed consolidated balance sheets. As of December 31, 2019, prepaid expenses and other current assets included a net unbilled contract asset of $125.2 million related to the Europe Agreement, which represents the net of the above-mentioned unbilled contract asset of $130.0 million, and $4.8 million of deferred revenue presented above.

The revenue recognized under the Europe Agreement for the year ended December 31, 2019 included an increase in revenue of $124.7 million resulting from changes to estimated variable consideration in the current year relating to performance obligations satisfied or partially satisfied in previous periods. The remainder of the transaction price related to the Europe Agreement includes $45.4 million of variable consideration from estimated future co-development billing and is expected to be recognized over the remaining development service period.

Amounts recognized as revenue under the U.S./RoW and China Agreements with AstraZeneca were as follows (in thousands):

		Years Ended December 31,		
Agreement	Performance Obligation	2019	2018	2017
U.S. / RoW and China	License revenue	$ 47,681	$ 7,946	$ 9,933
	Development revenue	84,629	104,970	100,928
	China performance obligation	$ 90	$ —	$ —

The transaction price related to consideration received and accounts receivable has been allocated to each of the following performance obligations under the U.S./RoW Agreement and China Agreement, along with any associated deferred revenue as follows (in thousands):

U.S. / RoW and China Agreements	Cumulative Revenue Through December 31, 2019	Deferred Revenue at December 31, 2019		Total Consideration Through December 31, 2019
License	$ 341,844	$ —		$ 341,844
Co-development, information sharing & committee services	493,266	8,452		501,718
China performance obligation	90	140,872		140,962
Total license and development revenue	$ 835,200	$ 149,324	*	$ 984,524

* Contract assets and liabilities related to rights and obligations in the same contract are recorded net on the condensed consolidated balance sheets. As of December 31, 2019, long-term deferred revenue included $99.3 million related to the U.S./RoW and China Agreement, which represents the net of $149.3 million of deferred revenue presented above and the above-mentioned $50.0 million unbilled contract asset.

The revenue recognized under the U.S./RoW Agreement and China Agreement for the year ended December 31, 2019 included an increase in revenue of $62.6 million resulting from changes to estimated variable consideration in the current year relating to performance obligations satisfied or partially satisfied in previous periods. The remainder of the transaction price related to the U.S./RoW Agreement and China Agreement includes $130.4 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, which are expected to be recognized in a pattern consistent with estimated deliveries of the commercial drug product.

Product Revenue, Net

	Years Ended December 31,	
	2019	2018
	(dollars in thousands)	
Product revenue, net:		
API product	$ (36,324)	$ 64,776
Drug product		
Gross revenue	2,803	—
Price adjustment	(936)	—
Sales rebates and other discounts	(167)	—
Drug product revenue, net	1,700	—
Total product revenue, net	$ (34,624)	$ 64,776

As described above, the Japan Amendment obligates Astellas to purchase API from the Company to conduct commercial scale manufacturing validation for roxadustat drug product in anticipation of commercial launch in Japan. The Company fulfilled all the delivery obligations under the term of the Japan Amendment during the year ended December 31, 2018, and recognized the related product revenue of $64.8 million in the same period based on a transaction price that was subject to potential future adjustments, which represented a form of variable consideration. A change in estimated variable consideration incurred in 2019 at the time the actual listed price for roxadustat was issued by the Japanese Ministry of Health, Labour and Welfare, which resulted in a total difference of $36.3 million between the estimated and the actual listed price and yield from the manufacture of bulk product tablets.

In addition, the Company started commercial sales of roxadustat drug product in China in the third quarter of 2019. Drug product revenue is recognized in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those products, net of price adjustment, contractual sales rebate and other discounts. For the year ended December 31, 2019, a $0.9 million of price adjustment was recorded based on government-listed price guidance and estimated channel inventory levels. The contractual sales rebate and other discounts were immaterial for the year ended December 31, 2019.

Other Revenues

Other revenues consist primarily of collagen material sold for research purposes. Other revenues were immaterial for each of the three years ended December 31, 2019.

Deferred Revenue

Deferred revenue represents amounts billed, or in certain cases, yet to be billed to the Company’s collaboration partners for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met. The current portion of deferred revenue represents the amount to be recognized within one year from the balance sheet date based on the estimated performance period of the underlying performance obligations. The long-term portion of deferred revenue represents amounts to be recognized after one year through the end of the non-contingent performance period of the underlying performance obligations.

Deferred revenue includes amounts allocated to the China unit of accounting under the AstraZeneca arrangement as revenue recognition associated with this unit of accounting is tied to the commercial launch of the products within China. As of December 31, 2018, such deferred revenue was included in long-term deferred revenue. As of December 31, 2019, following receipt of the Chinese Good Manufacturing Practices license by FibroGen Beijing in the second quarter of 2019, approximately $0.8 million of the related deferred revenue 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, as a result of the transfer of control of commercial drug product in China.

4. 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, 2019			
	Level 1	Level 2	Level 3	Total
US treasury notes and bills	$ 347,383	$ 80,123	$ —	$ 427,506
Bond and mutual funds	10,816	—	—	10,816
Equity investments	255	—	—	255
Money market funds	85,551	—	—	85,551
Certificate of deposit	—	30,032	—	30,032
Total	$ 444,005	$ 110,155	$ —	$ 554,160

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
US treasury notes and bills	$ 292,317	$ 224,953	$ —	$ 517,270
Bond and mutual funds	10,484	—	—	10,484
Equity investments	234	—	—	234
Money market funds	541	—	—	541
Term deposit	—	80,000	—	80,000
Certificate of deposit	—	29,910	—	29,910
Total	$ 303,576	$ 334,863	$ —	$ 638,439

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 fourth quarter of 2019, there was a $29.8 million transfer of assets 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, 2018 and 2017.

The fair values of the Company's financial liabilities that are carried at historical cost are as follows (in thousands):

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Lease obligations	$ —	$ —	$ 1,544	$ 1,544

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Lease obligations	$ —	$ —	$ 98,105	$ 98,105

The fair value of the Company's financial liabilities were derived by using an income approach, which required Level 3 inputs such as discounted estimated future cash flows.

As of December 31, 2018, the Company had $96.2 million in lease obligations related to its building leases under build-to-suit arrangements. Upon the adoption of ASC 842 as of January 1, 2019, using the modified retrospective transition method, the Company derecognized these liabilities previously recognized under ASC 840 build-to-suit designation. Refer to Note 2 for details.

There were no transfers of liabilities between levels for the years ended December 31, 2019, 2018 and 2017.

5. Leases

The Company currently has two building leases treated as finance leases.

In 2006, the Company entered into a long-term property lease with Alexandria for its corporate headquarters in San Francisco, California, with an initial term of 15 years, scheduled to expire in 2023. The Company has an option to extend the lease for an additional 10 years through 2033. 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. 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.

In 2013, the Company entered into a long-term property lease with Beijing Economic-Technological Development Area ("BDA") Management Committee for a pilot plant located in Beijing Yizhuang Biomedical Park ("BYBP") of BDA. The building is leased for an initial lease term of eight years, scheduled to expire in 2021. Renewal options are not specified within the lease contract. The lease contract provides for fixed quarterly rent payments, with scheduled increases that occur as detailed in the lease contract. This lease requires the Company to pay all operating and maintenance costs, and a fixed amount for property management fees.

The Company currently has seven additional real estate leases for space within a building, which are treated as operating leases. These leases have lease terms ranging from two to four years. 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 for office equipment, scientific devices and automobile leases, with contracted lease terms ranging from two to five years, treated as finance leases or operating leases, respectively.

The Company's lease assets and related lease liabilities were as follows (in thousands):

	Balance Sheet Line Item	December 31, 2019
Assets		
Finance:		
Right-of-use assets - cost		$ 49,909
Accumulated amortization		(10,307)
Finance lease right-of-use assets, net	Finance lease right-of-use assets	39,602
Operating:		
Right-of-use assets - cost		2,736
Accumulated amortization		(805)
Operating lease right-of-use assets, net	Other assets	1,931
Total lease assets		$ 41,533
Liabilities		
Current:		
Finance lease liabilities	Finance lease liabilities, current	$ 12,351
Operating lease liabilities	Accrued and other current liabilities	983
Non-current:		
Finance lease liabilities	Finance lease liabilities, non-current	37,610
Operating lease liabilities	Other long-term liabilities	942
Total lease liabilities		$ 51,886

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

	Statement of Operations Line Item	Year Ended December 31, 2019
Finance lease cost:		
Amortization of right-of-use assets	Research and development, Selling, general and administrative expenses	$ 10,307
Interest on lease liabilities	Interest expense	2,373
Operating lease cost	Research and development, Selling, general and administrative expenses	891
Sublease income	Selling, general and administrative expenses	(1,385)
Total lease cost		$ 12,186

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

	Year Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 914
Operating cash flows from finance leases	2,196
Financing cash flows from finance leases	11,925
Right-of-use assets obtained in exchange for new lease liabilities:	
Finance leases	49,909
Operating leases	$ 2,736

Lease term and discount rate were as follows at December 31, 2019:

	December 31, 2019
Weighted-average remaining lease term (years):	
Finance leases	3.6
Operating leases	2.1
Weighted-average discount rate:	
Finance leases	4.42%
Operating leases	4.75%

Maturities of lease liabilities are as follows:

Year Ending	Finance Leases	Operating Leases
2020	$ 14,078	$ 1,043
2021	13,676	668
2022	13,878	307
2023	12,523	—
Total future lease payments	54,155	2,018
Less: Interest	(4,194)	(93)
Present value of lease liabilities	$ 49,961	$ 1,925

The following information was previously disclosed under ASC 840 as of December 31, 2018:

Future minimum lease payments under all non-cancelable operating lease obligations as of December 31, 2018 were as follows (in thousands):

Year Ending	Operating Leases
2019	$ 444
2020	232
2021	25
2022	16
2023	—
Total minimum payments	$ 717

Future minimum lease payments, on a consolidated basis, under the Company's facility lease financing obligations as of December 31, 2018 were as follows (in thousands):

Year Ending	Lease financing obligations
2019	$ 14,379
2020	14,664
2021	14,179
2022	14,335
2023	12,872
Total minimum payments	$ 70,429

6. Balance Sheet Components

Cash and Cash Equivalents

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

	December 31,	
	2019	2018
Cash	$ 40,715	$ 38,783
US treasury notes and bills	—	49,934
Money market funds	85,551	541
Total cash and cash equivalents	$ 126,266	$ 89,258

Investments

The Company's investments consist of available-for-sale debt investments, marketable equity investments, term deposit and certificate of deposit. 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, 2019			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
US treasury notes and bills	$ 426,995	$ 536	$ (25)	$ 427,506
Certificates of deposit	30,000	32	—	30,032
Bond and mutual funds	10,730	86	—	10,816
Equity investments	125	130	—	255
Total investments	$ 467,850	$ 784	$ (25)	$ 468,609

	December 31, 2018			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
US treasury notes and bills	$ 467,296	$ 109	$ (69)	$ 467,336
Term deposit	80,000	—	—	80,000
Certificates of deposit	30,000	—	(90)	29,910
Bond and mutual funds	10,464	20	—	10,484
Equity investments	125	109	—	234
Total investments	$ 587,885	$ 238	$ (159)	$ 587,964

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

	December 31, 2019
Within one year	$ 407,491
After one year through four years	50,047
Total debt investments	457,538
Bond and mutual funds	10,816
Equity investments	255
Total investments	$ 468,609

The Company periodically reviews its available-for-sale investments and term deposit 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, 2019, the Company did not recognize any other-than-temporary impairment loss.

Inventories

Inventories consisted of the following (in thousands):

	December 31, 2019
Raw materials	$ 325
Work-in-progress	2,264
Finished goods	4,298
Total inventories	$ 6,887

The Company started capitalizing inventory costs in June 2019 when FibroGen China began productions of roxadustat for commercial sales purposes. The provision to write-down excess and obsolete inventory was nominal for the year ended December 31, 2019.

Prepaid expenses and other current assets

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

	December 31,	
	2019	2018
Unbilled contract assets	$ 180,000	$ —
Deferred revenues from associated contracts	(54,790)	—
Net unbilled contract assets	125,210	—
Prepaid assets	6,464	2,705
Other current assets	1,717	2,224
Total prepaid expenses and other current assets	$ 133,391	$ 4,929

The unbilled contract assets as of December 31, 2019 were related to two regulatory milestones totaling $130.0 million under the Europe Agreement with Astellas associated with the planned MAA submission in Europe, and a $50.0 million regulatory milestone under the U.S./RoW Agreement with AstraZeneca associated with the NDA submission in the U.S., which was submitted in December 2019 and accepted for review in February 2020. See Note 3 for details.

Property and Equipment

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

	December 31,	
	2019	2018
Leasehold improvements	$ 101,548	$ 101,200
Building shell	—	53,880
Laboratory equipment	17,329	16,405
Machinery	8,217	8,382
Computer equipment	8,399	6,473
Furniture and fixtures	5,822	5,690
Construction in progress	1,792	367
Total property and equipment	$ 143,107	$ 192,397
Less: accumulated depreciation	(100,364)	(65,199)
Property and equipment, net	$ 42,743	$ 127,198

As of December 31, 2018, the Company had $53.9 million building shell cost and $13.5 million accumulated depreciation related to its building leases under build-to-suit arrangements. Upon the adoption of ASC 842 as of January 1, 2019, using the modified retrospective transition method, the Company derecognized these assets previously recognized under ASC 840 build-to-suit designation. Up to December 31, 2018, the leasehold improvements related to these building leases were depreciated over the life of the building under ASC 840. Upon the adoption of ASC 842, these leasehold improvements should have a useful life based on the lease term. As a result, at the adoption date, the Company recorded a cumulative adjustment of $38.9 million to the opening accumulated depreciation for these leasehold improvements so that their net balance equals the undepreciated amount had the useful life of the leasehold improvements always been equal to the lease terms. Refer to Note 2 for details.

Depreciation expense for the years ended December 31, 2019, 2018 and 2017 was $11.1 million, $6.6 million, and $6.1 million, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2019	2018
Preclinical and clinical trial accruals	$ 16,279	$ 35,413
API product price adjustment	36,324	—
Payroll and related accruals	19,784	21,430
Property taxes and other	2,044	1,095
Professional services	4,842	2,648
Other	4,543	5,537
Total accrued liabilities	$ 83,816	$ 66,123

The amount of $36.3 million accrued as of December 31, 2019 was related to the change in estimated variable consideration of API product at the time the roxadustat listed price was issued by the Japanese Ministry of Health, Labour and Welfare. Refer to Note 3 for details.

Other Long-term Liabilities

Other long-term liabilities consisted of the following (in thousands):

	December 31,	
	2019	2018
Accrued long-term co-promotional expenses	$ 53,071	$ —
Other long-term tax liabilities	8,913	8,138
Operating lease liabilities, non-current	942	—
Other	1,340	1,855
Total other long-term liabilities	$ 64,266	$ 9,993

The accrued long-term co-promotional expenses of $53.1 million as of December 31, 2019 was related to the estimated amount payable to AstraZeneca for its sales and marketing efforts related to the commercial launch for roxadustat in China. The payment for such amount is not expected to occur within the next year.

7. 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, 2019 and 2018, the Company had USD equivalent of $10.6 million and $10.8 million of principal outstanding, respectively, and $6.2 million and $6.0 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.

8. Commitments and Contingencies

Lease Obligations

In 2006, upon signing the Company's above-mentioned long-term property lease agreement with Alexandria, a stand-by letter of credit $7.3 million was established which has been included in restricted time deposits on the Company's consolidated balance sheet. Starting the fourth quarter of 2016, on an annual basis, a portion of this letter of credit was released. As a result, the restriction of a $2.1 million was removed during the year ended December 31, 2019. The agreement also included an expansion option to occupy part of an adjacent building, for which the Company gave notice to its landlord that it would not exercise this expansion option. This resulted in a $5.0 million payment liability to the landlord which is being financed over the remaining lease term of its lease. The related balance was $1.5 million as of December 31, 2019, with $0.4 million included in accrued and other current liabilities, and $1.1 million included in long-term portion of lease obligations on the Company's consolidated balance sheet.

Legal Proceedings

The Company a party to various legal actions that arose in the ordinary course of its business. The Company recognizes accruals for any legal action when it concludes that a loss is probable and reasonably estimable. The Company did not have any material accruals for any currently active legal action in its consolidated balance sheets as of December 31, 2019 and 2018, as it could not predict the ultimate outcome of these matters, 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 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.

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.

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. Future milestone payments for research and pre-clinical stage development programs consisted of up to approximately $11.0 million in total potential future milestone payments under the Company's license agreements with Dana-Farber Cancer Institute, University of Miami and Medarex, Inc. 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.

9. Equity and Stock-based Compensation

Subsidiary Stock and Non-Controlling Interests

FibroGen Europe

As of December 31, 2019 and 2018, 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 China

FibroGen China had 6,758,000 Series A Preference Shares outstanding as of December 31, 2019 and 2018, respectively. The holders of the FibroGen China 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 China 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 China 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 China Series A Preference Shares is convertible into the number of fully paid and non-assessable shares of Common Stock of FibroGen China 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 China Series A Preference Shares have a conversion price that is equal to the original issuance price such that the conversion ratio to FibroGen China Common Stock is 1:1 as of all periods presented.

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

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

Non-Controlling Interests

Non-controlling interest positions related to the issuance of subsidiary stock as described above are reported as a separate component of consolidated equity from the equity attributable to the Company's stockholders at December 31, 2019 and 2018. 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. Upon the initial public offering and as described above, all eligible FibroGen Europe preferred shares were exchanged for 958,996 shares of FibroGen Common Stock. No other FibroGen Europe shares have the right to be exchanged for FibroGen, Inc. Common Stock.

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,	
	2019	2018
Common stock outstanding	87,657	85,432
Stock options outstanding	10,018	10,430
RSUs outstanding	1,483	1,428
Common stock warrants outstanding	—	4
Shares reserved for future stock options and RSUs grant	7,725	6,041
Shares reserved for future ESPP offering	3,337	2,618
Total shares of common stock reserved	110,220	105,953

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 ("ISO") may be granted only to employees and officers of the Company. Nonqualified stock options ("NSO") 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 ISO or an NSO. 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, 2019, the Company has reserved 7,724,691 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, 2019 and 2018, no shares of Common Stock were subject to repurchase by the Company.

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 per Share	Weighted Average Remaining Contractual Life (In Years)	Aggregate Intrinsic Value (In thousands)
Outstanding at December 31, 2018	10,430	$ 20.25		
Granted	1,909	53.75		
Exercised	(1,642)	10.15		
Expired	(21)	50.40		
Forfeited	(658)	44.65		
Outstanding at December 31, 2019	10,018	26.63	5.17	$ 193,226
Vested and expected to vest, December 31, 2019	10,018	26.63	5.17	193,226
Exercisable at December 31, 2019	7,318	$ 18.63	3.89	$ 183,707

The total intrinsic value of options exercised during the years ended December 31, 2019, 2018 and 2017 was $59.2 million, $97.5 million, and $111.9 million, respectively.

The following table summarizes RSU activity:

	Shares (In thousands)	Fair Value at Grant
Unvested at December 31, 2018	1,428	$ 38.26
Granted	1,110	54.74
Vested	(715)	37.71
Forfeited	(340)	46.15
Unvested at December 31, 2019	1,483	$ 49.05

Among the vested RSUs during the year ended December 31, 2019, 448,647 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, 2019, 2018 and 2017 was $54.74, $53.69 and $26.59, 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 commencing 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 135,115 shares, 230,317 shares and 250,834 shares purchased by employees under the 2014 Purchased Plan for the years ended December 31, 2019, 2018 and 2017, respectively.

The expected term of 2014 ESPP shares is the average of the remaining purchase periods under each offering period.

Stock-Based Compensation

Stock-based compensation expense allocated to research and development and selling, general and administrative expense for the years ended December 31, 2019, 2018 and 2017 was as follows (in thousands):

	Years Ended December 31,		
	2019	2018	2017
Research and development	$ 41,015	$ 30,491	$ 21,807
Selling, general and administrative	25,252	21,651	15,732
Total stock-based compensation expense	$ 66,267	$ 52,142	$ 37,539

The Company estimates the fair value of stock options using the Black-Scholes option valuation model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards.

Prior to the Company's initial public offering, the Company, in making its determinations of the fair value of its Common Stock, considered a variety of quantitative and qualitative factors, including (i) net present value of the Company's projected earnings, (ii) fair market value of the stock of comparable publicly-traded companies, (iii) any third party transactions involving the Company's convertible preferred stock, (iv) liquidation preferences of the Company's preferred stock and the likelihood of conversion of the preferred stock, (v) changes in the Company's business operations, financial condition and results of operations over time, including cash balances and burn-rate, (vi) the status of new product development, and (vii) general financial market conditions. Subsequent to the IPO, 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 was 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.
- Expected Volatility. The Company considers its historical volatility data for volatility considerations for its ESPP. The expected volatility for all other stock-based compensation is currently based upon the historical volatility of comparable public entities. In evaluating comparable companies, the Company considered factors such as industry, stage of life cycle, size and duration as a public company.
- 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 stock options.
- 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,		
	2019	2018	2017
Stock Options			
Expected term (in years)	5.3	5.4	5.7
Expected volatility	68.0 %	67.9 %	71.5 %
Risk-free interest rate	2.4 %	2.7 %	2.2 %
Expected dividend yield	—	—	—
Weighted average estimated fair value	$ 31.98	$ 32.12	$ 16.96
ESPPs			
Expected term (in years)	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0
Expected volatility	48.1 - 62.1 %	47.3 - 75.3 %	52.8 - 77.2 %
Risk-free interest rate	1.3 - 2.9 %	0.8 - 2.9 %	0.5 - 1.6 %
Expected dividend yield	—	—	—
Weighted average estimated fair value	$ 19.27	$ 16.27	$ 9.41

As of December 31, 2019, there was $57.5 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 2.32 years. As of December 31, 2019, there was $52.9 million of total unrecognized compensation costs, net of estimated forfeitures, related to non-vested RSUs granted that will be recognized on a straight-line basis over the weighted-average period of 2.36 years.

Warrants

During the year ended December 31, 2019, a warrant to purchase 4,430 shares of our common stock was exercised and there was no warrant to purchase shares of Common Stock outstanding at December 31, 2019.

10. Net Loss Per Share

The following weighted impacts of outstanding securities were excluded from the calculation of diluted net loss per share because their effect would have been anti-dilutive for the three years presented (in thousands):

	Years Ended December 31,		
	2019	2018	2017
Employee stock options	7,602	7,815	8,936
RSUs	1,187	820	799
ESPP	260	195	206
Warrants	1	4	4
	9,050	8,834	9,945

11. FibroGen, Inc. 401(k) Plan

Substantially all of the Company's full-time United States of America-based employees are eligible to make contributions to the Company's 401(k) Plan. Under this plan, participating employees may defer up to 60% of their pretax salary during the year, but not more than statutory limits. The Company may elect to match employee contributions. Matching contributions of $3.0 million, $2.9 million and $2.5 million were made during years ended December 31, 2019, 2018 and 2017, respectively.

12. Income Taxes

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

	Years Ended December 31,		
	2019	2018	2017
Domestic	$ 2,538	$ (38,472)	$ (80,735)
Foreign	(79,180)	(47,644)	(39,819)
Loss before provision for income taxes	$ (76,642)	$ (86,116)	$ (120,554)

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

	Years Ended December 31,		
	2019	2018	2017
Current:			
Federal	$ —	$ —	$ —
State	—	2	2
Foreign	328	302	319
Total current	328	304	321
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
Total deferred	—	—	—
Total provision for income taxes	$ 328	$ 304	$ 321

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

	Years Ended December 31,		
	2019	2018	2017
Tax at statutory federal rate	21.0%	21.0%	34.0%
State tax	—%	—%	—%
Stock-based compensation expense	6.3%	14.5%	18.5%
Change in deferred tax assets due to rate change	—%	—%	43.9%
Change in valuation allowance due to rate change	—%	—%	(43.9)%
Net operating losses not benefitted	(2.9)%	(23.2)%	(43.8)%
Foreign net operating losses not benefitted	(21.7)%	(11.6)%	(6.7)%
Orphan drug credit	—%	—%	(2.0)%
Deduction limitation on executive compensation	(2.5)%	(0.5)%	—%
Other	(0.6)%	(0.6)%	(0.3)%
Total	(0.4)%	(0.4)%	(0.3)%

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

	December 31,	
	2019	2018
Federal and state net operating loss carryforwards	$ 91,267	$ 91,683
Tax credit carryforwards	52,243	45,885
Foreign net operating loss carryforwards	37,786	21,295
Stock-based compensation	11,159	9,281
Lease obligations	10,698	2,511
Reserves and accruals	5,353	6,072
Deferred revenue	13,323	16,454
Fixed assets	—	356
Other	284	450
Subtotal	222,113	193,987
Less: Valuation allowance	(213,847)	(193,987)
Net deferred tax assets	8,266	—
Fixed assets	(8,266)	—
Other	—	—
Net deferred tax liabilities	(8,266)	—
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 $19.9 million, $34.4 million and $30.5 million for the years ended December 31, 2019, 2018 and 2017, 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.

At December 31, 2019, the Company had net operating loss carryforwards available to offset future taxable income of approximately $404.6 million and $129.4 million for federal and state tax purposes, respectively. These carryforwards will begin to expire in 2026 for federal and 2020 for state purposes, if not utilized before these dates. The Company also had foreign net operating loss carryforwards of approximately $152.2 million which expire between 2020 and 2029 if not utilized.

At December 31, 2019, the Company had approximately $54.1 million of federal and $29.4 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 2020 and the California research credits have no expiration dates.

On December 22, 2017, the Tax Cuts and Jobs Act ("Tax Act") was signed into law making significant changes to the Internal Revenue Code. Changes include, but are not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, the transition of U.S international taxation from a worldwide tax system to a territorial system, and a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings. In the fourth quarter of 2018, the Company completed its analysis to determine the effect of the Tax Act and no material adjustments were recognized as of December 31, 2018. Developing interpretations of the provisions of the Tax Act, changes to U.S. Treasury regulations, administrative interpretations or court decisions interpreting the Tax Act in the future periods may require further adjustments to the Company's analysis.

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, 2019 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.

Uncertain Tax Positions

The Company had unrecognized tax benefits of approximately $32.3 million as of December 31, 2019. Approximately $0.5 million of unrecognized tax benefits, if recognized, would affect the effective tax rate. The interest accrued as of December 31, 2019 and 2018 was immaterial.

A reconciliation of the beginning and ending amounts of unrecognized income tax benefits during the three years ended December 31, 2019 is as follows (in thousands):

	Federal and State
Balance as of December 31, 2016	$ 19,654
Increase due to prior positions	303
Increase due to current year position	5,448
Decrease due to U.S. tax rate change	(2,044)
Balance as of December 31, 2017	23,361
Increase due to prior positions	379
Increase due to current year position	4,216
Balance as of December 31, 2018	27,956
Decrease due to prior positions	(111)
Increase due to current year position	4,418
Balance as of December 31, 2019	$ 32,263

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 2010 to 2019. The Company is not currently under audit in any tax jurisdiction.

13. Related Party Transactions

Astellas is an equity investor in the Company and considered a related party. During the years ended December 31, 2019, 2018 and 2017, the Company recorded revenue related to collaboration agreements with Astellas of $122.5 million, $100.0 million, and $20.1 million, respectively. The related party revenue for the year ended December 31, 2019 included a change in estimated variable consideration that resulted in a $36.3 million reduction to revenue related to the product revenue of $64.8 million for API recorded in 2018. See Note 3 and below for details.

During the years ended December 31, 2019, 2018 and 2017, the Company recorded expense related to collaboration agreements with Astellas of $2.8 million, $1.5 million and $1.0 million, respectively.

As of December 31, 2019 and 2018, accounts receivable from Astellas were $4.8 million and $47.2 million, respectively, and amounts due to Astellas were $36.9 million and $0.4 million, respectively. The amounts due are included in accrued liabilities on the consolidated balance sheets. The accounts receivable from Astellas as of December 31, 2018 included $43.8 million related to the delivery of roxadustat API to Astellas during the fourth quarter of 2018. The sale of API was pursuant to the Japan Amendment allowing Astellas to manufacture roxadustat drug product for commercialization in Japan. The amount was received during the first quarter of 2019. The amounts due to Astellas as of December 31, 2019 included $36.3 million of a change in estimated variable consideration related to the API product revenue recognized in 2018, at the time the roxadustat listed price was issued by the Japanese Ministry of Health, Labour and Welfare. Refer to Note 3 for details.

Prepaid expenses and other current assets as of December 31, 2019 included $125.2 million of net unbilled contract assets, representing a $130.0 million unbilled contract asset related to two regulatory milestones under the Europe Agreement with Astellas associated with the planned MAA submission to the EMA, net of $4.8 million of associated deferred revenue. See Note 3 for details. According to the Europe Agreement, this $130.0 million is not billable to Astellas until the submission of an MAA, therefore the net contract asset was included in the prepaid expenses and other current assets line on the Company's consolidated balance sheet as of December 31, 2019. There was no such contract asset balance as of December 31, 2018.

14. 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 bill-to region, are as follows (in thousands):

	Years Ended December 31,		
	2019	2018	2017
Europe	$ 132,400	$ 112,916	$ 110,861
Japan (related party)	122,475	100,002	20,111
All other	1,702	40	24
Total revenue	$ 256,577	$ 212,958	$ 130,996

Revenues to other regions include the Company commercial sales of roxadustat drug product in China starting in the third quarter of 2019. See Note 3 for details.

Geographic Long-Lived Assets

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

	December 31,	
	2019	2018
United States	$ 27,325	$ 103,539
China	15,418	23,659
Total property and equipment	$ 42,743	$ 127,198

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

	December 31,	
	2019	2018
United States	$ 39,237	$ —
China	365	—
Total finance lease right-of-use assets	$ 39,602	$ —
United States	$ 75	$ —
China	1,856	—
Total operating lease right-of-use assets	$ 1,931	$ —

Customer Concentration

Substantially all of the Company's revenues to date have been generated from the following collaboration partners that respectively accounted for 10% or more of the Company's total revenue and accounts receivable:

	Percentage of Revenue			Percentage of Accounts Receivable	
	Years Ended December 31,			December 31,	
	2019	2018	2017	2019	2018
Astellas—Related party	48%	47%	15%	17%	74%
AstraZeneca	52%	53%	85%	81%	26%

Schedule II: Valuation and Qualifying Accounts
(in thousands)

	Balance at Beginning of Year	Charged (Credited) to Statement of Operation	Charged to Other Accounts - Equity	Deductions, Net	Balance at End of Year
Valuation allowances for deferred tax assets					
Year ended December 31, 2019	$ 193,987	$ 19,860	$ —	$ —	$ 213,847
Year ended December 31, 2018	$ 159,540	$ 34,447	$ —	$ —	$ 193,987
Year ended December 31, 2017	$ 128,995	$ 11,039	$ 19,506	$ —	$ 159,540

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Attached as exhibits 31.1 and 31.2 to this Annual Report on Form 10-K 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 on Form 10-K 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, 2019, the end of the period covered by this Annual Report on Form 10-K. Disclosure controls and procedures (as defined in Rules 13a-15(e) and 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 U.S. Securities and Exchange Commission'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 management's evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of December 31, 2019 at the reasonable assurance level.

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. 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.

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, 2019, 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 management's evaluation of our internal control over financial reporting, management concluded that our internal control over financial reporting was effective as of December 31, 2019.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2019 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Changes in Internal Control over Financial Reporting

There was no change 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, 2019 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our Proxy Statement for our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019.

Code of Conduct

We have adopted a Code of Business Conduct which 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 our Proxy Statement for our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019.

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 our Proxy Statement for our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our Proxy Statement for our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement for our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) We have filed the following documents as part of this Annual Report on Form 10-K:

1. Consolidated Financial Statements

Information in response to this Item is included in Part II, Item 8 of this Annual Report on Form 10-K.

2. Financial Statement Schedules

Schedule II is included on page 166. 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 on Form 10-K 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.	—	—	—	—
10.1(i)+	FibroGen, Inc. Amended and Restated 2005 Stock Plan.	S-1	333-199069	10.3(i)	10/1/2014
10.1(ii)+	Forms of stock option agreement, restricted stock purchase agreement and stock appreciation right agreement under the FibroGen, Inc. Amended and Restated 2005 Stock Plan.	S-1	333-199069	10.3(ii)	10/1/2014
10.1(iii)+	Form of stock option agreement under the FibroGen, Inc. Amended and Restated 2005 Stock Plan applicable to options exchanged pursuant to FibroGen, Inc.'s 2010 amendment and exchange offer.	S-1	333-199069	10.3(iii)	10/1/2014
10.1(iv)+	Form of 2010 amendment to the form of stock option agreement under the FibroGen, Inc. Amended and Restated 2005 Stock Plan applicable to options amended pursuant to FibroGen, Inc.'s 2010 amendment and exchange offer.	S-1	333-199069	10.3(iv)	10/1/2014

10.1(v)+	Form of 2013 amendment to the form of stock option agreement under the FibroGen, Inc. Amended and Restated 2005 Stock Plan applicable to options amended or exchanged pursuant to FibroGen, Inc.'s 2010 amendment and exchange offer.	S-1	333-199069	10.3(v)	10/1/2014
10.2+	FibroGen, Inc. 2014 Equity Incentive Plan and forms of agreement thereunder.	S-1/A	333-199069	10.4	11/12/2014
10.3+	FibroGen, Inc. 2014 Employee Stock Purchase Plan.	S-1/A	333-199069	10.5	11/12/2014
10.4+	FibroGen, Inc. Non-Employee Director Compensation Policy, as amended.	10-Q	001-36740	10.6	11/12/2019
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	10.9	11/8/2017
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.	S-1/A	333-199069	10.17	10/23/2014
10.16†	Amended and Restated License, Development and Commercialization Agreement by and between Registrant and AstraZeneca AB, effective as of July 30, 2013.	10-Q/A	001-36740	10.16	12/14/2017
10.17†	License Agreement by and between FibroGen, Inc. and the University of Miami and its School of Medicine, dated as of May 23, 1997.	S-1	333-199069	10.19	10/1/2014
10.18†	First Amendment to May 23, 1997 License Agreement by and between FibroGen, Inc. and University of Miami, effective as of July 29, 1999.	S-1	333-199069	10.20	10/1/2014
10.19	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
10.20	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
10.21†	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.	S-1	333-199069	10.23	10/1/2014
10.22†	License Agreement by and between FibroGen, Inc. and the Dana-Farber Cancer Institute, Inc., effective as of March 29, 2006.	S-1	333-199069	10.24	10/1/2014
10.23	Amendment No. 1 to License agreement by and between FibroGen, Inc. and Dana-Farber Cancer Institute, Inc., effective as of February 28, 2006.	S-1	333-199069	10.25	10/1/2014

10.24	Amendment No. 2 to License Agreement by and between FibroGen, Inc. and Dana-Farber Cancer Institute, Inc., effective as of March 14, 2006.	S-1	333-199069	10.26	10/1/2014
10.25+	Form of Indemnity Agreement by and between FibroGen, Inc. and its directors and officers.	S-1/A	333-199069	10.27	10/23/2014
10.26(i)†	Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of November 29, 2007.	S-1	333-199069	10.28(i)	10/1/2014
10.26(ii)†	Letter Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of June 26, 2008.	S-1	333-199069	10.28(ii)	10/1/2014
10.26(iii)†	Letter Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of August 18, 2008.	S-1	333-199069	10.28(iii)	10/1/2014
10.26(iv)†	Amendment No. 1 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of May 28, 2009.	S-1	333-199069	10.28(iv)	10/1/2014
10.26(v)†	Amendment No. 3 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of November 5, 2010.	S-1	333-199069	10.28(v)	10/1/2014
10.26(vi)†	Amendment No. 4 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of January 24, 2011.	S-1	333-199069	10.28(vi)	10/1/2014
10.26(vii)†	Amendment No. 5 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of April 15, 2011.	S-1	333-199069	10.28(vii)	10/1/2014
10.26(viii)†	Amendment No. 6 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of May 26, 2011.	S-1	333-199069	10.28(viii)	10/1/2014
10.26(ix)†	Amendment No. 7 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of January 1, 2012.	S-1	333-199069	10.28(ix)	10/1/2014
10.26(x)†	Amendment No. 8 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of July 10, 2012.	S-1	333-199069	10.28(x)	10/1/2014
10.26(xi)†	Amendment No. 9 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of November 26, 2012.	S-1	333-199069	10.28(xi)	10/1/2014

10.26(xii)†	Amendment No. 10 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of June 21, 2013.	S-1	333-199069	10.28(xii)	10/1/2014
10.26(xiii)†	Amendment No. 11 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of July 9, 2013.	S-1	333-199069	10.28(xiii)	10/1/2014
10.26(xiv)†	Amendment No. 12 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of August 1, 2013.	S-1	333-199069	10.28(xiv)	10/1/2014
10.26(xv)†	Amendment No. 13 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of March 6, 2014.	S-1	333-199069	10.28(xv)	10/1/2014
10.26(xvi)†	Amendment No. 14 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of February 5, 2014.	S-1	333-199069	10.28(xvi)	10/1/2014
10.26(xvii)†	Amendment No. 15 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of October 20, 2014.	10-Q	001-36740	10.28(xvii)	11/12/2015
10.26(xviii)†	Amendment No. 16 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of December 8, 2014.	10-Q	001-36740	10.28(xviii)	11/12/2015
10.26(xix)†	Amendment No. 17 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of December 8, 2014.	10-Q	001-36740	10.28(xix)	11/12/2015
10.26(xx)†	Amendment No. 18 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of February 15, 2015.	10-Q	001-36740	10.28(xx)	11/12/2015
10.26(xxi)†	Amendment No. 19 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of March 1, 2015.	10-Q	001-36740	10.28(xxi)	11/12/2015
10.26(xxii)†	Amendment No. 20 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of June 1, 2015.	10-Q	001-36740	10.28(xxii)	11/12/2015
10.26(xxiii)†	Amendment No. 21 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of May 29, 2015.	10-Q	001-36740	10.28(xxiii)	11/12/2015

10.26(xxiv)†	Amendment No. 23 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of September 1, 2015.	10-Q	001-36740	10.28(xxiv)	11/12/2015
10.26(xxv)†	Amendment No. 22 to the Process Development and Clinical Supply Agreement, by and between FibroGen, Inc. and Boehringer Ingelheim Biopharmaceuticals GmbH, effective as of April 14, 2016.	10-Q	001-36740	10.26(xxv)	8/8/2016
10.26(xxvi)†	Amendment No. 24 to the Process Development and Clinical Supply Agreement, by and between FibroGen, Inc. and Boehringer Ingelheim Biopharmaceuticals GmbH, retroactively effective as of September 15, 2015.	10-Q	001-36740	10.26(xxvi)	8/8/2016
10.26(xxvii)†	Amendment No. 25 to the Process Development and Clinical Supply Agreement, by and between FibroGen, Inc. and Boehringer Ingelheim Biopharmaceuticals GmbH, retroactively effective as of October 15, 2015.	10-Q	001-36740	10.26(xxvii)	8/8/2016
10.26(xxviii)†	Amendment No. 26 to the Process Development and Clinical Supply Agreement, by and between FibroGen, Inc. and Boehringer Ingelheim Biopharmaceuticals GmbH, effective as of June 30, 2016.	10-Q	001-36740	10.26(xxviii)	8/8/2016
10.26(xxix)†	Amendment No. 27 to the Process Development and Clinical Supply Agreement, by and between FibroGen, Inc. and Boehringer Ingelheim Biopharmaceuticals GmbH, effective as of July 25, 2016.	10-Q	001-36740	10.26(xxix)	11/8/2016
10.26(xxx)†	Amendment No. 28 to the Process Development and Clinical Supply Agreement, by and between FibroGen, Inc. and Boehringer Ingelheim Biopharmaceuticals GmbH, effective as of September 22, 2016.	10-Q	001-36740	10.26(xxx)	11/8/2016
10.26(xxxi)†	Amendment No. 29 to the Process Development and Clinical Supply Agreement, by and between FibroGen, Inc. and Boehringer Ingelheim Biopharmaceuticals GmbH, effective as of December 20, 2016.	10-K	001-36740	10.26(xxxi)	3/1/2017
10.26(xxxii)†	Amendment No. 30 to the Process Development and Clinical Supply Agreement, by and between FibroGen, Inc. and Boehringer Ingelheim Biopharmaceuticals GmbH, effective as of December 20, 2016.	10-K	001-36740	10.26(xxxii)	3/1/2017
10.26(xxxiii)†	Amendment No. 31 to the Process Development and Clinical Supply Agreement, by and between FibroGen, Inc. and Boehringer Ingelheim Biopharmaceuticals GmbH, effective as of March 2, 2017	10-Q	001-36740	10.26(xxxiii)	5/9/2017

10.26(xxxiv)†	Amendment No. 32 to the Process Development and Clinical Supply Agreement, by and between FibroGen, Inc. and Boehringer Ingelheim Biopharmaceuticals GmbH, effective as of September 1, 2017	10-K	001-36740	10.26(xxxiv)	2/27/2018
10.26(xxxv)†	Work Order No. 1 to the Process Development and Clinical Supply Agreement, by and between FibroGen, Inc. and Boehringer Ingelheim Biopharmaceuticals GmbH, effective as of September 1, 2017	10-K	001-36740	10.26(xxxv)	2/27/2018
10.26(xxxvi)†	Amendment No. 33 to the Process Development and Clinical Supply Agreement, by and between FibroGen, Inc. and Boehringer Ingelheim Biopharmaceuticals GmbH, effective as of January 4, 2019	10-Q	001-36740	10.26(xxxvi)	5/9/2019
10.27†	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
10.28*†	Commercial Supply Agreement by and between FibroGen, Inc. and Catalent Pharma Solutions, LLC, effective as of January 1, 2020	--	--	--	--
10.29+	Offer Letter, by and between FibroGen, Inc. and Pat Cotroneo, dated as of October 23, 2000.	S-1	333-199069	10.31	10/1/2014
10.30+	Offer Letter, by and between FibroGen, Inc. and K. Peony Yu, dated as of November 21, 2008.	S-1	333-199069	10.30	10/1/2014
10.31+	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
10.32*+	Offer Letter, by and between FibroGen, Inc. and Christine Chung, dated as of June 17, 2008.	--	--	--	--
10.33*+	Offer Letter, by and between FibroGen, Inc. and Elias Kouchakji, dated as of January 24, 2014.	--	--	--	--
10.34*+	Offer Letter, by and between FibroGen, Inc. and Enrique Conterno, dated as of December 17, 2019.	--	--	--	--
10.35*+	Form of Executive Officer Change in Control and Severance Agreement	--	--	--	--
21.1	Subsidiaries of FibroGen, Inc.	S-1/A	333-199069	21.1	10/24/2014
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	—	—	—	—
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.
† Confidential Information Omitted.
\+ 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 on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Francisco, State of California.

FIBROGEN, INC.

Date: March 2, 2020	By:	/s/ Enrique Conterno Enrique Conterno Chief Executive Officer *(Principal Executive Officer)*
Date: March 2, 2020	By:	/s/ Pat Cotroneo Pat Cotroneo Senior Vice President, Finance 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 Pat Cotroneo, 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 on Form 10-K, 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)*	March 2, 2020
/s/ Pat Cotroneo **Pat Cotroneo**	Senior Vice President, Finance and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 2, 2020
/s/ James A. Schoeneck **James A. Schoeneck**	Chairman of the Board and Director	March 2, 2020
/s/ Suzanne Blaug **Suzanne Blaug**	Director	March 2, 2020
/s/ Jeffrey L. Edwards **Jeffrey L. Edwards**	Director	March 2, 2020
/s/ Jeffrey W. Henderson **Jeffrey W. Henderson**	Director	March 2, 2020
/s/ Maykin Ho, Ph.D. **Maykin Ho, Ph.D.**	Director	March 2, 2020
/s/ Thomas F. Kearns Jr. **Thomas F. Kearns Jr.**	Director	March 2, 2020
/s/ Kalevi Kurkijärvi, Ph.D. **Kalevi Kurkijärvi, Ph.D.**	Director	March 2, 2020
/s/ Gerald Lema **Gerald Lema**	Director	March 2, 2020
/s/ Rory B. Riggs **Rory B. Riggs**	Director	March 2, 2020
/s/ Roberto Pedro Rosenkranz, Ph.D., M.B.A. **Roberto Pedro Rosenkranz, Ph.D., M.B.A.**	Director	March 2, 2020
/s/ Toshinari Tamura, Ph.D. **Toshinari Tamura, Ph.D.**	Director	March 2, 2020

Exhibit 4.4

DESCRIPTION OF CAPITAL STOCK

General

The following description summarizes the most important terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description of the matters set forth in this "Description of Capital Stock," you should refer to our amended and restated certificate of incorporation and amended and restated bylaws, which are included as exhibits to our Annual Report on Form 10-K, and to the applicable provisions of Delaware law.

Our authorized capital stock consists of 225,000,000 shares of common stock, par value $0.01 per share and 125,000,000 shares of preferred stock, par value $0.01 per share.

Common Stock

Voting Rights

Each holder of our common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders, except as otherwise expressly provided in our amended and restated certificate of incorporation or required by applicable law. We have not provided for cumulative voting for the election of directors in our amended and restated certificate of incorporation.

Economic Rights

Dividends and Distributions. Subject to the prior rights of holders of all classes and series of stock at the time outstanding having prior rights as to dividends, the holders of common stock will be entitled to receive, when, as and if declared by our board of directors, out of any assets legally available therefor, such dividends as may be declared from time to time by our board of directors.

Liquidation Rights. In the event of our liquidation, dissolution or winding-up, upon the completion of the distributions required with respect to any series of preferred stock that may then be outstanding, the remaining assets legally available for distribution to stockholders shall be distributed ratably among the holders of common stock and any participating preferred stock outstanding at that time.

Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock.

Preferred Stock

Our amended and restated certificate of incorporation provides that our board of directors may, without further action by our stockholders, fix the rights, preferences, privileges and restrictions of up to an aggregate of 125,000,000 shares of preferred stock in one or more series and authorize their issuance. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of our common stock. The issuance of our preferred stock could adversely affect the voting power of holders of our common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation, which could decrease the market price of our common stock. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change of control or other corporate action. No shares of preferred stock are outstanding, and we have no present plan to issue any shares of preferred stock.

Exhibit 4.4

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company. Its address is 6201 15th Avenue, Brooklyn, New York 11219.

[*] = 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 10.28

Confidential

COMMERCIAL SUPPLY AGREEMENT

(Roxadustat)

This Commercial Supply Agreement (the "**Agreement**") is effective as of January 1, 2020 (the "**Effective Date**"), by and between FibroGen, Inc., a Delaware corporation with offices located at 409 Illinois Street, San Francisco, California 94158, and its Affiliates (collectively, "**FibroGen**"), and Catalent Pharma Solutions, LLC, a Delaware limited liability corporation having an address at 14 Schoolhouse Road, Somerset, New Jersey 08873 ("**Catalent**"). Catalent and each of its Affiliates shall collectively be referred to herein as "**Catalent**". FibroGen and Catalent may be referred to individually as a "**Party**", and collectively as the "**Parties**".

RECITALS

A. FibroGen owns or controls certain technology and intellectual property relating to the compound known as roxadustat (or FG-4592);

B. Catalent is a leading provider of advanced technologies, and development, manufacturing and packaging services, for pharmaceutical, biotechnology and consumer healthcare companies; and

C. FibroGen desires to engage Catalent to perform Manufacturing Services (as defined below) for FibroGen, including without limitation the manufacture and supply of roxadustat bulk drug product, and Catalent desires to provide such services on the terms set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the Parties hereto agree as follows:

ARTICLE 1
DEFINITIONS

The following capitalized terms, whether used in the singular or plural, shall have the meanings ascribed to them below for purposes of this Agreement:

1.1 "**Acknowledgement**" has the meaning set forth in Section 2.2.2.

1.2 "**Affiliate**" means, with respect to either Party, any other corporation or business entity that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, the term "control" means direct or indirect ownership of more than fifty percent (50%) of the outstanding voting securities or other ownership interests or the power to direct or cause the direction of the management or policies of such entity, whether through the ownership of voting securities, by contract, or otherwise. Affiliates of FibroGen shall include, without limitation, any wholly foreign owned entities (whether owned or controlled directly by FibroGen or through one of its subsidiaries).

1.3 "**ANVISA**" means Brazil's National Health Surveillance Agency.

1.4 "**API**" means FibroGen's proprietary active pharmaceutical ingredient designated as FG-4592 (roxadustat), as further described in the Specifications.

1.5 "**Applicable Law(s)**" means, with respect to FibroGen, all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of each jurisdiction in which API or Product is produced, marketed, distributed, used or sold; and, with respect to Catalent, all laws, rules, and regulations applicable to the Manufacturing Services or otherwise bearing on the performance of this Agreement, and the relevant Purchase Order, including, as applicable, cGMP and other regulatory standards or requirements of Regulatory Authorities.

1.6 "**Batches**" or a "**Batch**" of Product means a specific quantity of tablets defined in **Attachment A** hereto that is intended to have uniform character and quality, within specified limits as described in more detail in Attachment A hereto).

1.7 "**Batch Documentation Package**" means all of the documentation associated with the production, manufacturing, packaging, labeling, testing, and release of a given Batch or Blend, including without limitation, Executed Batch Records, sampling documentation, raw data, test results, deviation reports, the Certificate of Analysis, the Certificate of Compliance, and any additional documentation required under the applicable Quality Agreement. Unless otherwise agreed to in a signed writing by both Parties, the Batch Documentation Package shall be in the English language.

1.8 "**Binding Forecast**" has the meaning set forth in Section 2.7.

1.9 "**Blend**" means a theoretical yield of [ ] ([ ]) kilograms of drug product blend that is to be compressed into Batches (tablets of different strengths) and produced according to a single manufacturing order during the same cycle of manufacture as specified in the applicable Purchase Order. For clarity, a Blend refers to a mixture that contains API and excipients, and is lubricated and ready for compression into different strengths of Product, as described in more detail in Attachment A hereto.

1.10 "**Catalent Background Intellectual Property**" means all Intellectual Property that is: (a) used in the course of performing Manufacturing Services under this Agreement; and (b) (i) owned or controlled by Catalent prior to the Effective Date of this Agreement, or (ii) made, conceived or reduced to practice outside the scope of this Agreement without the use of any FibroGen Confidential Information, FibroGen-supplied Materials or Product. For clarity, Catalent Background Intellectual Property shall not include any FibroGen Intellectual Property, FibroGen Owned Work Product, Product, or Manufacturing Process(es), or any other Intellectual Property relating to FibroGen-supplied Materials or Product.

1.11 "**Catalent Confidential Information**" means all confidential and proprietary information actually disclosed by Catalent to FibroGen in the course of performing Manufacturing Services under this Agreement and approved Purchase Orders. For clarity, Catalent Confidential Information shall not include any FibroGen Confidential Information, API, Product, or FibroGen Owned Work Product.

1.12 "**Catalent Facility(ies)**" means the facility(ies) listed in Section 3.1 hereto, which facility(ies) are owned and operated by Catalent and will be used for the performance of Manufacturing Services, and the production of Product.

1.13 "**Catalent Owned Work Product**" shall have the meaning as set forth in Section 10.1.

1.14 "**Certificate of Analysis**" means a document prepared by Catalent certifying that a particular Batch of Product was tested and conforms to the Specifications. Unless otherwise agreed to in a signed writing by both Parties, the Certificate of Analysis shall be in the English language.

1.15 "**Certificate of Compliance**" means a document prepared by Catalent that states that a particular Batch of Product was manufactured in compliance with the Quality Agreement and: (a) lists the manufacturing date, unique Batch number, Product number, and quantity of Product in such Batch; (b) certifies that such Batch was manufactured in accordance with the Master Batch Record and all Applicable Laws including cGMP; and (c) certifies all excursions and investigations associated with the Batch have been closed and found to not impact the Batch. The Parties shall from time to time agree upon a format or formats for the Certificate of Compliance to be used under this Agreement. Unless otherwise agreed to in a signed writing by both Parties, the Certificate of Compliance shall be in the English language.

1.16 "**cGMP**" means the current good manufacturing practices for the manufacture of pharmaceutical products, including without limitation: (a) the United States Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. §321 et seq.) and the regulatory requirements for current good manufacturing practices as promulgated by the FDA thereunder; including without limitation 21 C.F.R. Part 11 (as applicable to electronic systems used in the manufacture of Product), 21 C.F.R. Parts 210 and 211 as amended; and (b) the regulatory requirements for current good manufacturing practices as promulgated by the International Conference on Harmonization (ICH); and (c) Guidance for Industry Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients; and/or the European Community Directive 2003/94/EC of October 8, 2003; and (d) the EC Guide to Good Manufacturing Practice for Medicinal Intermediate Products; and (e) 2003/94/EEC Directive (as supplemented by Volume 4 of EudraLex published by the European Commission), as amended, if and as implemented in the relevant constituent country; and (f) all additional Regulatory Authority documents and regulations that replace, amend, modify, supplant or complement any of the foregoing and any amendments to the foregoing; and (g) any and all current Good Manufacturing Practices applicable to the manufacture, testing and/or any other processing of pharmaceutical products in other countries and territories worldwide where the respective Final Products are sold or otherwise marketed from time to time provided that Catalent is informed about such other Good Manufacturing Practices by FibroGen in accordance with the Quality Agreement within a reasonable time so as not to delay release of the Final Product.

1.17 "**Confidential Information**" means FibroGen Confidential Information and/or Catalent Confidential Information, as the context requires.

1.18 "**Contract Year**" means, (i) for the first Contract Year, the period beginning on the Effective Date and ending on December 31, 2020 ("Contract Year 1") and (ii) following Contract Year 1, each consecutive twelve (12) month period beginning on January 1 and ending on December 31 ("Contract Year 2", "Contract Year 3", etc.).

1.19 "**Delivery**" shall mean that Product shall be made available pursuant to Section 4.3 of this Agreement; and "**Delivery Date**" shall mean the date specified for Delivery of Product pursuant to a Purchase Order or Acknowledgement in accordance with Section 2.2.

1.20 "**Demand**" means the number of units of Product required by FibroGen, or its Designees, to fulfill all of its requirements for [ ] in the Territory for the applicable Contract Year. "**Demand Records**" has the meaning set forth in Section 2.4.1.

1.21 "**Designee**" means a designee of FibroGen that has been granted the right to receive Product, as specified in writing by FibroGen to Catalent.

1.22 "**DQSA**" shall have the meaning described in Section 11.2.9 hereof.

1.23 "**EMA**" means the European Medicines Agency, or any successor agency thereto.

1.24 "**Executed Batch Records**" means the collection of records that provides a traceable history of how a Batch of Product was produced.

1.25 "**FDA**" means the United States Food and Drug Administration, or any successor agency thereto, having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products in the United States.

1.26 "**FibroGen Confidential Information**" means any research, development, clinical, manufacturing, or commercialization strategies, and all related technical and other data and information, whether patented or unpatented, that relate to FibroGen-supplied Materials, FibroGen's compound structures, synthesis, formulation and manufacturing methods, test methods, operations, technologies, forecasts and business and scientific plans, including without limitation, trade secrets, know-how, and other intellectual property, that is disclosed to, or supplied to Catalent in any form by or on behalf of FibroGen pursuant to this Agreement, or data, results, and information included in or relating to the Products generated or otherwise obtained by Catalent in the course of performing Manufacturing Services pursuant to this Agreement. For clarity, all Product, Batch Documentation Package, Master Batch Records, FibroGen Intellectual Property, FibroGen-supplied Materials and FibroGen Owned Work Product, shall be deemed to be FibroGen Confidential Information.

1.27 "**FibroGen Intellectual Property**" means all Intellectual Property owned or controlled by FibroGen.

1.28 "**FibroGen Owned Work Product**" has the meaning set forth in Section 10.1.

1.29 "**FibroGen Review Period**" has meaning set forth in Section 4.2

1.30 "**Final Product**" means a final product sold to the public that includes Product supplied hereunder.

1.31 "**FibroGen-supplied Materials**" means any materials (including API, reference standards, progeny, derivatives, and modifications thereof) that are provided by or on behalf of FibroGen to Catalent for the purpose of performing Manufacturing Services, as further described in Attachment D.

1.32 "**FMD**" has the meaning set forth in Section 11.2.9 hereof.

1.33 "**Intellectual Property**" means all Patents, copyrights, trade secrets, know-how, inventions, and all other intellectual property rights that are owned or controlled by a Party (whether patentable or not), including all applications and registrations with respect thereto.

1.34 "**Joint Manufacturing Committee**" or "**JMC**" shall have the meaning set forth in Section 3.8.

1.35 "**Key Performance Indicators**" or "**KPI(s)"** has the meaning set forth in Section 3.8 hereof.

1.36 "**Latent Defects**" has the meaning set forth in Section 4.2.4.

1.37 "**Long Lead Time Materials**" has the meaning set forth in Section 3.2.1.

1.38 "**Manufacturing Process**" means the production process for the manufacture of Product.

1.39 "**Manufacturing Services**" has the meaning set forth in Section 2.3.

1.40 "**Master Batch Record**" or "**MBR**" means the document agreed on by the Parties in a signed writing that defines the Manufacturing Process of a particular Product, and pertains to the manufacture and supply of each Batch of Product, as may be amended from time to time by a signed writing of the Parties. The Master Batch Record shall include, without limitation, the appropriate applicable requirements for components (such as Raw Materials, FibroGen-supplied Materials, intermediates, in-process materials, and packaging materials and labels) and quantities of each as used; major production equipment; detailed production instructions, including sequences to be followed; sampling instructions and in-process controls with their acceptance criteria; time limits for completion of individual processing steps and/or the total process; expected yield ranges at appropriate phases of processing or of time; special notations and precautions to be followed; and instructions for storage of the intermediate, in-process material, Product to assure its viability for use. The Master Batch Record shall be presented in the English language. The Master Batch Record shall also incorporate by reference, without limitation, such additional information as may be required under the Quality Agreement.

1.41 "**MHRA**" means the United Kingdom Medicines and Healthcare products Regulatory Agency.

1.42 "**[ ] Requirement**" has the meaning set forth in Section 2.4.

1.43 "**Non-Conforming FibroGen-supplied Materials**" has the meaning set forth in Section 3.2.2(b).

1.44 "**Non-Conforming Processing**" has the meaning set forth in Section 4.2.1.

1.45 "**Non-Conforming Product**" has the meaning set forth in Section 4.2.1.

1.46 "**Other Services**" has the meaning set forth in Section 2.6 hereof.

1.47 "**PAI**" means a pre-approval inspection of the Catalent Facility as required by a Regulatory Authority.

1.48 "**Patents**" means, with respect to an invention, any patent or patent application, and any patent issuing therefrom, together with any extensions, reissues, reexaminations, substitutions, renewals, divisions, continuations, continuations-in-part, and foreign equivalents thereof, and any patent or patent application claiming priority to any application in common with any such patent containing a disclosure substantially similar to that of any such patent, all to the extent the foregoing contain claims covering such invention.

1.49 "**Process**" or "**Processing**" means the compounding, filling or tableting, encapsulating, producing and bulk packaging (but not secondary or retail packaging) of FibroGen-supplied Materials and Raw Materials into Product by Catalent, in accordance with the Specifications and under the terms of this Agreement.

1.50 "**Processing Date**" means the day on which the first step of physical processing occurs.

1.51 "**Product**" means the bulk pharmaceutical drug product containing the API, as more specifically described in the Specifications, in the form attached hereto as Attachment E, and as may be further amended by the Parties.

1.52 "**Product Maintenance Services**" has the meaning set forth in Section 2.5.

1.53 "**Product Storage Fees**" has the meaning set forth in Section 4.4, and as further described in this Agreement in Attachment A. For clarity, Product Storage Fees shall not include storage of API.

1.54 "**Purchase Order(s)**" has the meaning set forth in Section 2.2.2.

1.55 "**Quality Agreement**" means the quality agreement agreed on by Catalent and FibroGen in a signed writing that relates to the manufacture of Product, as may be amended from time to time by a signed writing of the Parties, and as more fully set forth in Article 8.

1.56 "**Raw Material**" means all ingredients, excipients, packaging materials, and reagents, including labels, solvents and other components other than FibroGen-supplied Materials that are required to perform the Manufacturing Services and/or manufacture the Product.

1.57 "**Recall**" has the meaning set forth in Section 6.6.1.

1.58 "**Registration**" has the meaning set forth in Section 6.1.

1.59 "**Regulatory Approval**" means each approval, permit, product and/or establishment license, registration or authorization, including each approval pursuant to U.S. Investigational New Drug Applications, New Drug Applications and Abbreviated New Drug Applications (or equivalent non-U.S. filings, such as European marketing authorization applications), as applicable, of a Regulatory Authority that is necessary or advisable in connection with the development, manufacture, testing, use, storage, exportation, importation, transport, promotion, marketing, distribution or sale of API or Product in the Territory.

1.60 "**Regulatory Authority(ies)**" means the FDA (for the USA), EMA (for the EU), ANVISA (for Brazil), MHRA (for the UK), and/or all other applicable, national, multi-national, state, regional or local regulatory agency, department, bureau, body or other governmental entity involved in or responsible for regulation of the relevant subject, as the context requires in this Agreement. Notwithstanding the foregoing, Regulatory Authorities shall include the relevant health, environmental, and safety agency pertaining to the country in which Manufacturing Services are performed.

1.61 "**Regulatory Filing**" means any or all applications submitted to Regulatory Authorities for the purpose of registering the Product, the Manufacturing Process, and/or Final Product as required by statute or regulation, and any amendments or supplements thereto, and any other filings required by the Regulatory Authorities relating to the manufacture, testing, sale or distribution of Product and/or Final Product (as applicable).

1.62 "**Representatives**" of an entity mean such entity's duly authorized officers, directors, employees, agents, accountants, attorneys or other professional advisors.

1.63 "**Rolling Forecast**" has the meaning set forth in Section 2.7.

1.64 "**Seizure**" means any action by the FDA or other Regulatory Authority to detain Final Products manufactured from Product or prevent the distribution, prescription, consumption or release of such Final Products manufactured from Product.

1.65 "**Specifications**" means the Product, Raw Material, and other specifications detailed in Attachment E, including reference standards agreed on by the Parties in one or more signed writings, including as applicable the characteristics, formulae, labeling, expiry date, storage requirements, and as may be amended from time to time by a signed writing of the Parties with Catalent's consent not to be unreasonably withheld.

1.66 "**Special Packaging**" means packaging that is not industry standard or commonly used by Catalent for commercial products, which shall include metal drums, or special tape. Special Packaging shall not include fiber drums, plastic drums, serialized seals, temperature/humidity monitoring devices, and similar packaging.

1.67 "**Subcontractor**" means any independent entity that Catalent contracts with FibroGen's prior written consent pursuant to Section 3.7 to perform any Manufacturing Services or meet any obligations that are required under the terms and conditions of this Agreement and applicable Purchase Orders.

1.68 "**Term**" has the meaning set forth in Article 16.

1.69 "**Territory**" means [ ] with the exception of [ ]and the countries then being sanctioned by the United States, as listed by the Office of Foreign Asset Control.

1.70 "**Third Party**" means any entity other than FibroGen, Catalent, and FibroGen's Designees.

1.71 "**Unit**" has the meaning set forth on Attachment A.

1.72 "**Unit Pricing**" has the meaning set forth in Section 5.2.1.

1.73 "**Vendor**" has the meaning set forth in Section 3.2.1(b).

1.74 "**Waste**" means any "hazardous substance" and/or "hazardous material" and/or any other waste material, pollutant and/or contaminant of any kind as defined by the Regulatory Authority(ies) having jurisdiction at the Catalent Facility, including, without limitation, any Raw Materials, in-process materials, routine process waste or any by-product arising from any activities conducted pursuant to this Agreement.

ARTICLE 2
PURCHASE ORDERS AND SUPPLY; FORECASTS

2.1 Agreement. This Agreement establishes the general terms and conditions applicable to Catalent's manufacturing and supply of the Product to FibroGen. This Agreement is intended to allow the Parties to contract for the performance of manufacturing and supply of the Product through the execution of separate written Purchase Orders (defined below in Section 2.2.2) in accordance with this Agreement. Each Purchase Order shall become part of and incorporated by reference into this Agreement and each Purchase Order shall be subject to all of the terms and conditions of this Agreement. Any changes to a Purchase Order shall be agreed to in a signed writing by the Parties prior to any such changes being effective.

2.2 Purchase Order(s).

2.2.1 Each Purchase Order complying with the requirements of this Section shall be valid and binding upon the submission of such Purchase Order by FibroGen, subject to Section 2.2.2. Each such Purchase Order submitted by FibroGen shall be governed by the terms and conditions of this Agreement.

2.2.2 From time to time as provided in this Section, FibroGen shall submit to Catalent a binding, non-cancelable purchase order for Product specifying the number of Blends of Product to be manufactured, the Batch size (to the extent the Specifications permit Batches of different sizes), number of Batches of specific strengths, and the requested Delivery Date and FibroGen Designee address for each Batch of Product (each, a "**Purchase Order**"); *provided*, the Delivery Date may not be less than [ ] ([ ]) days after the date such Purchase Order is submitted unless agreed on by Catalent. Within [ ] ([ ]) business days following receipt of a

Purchase Order, Catalent shall issue a written acknowledgement (each, an "**Acknowledgement**") that it accepts or rejects such Purchase Order. Each acceptance Acknowledgement shall either confirm the Delivery Date set forth in the Purchase Order or set forth an alternative Delivery Date in view of the Binding Forecast. Catalent and FibroGen will jointly work towards establishing the alternate Delivery Date. Catalent may reject any Purchase Order if it exceeds [ ] percent ([__]%) of the Binding Forecast or is otherwise not given in accordance with this Agreement. In the event of a conflict between the terms of any Purchase Order or Acknowledgment and this Agreement, the terms of this Agreement shall control. FibroGen shall submit a Purchase Order for the amount set forth in the applicable Binding Forecast in increments of []. Purchase Orders for quantities of Product in excess of the Binding Forecast (as defined in Section 2.7) shall be submitted by FibroGen at least [ ] ([]) days in advance of the Delivery Date requested in the Purchase Order.

2.2.3 Catalent shall use [ ] efforts to manufacture and supply FibroGen with quantities of Product in excess of [__] of the quantities specified in the Binding Forecast, or with a Delivery Date earlier than those specified in the Binding Forecast, subject to Catalent's other supply commitments and manufacturing, packaging and equipment capacity. Catalent shall at all times maintain (i) sufficient manufacturing capacity at the Catalent Facility, and (ii) sufficient stocks of Raw Materials, in each case enabling Catalent to manufacture [ ]) of the quantities of Product set forth in the most recent Binding Forecast. [ ].

2.2.4 FibroGen may modify the Delivery Date or quantity of Product in a Purchase Order only by submitting a written change order to Catalent and communicating Product strengths at least [ ] ([ ]) days in advance of the earliest Processing Date covered by such change order. Such change order shall be effective and binding against Catalent only upon the written approval of Catalent (such approval not to be unreasonably withheld), and, notwithstanding any such written approval, FibroGen shall remain responsible for the Binding Forecast. Notwithstanding any amount due to Catalent under Section 5.3, if FibroGen fails to place Purchase Orders sufficient to satisfy the Binding Forecast, FibroGen shall pay to Catalent in accordance with Article 5 an amount equal to the Unit Pricing for all Units that would have been Processed if FibroGen had placed Purchase Orders sufficient to satisfy the Binding Forecast. Neither changes to nor postponement of any Blend or Batch of Product, nor the payment of the fees described in this Section, will reduce or in any way affect the Binding Forecast obligations set forth in Section 2.7. Additionally, and notwithstanding anything to the contrary in this Section 2.2.4, Catalent shall have no further obligation with respect to such Purchase Order, until FibroGen supplies conforming FibroGen-supplied Materials set forth in Section 3.2.2(a). Any deferment of Purchase Orders to the extent caused by FibroGen's failure to supply FibroGen-supplied Materials in accordance with this Section 2.2.4 shall not constitute a breach of this Agreement by Catalent.

2.3 Supply. Subject to the terms and conditions of this Agreement, Catalent hereby agrees to manufacture and supply FibroGen (and other Designees) with the amounts of Product ordered by FibroGen pursuant to the Purchase Orders submitted in accordance with this Agreement. Such manufacture and supply of Product, including (a) the compounding, filling, or tableting, producing and bulk packaging (but not secondary or retail packaging) of FibroGen-supplied Materials and Raw Materials into Product by Catalent, in accordance with the Specifications and under the terms of this Agreement; (b) Product Maintenance Services as described in Section 2.5 (and Attachment B hereto); (c) the provision of other deliverables, such as the Batch Document Package; and (d) Other Services (collectively, the "**Manufacturing Services**") shall be performed in a professional manner consistent with industry standards and in compliance with the terms and conditions of this Agreement, the Quality Agreement, the Specifications and all Applicable Laws.

During [ ], Catalent covenants and agrees that it shall manufacture and supply Product [ ] pursuant to this Agreement and shall not [ ]. It is understood and agreed that FibroGen may [ ], and nothing in this Agreement shall be construed to prevent FibroGen from doing so provided that the foregoing shall not limit FibroGen's [ ].

2.4 [ ].

2.4.1 Demand Records; Audit Rights. FibroGen will keep complete and accurate books and records relating to the Demand, in sufficient detail to enable the calculation and verification of applicable [ ] in any given Contract Year ("**Demand Records**"). Upon the written request and not more than once per calendar year, Catalent shall be entitled to audit, or to have an independent accountant audit, such Demand Records. FibroGen shall provide Catalent or such auditors, as applicable, with access during normal business hours at FibroGen's relevant location and to such of the pertinent Demand Records of FibroGen as may be reasonably necessary to verify the matters in question. Such access shall include the right of Catalent or the independent accounting firm to interview FibroGen's personnel if reasonable. Each such examination shall be limited to pertinent Demand Records for any year ending not more than [ ] ([ ]) years prior to the date of such request. Before permitting such independent accounting firm to have access to such Demand Records and personnel, FibroGen may require such independent accounting firm and its personnel involved in such audit, to sign a confidentiality and use agreement to prohibit the independent accounting firm and its personnel from disclosing FibroGen's financial and proprietary information except to Catalent as contemplated by this section of the Agreement. Furthermore, the number of such audit personnel shall be limited to [ ] person.

2.5 Product Maintenance Services. Catalent shall provide and FibroGen will receive those product maintenance services specified in Attachment B (the "**Product Maintenance Services**").

2.6 Other Services. Catalent shall provide other Product-related services set forth in Attachment C, such as validation services, supported by Catalent on an as-needed basis under a countersigned quotation and preapproved in writing by FibroGen ("**Other Services**") as set forth in Attachment C. The terms and conditions of this Agreement shall govern and apply to such services.

2.7 Forecast. On or around the [ ] ([ ]) day of each [ ], beginning at least [ ], or such other date as agreed by the Parties, and continuing during the Term of this Agreement on a monthly basis, FibroGen shall furnish to Catalent a written [ ] ([ )] month rolling forecast of the quantities of Product that FibroGen anticipates FibroGen will require for Product to be delivered under a Purchase Order (each, a "**Rolling Forecast**"). By way of example, the Rolling Forecast delivered in [ ] will cover the period from [ ] through [ ]. The first [ ] ([ ]) months of each Rolling Forecast shall constitute a binding order for the quantities of Product in such Rolling Forecast (the "**Binding Forecast**") and the following [ ] months of the Rolling Forecast shall be non-binding, good-faith estimates.

2.8 Shortfalls in Supply. If Catalent fails to meet its supply obligations to FibroGen under this Agreement, then Catalent shall use [ ] efforts to cure such failure as soon as practicable. During such supply failure, Catalent shall use [ ] efforts to allocate manufacturing capacity to the manufacture and supply of Product to FibroGen or other Designees, until such supply failure is remedied. If any supply failure continues in effect for a period of more than [ ] ([ ]) days, Catalent and FibroGen shall meet and work together reasonably and in good faith to seek a prompt and commercially reasonable solution to the problem causing the supply failure.

ARTICLE 3
OTHER OBLIGATIONS

3.1 Catalent Facility. All Product manufactured for FibroGen hereunder shall be manufactured solely by Catalent at the Catalent facility located at [ ] ("[**] Facility**") and for the purpose of a second option to support Product release and stability testing at the Catalent facility located at [ ] ("[**] Facility**") or such other facility as agreed by the Parties in writing (collectively, the "**Catalent Facility**"). The Catalent Facility may not be changed without an amendment to this Agreement.

3.2 Raw Materials and FibroGen-supplied Materials.

3.2.1 Raw Materials.

(a) Procurement. Catalent shall be responsible for procuring, inspecting and releasing adequate Raw Materials as necessary to meet [] of the Binding Forecast, unless otherwise agreed by the Parties in writing. Catalent shall not be liable for any delay in delivery of Product if (i) Catalent is unable to obtain, in a timely manner, a particular Raw Material necessary for Processing and (ii) Catalent placed orders for such Raw Materials (other than Long Lead Time Materials) promptly following receipt of FibroGen's Binding Forecast and in view of the Raw Materials procurement necessary for the Rolling Forecast. As used herein, "**Long Lead Time Materials**" means any Raw Material that is subject to purchase lead time beyond the Binding Forecast time frame, as identified in Attachment D. Catalent shall maintain a stock of Long Lead Time Materials as necessary to meet the then-current Rolling Forecast. For clarity, [ ].

(b) If FibroGen requires a change to a specific supplier, manufacturer or vendor ("**Vendor**") to be used for Raw Material, then such Vendor will be identified in the Specifications and the Raw Materials from such Vendor shall be deemed FibroGen-supplied Materials for purposes of the other Sections of this Agreement. [ ]. If FibroGen decides to use a specific vendor, FibroGen will be responsible for [ ].

(c) In the event of (i) a Specification change requested by FibroGen (ii) obsolescence of any Raw Material or (iii) expiration or termination of this Agreement by FibroGen other than due to a material breach of Catalent, [ ].

(d) Raw Materials Compliance. All Raw Materials used in the Manufacturing Process shall comply with the applicable Specifications, Purchase Order, and Quality Agreement, or as otherwise agreed in a signed writing by the Parties. Catalent or a Subcontractor approved in accordance with Section 3.7 shall perform testing and evaluation of the Raw Materials as required to meet the foregoing obligations.

(e) Retention and Reserve Samples. Catalent shall identify and retain certain reserve samples as set forth in the Quality Agreement, the Master Batch Record, the applicable standard operating procedures and Applicable Laws, or as otherwise agreed to in a signed writing by Catalent and FibroGen.

(f) Artwork and Labeling. FibroGen shall provide or approve, prior to the procurement of applicable Raw Material, all artwork, advertising and labeling information necessary for Processing, if any. Such artwork, advertising and labeling information is and shall remain the exclusive property of FibroGen, and FibroGen shall be solely responsible for the content thereof. Such artwork, advertising and labeling information or any reproduction thereof may not be used by Catalent in any manner other than performing its obligations hereunder without FibroGen's written consent. The content of all artwork provided by or on behalf of FibroGen to Catalent shall comply with all Applicable Laws.

3.2.2 FibroGen-supplied Materials.

(a) FibroGen shall supply to Catalent, at FibroGen's cost, FibroGen-supplied Materials in quantities sufficient to meet FibroGen's requirements for Product. FibroGen shall deliver such items and associated Certificates of Analysis to the Catalent Facility no later than [ ] ([ ]) days (but not earlier than [ ] ([ ]) days) before the commencement of Manufacturing Services. Catalent shall use FibroGen-supplied Materials solely for performance of the Manufacturing Services. Catalent shall not transfer the FibroGen-supplied Materials, or otherwise provide access to the FibroGen-supplied Materials to any Third Party without the prior written consent of FibroGen. Catalent agrees that no express or implied licenses or other rights relating to the FibroGen-

supplied Materials are provided to Catalent under any Patents, trade secrets or other proprietary rights of FibroGen except to use such FibroGen-supplied Materials solely in accordance with this Agreement and the applicable Purchase Orders. Prior to delivery of any FibroGen-supplied Materials, FibroGen shall provide to Catalent a copy of all associated material safety data sheets, safe handling instructions and health and environmental information and any governmental certification or authorization that may be required under Applicable Laws relating to the API and Product, and thereafter shall provide promptly any update thereto. FibroGen shall be responsible at its expense for securing any necessary export, import or other governmental clearance, permit or certification required in respect of such supply. Additionally, FibroGen represents and warrants that all FibroGen-supplied Materials shall have been produced in accordance with Applicable Laws, shall comply with all applicable specifications, including the Specifications, shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement.

(b) Catalent shall inspect all FibroGen-supplied Materials received to verify their identity. Unless otherwise expressly required by the Specifications or pursuant to Attachment A, Catalent shall have no obligation to test Fibrogen-supplied Materials it receives to confirm that they meet the associated specifications, certificate of analysis or otherwise; but in the event that Catalent detects a nonconformity with the Specifications, Catalent shall give FibroGen prompt notice of such nonconformity. Catalent shall not be liable for any defect in FibroGen-supplied Materials, or in Product as a result of FibroGen-supplied Materials not meeting the associated specifications ("**Non-Conforming FibroGen-supplied Materials**"), unless Catalent did not perform the foregoing obligations in accordance with the Specifications. Catalent shall follow FibroGen's reasonable written instructions in respect of return or disposal of Non-Conforming FibroGen-supplied Materials [ ].

(c) FibroGen shall retain title to FibroGen-supplied Materials at all times (including while at the Catalent Facility and in transit) and shall bear the risk of loss of any such FibroGen-supplied Materials. FibroGen shall obtain and maintain insurance for such items while at the Catalent Facility and in transit to and from any Catalent Facility. Catalent shall not reverse engineer, attempt to determine the structure or chemical composition of any of the FibroGen-supplied Materials, or make any modifications or derivatives of the FibroGen-supplied Materials, except as expressly allowed under each Purchase Order. Upon completion of all Manufacturing Services with respect to specific FibroGen-supplied Materials, or earlier upon FibroGen's request, Catalent shall return all FibroGen-supplied Materials provided hereunder to FibroGen, or at FibroGen's option, destroy (with certification of disposition)[ ].

(d) FibroGen will not release any Batch of Product if the required certificates of conformance indicate that Product does not comply with the Specifications. All Product delivered to FibroGen by Catalent shall be held, used and disposed of by or on behalf of FibroGen in accordance with Applicable Laws, and FibroGen will otherwise comply with Applicable Laws relating to FibroGen's performance under this Agreement.

3.3 Manufacturing Standards. Catalent shall manufacture all Product in a professional manner and in accordance with Applicable Law and in compliance with the terms and conditions of the applicable Purchase Order, Specifications, this Agreement, and the Quality Agreement.

3.4 Documentation for Manufacture of Product. Catalent shall keep complete, accurate accounts, notes, data and records pertaining to the manufacture, processing, testing, packaging and storage of the Product, including without limitation (a) Executed Batch Records for Product manufactured in accordance with cGMP and (b) any other records required to be maintained under the Quality Agreement, or Applicable Laws. Catalent shall retain all such records for a period as set forth in the Quality Agreement, and shall provide such records to FibroGen upon reasonable advance notice. Catalent shall notify FibroGen in writing prior to the destruction of

any records retained under this Section and, at FibroGen's request, shall transfer such records to FibroGen at FibroGen's reasonable expense.

3.5 Analytical Testing. Catalent may designate a Subcontractor in accordance with Section 3.7, to perform the analytical testing on Raw Materials, Products, intermediates, and all other materials used in the Manufacturing Process as set forth in the current Master Batch Records, current Specifications, and/or as otherwise agreed in a signed writing by Catalent and FibroGen.

3.6 FibroGen-supplied Materials and Raw Materials Storage. As part of the Manufacturing Services, Catalent shall ensure that all, FibroGen-supplied Materials and Raw Materials that are to be used in the manufacture of Product, as well as all Products, intermediates, and all other materials used in the Manufacturing Process in Catalent's control, are stored in accordance with the terms and conditions of this Agreement, the Specifications or the MBR (as applicable), retest date letters (reference standard), the Quality Agreement, all Applicable Law, and/or as otherwise mutually agreed to in a signed writing by Catalent and FibroGen, at no additional cost[ ].

3.7 Approval of Subcontracting. Catalent shall not subcontract, sublicense or otherwise delegate any material obligations under this Agreement without FibroGen's prior written approval. All Subcontractors shall have entered into agreements with Catalent to enable Catalent to comply with all obligations hereunder relating to performance of Manufacturing Services hereunder, including without limitation, obligations relating to FibroGen Confidential Information and FibroGen Intellectual Property. FibroGen may also approve certain Catalent Affiliates to perform subcontracted work, and such Catalent Affiliates who are so approved and identified on the Purchase Order may perform the subcontracted work as described in such Purchase Order.

3.8 Key Performance Indicators. FibroGen and Catalent (through the JMC) shall set targets in writing for performance and minimum standards where applicable, for each of the Key Performance Indicators, and the actual performance versus targets will be measured, with the understanding and agreement by the Parties that such KPIs shall be set for tracking purposes only, with no obligations on Catalent to meet them, nor consequences for failure to meet them. All such changes to the KPIs or the review and assessment shall be recorded in writing. The Parties shall supply each other with appropriate data to calculate the KPIs.

3.9 Joint Manufacturing Committee. After the Effective Date, Catalent and FibroGen shall establish a joint steering committee (the "**Joint Manufacturing Committee**" or "**JMC**") consisting of at least [ ] ([ ]) members appointed by each Party meeting biannually or as otherwise scheduled. The JMC shall be responsible for reviewing the ongoing relationship of the Parties, considering and attempting to achieve resolution of any disputes referred to it pursuant to Section 18.8 hereof and addressing such other matters as the Parties may mutually agree. For the avoidance of doubt, the JMC is not authorized to amend this Agreement.

ARTICLE 4
ACCEPTANCE/REJECTION; DELIVERY

4.1 Batch Records and Data; Catalent Internal Release.

Except for Batches that are being investigated or retested, at the time of Catalent Internal Release to FibroGen (or Designee), each Batch of Product shall have no more than [ ] ([ ]) calendar days elapsed from the start of the then-current approved shelf life. Unless otherwise agreed to by the Parties in writing, after Catalent completes Processing of a Batch or Blend, Catalent shall provide FibroGen with copies of Batch records prepared in accordance with the Specifications and allow FibroGen [ ] ([ ]) business day review period to confirm the Batch records meet the requirements set forth in the Specifications. Catalent shall also provide FibroGen or its

Designee with Catalent's certificate of analysis for such Batch. Issuance of a certificate of conformance/analysis by Catalent constitutes release of the Batch by Catalent ("**Catalent Internal Release**"). FibroGen shall be responsible for final release of Product to the market.

4.2 FibroGen Review Period; Acceptance and Rejection Procedure.

4.2.1 Testing; Rejection. Catalent will complete Catalent Internal Release and promptly provide FibroGen with copies of all relevant components of the Batch Documentation Package (including but not limited to: (i) a Certificate of Analysis; (ii) a Certificate of Compliance; (iii) TSE/BSE; (iv) Material Safety Data Sheets (MSDS); and (v) analytical test results specified in the Quality Agreement). Catalent shall also if requested by FibroGen provide Product samples, and thereafter, FibroGen will, no later than [ ] ("**FibroGen Review Period**"), notify Catalent whether the Batch conforms to the Specifications. Upon receipt of notice from FibroGen that a Batch meets the Specifications, or upon failure of FibroGen to respond by the end of the FibroGen Review Period, the Batch shall be deemed accepted by FibroGen and FibroGen shall have no right to reject such Batch, except as set forth in Section 4.2.4 ("**FibroGen Acceptance**"). If FibroGen notifies Catalent in writing (a "**Complaint**") that a Batch does not conform to the Specifications or otherwise does not meet the warranty set forth in Section 11.2.6 ("**Non-Conforming Product**"), and [ ]then Catalent shall conduct an appropriate investigation to determine whether Catalent agrees with FibroGen that Product is Non-Conforming Product and to determine the cause of any nonconformity. If Catalent agrees that Product is Non-Conforming Product and [ ], then Section 4.2.3. shall apply. Catalent shall cooperate with FibroGen in determining the cause of any Non-Conforming Product, including quality problems involving a Product, identifying corrective/preventive action and ensuring the implementation and effectiveness thereof.

4.2.2 Discrepant Results. If the Parties disagree as to whether Product is Non-Conforming Product and/or whether the cause of the nonconformity is Non-Conforming Processing, and this is not resolved within [ ] ([ ]) days of the Complaint date, the Parties shall cause a mutually acceptable independent Third Party nominated by the JMC to review records, test data and to perform comparative tests and/or analyses on samples of the alleged Non-Conforming Product and its components, including FibroGen-supplied Materials. The independent Third Party's results as to whether or not Product is Non-Conforming Product and the cause of any nonconformity shall be final and binding. Unless otherwise agreed by the Parties in writing, the costs associated with such testing and review shall be borne by Catalent if Product is Non-Conforming Product attributable to Non-Conforming Processing, by FibroGen if Product is deemed Conforming, and shared equally between the Parties in all other circumstances. [ ]

4.2.3 Non-Conforming Processing. At FibroGen's direction and option, Catalent shall either (A) Process, [ ] another Batch of Product as a replacement for any Batch of Non-Conforming Product attributable to Non-Conforming Processing, [ ], or (B) credit or refund FibroGen for such rejected Batch. For the avoidance of doubt, FibroGen shall be liable to pay for either the rejected Batch(es) or the replacement Batch(es), but not both. [ ]

4.2.4 Latent Defects. If any Product is subsequently found to contain a Latent Defect (as defined below) after FibroGen's receipt of the applicable Batch and Batch Documentation Package and such Product has not yet reached [ ], then FibroGen may bring a Complaint to Catalent for Non-Conforming Product, [ ], and Sections 4.2.1, 4.2.2 and 4.2.3, shall apply. The Parties will work together in good faith to determine the origin of the Latent Defect, including by review of any applicable reserve samples of the applicable Batch of Product retained at Catalent and through Section 4.2.3, which shall apply if there is a dispute between the Parties regarding whether a Latent Defect exists or what the origin of the defect is. For purposes of this Section 4.2.4, "**Latent Defect**" means [ ].

4.3 Delivery Terms; Storage. Promptly following Catalent's Internal Release of Product (which includes FibroGen's right of [ ] ([ ]) business days review as set forth in Section 4.1), Catalent shall deliver Product to FibroGen or Designee by making Product available [ ] (Incoterms 2010) Catalent Facility ("**Delivery**") and shall invoice FibroGen. Sole and exclusive title to Product shall always remain with FibroGen; and risk of its loss shall transfer to FibroGen upon Catalent's tender of Delivery. In the event Catalent arranges logistics services for FibroGen at FibroGen's request, such services are performed by Catalent as a convenience to FibroGen only and do not alter the terms and limitations set forth in this Section 4.3. If the Purchase Order does not specify disposition of Product, then Catalent shall store such Product in accordance with the storage requirements (as defined in the Specifications and the MBR as applicable and this Agreement) until such time as FibroGen requests shipment or other disposition or use of such Product. If Catalent provides storage services (as outlined in Section 4.4 below), title to such items shall pass to FibroGen upon transfer to storage. Catalent shall not be responsible for Product in transit, including any cost of insurance or transport fee for Product, or any risk associated with transit or customs delays, storage and handling.

4.4 Product Storage Fees. If FibroGen fails to take possession of any Product within [ ] ([ ]) business days of the scheduled Delivery Date, Catalent shall store such Product and have the right to invoice FibroGen monthly following such scheduled Delivery Date for reasonable administration and storage costs ("**Product Storage Fees**").

4.5 Bill and Hold. From time to time, at FibroGen's request the agreed Delivery Date of the Purchase Order may be extended under a bill and hold arrangement as more fully set forth below. For each such Batch of stored Product, FibroGen agrees that: [ ].

ARTICLE 5
PAYMENTS

5.1 Compensation. Except as otherwise provided hereunder, Catalent shall not charge FibroGen for (a) [ ], or (b) any [ ]; or, (c) any Manufacturing Services, Products, or costs [ ].

5.2 Fees; Invoicing. In consideration for Catalent performing Manufacturing Services and other services hereunder:

5.2.1 Unit Pricing and Unit Pricing Increase. FibroGen shall pay Catalent the unit pricing for Product Delivered pursuant to this Agreement as set forth on Attachment A (together with any subsequent updates pursuant to pricing, the "**Unit Pricing**"). Unit Pricing includes all fees for the Manufacturing Services, including, but not limited to, all packaging other than Special Packaging, storage of FibroGen-supplied Materials and Raw Materials, and release testing and other work to be performed as set forth in the Specifications, but excluding cost of API, Product Maintenance Services, or Other Services. The Unit Pricing shall be adjusted on an [ ] basis, effective on [ ] during the Term, upon [ ] ([ ]) days' prior written notice from Catalent to FibroGen, to reflect increases in, among other things, labor, utilities and overhead and shall be in an aggregate increased amount no greater than [ ]. In addition, price increases for Raw Materials referenced in Attachment D shall be passed through to FibroGen at the time of such price increase to Catalent if the price increase for the Raw Material is greater than [ ] percent ([ ]%) through an adjustment to the then prevailing Unit Pricing at the prices actually imposed by such Raw Materials suppliers.

5.2.2 Product Maintenance. FibroGen shall pay Catalent the annual fees for Product Maintenance Services set forth on Attachment A. Catalent shall submit an invoice to FibroGen for such fees beginning upon the Effective Date and prorated for the calendar days remaining in the then current year, and the

first day of each calendar year thereafter during the Term. All fees associated with Product Maintenance Services described in Attachment B are included in the annual fee described in Attachment A.

5.2.3 Other Fees that are not Product Maintenance Fees or Unit Pricing. Catalent shall provide quotes for all fees for services or costs. FibroGen shall pay Catalent for all other fees for services or costs approved in writing in advance by FibroGen explicitly set forth in this Agreement or a Purchase Order, including pursuant to Attachment C, 2.6 (Other Services), 4.4 (Product Storage Fees), 4.5 (Bill and Hold) fees, and any validation services. Catalent shall submit an invoice to FibroGen for such fees as and when appropriate.

5.3 Payment Terms. Catalent shall submit an invoice to FibroGen for such fees upon tender of Delivery of Product as provided in Section 4.3. FibroGen will pay Catalent [ ] invoiced in accordance with this Article 5 within [ ] ([ ]) days of date of such invoice, provided that: [ ]. All invoices and payments hereunder shall be in U.S. Dollars (USD). All such invoices relating to this Agreement must have the invoice coding as indicated in the Purchase Order and be sent to:

Accounts Payable
FibroGen, Inc.
409 Illinois Street
San Francisco, CA 94158
AP@FibroGen.com

5.4 Taxes and Other Surcharges. All taxes, duties and other amounts (excluding taxes based on net income and franchise taxes) assessed in respect of FibroGen-supplied Materials or in connection with the sale or delivery of Product hereunder, whether assessed prior to or upon provision or sale, and whether assessed on Catalent or FibroGen, are the responsibility of FibroGen, and either FibroGen shall reimburse Catalent for all such taxes, duties or other amounts paid by Catalent or such sums will be itemized and added to invoices directed at FibroGen, with supportive documentation to be provided by FibroGen to Catalent, as needed to comply with this Section 5.4. If any deduction or withholding in respect of tax or otherwise is required by law to be made from any of the sums payable hereunder, FibroGen shall be obliged to pay to Catalent such greater sum as will leave Catalent, after deduction or withholding as is required to be made, with the same amount as it would have been entitled to receive in the absence of any such requirement to make a deduction or withholding. Catalent shall use all reasonable endeavors to obtain the relevant withholding or deducting certificate or certificates in a form which FibroGen can utilize in order to enable it to recover or obtain credit from the relevant taxing or other government authority the amount so withheld or deducted. In determining the applicability of any withholding tax, the provision of any relevant bilateral income tax treaties or regulatory instrument or document shall be taken into account.

ARTICLE 6
REGULATORY OBLIGATIONS

6.1 Registrations, Permits and Licenses. All Catalent Facilities will be properly licensed and have all necessary permits to perform the Manufacturing Services. Catalent shall secure and maintain in good order, at its sole cost and expense, such current governmental registrations, permits, approvals and licenses (including Catalent Facilities licenses) as are required by Applicable Law and applicable Regulatory Authorities in order for Catalent to perform all of its obligations under this Agreement and each Purchase Order (each, a "**Registration**"), for so long and insofar as is necessary to permit Catalent to perform any of its obligations under this Agreement. Catalent shall supply such Registrations and all related documents, including all permits and licenses related to Catalent Facilities to FibroGen or a FibroGen Designee upon request by FibroGen, to the extent specifically related to the Product or the Manufacturing Services or Deliverables hereunder.

6.2 Regulatory Communications and Correspondence. Any and all communications from and to the FDA or other Regulatory Authorities related to the manufacture of the Products at the Catalent Facility shall be handled in accordance with the terms and conditions of the Quality Agreement, or as otherwise agreed in a signed writing by Catalent and FibroGen.

6.3 Regulatory Inspections.

6.3.1 Inspection by Regulatory Authorities. Upon the request of any Regulatory Authority having jurisdiction over the manufacture of Product hereunder, such Regulatory Authority shall have access to observe and inspect Catalent's facilities (including Catalent Facility) and procedures used for the manufacture, release and stability testing, and/or warehousing of all Product, and to inspect such facilities (including Catalent Facility) for compliance with cGMP and other Applicable Law. FibroGen Representatives shall be permitted to be on site for (but not participate in) any such inspections by Regulatory Authorities. Catalent specifically agrees to cooperate with any inspection by a Regulatory Authority, whether prior to or after regulatory approval of Product manufactured by Catalent, and to provide FibroGen with a copy of any document received including any inspection report resulting from any such inspection by a Regulatory Authority (redacted as appropriate to protect any confidential information of Catalent or Catalent's other customers), which document/report shall be received by FibroGen no later than [ ] ([ ]) business days from such inspection. Catalent agrees that Catalent shall promptly notify FibroGen of any regulatory inspections relating to Product as further set forth in the Quality Agreement. For clarity, the foregoing reporting requirements do not impact Catalent's reporting obligations to FibroGen as set forth in Section 6.6.2. If Catalent is purchasing Raw Materials from a Third Party for use in manufacturing Product, Catalent shall use [ ] efforts to ensure that such supplier's facilities and procedures are similarly subject to the provisions of this Section as to the manufacture of such Raw Materials. FibroGen shall carry out audits pursuant to the Quality Agreement. Among other requirements set forth in the Quality Agreement, Catalent will be required to permit Regulatory Authorities to carry out a PAI. The Parties hereby acknowledge that Regulatory Authorities may require to inspect the Catalent Facilities in order to approve them.

6.3.2 Remedial Actions. Catalent shall notify FibroGen immediately in writing in the event any action is taken or threatened by a Regulatory Authority relating to the manufacture, supply, or storage of Product by Catalent, or relating to Catalent Facility in which such manufacture, supply, or storage occurs, or which may impair the ability of Catalent to manufacture, supply, or store Product (including without limitation any impairment to Catalent's ability to manufacture Product conforming to the applicable Specifications) in accordance with this Agreement. In any event, Catalent shall use [ ] efforts to address and resolve any issues, concerns or warnings from any Regulatory Authority that impact Catalent's ability to manufacture, supply, or store Product in accordance with this Agreement, the Specifications and MBR (as applicable). To the extent Catalent must implement a plan of remediation or for other modifications or changes to Catalent's Facility in order to address and resolve any such issues, concerns or warnings from any Regulatory Authority, Catalent shall: (a) prepare such plan as soon as practicable; (b) provide a draft of the plan to FibroGen to the extent specifically referencing the production of the Product; and (c) implement and complete all aspects of the plan as agreed with FibroGen soon as practicable.

6.4 Regulatory Authority Fees. [ ], which fees result directly from Catalent's formulation, development, manufacturing, processing, filling, packaging, storing or testing of FibroGen's Product or FibroGen-supplied Materials, other than pursuant to Attachment B. Catalent will invoice FibroGen for reimbursement of all other payments or fees at the time they are actually incurred by Catalent as a direct pass-through cost with no associated overhead or administration costs. FibroGen shall pay all invoices pursuant to Article 5 hereof.

6.5 Regulatory Filings and Maintenance; Cooperation in Obtaining Government Approvals. Catalent shall provide information and documentation to support FibroGen's Regulatory Filings and in maintaining

Regulatory Authority approvals for the Product, as necessary, and shall prepare and maintain manufacturing files, certificates, authorizations, data and other records that pertain to the manufacture of the Product as further set forth in the Quality Agreement or applicable Purchase Order, or as otherwise agreed to in a signed writing by Catalent and FibroGen. FibroGen (or other Designees) shall have the exclusive right to prepare and submit any and all Regulatory Filings regarding any products containing Product and Final Product, and including filing any amendments or supplements thereto and pursuing such Regulatory Filings for approval or registration. Any and all such Regulatory Filings regarding API, Product or Final Products, and any approvals obtained thereon, will be owned solely by and held in the name of FibroGen (or other Designees, as applicable). To the extent required or appropriate under Applicable Law, any such Regulatory Filings, or any approvals obtained thereon, may list Catalent as a manufacturer of the Product under this Agreement. Notwithstanding the above, FibroGen (or other Designees) shall not identify Catalent in any ANDA/NDA application or other such initial regulatory filing or submission without Catalent's prior written acknowledgment. Such acknowledgment shall not be unreasonably withheld and shall be memorialized in a writing signed by authorized Representatives of both Parties. FibroGen shall provide Catalent with notice of any Regulatory Filings that name Catalent as a manufacturer of the Product and provide Catalent with a copy of each Regulatory Approval required to distribute, market or sell Product in the Territory.

6.6 Recalls.

6.6.1 Responsibility. If a Regulatory Authority orders or requires the recall of Product supplied pursuant to this Agreement or if either Catalent or FibroGen believes a recall, field alert, Product withdrawal or field correction ("**Recall**") may be necessary with respect to Product supplied under this Agreement, the Party receiving the notice from the Regulatory Authority or that holds such belief shall promptly notify the other Party in writing. Recalls or Seizures of Final Product will be further handled by the Quality Agreement between the Parties.

6.6.2 Communication. Catalent shall keep FibroGen fully and promptly informed of any notification, event or other information, whether Catalent receives directly or indirectly, which notification, event or other information (a) might affect the marketability, safety, or effectiveness of the Product; or (b) might result in a Recall or Seizure. Upon request, Catalent shall cooperate with, and provide reasonable assistance in a timely manner to FibroGen in connection with any Recall or Seizure, including without limitation providing information relating to a potential or actual Recall or Seizure within [ ] ([ ]) business day after FibroGen's request therefor, to the extent such information is readily available to Catalent. In the event that Catalent believes that a Recall may be necessary or appropriate, Catalent shall notify FibroGen within [ ] ([ ]) business day.

6.6.3 Replacement; Refund. The cost of any Recall shall be borne by FibroGen, and FibroGen shall reimburse Catalent for expenses incurred in connection with any Recall, in each case except to the extent such Recall is caused by Catalent's breach of its manufacturing obligations under this Agreement or Catalent's violation of Applicable Laws or its negligence or willful misconduct, in which case Catalent shall bear [ ].

ARTICLE 7
HAZARDS AND SAFETY

7.1 Hazards. As of the effective date of each applicable Purchase Order, FibroGen shall provide Catalent with all information then known to FibroGen and in FibroGen's possession or control concerning any hazardous conditions or Wastes associated with exposure to or the handling, storage, use, or disposal of FibroGen-supplied Materials and Product, including without limitation Materials Safety Data Sheets for FibroGen-supplied Materials and Product.

7.2 Safety. Catalent shall in accordance with Catalent's internal procedures and Applicable Law, inform its employees, contractors and other personnel of any known or reasonably ascertainable chemical and processing hazards associated with the Raw Materials, FibroGen-supplied Materials, Product, or any Wastes generated through performance of the Manufacturing Services hereunder, and provide such persons with training in the proper methods of handling and disposing of such items. Catalent shall be responsible for maintaining safety procedures and required training documentation for Catalent's handling and manufacture of the Product, FibroGen-supplied Materials, and all Raw Materials and components thereof, and for the generation, treatment, storage and disposal of Wastes relating thereto all of which shall comply with all applicable national and local environmental and occupational safety and health requirements where the Waste is located. FibroGen shall have the right to audit and comment on such procedures. In accordance with the Quality Agreement, each Party shall promptly notify the other of any information or notice of which it becomes aware concerning the Product, including, without limitation, any threatened or pending action by any Regulatory Authority. FibroGen shall be responsible for handling all complaints and communications from Regulatory Authorities with respect to the Final Product or Product, except to the extent such complaints and communications relate to the Catalent Facility. Catalent shall cooperate in resolving such complaints and responding to such communications to the extent such cooperation is reasonably requested by FibroGen.

7.3 Waste Handling; Notification. At Catalent's expense, Catalent or an approved Subcontractor shall handle, label, package, store, transport and dispose of all Wastes generated through performance of the Manufacturing Services hereunder in material compliance with all Applicable Laws, and be responsible for such actions therefor. Each Party shall promptly notify the other of any health hazards or potential health hazards of which it is or becomes aware concerning exposure to or handling of the Raw Materials, FibroGen-supplied Materials, Product, or Wastes.

7.4 Accident Reports/Adverse Event Reporting. It is understood and agreed that FibroGen (or other Designees) shall have the sole right and responsibility for reporting to the applicable and appropriate Regulatory Authorities any adverse events involving the Product or Final Product (as applicable). Catalent shall provide FibroGen all reasonable assistance in complying with such reporting requirements. Catalent shall report to FibroGen immediately within [ ] ([ ]) business day all material accidents related to the manufacture, handling, use or storage of any Raw Materials, FibroGen-supplied Materials, or Product, including, without limitation: (a) accidents resulting in significant personal injury requiring more than first aid treatment, (b) accidents resulting in chronic illness or loss of consciousness, (c) accidents resulting in material property damage, (d) accidents resulting in material environmental release, and (e) accidents that result in regulatory, safety, health or environmental audits. Catalent shall notify FibroGen of any information of which Catalent becomes aware concerning any side effect, injury, toxicity or sensitivity reaction, or any unexpected incident, and the severity thereof, that is associated with the manufacturing of Product.

ARTICLE 8
QUALITY ASSURANCE

8.1 Quality Agreement. Prior to any Regulatory Filing for the Product that names Catalent as a manufacturer of Product and in any case before first cGMP Manufacturing of the Product, the Parties shall agree upon and execute a quality agreement (the "**Quality Agreement**"). The Quality Agreement shall set forth the responsibilities of the Parties with respect to pharmacovigilance, quality assurance, document retention, notification obligations relating to Regulatory Authority inquiries and activities, audit and inspection rights, and similar matters with respect to the manufacture of Product including Recalls, returned goods, and authorization for Recalls.

8.2 Changes to Specifications. All Specifications, and any change to the Specifications agreed by the Parties from time to time, shall be in writing, dated and signed by the Parties. Any change to the Manufacturing Process or MBR shall be deemed a Specification change. No change in the Specifications shall be implemented by Catalent, whether requested by FibroGen or requested or required by any Regulatory Authority, until the Parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change (including any change to Unit Pricing). Catalent shall respond promptly to any request made by FibroGen for a change in the Specifications, and both Parties shall use commercially reasonable, good-faith efforts to agree to the terms of such change in a timely manner. For changes to Specifications due to revisions to compendial specifications, such Specification changes shall be implemented by Catalent no later than the effective date of the corresponding change in the compendia. As soon as practicable after a request is made for any change in Specifications, Catalent shall notify FibroGen of the costs associated with such change and shall provide such supporting documentation as FibroGen may reasonably require. FibroGen shall pay all costs associated with FibroGen requested changes to the Specifications. Catalent shall pay for all costs associated with changes to the Specifications requested by Catalent or [ ], to the extent not resulting from a Specification change requested by FibroGen.

8.3 Quality Control. Catalent shall ensure that all Product manufactured for supply to FibroGen pursuant to this Agreement is subject to quality controls in conformance with customary practices, cGMP and regulatory standards. In addition, Catalent shall maintain and follow a quality control and testing program to confirm that all Product supplied hereunder conforms to the Specifications.

8.4 Responsibility for Quality Assurance and Quality Control. Responsibility for quality assurance and quality control of Product shall be allocated between FibroGen and Catalent as set forth in the Quality Agreement.

8.5 Audits; Observation of Product Manufacture. Notwithstanding anything to the contrary herein or in any Purchase Order, Catalent agrees that it shall not commence any manufacture of Product until FibroGen has approved the applicable Master Batch Record. On an ongoing basis, FibroGen, other Designees, and other authorized agents designated by FibroGen shall have the right to perform, directly or through its representatives or agents, certain audits of records and documentation, and to have Representatives of FibroGen (or representatives of FibroGen's designee, including representatives of FibroGen's partners or other Designees) visit each Catalent Facility during normal business hours to review Catalent's manufacturing operations, to assess its compliance with and the Quality Agreement, the quality-related obligations in this Agreement, and applicable regulatory standards, and to discuss any related issues with manufacturing and management personnel. Catalent shall cooperate fully in all such reviews, audits, and inspections. Catalent shall provide at no further cost personnel time and resources as may be available and commercially reasonable to complete such audits. FibroGen shall provide reasonable advance notice to Catalent of visits to Catalent Facility. FibroGen's Representatives (and/or representatives of FibroGen's designee or partner or other Designees) shall be granted access upon to (A) the portion of the Catalent Facility where Catalent performs Manufacturing Services, (B) relevant personnel involved in Manufacturing Services and (C) records pertaining to Manufacturing Services, in each case solely to the extent pertaining to the Product and for the purpose of verifying that Catalent is performing the Manufacturing Services in accordance with Applicable Laws, including cGMPs, the Specifications, Quality Agreement and the Master Batch Records. FibroGen, including its partners, Representatives and/or other Designees, may not conduct an audit under this Section more than [ ] during any [ ] ([ ]) month period, unless there is a material quality or compliance or security issue concerning Product, the Manufacturing Services, or the Manufacturing Process (as provided under Attachment B hereto); *except* that additional inspections may be conducted [ ]. Notwithstanding the foregoing, FibroGen (or its designee) may conduct an audit of Catalent's security procedures [ ] every [ ] ([ ]) months to ensure adequate Product security processes are in place. Audits and inspections shall be designed to minimize disruption of operations at the Catalent Facility. If following an inspection FibroGen considers that the

Products are not meeting the requirements set forth in Section 11.2.6, or the security requirements posed under Section 8.6 hereof are insufficient, FibroGen shall inform Catalent and Catalent shall take such immediate action as is necessary to ensure that the Product is or will be as warranted under Section 11.2.6. FibroGen shall have the right to re-conduct inspections and take further samples after Catalent has carried out its remedial actions at no additional costs.

8.6 Product Security. Catalent will ensure that all FibroGen-supplied Materials, including API and Product, while under the control of Catalent are under appropriately secure conditions with procedures in place to (a) protect the materials against diversion and theft, and (b) include mechanisms for full accounting and reconciliation of FibroGen Materials, including API and Product, in each case, as may be more fully set forth under the Quality Agreement. Catalent will promptly notify FibroGen should any breach or discrepancy thereof occur, and Catalent will work cooperatively with FibroGen to resolve any such breach or discrepancy, within the scope of its responsibilities under the Quality Agreement. [ ].

ARTICLE 9
LICENSE GRANTS; TRANSFER ASSISTANCE

9.1 Licenses to Catalent. During the Term, FibroGen hereby grants to Catalent a limited, royalty-free, non-exclusive, non-transferable license (without any right to sublicense) under any FibroGen Intellectual Property for the sole and limited purpose of Catalent's performance of its obligations under this Agreement, including, without limitation, the manufacture and supply of Product pursuant to any applicable Purchase Order(s). Catalent covenants that it shall not use or practice the FibroGen Intellectual Property for any use or purpose other than for the limited manufacturing and supply as provided in this Agreement, and shall not disclose, transfer, make public or sublicense any rights, data and information under the FibroGen Intellectual Property.

9.2 License to FibroGen. Catalent shall and hereby grants to FibroGen an irrevocable, perpetual, worldwide, fully paid, royalty-free, non-exclusive license, with the right to grant and authorize sublicenses, under any and all Catalent Background Intellectual Property and Catalent Owned Work Product that Catalent incorporates into the Product, the MBR, Batch Documentation Package and such other deliverables, in each case to practice such Catalent Background Intellectual Property for the sole and limited purpose of: selling, having sold, offering for sale, using, having sold, importing and/or exporting, and commercializing the Product (or any back-up compounds or next-generation compounds thereof).

9.3 Transfer Assistance. [ ].

ARTICLE 10
OWNERSHIP OF INTELLECTUAL PROPERTY AND MATERIALS

10.1 Rights to Intellectual Property.

10.1.1 Except as otherwise provided for hereunder, all Intellectual Property developed under this Agreement which relates exclusively to the Product, including the Batch Documentation Package, the MBR, the Manufacturing Process, and all other deliverables required by this Agreement, including any improvements or modifications thereto (collectively, "**FibroGen Owned Work Product**") shall be owned by FibroGen and Catalent shall and hereby assigns all of Catalents's rights, title and interest in the FibroGen Owned Work Product to FibroGen. For clarity, FibroGen Owned Work Product shall not include Catalent Background Intellectual Property, and, except as set forth in Section 9.2, no rights to Catalent Background Intellectual Property are provided for hereunder. FibroGen Owned Work Product shall be deemed FibroGen Confidential Information.

Catalent shall execute documents and take other actions as FibroGen reasonably requests (at FibroGen's expense) for purposes of applying for, obtaining, perfecting, evidencing, sustaining and enforcing FibroGen's interest in the FibroGen Owned Work Product. The content of all artwork provided by or on behalf of FibroGen to Catalent shall and shall continue to be the sole and exclusive property of FibroGen.

10.1.2 Catalent shall own Intellectual Property relating to its Manufacturing Services under this Agreement, including those that are generally applicable to developing, formulating, manufacturing, filling, processing, packaging, analyzing, or testing pharmaceutical products generally to the extent not specific to the manufacture, formulation, filling, processing, packaging, analyzing, testing, use, sale, offer for sale, export and/or import of the Product and do not rely on or make a claim towards FibroGen Owned Work Product or FibroGen Confidential Information ("**Catalent Owned Work Product**"). All Catalent Owned Work Product shall be solely owned by Catalent.

10.2 FibroGen-supplied Materials. As between the Parties and without prejudice to any other ownership rights hereunder, FibroGen shall own all rights and interests in and title to the FibroGen-supplied Materials, including API.

10.3 Intellectual Property Controls. Catalent shall require any of its employees, approved Subcontractors, and employees of such approved Subcontractors to hold any of FibroGen Confidential Information and FibroGen-supplied Materials in strict trust and confidence, and shall require such employees, approved Subcontractors, and employees of such approved Subcontractors to assign all right, title and interest in and to FibroGen Owned Work Product to Catalent so that Catalent may comply with its obligations under this Agreement. Furthermore, Catalent shall protect all FibroGen Confidential Information in no less than the same manner it uses to protect its own confidential information.

ARTICLE 11
REPRESENTATIONS AND WARRANTIES

11.1 FibroGen. FibroGen hereby represents and warrants to Catalent that, as of the Effective Date:

11.1.1 Power and Authority. FibroGen is duly formed and validly existing under the laws of its jurisdiction of formation and has all requisite corporate power and authority to execute and enter into this Agreement and to perform its obligations hereunder. Furthermore, FibroGen represents and warrants to Catalent that neither FibroGen nor any of its employees has (to the best of its knowledge) or will perform any of the following acts, either directly or through a Third Party, in connection with this Agreement: (a) pay, offer or promise to pay, or authorize the payment of, any money; (b) give or promise to give, or authorize the giving of, any services or anything else of value; or (c) enter into any other transactions, to or with any official or employee of any governmental agency or instrumentality, or of a public international organization, or of any agency or subdivision thereof, or to any political party or official thereof or to any candidate for political office, in each case for the purpose of: (i) influencing any act or decision of that person in his/her official capacity, including a decision to fail to perform his/her official functions with such governmental agency or instrumentality or such public international organization or such political party; (ii) inducing such person to use his/her influence with such governmental agency or instrumentality or such public international organization or such political party to affect or influence any act or decision thereof; or (iii) securing any improper advantage.

11.1.2 Execution, Delivery and Performance of the Agreement. FibroGen has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement. This Agreement shall be duly executed and delivered on behalf of FibroGen, and constitute a legal, valid, binding obligation, enforceable against FibroGen and its

successors and assigns in accordance with its terms and conditions. The execution, delivery and performance of this Agreement does not materially breach, conflict with, violate, contravene or constitute a default under any contracts, arrangements or commitments to which FibroGen is a party or by which it is bound nor does the execution, delivery and performance of this Agreement by FibroGen violate any order, law or regulation of any court or Regulatory Authority having authority over it.

11.1.3 Materials and Information. FibroGen is free to supply to Catalent the FibroGen Confidential Information and FibroGen-supplied Materials supplied by FibroGen to Catalent.

11.1.4 License. FibroGen has the right, power and authority to grant Catalent the license set forth in Section 9.1 above.

11.1.5 All FibroGen-supplied Materials shall have been produced in accordance with Applicable Laws, shall comply with all applicable specifications, including the Specifications, shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement. If FibroGen learns of the noncompliance of an Applicable Law that materially impacts the Manufacturing Services by an employee, agent, or Subcontractor being used by Fibrogen, Fibrogen will promptly so notify Catalent in writing, and appropriate action will be taken by FibroGen in consultation with Catalent, as may be practical and appropriate under the circumstances.

11.1.6 The content of all artwork provided by or on behalf of FibroGen to Catalent shall comply with all Applicable Laws.

11.1.7 All Product delivered to FibroGen by Catalent shall be held, used and disposed of by or on behalf of FibroGen in accordance with this Agreement and Applicable Laws, and FibroGen will otherwise comply with Applicable Laws relating to FibroGen's performance under this Agreement.

11.1.8 FibroGen will not release any Batch of Product if the required certificates of conformance indicate that Product does not comply with the Specifications or if FibroGen (or its Designee) does not hold all necessary Regulatory Approvals to market and sell the Product, or in the conduct of any clinical trial utilizing Product or API.

11.1.9 To FibroGen's knowledge, there is (i) no patent owned by a Third Party related to the FibroGen Intellectual Property used to Process Product that would be infringed or misused by performance under this Agreement and (ii) no trade secret or other proprietary right of a Third Party related to the FibroGen Intellectual Property used to Process Product that would be infringed or misused by performance under this Agreement..

11.1.10 FibroGen has all authorizations and permits required to deliver (or have delivered) API to the Facility.

11.1.11 FibroGen further represents and warrants that no transaction or dealing under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanction, restriction or embargo administered by the United Nations, European Union, United Kingdom, or United States.

11.2 Catalent. Catalent hereby represents and warrants to FibroGen that, as of the Effective Date:

11.2.1 Power and Authority. Catalent is duly formed and validly existing under the laws of its jurisdiction of formation and has all requisite corporate power and authority to execute and enter into this Agreement and to perform its obligations hereunder.

11.2.2 Execution, Delivery and Performance of Agreement. Catalent has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement. This Agreement shall be duly executed and delivered on behalf of Catalent, and constitutes a legal, valid, binding obligation, enforceable against Catalent and its successors and assigns in accordance with its terms. The execution, delivery and performance of this Agreement does not materially breach, conflict with, violate, contravene or constitute a default under any contracts, arrangements or commitments to which Catalent is a party or by which it is bound nor does the execution, delivery and performance of this Agreement by Catalent violate any order, law or regulation of any court or Regulatory Authority having authority over it.

11.2.3 Compliance with Applicable Laws. Catalent is, to its knowledge, in compliance with all Applicable Laws, regulatory guidelines and industry standards relating to the performance of the Manufacturing Services. If Catalent learns of the noncompliance of an Applicable Law that materially impacts the Manufacturing Services by an employee, agent, or Subcontractor being used by Catalent, Catalent will promptly so notify FibroGen in writing, and appropriate action will be taken by Catalent at Catalent's sole expense.

11.2.4 No Patent Infringement. The Manufacturing Services to be performed under this Agreement, based on the practice of Catalent Background Intellectual Property as contemplated to be used to manufacture the Products hereunder, will not violate or infringe upon any patent, trade secret, copyright or other intellectual property held by a Third Party; it being understood that such representation shall not extent to any such infringement or violation based on FibroGen Intellectual Property, instructions, or specifications provided to Catalent. No Third Party has filed, pursued or maintained or threatened in writing to file, pursue or maintain any claim, lawsuit, charge, complaint or other action alleging infringement of a Third Party Patent or misappropriation of trade secret based on the practice of Catalent Background Intellectual Property as contemplated to be used to manufacture the Products hereunder. [ ].

11.2.5 License. Catalent has the right, power and authority to grant FibroGen the license set forth in Section 9.2 above and will not enter into any contract, arrangement or commitment in the future which prohibits the grant of such license.

11.2.6 Product Warranty. At the time of Delivery by Catalent as provided in Section 4.3, Product shall have been Processed in accordance with Applicable Laws and in conformity with the Master Batch Record, and will at the time of Delivery, conform to the Specifications and Purchase Order, and shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws; will have been packaged in accordance with the storage requirements as defined in the Specifications and Master Batch Records (as applicable); and will be transferred free and clear of any liens or encumbrances of any kind; provided, that Catalent shall not be liable for defects attributable to FibroGen-supplied Materials (including artwork, advertising and labeling).

11.2.7 Catalent will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b).

11.2.8 Catalent represents and warrants that no transaction or dealing under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanction, restriction or

embargo administered by the United Nations, European Union, United Kingdom, or United States. Furthermore, Catalent represents and warrants to FibroGen that neither Catalent nor any of its employees has (to the best of its knowledge) or will perform any of the following acts, either directly or through a Third Party, in connection with this Agreement: (a) pay, offer or promise to pay, or authorize the payment of, any money; (b) give or promise to give, or authorize the giving of, any services or anything else of value; or (c) enter into any other transactions, to or with any official or employee of any governmental agency or instrumentality, or of a public international organization, or of any agency or subdivision thereof, or to any political party or official thereof or to any candidate for political office, in each case for the purpose of: (i) influencing any act or decision of that person in his/her official capacity, including a decision to fail to perform his/her official functions with such governmental agency or instrumentality or such public international organization or such political party; (ii) inducing such person to use his/her influence with such governmental agency or instrumentality or such public international organization or such political party to affect or influence any act or decision thereof; or (iii) securing any improper advantage.

11.2.9 Catalent represents and warrants that, in furtherance of preventing fraud, bribery and corruption, racketeering, money laundering or terrorism, and ensuring product safety, it will comply with [ ].

11.3 Limitations. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER PARTY, AND NEITHER PARTY MAKES ANY OTHER REPRESENTATION, WARRANTY OR GUARANTEE OF ANY KIND WHATSOEVER, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 12
INDEMNIFICATION; LIMITATION OF LIABILITY

12.1 Indemnification by FibroGen. Subject to Section 12.3, FibroGen shall indemnify, defend and hold Catalent, and their directors, officers, employees and agents (the "**Catalent Indemnitees**") harmless from and against all losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys' fees and expenses) (collectively, the "**Losses**") incurred by Catalent Indemnitees to the extent such Losses arise out of, relate to or result from any claim, lawsuit or other action or threat by a Third Party relating to or arising out of [[ ]], except to the extent any such Losses arise out of or result from a Catalent Indemnitee's negligence, willful misconduct, or breach of its representations, warranties or obligations set forth in this Agreement.

12.2 Indemnification by Catalent. Subject to Section 12.3, Catalent shall indemnify, defend and hold FibroGen, and their directors, officers, employees and agents (the "**FibroGen Indemnitees**") harmless from and against all Losses incurred by FibroGen Indemnitees to the extent such Losses arise out of or result from any claim, lawsuit or other action or threat by a Third Party relating to or arising out of [ ] in each case except to the extent any such Losses arise out of or result from a FibroGen Indemnitee's negligence, willful misconduct, or breach of its representations, warranties or obligations set forth in this Agreement.

12.3 Indemnification Procedures.

12.3.1 Identification of Indemnitor and Indemnitee. An "**Indemnitor**" means the indemnifying Party. An "**Indemnitee**" means the indemnified Party and their respective directors, officers, employees and agents.

12.3.2 Indemnification Procedures. An Indemnitee which intends to claim indemnification under Section 12.1 or Section 12.2 hereof shall promptly notify the Indemnitor in writing of any claim, lawsuit or other action (including a copy of any related complaint, summons, notice or other instrument) in respect of which the Indemnitee or any of their respective directors, officers, employees and agents intend to claim such indemnification; ***provided, however***, that failure to provide such notice within a reasonable period shall not relieve the Indemnitor of its obligations under this Article 12 except to the extent, if any, the Indemnitor is prejudiced by such failure. The Indemnitee and their respective directors, officers, employees and agents shall additionally [ ]. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and expense. FibroGen always has the right to control proceedings relating to API and Product

12.4 LIMITATIONS OF LIABILITY.

12.4.1 IN THE EVENT OF ANY CLAIM FOR LOST, DAMAGED OR DESTROYED API OR OTHER FIBROGEN-SUPPLIED MATERIALS, [ ].

12.4.2 CATALENT'S TOTAL LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED [ ].

12.4.3 THE LIMITATIONS OF LIABILITY IN SECTIONS 12.4.1 AND 12.4.2 SHALL NOT APPLY TO THE EXTENT ARISING OUT OF:

(a) [ ];

(b) [ ];

(c) [ ];

(d) [ ]; OR

(e) [ ].

12.5 DISCLAIMER OF CONSEQUENTIAL DAMAGES. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR LOSS OF REVENUES, PROFITS OR DATA ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, WHETHER IN CONTRACT OR IN TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 13
INSURANCE

Each Party shall, at its own cost and expense, obtain and maintain in full force and effect during the Term the following: (A) Commercial General Liability and/or Foreign Liability Insurance with a per occurrence limit of $[ ] ([ ] United States Dollars) or equivalent and an annual aggregate limit of $[ ] United States Dollars) or equivalent; (B) Products and Completed Operations Liability Insurance with a per occurrence limit of not less than $[ ] ([ ] United States Dollars) or equivalent covering each Party's own operations arising out of or connecting with this Agreement, providing coverage for bodily injury and property damage claims; (C) Workers' Compensation as required by any applicable law or regulation and in accordance with the provisions of the laws of the nation, state, territory or province having jurisdiction over FibroGen's employees. If any such jurisdiction has a social scheme to provide insurance or benefits to injured workers, the relevant Party must be in full

compliance with the laws of such jurisdiction. Employer's Liability insurance will be provided in amounts not less than the local currency equivalent of US$[ ] ([] United States Dollars) or equivalent per accident and US[ ] ([ ] United States Dollars) or equivalent per employee for disease, provided that such coverage is available in the nation, state, territory or province having jurisdiction over each Party's employees. If there is an exposure of injury to each Party's employees under the U.S. Longshoremen's and Harbor Workers' Compensation Act, the Jones Act or under the laws, regulations or statutes applicable to maritime employees, coverage will be included for such injuries or claims; and (D) Auto Liability insurance in a minimum amount of $[ ] ([ ] United States Dollars) or equivalent combined single limit for all vehicles used in connection with the performance of this contract. Each Party shall, at its own cost and expense, obtain and maintain in full force and effect during the Term, All Risk Property Insurance, including transit coverage, an amount equal to [ ] while in, or in transit to, or from, a Catalent facility. If any of the required policies of insurance are written on a claims made basis, such policies shall be maintained throughout the Term and for a period of at least [ ] ([ ]) years thereafter. Each insurance policy that is required under this Agreement shall be obtained from an insurance carrier with an A.M. Best or equivalent rating of at least A- VII or an S&P rating of A. Each Party may self-insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP net worth is greater than $[ ] United States Dollars or equivalent or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than $[ ] United States Dollars or equivalent. Upon the other Party's written request from time to time, each Party shall promptly furnish to the other Party a certificate of insurance or other evidence of the required insurance.

ARTICLE 14
CONFIDENTIALITY

14.1 Definition. As used in this Agreement, the term "**Confidential Information**" means all confidential information of the disclosing person of whatever type, including all information furnished by or on behalf of Catalent or FibroGen (as the case may be, "**Discloser**"), its Affiliates or any of its or their respective Representatives, to the other Party (for purposes of this Article 14, "**Recipient**"), its Affiliates or any of its or their respective Representatives, whether furnished before, on or after the Effective Date and furnished in any form, including written, verbal, visual, electronic or in any other media or manner and information acquired by observation or otherwise during any site visit at the other Party's facility. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other Intellectual Property (whether or not patented), analyses, compilations, business or technical information and other materials prepared by either Party, their respective Affiliates, or any of its or their respective Representatives, containing or based in whole or in part on any Confidential Information furnished by Discloser, its Affiliates or any of its or their respective Representatives. Confidential Information also includes the existence and terms of this Agreement.

14.2 Exclusions. Notwithstanding anything in Section 14.1 to the contrary, Confidential Information does not include information that Recipient can demonstrate upon competent written proof (A) is or becomes generally available to the public or within the industry to which such information relates other than as a result of a breach of this Agreement, (B) is already known by Recipient at the time of disclosure without obligations of confidentiality, (C) becomes available to Recipient on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis or (D) was or is independently developed by or for Recipient without reference to Discloser's Confidential Information.

14.3 Mutual Obligation. Recipient (A) will keep confidential all Confidential Information, employing such protections as it would use for its own Confidential Information of a similar type but in no case less than reasonable protections under the circumstances, (B) will not use Discloser's Confidential Information except in connection with the performance of its obligations under this Agreement and (C) will not disclose to any Third Party, without Discloser's prior written consent, Discloser's Confidential Information, except that Recipient may disclose Discloser's Confidential Information to any of its Affiliates and its or their respective Representatives

(and in FibroGen's case, Designees) that (A) need to know such Confidential Information for the purpose of performing under this Agreement, (B) are advised of the contents of this Article and (C) are bound to Recipient by obligations of confidentiality and non-use at least as restrictive as the terms of this Article. Each Party shall be jointly and severally responsible for any breach of this Article by its Affiliates or any of its or their respective Representatives.

14.4 Permitted Disclosure. Recipient may disclose Discloser's Confidential Information to the extent required by law or regulation; *provided*, that prior to making any such legally required disclosure, Recipient shall give Discloser as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances, and Recipient will cooperate with Discloser in Discloser's efforts to obtain protective order, confidential treatment or other legal remedy. Any such disclosure, however, shall not relieve Recipient of its obligations under this Agreement. In addition, FibroGen may use Catalent's name and disclose Catalent Confidential Information to potential investors or other lending sources who have a specific need to know such Confidential Information in connection with a proposed financing arrangement so long as the Third Party to whom such Confidential Information is disclosed is bound to FibroGen by obligations of confidentiality and non-use at least as restrictive as the terms of this Article, and subject to the restrictions set forth in this Article 14.

14.5 No Implied License. Except as expressly set forth in Section 14.1, Recipient will obtain no right of any kind or license under any of Discloser's Confidential Information, including any patent application or patent, by reason of this Agreement. Discloser's Confidential Information will remain Discloser's sole property, subject to Article 10.

14.6 Return of Confidential Information. Upon expiration or termination of this Agreement, Recipient will (and will cause its Affiliates and its and their respective Representatives to) cease its use and, upon written request, within [ ] ([ ]) days either return or destroy (and certify as to such disposition) all of Discloser's Confidential Information, including any copy of such information, except for a single copy, which may be retained for the sole purpose of ensuring compliance with its obligations under this Agreement. In addition, Catalent shall require that all authorized Subcontractors and Affiliates performing Services have similarly returned or destroyed all FibroGen Confidential Information.

14.7 Survival. The obligations of this Article will terminate [ ] years from the expiration or termination of this Agreement, except with respect to trade secrets, for which the obligations of this Article will continue for so long as such information remains a trade secret under law.

ARTICLE 15
PRESS RELEASES; USE OF NAMES

15.1 Press Releases. Neither Party shall issue or disclose any press release, publicity or other form of public written disclosure regarding this Agreement or the terms hereof without receiving the other Party's express prior written consent, except required under Applicable Laws, by any governmental agency or by the rules of any stock exchange on which the securities of the disclosing Party are listed, in which case the Party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other Party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

15.2 Use of Names. Except as expressly set forth in Section 14.4, neither Party shall make use of the name, trademark, logo or symbol of the other Party of its Affiliates or any of their respective officers, directors, employees, or agents, in any advertising or promotional material, or otherwise, in connection with this Agreement or any related agreements, without the prior written consent of the other Party.

ARTICLE 16
TERM; TERMINATION

16.1 Term. This Agreement shall commence on the Effective Date and shall continue until the end of [ ] ("**Initial Term**"), and automatically extend for [ ] year periods (each a "**Renewal Term**"). Either Party may provide the other with [ ] ([ ]) months' written notice of termination with or without cause, provided the date of termination cannot occur before [ ]. The Initial Term and Renewal Terms are collectively referred to as the "**Term**".

16.2 Termination. This Agreement may be terminated as follows:

16.2.1 Material Breach. Either Party may terminate this Agreement or Purchase Order by written notice to the other Party, for any material breach of this Agreement or Purchase Order by the other Party, if such breach is not cured within [ ] ([ ]) days after the breaching Party receives written notice of such breach from the non-breaching Party. Such termination shall be effective upon expiration of such cure period.

16.2.2 Insolvency. Either Party may terminate this Agreement and all Purchase Orders upon notice to the other Party, upon (a) the dissolution, termination of existence, liquidation or business failure of the other Party; (b) the appointment of a custodian or receiver for the other Party who has not been terminated or dismissed within [ ] ([90]) days of such appointment; or (c) the institution by the other Party of any proceeding under national, federal or state bankruptcy, reorganization, receivership or other similar laws affecting the rights of creditors generally or the making by such Party of a composition or any assignment for the benefit of creditors under any national, federal or state bankruptcy, reorganization, receivership or other similar law affecting the rights of creditors generally, which proceeding is not finally dismissed within [ ] ([ ]) days of filing. All rights and licenses granted pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code, licenses of rights of "intellectual property" as defined therein.

16.3 Consequences of Termination.

16.3.1 Generally. If FibroGen delivers to Catalent a notice of termination of this Agreement pursuant to Section 16.2, Catalent shall use [ ] efforts to wind-down all Manufacturing Services in accordance with its responsibilities under Applicable Laws, and use [ ] efforts to reduce or eliminate further costs, and to cancel, if permitted under the terms of applicable agreements, any Third Party obligations. Except for invoices or Purchase Orders directly related to Catalent's material breach of this Agreement pursuant to Section 16.2.1, hereof FibroGen shall pay Catalent all invoiced amounts outstanding hereunder, plus, upon receipt of invoice therefor, for any [ ] and [ ] in the event that this Agreement is terminated for any reason other than by FibroGen pursuant to Section 16.2.2, all Product being Processed pursuant to Purchase Orders (or, alternatively, FibroGen may instruct Catalent to complete such work in process, and the resulting completed Product shall be governed by clause (ii)). In the event that this Agreement is terminated for any reason other than by FibroGen pursuant to Section 16.2.2, FibroGen shall pay Catalent for[ ], in connection with Catalent's performance of this Agreement, so long as such costs, expenses or commitments were made by Catalent consistent with FibroGen's most recent Binding Forecast and the vendor's [ ]. In addition, Catalent shall return to FibroGen all FibroGen-supplied Materials together with any Product existing, generated, or in progress as of the date of termination. For avoidance of doubt, all services and delivery fees in connection with the transition shall be borne by FibroGen, unless the termination is due to breach of this Agreement by Catalent.

16.3.2 Return of Product. At FibroGen's request or upon expiration or termination of this Agreement, Catalent shall promptly: return or, at FibroGen's written request, destroy (with certification of such destruction), all quantities of Product, FibroGen-supplied Materials, Raw Materials, intermediates and in-process

materials being held by Catalent under this Agreement and outstanding Purchase Order(s). Such actions shall be taken at FibroGen's pre-approved cost and expense.

16.3.4 Accrued Rights. Except as otherwise expressly set forth herein, any termination or expiration of this Agreement shall be without prejudice to any right which shall have accrued to the benefit of either Party prior to such expiration or termination.

16.4 Right to Return and Settle. If Catalent requests in writing from FibroGen direction with respect to disposal of any inventories of Product, FibroGen-supplied Materials, equipment, samples or other items belonging to FibroGen and is unable to obtain a response from FibroGen despite written notice as required under Section 18.1 hereof, after making commercially reasonable efforts to do so, Catalent shall be entitled to (A) return all such items to FibroGen, and (B) set-off any and all amounts due to Catalent or any of its Affiliates from FibroGen against any credits FibroGen may hold with Catalent or any of its Affiliates. Catalent shall in no event dispose of Product without FibroGen's prior written consent.

16.5 Surviving Rights. Sections[ ], and the rights and obligations contained therein shall survive the termination or expiration of this Agreement to the extent expressly stated therein.

ARTICLE 17
FORCE MAJEURE

Except as to payments required under this Agreement, neither Party shall be liable hereunder for any failure in performance if such delay or failure is caused by fire, flood, explosion, storm, acts of God, acts of any government or government agency or other causes beyond such Party's reasonable control, provided that, upon the occurrence of any event of force majeure, (a) the Party whose performance is thereby affected shall promptly notify the other Party of the force majeure event and the circumstances so surrounding and of the expected duration thereof and shall take all reasonable steps to mitigate such delay or failure to perform and (b) if the delay or failure to perform continues for more than [ ] ([ ]) days, the unaffected Party may terminate this Agreement upon written notice to the affected Party. Upon cessation of such force majeure event, the affected Party shall promptly resume performance under this Agreement as soon as it is possible for the Party to do so.

ARTICLE 18
MISCELLANEOUS

18.1 Notices. Any notice required or permitted to be given under this Agreement by any Party shall be in writing and shall be (a) delivered personally, (b) sent by registered mail, return receipt requested, postage prepaid, (c) sent by a nationally-recognized courier service guaranteeing next-day or second day delivery, charges prepaid, or (d) delivered by facsimile (with documented evidence of transmission), to the addresses of the other Party set forth below, or at such other addresses as may from time to time be furnished by similar notice by any Party. The effective date of any notice under this Agreement shall be the date of receipt by the receiving Party.

To FibroGen:
FibroGen, Inc.
409 Illinois Street
San Francisco, CA 94158
Attn: Legal Department
Telephone: + 1 415 978-1200

To Catalent	Catalent Pharma Solutions, LLC 1100 Enterprise Drive Winchester, KY 40391 Attn: General Manager Telephone: +1 859-745-2200
With a copy to:	Catalent Pharma Solutions, LLC 14 Schoolhouse Road Somerset, NJ 08873 Attn: General Counsel (Legal Department) E-Mail: GenCouns@catalent.com Facsimile: +1 (732) 537-6491

18.2 Governing Law. This Agreement shall be governed by, construed and interpreted in accordance with the laws of the State of [ ], United States of America, without reference to conflict of laws principles. The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof, as follows: the matter shall be referred first to the JMC having responsibility for the subject matter of the dispute. The JMC shall negotiate in good faith to resolve such dispute in a mutually satisfactory manner for up to [ ] ([ ]) days. If such efforts do not result in mutually satisfactory resolution of the dispute, then such dispute may be submitted by either Party to arbitration by the [ ] by [ ] arbitrator selected by the Parties; provided, either Party will have the right to withdraw from the arbitration at any time, and termination of such participation will be effective upon written notice to the other Party. If no agreement on an arbitrator can be reached within [ ] ([ ]) days after the [ ] offers names of potential arbitrators, then the [ ] will choose one arbitrator having reasonable experience in commercial transactions of the type described in this Agreement. The arbitration shall take place in the English language in [ ], in accordance with the [ ] administered arbitration rules then in effect, and judgment upon any award rendered in such arbitration will be binding and may be entered in any court having jurisdiction of the matter. The arbitration shall commence within [ ] ([ ]) days of the date on which an arbitrator is selected. The arbitrator's decision shall set forth a reasoned basis for any award of damages or finding of liability. The arbitrator shall not have power to [ ]. The arbitrator shall award to the prevailing Party, if any, its costs and attorneys' fees and expenses reasonably incurred in connection with the arbitration, in accordance with this Section. In any dispute resolution proceeding between the Parties in connection with this Agreement, the prevailing Party will be entitled to recover its reasonable attorney's fees and costs in such proceeding, including any subsequent or related enforcement proceeding, from the other Party.

18.3 Headings. All headings in this Agreement are for convenience of reference only and shall not affect the interpretation of this Agreement.

18.4 Exhibits. All exhibits, attachments or appendices referred to herein form an integral part of this Agreement and are incorporated into this Agreement by such reference.

18.5 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment without the other Party's consent to such Party's Affiliate or to a successor to all or substantially all of the assets or business of such Party to which this Agreement pertains, whether by asset sale, stock sale, merger, acquisition, or otherwise. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. Any purported assignment that is not

in conformance with this Section 18.5 shall be null, void and of no legal effect. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the successors and assigns of the Parties.

18.6 Severability. If any part of this Agreement shall be found to be invalid or unenforceable under applicable law in any jurisdiction, such part shall be ineffective only to the extent of such invalidity or unenforceability in such jurisdiction, without in any way affecting the remaining parts of this Agreement in that jurisdiction or the validity or enforceability of the Agreement as a whole in any other jurisdiction. In addition, the part that is ineffective shall be reformed in a mutually agreeable manner so as to as nearly approximate the intent of the Parties as possible.

18.7 Independent Contractors. Each of the Parties is an independent contractor and nothing herein contained shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between the Parties. Neither Party shall at any time enter into, incur, or hold itself out to Third Parties as having authority to enter into or incur, on behalf of the other Party, any commitment, expense, or liability whatsoever.

18.8 Conflict. In the event of conflict or ambiguity between or among the provisions of a particular Purchase Order, and the body of this Agreement or any amendments hereto and any other ancillary agreements, the terms and conditions of the body of this Agreement and amendments hereto shall prevail, govern, override, and control followed by the terms and conditions of ancillary agreements such as the Quality Agreement, Specifications, and Master Batch Records; and then finally the terms and conditions of the particular Purchase Order. Notwithstanding the foregoing, the Quality Agreement shall control with respect to quality assurance subject matters. For clarity, only explicit exceptions or modifications of named sections of this Agreement or other agreements set forth in a Purchase Order, shall act as exceptions, modifications or amendments of such agreements, and only then for the Product under such Purchase Order.

18.9 Waiver. No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition or of any other term, provision or condition of this Agreement.

18.10 Entirety; Amendments. This Agreement, including any exhibits or ancillary documents attached hereto or referenced herein, constitutes the full understanding of the Parties and a complete and exclusive statement of the terms of their agreement with respect to the specific subject matter hereof, and no terms, conditions, understandings or agreements purporting to modify or vary the terms thereof shall be binding unless hereafter made in a written instrument referencing this Agreement and signed by each of the Parties.

18.11 Counterparts. This Agreement and any amendment hereto may be executed in any number of counterparts, each of which shall for all purposes be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by portable document format (pdf), facsimile or original, and a pdf or facsimile signature shall be deemed to be and shall be as effective as an original signature.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date.

CATALENT PHARMA SOLUTIONS, LLC	**FIBROGEN, INC.**
By: /s/ Aris Gennadios, Ph.D.	By: /s/ Michael Martinelli
Name Aris Gennadios, Ph.D.	Name Michael Martinelli
Title: President	Title: VP Tech Dev
Date: 18 December 2019	Date: 1/8/2020

[*] = 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.

Confidential

ATTACHMENT A

UNIT PRICING, PURCHASE ORDERS AND ADDITIONAL FEES

[ ]

ATTACHMENT B

PRODUCT MAINTENANCE SERVICES

Product Maintenance Services are comprised of the following:

[ ]

ATTACHMENT C

OTHER SERVICES

The following services and items are *not* included in Product Maintenance Services and may be supported by Catalent on an as-needed basis under a countersigned quotation. The list below is provided for illustration purposes and not intended to represent an exhaustive list of Product requests or services provided by Catalent:

[ ]

Confidential

ATTACHMENT D

FibroGen-Supplied Materials and Raw Materials

[ ]

ATTACHMENT E

Product Specifications

[_]

Exhibit 10.32

June 17, 2008

Ms. Christine Chung
[PRIVATE ADDRESS]

Dear Chris,

FibroGen, Inc. is pleased to offer you the position of Senior Director, China, reporting to Sarah O'Dowd, Vice President and General Counsel. We are very excited about the possibility of you joining our team, and we look forward to the prospect of working with you in our innovative company! The following outlines the specific terms of our offer:

- Your salary will be $12,533.34 per month, less taxes and standard deductions as required by law. Paid bimonthly, this figure will annualize to $150,400. Your scheduled work week will be 32 hours.

- Pending any necessary approvals, including those of the Company's Board of Directors, and in compliance with applicable laws and regulations, we plan to offer you an option to purchase 50,000 shares of common stock of FibroGen, with a vesting base date of the first day of your employment, pursuant to the terms and conditions of the Company's 2005 Stock Plan, and may be amended or modified from time to time.

- The above option grant is in addition to the Stock Option grants previously awarded in accordance with terms of your Consulting Agreement:
  50,000 – with vesting base date of December 15, 2006, vesting ratably over 3 years
  40,000 – vesting upon achievement of the following milestones
    10,000 – vesting upon approval of CTA
    10,000 – vesting upon initiation of PRC clinical trial – with first patient, first visit.
    20,000 – vesting upon completion of significant business transaction – a) closing of significant investment from non-affiliate(s), or b) signing transaction with marketing partner.

- You will be entitled to fly business class outside of North America

- You will be eligible for certain FibroGen employee benefits, which will include medical, vision and dental health insurance. Additionally, we offer a 401(k) plan, which provides you with the opportunity for pre-tax long-term savings by deferring from 1-60% of your annual salary, subject to certain maximums. These benefits may be modified or terminated from time to time, and a benefit summary has been included with this letter. More detailed information regarding your benefits will be provided at your New Employee Orientation, shortly after you begin employment.

- As a 32 hour-per-week employee, you will receive twelve (12) days of paid vacation each year, which will accrue at the rate of 1 day per month beginning from your first day of employment at FibroGen.

- You will abide by FibroGen's strict company policy that prohibits any new employee from using or bringing with them from any prior employer any proprietary information, trade secrets, proprietary materials or processes of such former employers. Moreover, because the Company's proprietary information is extremely important, this offer is expressly subject to your executing the enclosed Confidential Information, Secrecy and Invention Agreement for Employees. You also agree to follow all other rules and policies that the Company may announce from time to time.

- You will also be required to sign the Employment Eligibility Verification (Form I-9). (You will need to complete and return Section One of the I-9 form along with your signed offer letter). On your first day of employment, please bring the necessary documents that establish your identity and employment eligibility. Acceptable documents are listed on the reverse side of the I-9 form. Such documentation must be provided to us within three (3) business days of your date of hire, or our employment relationship with you may be terminated.

  You should be aware that your employment with the Company is for no specified period and constitutes "at-will" employment. As a result, you are free to resign at any time, for any reason, with or without cause or notice. Similarly, the Company is free to conclude its employment with you at any time. The changing needs of the Company could also result in changes to certain aspects of your employment, such as compensation, responsibilities, location, etc. These provisions expressly supersede any previous representations, oral or written. Your at-will employment cannot be modified or amended except by written agreement signed by both you and the President of the Company.

  Any dispute or claim, including all contract, tort, discrimination and other statutory claims, arising under or relating to your employment or termination of your employment with the Company but excepting claims under applicable workers' compensation law and unemployment insurance claims ("arbitrable claims") alleged against the Company and/or its agents shall be resolved by arbitration. However, you and the Company agree that this arbitration provision shall not apply to any disputes or claims relating to or arising out of the misuse or misappropriation of the Company's trade secrets. Such arbitration shall be final and binding on the parties and shall be the exclusive remedy for arbitrable claims. You and the Company hereby waive any rights each may have to a jury trial in regard to the arbitrable claims. Arbitration shall be conducted by the American Arbitration Association in San Mateo (or other mutually agreed upon city) under the National Rules for the Resolution of Employment Disputes. In any arbitration, the burden of proof shall be allocated as provided by applicable law. The Company agrees to pay the fees and costs of the arbitrator. However, the arbitrator shall have the same authority as a court to award equitable relief, damages, costs, and fees (excluding the costs and fees for the arbitrator) as provided by law for the particular claims asserted.

Unless otherwise notified by the Company, this offer of employment is effective for 5 business days from the date of this letter. There are two originals of this letter enclosed. If all of the foregoing is satisfactory, please sign and date each original and return one to me within five business days in the enclosed envelope, saving the other original for yourself. Please also complete the following enclosed forms and mail them back with your signed offer letter:

- I-9 Form
- Confidential Information, Secrecy and Invention Agreement
- FibroGen Employment Application

Chris, we look forward to your joining our team at FibroGen.

Sincerely,

/s/ Ted A. Tucker
Ted A. Tucker
Vice President, Human Resources

ACCEPTED AND AGREED TO this

18th Day of June, 2008

/s/ Christine Chung
Christine Chung

June 18th, 2008
Intended Start Date

Enclosures:

- Benefits Summary
- Duplicate Letter
- Return Envelope
- Employment Eligibility Verification (I-9) Form
- Confidential Information, Secrecy and Invention Agreement
- FibroGen Employment Application

Exhibit 10.33

January 24, 2014

Elias Kouchakji, MD
[PRIVATE ADDRESS]

Dear Elias,

FibroGen, Inc. is pleased to offer you the position of Vice President, Drug Safety in our Clinical Development department reporting to Frank Valone, MD, Chief Medical Officer. We are very excited about the possibility of you joining our team, and we look forward to the prospect of working with you in our innovative company! The following outlines the specific terms of our offer:

- Your salary will be $29,167.00 per month, less taxes and standard deductions as required by law. Paid bimonthly, this figure will annualize to $350,000

- You will be paid an employment bonus of $25,000 less taxes and standard deductions.

- You will also be eligible to participate in the FibroGen Incentive Compensation Plan.

- Pending any necessary approvals, including those of the Company's Board of Directors and Stockholders, and in compliance with applicable laws and regulations, we plan to offer you an option to purchase 100,000 shares of common stock of FibroGen, pursuant to the terms and conditions of the Company's 2005 Stock Plan, and may be amended or modified from time to time.

- You will be eligible for certain FibroGen employee benefits, which will include medical, vision and dental health insurance. Additionally, we offer a 401(k) plan, which provides you with the opportunity for pre-tax long-term savings by deferring from 1-60% of your annual salary, subject to certain maximums. These benefits may be modified or terminated from time to time, and a benefit summary has been included with this letter. More detailed information regarding your benefits will be provided at your New Employee Orientation, shortly after you begin employment.

- You will be eligible to participate in our Corporate Relocation Program – which includes payment of certain expenses associated with your relocation to the Bay Area. Details of the services available to you are outlined in a separate, attached document. As the IRS may consider some of these benefits taxable income, we recommend you consult with your tax advisor.

- As a full-time employee, you will receive fifteen (15) days of paid vacation each year, which will accrue at the rate of 1.25 days per month beginning from your first day of employment at FibroGen.

- You will abide by FibroGen's strict company policy that prohibits any new employee from using or bringing with them from any prior employer any proprietary information, trade secrets, proprietary materials or processes of such former employers. Moreover, because the Company's proprietary information is extremely important, this offer is expressly subject to your executing the enclosed Confidential Information, Secrecy and Invention Agreement for Employees. You also agree to follow all other rules and policies that the Company may announce from time to time.

- You will also be required to sign the Employment Eligibility Verification (Form I-9). (You will need to complete and return Section One of the I-9 form along with your signed offer letter). On your first day of employment, please bring the necessary documents that establish your identity and employment eligibility. Acceptable documents are listed on the reverse side of the I-9 form. Such documentation must be provided to us within three (3) business days of your date of hire, or our employment relationship with you may be terminated

- You should be aware that your employment with the Company is for no specified period and constitutes "at-will" employment. As a result, you are free to resign at any time, for any reason, with or without cause or notice. Similarly, the Company is free to conclude its employment with you at any time. The changing needs of the Company could also result in changes to certain aspects of your employment, such as compensation, responsibilities, location, etc. These provisions expressly supersede any previous representations, oral or written. Your at-will employment cannot be modified or amended except by written agreement signed by both you and the President of the Company.

- Any dispute or claim, including all contract, tort, discrimination and other statutory claims,
arising under or relating to your employment or termination of your employment with the Company but excepting claims under applicable workers' compensation law and unemployment insurance claims ("arbitrable claims") alleged against the Company and/or its agents shall be resolved by arbitration. However, you and the Company agree that this arbitration provision shall not apply to any disputes or claims relating to or arising out of the misuse or misappropriation of the Company's trade secrets. Such arbitration shall be final and binding on the parties and shall be the exclusive remedy for arbitrable claims. You and the Company hereby waive any rights each may have to a jury trial in regard to the arbitrable claims. Arbitration shall be conducted by the American Arbitration Association in San Mateo (or other mutually agreed upon city) under the National Rules for the Resolution of Employment Disputes. In any arbitration, the burden of proof shall be allocated as provided by applicable law. The Company agrees to pay the fees and costs of the arbitrator. However, the arbitrator shall have the same authority as a court to award equitable relief, damages, costs, and fees (excluding the costs and fees for the arbitrator) as provided by law for the particular claims asserted.

- This offer of employment is made contingent upon successful completion of FibroGen, Inc.'s background check. This includes verification of the information provided online and your employment application. If necessary, you will be contacted to resolve any discrepancies in the verification of information. Whether you have successfully "passed" the background check is solely within FibroGen's discretion. Your employment hire date will be determined after the completion of the background check process and your signed acceptance of this offer.

Unless otherwise notified by the Company, this offer of employment is effective for 5 business days from the date of this letter. There are two originals of this letter enclosed. If all of the foregoing is satisfactory, please sign and date each original and return one to me within five business days in the enclosed envelope, saving the other original for yourself. Please also complete the following enclosed forms and mail them back with your signed offer letter:

- I-9 Form
- Confidential Information, Secrecy and Invention Agreement
- FibroGen Employment Application
- FibroGen Relocation Assistance Terms
- FibroGen Relocation Repayment Agreement

Elias, we look forward to your joining our team at FibroGen.

Sincerely,

/s/ Ted A. Tucker
Ted A. Tucker
Vice President, Human Resources

ACCEPTED AND AGREED TO this

31 Day of January, 2014

/s/ Elias Kouchakji, MD
Elias Kouchakji, MD

February 10, 2014
Intended Start Date

Enclosures:

Benefits Summary
Duplicate Letter
Return Envelope
Employment Eligibility Verification (I-9) Form
Confidential Information, Secrecy and Invention Agreement
FibroGen Employment Application
FibroGen Relocation Assistance Package

Exhibit 10.34

December 17, 2019

Enrique Conterno
[PRIVATE ADDRESS]

Dear Enrique,

FibroGen, Inc. is pleased to offer you the position of **Chief Executive Officer** reporting to the Board of Directors (the "**Board**") under the terms and conditions set forth in this letter (the "**Offer Letter")**. The effective date ("**Effective Date**") of your employment will be set, as mutually agreed upon in advance with FibroGen, Inc. ("**FibroGen**") and confirmed with Interim Chief Executive Officer, Jim Schoeneck.

This offer of employment is made contingent upon successful completion of FibroGen's background check and upon completion of all required documentation that will be made available to you on the Effective Date or by your intended start date. This includes verification of the information provided online and your employment application. If necessary, you will be contacted to resolve any discrepancies in the verification of information. Your employment hire date will be determined after the completion of the background check process and your signed acceptance of this Offer Letter.

The terms of this offer of employment are as follows:

1. **Position/Duties.** As Chief Executive Officer of the Company, you will be responsible for the general management of the affairs of the Company. You shall devote your best efforts and full business time, skill and attention to the performance of your duties. You will also be expected to adhere to the general employment policies and practices of the Company that may be in effect from time to time, except that when the terms of this Offer Letter conflict with the Company's general employment policies or practices, this Offer Letter will control. You will work out of the Company's offices in San Francisco, California. The Company may change your position, duties, work location and compensation from time to time in its discretion, subject to the terms and conditions set forth herein. During employment, you will also serve as a member of the Board, subject to your future election by FibroGen stockholders, and you shall submit your resignation from the Board upon the termination of your employment. If you wish to serve on the Board of Directors of a separate company, you may do so subject to approval by the Board, and to the extent such service does not conflict with FibroGen responsibilities.

2. Compensation. FibroGen will pay you a starting annual salary of $800,000 payable in semi-monthly installments on our regular paydays in accordance with FibroGen's standard payroll policies. Your salary will begin as of the Effective Date. The position is classified as exempt and therefore not eligible for overtime pay. The first and last payment by FibroGen to you will be adjusted, if necessary, to reflect a commencement or termination date other than the first or last working day of a pay period.

3. Signing Bonus. FibroGen will pay you a sign-on bonus in the amount of $250,000 (subject to applicable payroll taxes and withholdings) to be payable on the first payroll date which occurs after ninety (90) days following the Effective Date of your employment, including to cover all costs associated with your relocation, and any commuting or services prior to relocation to the San Francisco Bay Area.

4. Stock Options and Restricted Stock Units. Pending approval by the FibroGen Compensation Committee, you will be granted the following equity incentive grant(s) pursuant to the terms and conditions of the Equity Plan effective on the date of acceptance of this letter (the "**Equity Plan**"), as may be amended or modified from time to time:
    - a stock option to purchase 300,000 shares of FibroGen's Common Stock with an exercise price set at the fair market value on the date of grant ("**Stock Options**"); and
    - a grant of 60,000 restricted stock units relating to shares of FibroGen's Common Stock ("**RSUs**").

    The actual number of shares subject to the grant hereunder may be adjusted, if required, for events such as stock splits, stock dividends, etc. pursuant to the Equity Plan. The Stock Options and RSUs will vest according to the standard schedule set forth in the Grant Notice and Award Notice for such grants.

5. Bonus Plan. You will be eligible to participate in FibroGen's Incentive Compensation Plan (the "**Bonus Plan**") adopted by FibroGen for its employees on such terms as the Board may determine in its discretion.

   The CEO target bonus for level is 75%. Under the terms of the Plan, both corporate and individual performance is assessed annually and subject to final approval by the Board. Employees hired during the course of a year will have a pro-rated bonus provided they commence their employment on or before September 30th of a calendar year. To remain eligible, employees must maintain satisfactory performance and be in an active status on the day of payment. Payments are expected to occur no later than the 15th of March in the year following the performance cycle.

6. Change in Control and Severance Agreement. You will be eligible to enter into the Company's Change in Control and Severance Agreement approved by the Board that provides for certain severance benefits upon a termination following a Change in Control (as defined therein) and upon certain other terminations.

7. Benefits. During the term of your employment, you will be eligible to participate in FibroGen's benefits program, which may include FibroGen's vacation benefits and other employee benefits such as medical, vision and dental health insurance, covering employees and officers. Your vacation benefit will accrue at four weeks per year. These benefits may be modified or subject to change from time to time. A copy of FibroGen's current benefits summary has been provided to you.

8. Employment Eligibility. You will also be required to sign the Employment Eligibility Verification (Form I-9). (You will need to complete and return Section One of Form I-9 along with your signed Offer Letter). On or prior to your first day of employment, please provide the necessary original documents that establish your identity and employment eligibility to work in the United States. Acceptable documents are listed on the reverse side of Form I-9. Such documentation must be provided to us within three (3) business days of your date of hire, or our employment relationship with you may be terminated.

9. Proprietary Information. You will abide by FibroGen's strict company policy that prohibits any new employee from using or bringing with them from any prior employer any proprietary information, trade secrets, proprietary materials or processes of such former employers. Moreover, because FibroGen's proprietary information is extremely important, this offer of employment is expressly subject to your execution of the enclosed Confidential Information, Secrecy and Invention Agreement for Employees.

10. At Will Employment. You should be aware that your employment with FibroGen is for no specified period and constitutes "at-will" employment. As a result, both FibroGen and you are free to terminate the employment relationship at any time, for any reason or for no reason, and with or without advance notice. The changing needs of FibroGen could also result in changes to certain aspects of your employment, such as compensation, responsibilities, location, etc. These provisions expressly supersede any previous representations, oral or written. Your at-will employment cannot be modified or amended except by written agreement signed by you, and a Company officer approved by the Board.

11. Arbitration. In connection with this Agreement, we request that you execute the enclosed FibroGen Arbitration Agreement.

12. Indemnification. FibroGen will enter into with you the enclosed Indemnity Agreement

Unless otherwise notified by FibroGen, this offer of employment is effective until 5:00 p.m. PST on December 20, 2019. However, if you have any questions regarding the above provisions, please do not hesitate to contact us.

FibroGen retains the right to amend its employment policies and practices, compensation plans, policies and programs, and forms of employment related agreements from time to time. In the event of conflict between the terms contained in this Offer Letter and any other document, the terms of this Offer Letter (including any amendment to this letter) shall control. This Offer Letter may only be modified in a written document signed by you and an authorized representative of FibroGen. This Offer Letter will be governed by and enforced under the laws of the State of California, without regard to any conflict of law rules, and will inure to the benefit of, be binding on and be enforceable by, the parties and their respective successors, heirs, agents and assigns. This Offer Letter may be executed in counterparts and by .pdf, facsimile or other electronic means and, when so executed, will have the same force and effect as an original, and constitute a binding agreement of the Parties.

Enclosed are two original copies of this Offer Letter. If all of the foregoing terms are satisfactory and acceptable to you, please sign and date each original and (i) return one to me within the time frame set forth above in the enclosed envelope, and (ii) save the other original for yourself. Please also complete the following enclosed forms and mail them back with your countersigned offer letter:

- FibroGen Employment Application
- Confidential Information, Secrecy And Invention Agreement
- Change in Control and Severance Agreement
- I – 9
- FibroGen Arbitration Agreement
- FibroGen Indemnity Agreement

We look forward to your joining our team at FibroGen.

Sincerely,

/s/ Thomas F. Kearns, Jr.

Thomas F. Kearns, Jr.
Chairman, FibroGen, Inc. Board of Directors

ACCEPTED AND AGREED TO this

21 Day of December, 2019

/s/ Enrique Conterno

Name

Jan 6, 2020

Intended Start Date

Enclosures:

Benefits Overview
Duplicate Letter
FibroGen Arbitration Agreement
Change in Control and Severance Agreement
FibroGen Indemnity Agreement
Return Envelope
FibroGen Employment Application
Confidential Information, Secrecy And Invention Agreement
I-9

FIBROGEN, INC.

CHANGE IN CONTROL AND SEVERANCE AGREEMENT

This Change in Control and Severance Agreement (this "Agreement") is dated as of _____ (the "Effective Date"), by and between [_____] ("Executive") and FibroGen, Inc., a Delaware corporation (the "Company"). This Agreement is intended to provide Executive with certain benefits described herein upon the occurrence of specific events.

RECITALS

A. It is expected that the Company from time to time will consider the possibility of a Change in Control. The Company's Board of Directors (the "Board") recognizes that such consideration can be a distraction to Executive and can cause Executive to consider alternative employment opportunities. The Board believes that it is in the best interests of the Company and its stockholders to assure that the Company will have the continued dedication and objectivity of Executive, notwithstanding the possibility, threat or occurrence of a Change in Control (as defined below).

B. The Company's Board believes it is in the best interests of the Company and its shareholders to retain Executive and provide incentives to Executive to continue in the service of the Company.

C. The Board further believes that it is imperative to provide Executive with certain benefits upon a qualifying termination of Executive's employment (whether in connection with a Change in Control or otherwise) which benefits are intended to provide Executive with financial security and provide sufficient income and encouragement to Executive to remain with the Company, notwithstanding the possibility of a Change in Control and/or termination of Executive's employment with the Company under certain circumstances.

Now therefore, in consideration of the mutual promises, covenants and agreements contained herein, and in consideration of the continuing employment of Executive by the Company, the parties hereto agree as follows:

1. At-Will Employment. The term of the Agreement shall begin on the Effective Date and shall end on the third anniversary of the Effective Date. Executive's employment is at-will, which means that the Company may terminate Executive's employment at any time, with or without advance notice, and with or without Cause. Similarly, Executive may resign Executive's employment at any time, with or without advance notice. Executive shall not receive any compensation of any kind, including, without limitation, Stock Awards (as defined below), or other equity award vesting acceleration and severance benefits, following Executive's termination of employment with the Company in connection with a Change in Control, except as expressly provided herein.

2. Accrued Wages, Bonus and Vacation, Expenses. Without regard to the reason for, or the timing of, Executive's termination of employment: (i) the Company shall pay Executive any unpaid base salary due for periods prior to and including the date of Separation from Service (as defined below); (ii) the Company shall pay Executive all of Executive's accrued and unused vacation through the date of Separation from Service; (iii) the Company shall pay Executive any earned (as determined and approved by the Board prior to the Separation from Service) but not yet paid incentive bonus from the prior fiscal year, which bonus shall be paid in accordance with the Company's regular bonus payment process and in any event by no later than March 15 of such subsequent year; and (iv) following submission of proper expense reports by Executive, the Company shall reimburse Executive for all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the Separation from Service. These payments shall be made promptly upon or following termination and within the period of time mandated by law (or in the case of an earned bonus, within the time period set forth in the Company's bonus plan and in any event by no later than March 15 of the calendar year following the year in which the bonus was earned).

3. Severance Benefits. Executive shall be eligible for severance benefits ("Severance Benefits") in the amounts and under the conditions set forth in subsections 3(a), 3(b) and 3(c) below. For the avoidance of doubt, Executive shall not receive Severance Benefits under more than one such subsection. Notwithstanding any other provision hereof, no Severance Benefits shall be provided upon termination of employment unless such termination constitutes a "separation from service" (within the meaning of Treasury Regulation Section 1.409A-1(h), a "Separation from Service").

(a) Benefits upon a Termination in Connection with or Following a Change in Control. If Executive's employment is terminated by the Company without Cause (as defined below), and other than as a result of death or disability, or Executive resigns his or her employment with the Company for Good Reason (as defined below) in connection with or within twelve (12) months following the effective date of a Change in Control, and provided that Executive delivers an effective release of claims as required under Section 4 below, then Executive shall be entitled to the following Severance Benefits:

(i) The Company shall pay Executive an amount equal to the sum of (A) twenty-four (24) months of Executive's then current base salary and (B) one-and-a-half (1.5) times Executive's then current target bonus, ignoring any decrease in base salary or target bonus that forms the basis for Good Reason, less all applicable withholdings and deductions, paid over the twenty-four (24) month period immediately following the Separation from Service in accordance with the Company's regular payroll practices, on the schedule described in Section 4 below.

(ii) The Company shall pay Executive's expenses for continuing his or her health care coverage and the coverage of his or her dependents who are covered at the time of the Executive's Separation from Service (the "COBRA Premiums") under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") (or another state law equivalent), as applicable, for a period ending on the earlier of the eighteen (18) month anniversary of the Separation from Service or the date on which Executive becomes eligible to be covered by the health care plans of another employer; provided however that any Company obligation under this paragraph requires that Executive timely elects COBRA continuation coverage as required by applicable law. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Executive a taxable cash amount, which payment shall be made regardless of whether Executive or Executive's eligible family members elect health care continuation coverage (the "Health Care Benefit Payment"). The Health Care Benefit Payment shall be paid in monthly installments on the same schedule that the COBRA Premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company would have otherwise paid for COBRA Premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the expiration of the period during which the COBRA Premiums would have been paid.

(iii) All outstanding Stock Awards then held by Executive shall become fully vested and exercisable with respect to all of the shares subject thereto effective immediately prior to Executive's Separation from Service under this Section 3(a).

Notwithstanding the foregoing, in the event that Executive would be entitled to a greater level of severance benefits under the terms and conditions of a severance plan or policy provided by the Company or its successor to other

Company employees being terminated in connection with or within twelve (12) months following a Change in Control but for the existence of this Agreement (the "Change in Control Benefits"), Executive shall be entitled to receive the greater of the severance benefits under this Section 3(a) or the Change in Control Benefits, subject to the applicable terms and conditions thereof.

(b) Benefits Upon Certain Other Terminations. If Executive's employment is terminated by the Company without Cause, and other than as a result of death or disability, under circumstances other than those set forth in in the foregoing provisions of this Section 3, and provided that Executive delivers an effective release of claims as required under Section 4 below, then Executive shall be entitled to the following severance benefits:

(i) The Company shall pay Executive an amount equal to eighteen (18) months of Executive's then current base salary, less all applicable withholdings and deductions, paid over such eighteen (18) month period immediately following the Separation from Service in accordance with the Company's regular payroll practices, on the schedule described in Section 4 below.

(ii) The Company shall pay Executive's COBRA Premiums for a period ending on the earlier of the eighteen (18) month anniversary of the Separation from Service or the date on which Executive becomes eligible to be covered by the health care plans of another employer; provided however that any Company obligation under this paragraph requires that Executive timely elects COBRA continuation coverage as required by applicable law. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay the Health Care Benefit Payment. The Health Care Benefit Payment shall be paid in monthly installments on the same schedule that the COBRA Premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company would have otherwise paid for COBRA Premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the expiration of the period during which the COBRA Premiums would have been paid.

4. Release Prior to Payment of Severance Benefits. Prior to the payment of any of the Severance Benefits, Executive shall execute, and allow to become effective, a customary and standard employment release agreement in substantially the form attached hereto as **Exhibit A**, **Exhibit B**, or **Exhibit C**, as applicable, releasing the Company (and its successor) from any and all claims Executive may have against such entities related to or arising in connection with his or her employment and the terms of such employment and termination thereof (the "Release") within the time frame set forth therein, but not later than sixty (60) days following Executive's Separation from Service (the "Release Effective Date"). Such Release shall specifically relate to all of Executive's rights and claims in existence at the time of such execution and shall confirm Executive's continuing obligations to the Company (including but not limited to obligations under any confidentiality and/or non-solicitation agreement with the Company). No Severance Benefits will be paid prior to the Release Effective Date. Within five (5) days following the Release Effective Date, the Company will pay Executive the Severance Benefits Executive would otherwise have received on or prior to such date but for the delay in payment related to the effectiveness of the Release, with the balance of the benefits being paid as originally scheduled. Unless a Change in Control has occurred, the Board, in its sole discretion, may modify the form of the required Release to comply with applicable law and shall determine the form of the required Release, which may be incorporated into a termination agreement or other agreement with Executive. Notwithstanding the foregoing, if the Company (or, if applicable, the successor entity thereto) determines that any of the Severance Benefits constitute "deferred compensation" under Section 409A (defined below), then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, no Severance Benefits will be paid prior to the sixtieth (60th) day following Executive's Separation from Service. On the sixtieth (60th) day following the date of Separation from Service, the Company will pay to Executive in a lump sum the applicable Severance Benefits that Executive would otherwise have received on or prior to such date, with the balance of the Severance Benefits being paid as originally scheduled.

5. Limitation on Payments. If any payment or benefit (including payments and benefits pursuant to this Agreement) that Executive would receive in connection with a Change in Control from the Company or otherwise ("Transaction Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Company shall cause to be determined, before any amounts of the Transaction Payment are paid to Executive, which of the following two alternative forms of payment would result in Executive's receipt, on an after-tax basis, of the greater amount of the Transaction Payment notwithstanding that all or some portion of the Transaction Payment may be subject to the Excise Tax: (1) payment in full of the entire amount of the Transaction

Payment (a "Full Payment"), or (2) payment of only a part of the Transaction Payment so that Executive receives the largest payment possible without the imposition of the Excise Tax (a "Reduced Payment") . For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall cause to be taken into account all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes). If a Reduced Payment is made, (x) Executive shall have no rights to any additional payments and/or benefits constituting the Transaction Payment, and (y) reduction in payments and/or benefits will occur in the following order: (1) reduction of cash payments; (2) cancellation of accelerated vesting of equity awards other than stock options; (3) cancellation of accelerated vesting of stock options; and (4) reduction of other benefits paid to Executive. In the event that acceleration of vesting of equity award compensation is to be reduced, such acceleration of vesting will be cancelled in the reverse order of the date of grant of Executive's equity awards. In no event will the Company or any stockholder be liable to Executive for any amounts not paid as a result of the operation of this Section 5.

(a) The professional firm engaged by the Company for general tax purposes as of the day prior to the effective date of the Change in Control shall make all determinations required to be made under this Section 5. If the professional firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint a nationally recognized independent registered public accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such professional firm required to be made hereunder.

(b) The professional firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive within fifteen (15) calendar days after the date on which Executive's right to a Transaction Payment is triggered or such other time as reasonably requested by the Company or Executive. If the professional firm determines that no Excise Tax is payable with respect to the Transaction Payment, either before or after the application of the Reduced Amount, it shall furnish the Company and Executive with detailed supporting calculations of its determinations that no Excise Tax will be imposed with respect to such Transaction Payment. Any good faith determinations of the professional firm made hereunder shall be final, binding and conclusive upon the Company and Executive.

6. Successors.

(a) Company's Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the Company's, or ensure that the Company fully performs its, obligations under this Agreement and shall perform the Company's, or ensure that the Company performs its, obligations, under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under this Agreement, the term "Company" shall include any such successor.

(b) Executive's Successors. Without the written consent of the Company, Executive shall not assign or transfer any right or obligation under this Agreement to any other person or entity. Notwithstanding the foregoing, the terms of this Agreement and all rights of Executive hereunder shall inure to the benefit of, and be enforceable by, Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

7. Notices.

(a) General. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. In the case of Executive, mailed notices shall be addressed to him at the home address which he most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

(b) Notice of Termination. Any termination by the Company with or without Cause or by Executive as a result of a voluntary resignation for any reason shall be communicated by a notice of termination to the other party hereto given in accordance with this Agreement.

8. Arbitration. The Company and Executive shall attempt to settle any disputes arising in connection with this Agreement through good faith consultation. In the event that Executive and the Company are not able to resolve any such disputes within fifteen (15) days after notification in writing to the other, any dispute or claim arising out of or in connection with this Agreement will be finally settled by binding arbitration in San Francisco, California in accordance with the rules of the American Arbitration Association by one arbitrator mutually agreed upon by the parties. The arbitrator will apply California law, without reference to rules of conflicts of law or rules of statutory arbitration, to the resolution of any dispute. Except as set forth in Section 10(h) below, the arbitrator shall not have authority to modify the terms of this Agreement. The Company shall pay the costs of the arbitration proceeding. Each party shall, unless otherwise determined by the arbitrator, bear its or his or her own attorneys' fees and expenses, provided however that if Executive prevails in an arbitration proceeding, the Company shall reimburse Executive for his or her reasonable attorneys' fees and costs. Judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. Notwithstanding the foregoing, the Company and Executive may apply to any court of competent jurisdiction for preliminary or interim equitable relief, or to compel arbitration in accordance with this paragraph, without breach of this arbitration provision.

9. Definition of Terms. The following terms referred to in this Agreement shall have the following meanings:

(a) Cause. "Cause" for termination of Executive's employment will exist if Executive is terminated by the Company for any of the following reasons: (i) Executive's willful failure substantially to perform his or her duties and responsibilities to the Company or deliberate violation of a Company policy; (ii) Executive's commission of any act of fraud, embezzlement, dishonesty or any other willful misconduct that has caused or is reasonably expected to result in material injury to the Company; (iii) unauthorized use or disclosure by Executive of any proprietary information or trade secrets of the Company or any other party to whom Executive owes an obligation of nondisclosure as a result of his or her relationship with the Company; or (iv) Executive's willful breach of any of his or her obligations under any written agreement or covenant with the Company. The determination as to whether Executive is being terminated for Cause shall be made in good faith by the Company and shall be final and binding on Executive. The foregoing definition does not in any way limit the Company's ability to terminate Executive's employment relationship at any time as provided in Sections 1 and 10(d) of this Agreement, and the term "Company" will be interpreted to include any subsidiary, parent or affiliate of the Company, as appropriate.

(b) Change in Control. "Change in Control" means the first to occur of any of the following transactions that also constitutes a change in the ownership or effective control of the Company, or a change in the ownership of a substantial portion of the Company's assets, as described in Treasury Regulation Section 1.409A-3(i)(5): (A) a merger or consolidation in which the Company is not the surviving entity, except for a transaction the principal purpose of which is to change the state in which the Company is incorporated; (B) the sale, transfer or other disposition of all or substantially all of the assets of the Company (including the capital stock of the Company's subsidiary corporations); (C) any reverse merger in which the Company is the surviving entity but in which securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from those who held such securities immediately prior to such merger; or (D) an acquisition in a single or series of related transactions by any person or related group of persons (other than the Company or by a Company-sponsored employee benefit plan) of beneficial ownership (within the meaning of Rule 13d-3 of the Exchange Act) of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities.

(c) Good Reason. "Good Reason" for Executive's resignation of his or her employment shall exist following the occurrence of any of the following without Executive's written consent: (i) a material reduction in job duties or responsibilities inconsistent with the Executive's position with the Company;

provided, however, that any such reduction or change after a Change in Control will not constitute Good Reason if Executive retains reasonably comparable duties, and responsibilities with respect to the Company's business within the successor entity following a Change of Control; (ii) a material reduction of Executive's then current base salary or target bonus; (iii) the relocation of Executive's principal place of employment to a place that increases Executive's one-way commute by more than forty (40) miles as compared to Executive's then current principal place of employment immediately prior to such relocation; (iv) any material breach by the Company of the Plan or any other written agreement between the Company and the Executive; or (v) the failure by any successor to the Company to assume the Plan and any obligations under the Plan; provided, that the Executive gives written notice to the Company of the event forming the basis of the termination for Good Reason within sixty (60) days after the date on which the Company gives written notice to the Executive of the Company's affirmative decision to take an action set forth in clause (i), (ii), (iii), (iv) or (v) above, the Company fails to cure such basis for the Good Reason resignation within thirty (30) days after receipt of Executive's written notice and Executive terminates his or her employment within thirty (30) days following the expiration of the cure period.

(d) Plan. "Plan" collectively refers to (i) Company's Amended and Restated 2005 Stock Plan, adopted by the Board on February 17, 2005, as amended from time to time, (ii) Company's 2014 Equity Incentive Plan, adopted by the Board on September 9, 2014, as amended from time to time, and (iii) any preceding and succeeding plans thereto.

(e) Stock Awards. "Stock Award(s)" means any right to receive or purchase equity of the Company or other equity based award or compensation as granted under the Plan, including without limitation an Incentive Stock Option, a Nonstatutory Stock Option, a Stock Purchase Award, a Stock Bonus Award, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Unit Award, a Stock Appreciation Right, a Performance Stock Award or any Other Stock Award, each of the foregoing as defined under the Plan; *provided*, *however*, that a Stock Award shall not include any of the foregoing awards to the extent that the grant documentation evidencing such award explicitly provides that the terms of this Agreement shall be superseded by the provisions of such grant documentation.

10. Miscellaneous Provisions.

(a) Executive Obligations. Notwithstanding anything to the contrary contained herein, payment of any of the Severance Benefits will be conditioned upon (i) Executive continuing to comply with his or her obligations under his or her Confidential Information, Secrecy and Invention Agreement during the period of time in which Executive is receiving the Severance Benefits; and (ii) if Executive is a member of the Board, Executive's resignation from the Board, to be effective no later than the date of Separation from Service (or such other date as requested by the Board).

(b) Effect of Statutory Benefits. To the extent that any severance benefits are required to be paid to Executive upon termination of employment with the Company as a result of any requirement of law or any governmental entity in any applicable jurisdiction, the aggregate amount of severance benefits payable pursuant to Section 3 hereof shall not be reduced by such amount.

(c) No Duty to Mitigate. Executive shall not be required to mitigate the amount of any payment contemplated by this Agreement, nor shall any such payment be reduced by any earnings that Executive may receive from any other source.

(d) At-Will Employment Status. Nothing in this Agreement modifies Executive's at-will employment status. Either Executive or the Company can terminate the employment relationship at any time, with or without Cause.

(e) Waiver. No provision of this Agreement may be waived or discharged unless the waiver or discharge is agreed to in writing and signed by the Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(f) Integration. This Agreement supersedes all prior or contemporaneous agreements, whether written or oral, with respect to this Agreement; provided that, for clarification purposes, this Agreement shall not affect any agreements between the Company and Executive regarding intellectual property matters, non-

solicitation or non-competition restrictions or confidential information of the Company. This Agreement expressly supersedes and terminates all Change in Control and Severance Agreements entered into by and between Company and Executive prior to the Effective Date.

(g) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the internal substantive laws, but not the conflicts of law rules, of the State of California.

(h) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(i) Income and Employment Taxes. Executive is responsible for any applicable taxes of any nature (including any penalties or interest that may apply to such taxes) that the Company reasonably determines apply to any payment made hereunder. Executive's receipt of any benefit hereunder is conditioned on his or her satisfaction of any applicable withholding or similar obligations that apply to such benefit and any cash payment owed hereunder will be reduced to satisfy any such withholding or similar obligations that may apply.

(j) Code Section 409A. It is intended that each installment of the payments and benefits provided for in this Agreements constitute a separate "payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, it is intended that payments of the amounts set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code") (Section 409A of the Code, together, with any state law of similar effect, "Section 409A") provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, if the Company (or, if applicable, the successor entity thereto) determines that the severance payments and benefits provided under this Agreement(the "Agreement Payments") constitute "deferred compensation" under Section 409A and Executive is, on the date of his or her Separation from Service, a "specified employee" of the Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code (a "Specified Employee"), then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Severance Benefits described in Section 4(b) shall be delayed as follows: on the earlier to occur of (i) the date that is six months and one day after Executive's Separation from Service or (ii) the date of Executive's death (such earlier date, the "Delayed Initial Payment Date"), the Company (or the successor entity thereto, as applicable) shall pay to Executive a lump sum amount equal to the applicable benefit that Executive would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the benefit had not been so delayed pursuant to this Section 10(j). If a release revocation period spans two calendar years, then amounts will not be paid until the second of the two years to the extent necessary to avoid taxation under Section 409A.

(k) Legal Fees and Expenses. The parties shall each bear their own expenses, legal fees and other fees incurred in connection with the execution of this Agreement.

(l) Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

[*Signature Page Follows*]

In Witness Whereof, the parties have executed this Agreement as of the date first set forth above.

[EXECUTIVE NAME]

Name: _____

Date: _____

FIBROGEN, INC.

By: _____

Name: Michael D. Lowenstein

Title: Chief Legal Officer

Date: _____

EXHIBIT A

RELEASE AGREEMENT

In consideration of receiving certain benefits under my Change in Control and Severance Agreement with FibroGen, Inc. (the "Company") dated _____ (the "Agreement"), I have agreed to sign this Release. I understand that I am not entitled to benefits under the Agreement unless I sign this Release.

I understand that this Release, together with the Agreement, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company, affiliates of the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company that is not expressly stated therein. Certain capitalized terms used in this Release are defined in the Agreement.

I hereby confirm my obligations under my Confidential Information, Secrecy and Invention Agreement with the Company.

Except as otherwise set forth in this Release, I hereby generally and completely release the Company and its current and former directors, officers, executives, shareholders, shareholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, affiliates, and assigns (collectively, the "Released Parties") from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to my signing this Release (collectively, the "Released Claims"). The Released Claims include, but are not limited to: (1) all claims arising out of or in any way related to my employment with the Company or its affiliates, or the termination of that employment; (2) all claims related to my compensation or benefits, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, Stock Awards, or any other ownership interests in the Company or its affiliates; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (4) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (5) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) ("ADEA"), the federal Employee Retirement Income Security Act of 1974 (as amended), and the California Fair Employment and Housing Act (as amended)[1]. Notwithstanding the foregoing, the following are not included in the Released Claims (the "Excluded Claims"): (1) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company to which I am a party, the charter or bylaws of the Company, or under applicable law; (2) any rights related to vested securities of the Company that were granted to me during the course of my employment with the Company or any shares of capital stock or other securities of the Company that I purchased other than pursuant to Company's Plan; or (3) any rights which are not waivable as a matter of law. In addition, nothing in this Release prevents me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, the California Department of Fair Employment and Housing, or any other

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[1] Will need to revise for other states, as applicable.

local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company, except that I hereby waive my right to any monetary benefits in connection with any such claim, charge or proceeding. I hereby represent and warrant that, other than the Excluded Claims, I am not aware of any claims I have or might have against any of the Released Parties that are not included in the Released Claims.

I acknowledge that I am knowingly and voluntarily waiving and releasing any rights I may have under the ADEA. I also acknowledge that the consideration given for the Released Claims is in addition to anything of value to which I was already entitled. I further acknowledge that I have been advised by this writing, as required by the ADEA, that: (a) the Released Claims do not apply to any rights or claims that arise after the date I sign this Release; (b) I should consult with an attorney prior to signing this Release (although I may choose voluntarily not to do so); (c) I have forty-five (45) days to consider this Release (although I may choose to voluntarily sign it sooner); (d) I have seven (7) days following the date I sign this Release to revoke the Release by providing written notice to an officer of

the Company; and (e) the Release will not be effective until the date upon which the revocation period has expired unexercised, which will be the eighth day after I sign this Release ("Effective Date").

I have received with this Release all of the information required by the ADEA, including without limitation a detailed list of the job titles and ages of all employees who were terminated in this group termination and the ages of all employees of the Company in the same job classification or organizational unit who were not terminated, along with information on the eligibility factors used to select employees for the group termination and any time limits applicable to this group termination program.

I acknowledge that I have read and understand Section 1542 of the California Civil Code which reads as follows: **"A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor."** I hereby expressly waive and relinquish all rights and benefits under that section and any law of any jurisdiction of similar effect with respect to my release of any claims hereunder.

I hereby represent that I have been paid all compensation owed and for all hours worked, I have received all the leave and leave benefits and protections for which I am eligible, and I have not suffered any on-the-job injury for which I have not already filed a workers' compensation claim.

I hereby agree not to disparage the Company, or its officers, directors, executives, shareholders or agents, in any manner likely to be harmful to its or their business, business reputation, or personal reputation; *provided, however,* that I will respond accurately and fully to any question, inquiry or request for information when required by legal process.

I acknowledge that to become effective, I must sign and return this Release to the Company so that it is received not later than forty-five (45) days following the date it is provided to me, and I must not revoke it thereafter.

[EXECUTIVE NAME]

Name: _____

Date: _____

EXHIBIT B

RELEASE AGREEMENT

In consideration of receiving certain benefits under my Change in Control and Severance Agreement with FibroGen, Inc. (the "Company") dated _____ (the "Agreement"), I have agreed to sign this Release. I understand that I am not entitled to benefits under the Agreement unless I sign this Release.

I understand that this Release, together with the Agreement, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company, affiliates of the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company that is not expressly stated therein. Certain capitalized terms used in this Release are defined in the Agreement.

I hereby confirm my obligations under my Confidential Information, Secrecy and Invention Agreement with the Company.

Except as otherwise set forth in this Release, I hereby generally and completely release the Company and its current and former directors, officers, executives, shareholders, shareholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, affiliates, and assigns (collectively, the "Released Parties") from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to my signing this Release (collectively, the "Released Claims"). The Released Claims include, but are not limited to: (1) all claims arising out of or in any way related to my employment with the Company or its affiliates, or the termination of that employment; (2) all claims related to my compensation or benefits, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, Stock Awards, or any other ownership interests in the Company or its affiliates; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (4) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (5) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) ("ADEA"), the federal Executive Retirement Income Security Act of 1974 (as amended), and the California Fair Employment and Housing Act (as amended). Notwithstanding the foregoing, the following are not included in the Released Claims (the "Excluded Claims"): (1) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company to which I am a party, the charter or bylaws of the Company, or under applicable law; (2) any rights related to vested securities of the Company that were granted to me during the course of my employment with the Company or any shares of capital stock or other securities of the Company that I purchased other than pursuant to Company's Plan; or (3) any rights which are not waivable as a matter of law. In addition, nothing in this Release prevents me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, the California Department of Fair Employment and Housing, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company, except that I hereby waive my right to any monetary benefits in connection with any such claim, charge or proceeding. I hereby represent and warrant that, other than the Excluded Claims, I am not aware of any claims I have or might have against any of the Released Parties that are not included in the Released Claims.

I acknowledge that I am knowingly and voluntarily waiving and releasing any rights I may have under the ADEA. I also acknowledge that the consideration given for the Released Claims is in addition to anything of value to which I was already entitled. I further acknowledge that I have been advised by this writing, as required by the ADEA, that: (a) the Released Claims do not apply to any rights or claims that arise after the date I sign this Release; (b) I should consult with an attorney prior to signing this Release (although I may choose voluntarily not to do so); (c) I have twenty-one (21) days to consider this Release (although I may choose to voluntarily sign it sooner); (d) I have seven (7) days following the date I sign this Release to revoke the Release by providing written notice to an officer of the Company; and (e) the Release will not be effective until the date upon which the revocation period has expired unexercised, which will be the eighth day after I sign this Release ("Effective Date").

I acknowledge that I have read and understand Section 1542 of the California Civil Code which reads as follows: **"A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor."** I hereby expressly waive and relinquish all rights and benefits under that section and any law of any jurisdiction of similar effect with respect to my release of any claims hereunder.

I hereby represent that I have been paid all compensation owed and for all hours worked, I have received all the leave and leave benefits and protections for which I am eligible, and I have not suffered any on-the-job injury for which I have not already filed a workers' compensation claim.

I hereby agree not to disparage the Company, or its officers, directors, executives, shareholders or agents, in any manner likely to be harmful to its or their business, business reputation, or personal reputation; *provided, however,* that I will respond accurately and fully to any question, inquiry or request for information when required by legal process.

I acknowledge that to become effective, I must sign and return this Release to the Company so that it is received not later than twenty-one (21) days following the date it is provided to me, and I must not revoke it thereafter.

[EXECUTIVE NAME]

Name: _____

Date: _____

EXHIBIT C

RELEASE AGREEMENT

In consideration of receiving certain benefits under my Change in Control and Severance Agreement with FibroGen, Inc. (the "Company") dated _____ (the "Agreement"), I have agreed to sign this Release. I understand that I am not entitled to benefits under the Agreement unless I sign this Release.

I understand that this Release, together with the Agreement, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company, affiliates of the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company that is not expressly stated therein. Certain capitalized terms used in this Release are defined in the Agreement.

I hereby confirm my obligations under my Confidential Information, Secrecy and Invention Agreement with the Company.

Except as otherwise set forth in this Release, I hereby generally and completely release the Company and its current and former directors, officers, executives, shareholders, shareholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, affiliates, and assigns (collectively, the "Released Parties") from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to my signing this Release (collectively, the "Released Claims"). The Released Claims include, but are not limited to: (1) all claims arising out of or in any way related to my employment with the Company or its affiliates, or the termination of that employment; (2) all claims related to my compensation or benefits, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, Stock Awards, or any other ownership interests in the Company or its affiliates; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (4) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (5) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Executive Retirement Income Security Act of 1974 (as amended), and the California Fair Employment and Housing Act (as amended). Notwithstanding the foregoing, the following are not included in the Released Claims (the "Excluded Claims"): (1) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company to which I am a party, the charter or bylaws of the Company, or under applicable law; (2) any rights related to vested securities of the Company that were granted to me during the course of my employment with the Company or any shares of capital stock or other securities of the Company that I purchased other than pursuant to Company's Plan; or (3) any rights which are not waivable as a matter of law. In addition, nothing in this Release prevents me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, the California Department of Fair Employment and Housing, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company, except that I hereby waive my right to any monetary benefits in connection with any such claim, charge or proceeding. I hereby represent and warrant that, other than the Excluded Claims, I am not aware of any claims I have or might have against any of the Released Parties that are not included in the Released Claims.

I acknowledge that I have read and understand Section 1542 of the California Civil Code which reads as follows: **"A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor."** I hereby expressly waive and relinquish all rights and benefits under that section and any law of any jurisdiction of similar effect with respect to my release of any claims hereunder.

I hereby represent that I have been paid all compensation owed and for all hours worked, I have received all the leave and leave benefits and protections for which I am eligible, and I have not suffered any on-the-job injury for which I have not already filed a workers' compensation claim.

I hereby agree not to disparage the Company, or its officers, directors, executives, shareholders or agents, in any manner likely to be harmful to its or their business, business reputation, or personal reputation; *provided, however,* that I will respond accurately and fully to any question, inquiry or request for information when required by legal process.

I acknowledge that to become effective, I must sign and return this Release to the Company so that it is received not later than fourteen (14) days following the date it is provided to me, and I must not revoke it thereafter.

[EXECUTIVE NAME]

Name: _____

Date: _____

FIBROGEN, INC.

CHANGE IN CONTROL AND SEVERANCE AGREEMENT

This Change in Control and Severance Agreement (this "Agreement") is dated as of _____ (the "Effective Date"), by and between [_____] ("Executive") and FibroGen, Inc., a Delaware corporation (the "Company"). This Agreement is intended to provide Executive with certain benefits described herein upon the occurrence of specific events.

RECITALS

A. It is expected that the Company from time to time will consider the possibility of a Change in Control. The Company's Board of Directors (the "Board") recognizes that such consideration can be a distraction to Executive and can cause Executive to consider alternative employment opportunities. The Board believes that it is in the best interests of the Company and its stockholders to assure that the Company will have the continued dedication and objectivity of Executive, notwithstanding the possibility, threat or occurrence of a Change in Control (as defined below).

B. The Company's Board believes it is in the best interests of the Company and its shareholders to retain Executive and provide incentives to Executive to continue in the service of the Company.

C. The Board further believes that it is imperative to provide Executive with certain benefits upon a qualifying termination of Executive's employment (whether in connection with a Change in Control or otherwise) which benefits are intended to provide Executive with financial security and provide sufficient income and encouragement to Executive to remain with the Company, notwithstanding the possibility of a Change in Control and/or termination of Executive's employment with the Company under certain circumstances.

Now therefore, in consideration of the mutual promises, covenants and agreements contained herein, and in consideration of the continuing employment of Executive by the Company, the parties hereto agree as follows:

11. At-Will Employment. The term of the Agreement shall begin on the Effective Date and shall end on the third anniversary of the Effective Date. Executive's employment is at-will, which means that the Company may terminate Executive's employment at any time, with or without advance notice, and with or without Cause. Similarly, Executive may resign Executive's employment at any time, with or without advance notice. Executive shall not receive any compensation of any kind, including, without limitation, Stock Awards (as defined below), or other equity award vesting acceleration and severance benefits, following Executive's termination of employment with the Company in connection with a Change in Control, except as expressly provided herein.

12. Accrued Wages, Bonus and Vacation, Expenses. Without regard to the reason for, or the timing of, Executive's termination of employment: (i) the Company shall pay Executive any unpaid base salary due for periods prior to and including the date of Separation from Service (as defined below); (ii) the Company shall pay Executive all of Executive's accrued and unused vacation through the date of Separation from Service; (iii) the Company shall pay Executive any earned (as determined and approved by the Board prior to the Separation from Service) but not yet paid incentive bonus from the prior fiscal year, which bonus shall be paid in accordance with the Company's regular bonus payment process and in any event by no later than March 15 of such subsequent year; and (iv) following submission of proper expense reports by Executive, the Company shall reimburse Executive for all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the Separation from Service. These payments shall be made promptly upon or following termination and within the period of time mandated by law (or in the case of an earned bonus, within the time period set forth in the Company's bonus plan and in any event by no later than March 15 of the calendar year following the year in which the bonus was earned).

13. Severance Benefits. Executive shall be eligible for severance benefits ("Severance Benefits") in the amounts and under the conditions set forth in subsections 3(a), 3(b) and 3(c) below. For the avoidance of doubt,

Executive shall not receive Severance Benefits under more than one such subsection. Notwithstanding any other provision hereof, no Severance Benefits shall be provided upon termination of employment unless such termination constitutes a "separation from service" (within the meaning of Treasury Regulation Section 1.409A-1(h), a "Separation from Service").

(a) Benefits upon a Termination in Connection with or Following a Change in Control. If Executive's employment is terminated by the Company without Cause (as defined below), and other than as a result of death or disability, or Executive resigns his or her employment with the Company for Good Reason (as defined below) in connection with or within twelve (12) months following the effective date of a Change in Control, and provided that Executive delivers an effective release of claims as required under Section 4 below, then Executive shall be entitled to the following Severance Benefits:

(i) The Company shall pay Executive an amount equal to the sum of (A) eighteen (18) months of Executive's then current base salary and (B) one (1.0) times Executive's then current target bonus, ignoring any decrease in base salary or target bonus that forms the basis for Good Reason, less all applicable withholdings and deductions, paid over the eighteen (18) month period immediately following the Separation from Service in accordance with the Company's regular payroll practices, on the schedule described in Section 4 below.

(ii) The Company shall pay Executive's expenses for continuing his or her health care coverage and the coverage of his or her dependents who are covered at the time of the Executive's Separation from Service (the "COBRA Premiums") under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") (or another state law equivalent), as applicable, for a period ending on the earlier of the eighteen (18) month anniversary of the Separation from Service or the date on which Executive becomes eligible to be covered by the health care plans of another employer; provided however that any Company obligation under this paragraph requires that Executive timely elects COBRA continuation coverage as required by applicable law. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Executive a taxable cash amount, which payment shall be made regardless of whether Executive or Executive's eligible family members elect health care continuation coverage (the "Health Care Benefit Payment"). The Health Care Benefit Payment shall be paid in monthly installments on the same schedule that the COBRA Premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company would have otherwise paid for COBRA Premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the expiration of the period during which the COBRA Premiums would have been paid.

(iii) All outstanding Stock Awards then held by Executive shall become fully vested and exercisable with respect to all of the shares subject thereto effective immediately prior to Executive's Separation from Service under this Section 3(a).

Notwithstanding the foregoing, in the event that Executive would be entitled to a greater level of severance benefits under the terms and conditions of a severance plan or policy provided by the Company or its successor to other Company employees being terminated in connection with or within twelve (12) months following a Change in Control but for the existence of this Agreement (the "Change in Control Benefits"), Executive shall be entitled to receive the greater of the severance benefits under this Section 3(a) or the Change in Control Benefits, subject to the applicable terms and conditions thereof.

(b) Benefits upon a Termination in Connection with Change in Chief Executive Officer. If Executive's employment is terminated by the Company without Cause, and other than as a result of death or disability, or Executive resigns his or her employment with the Company for Good Reason within twelve (12) months following the start date of a non-interim Chief Executive Officer of the Company who is not Chief Executive Officer of the Company as of the Effective Date, and provided that Executive delivers an effective release of claims as required under Section 4 below, then Executive shall be entitled to the following severance benefits:

(i) The Company shall pay Executive an amount equal to the sum of (A) twelve (12) months of Executive's then current base salary and (B) a pro rata portion of Executive's then current target bonus (based on the number of days during the year in which the Separation from Service occurred that Executive

was employed by the Company), ignoring any decrease in base salary or target bonus that forms the basis for Good Reason, less all applicable withholdings and deductions, over the twelve (12) month period immediately following the Separation from Service in accordance with the Company's regular payroll practices, on the schedule described in Section 4 below.

(ii) The Company shall pay Executive's COBRA Premiums for a period ending on the earlier of the twelve (12) month anniversary of the Separation from Service or the date on which Executive becomes eligible to be covered by the health care plans of another employer; provided however that any Company obligation under this paragraph requires that Executive timely elects COBRA continuation coverage as required by applicable law. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay the Health Care Benefit Payment. The Health Care Benefit Payment shall be paid in monthly installments on the same schedule that the COBRA Premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company would have otherwise paid for COBRA Premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the expiration of the period during which the COBRA Premiums would have been paid.

(iii) All outstanding Stock Awards then held by Executive shall become vested and exercisable effective immediately prior to Executive's Separation from Service under this Section 3(b) with respect to the portion of the shares subject thereto that would have vested during the twelve (12) month period following Executive's termination of employment, had Executive remained employed by the Company during such period.

(c) Benefits Upon Certain Other Terminations. If Executive's employment is terminated by the Company without Cause, and other than as a result of death or disability, under circumstances other than those set forth in in the foregoing provisions of this Section 3, and provided that Executive delivers an effective release of claims as required under Section 4 below, then Executive shall be entitled to the following severance benefits:

(i) The Company shall pay Executive an amount equal to twelve (12) months of Executive's then current base salary, less all applicable withholdings and deductions, paid over such twelve (12) month period immediately following the Separation from Service in accordance with the Company's regular payroll practices, on the schedule described in Section 4 below.

(ii) The Company shall pay Executive's COBRA Premiums for a period ending on the earlier of the twelve (12) month anniversary of the Separation from Service or the date on which Executive becomes eligible to be covered by the health care plans of another employer; provided however that any Company obligation under this paragraph requires that Executive timely elects COBRA continuation coverage as required by applicable law. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay the Health Care Benefit Payment. The Health Care Benefit Payment shall be paid in monthly installments on the same schedule that the COBRA Premiums would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company would have otherwise paid for COBRA Premiums (which amount shall be calculated based on the premium for the first month of coverage), and shall be paid until the expiration of the period during which the COBRA Premiums would have been paid.

14. Release Prior to Payment of Severance Benefits. Prior to the payment of any of the Severance Benefits, Executive shall execute, and allow to become effective, a customary and standard employment release agreement in substantially the form attached hereto as **Exhibit A**, **Exhibit B**, or **Exhibit C**, as applicable, releasing the Company (and its successor) from any and all claims Executive may have against such entities related to or arising in connection with his or her employment and the terms of such employment and termination thereof (the "Release") within the time frame set forth therein, but not later than sixty (60) days following Executive's Separation from Service (the "Release Effective Date"). Such Release shall specifically relate to all of Executive's rights and claims in existence at the time of such execution and shall confirm Executive's continuing obligations to the Company (including but not limited to obligations under any confidentiality and/or non-solicitation agreement with the Company). No Severance Benefits will be paid prior to the Release Effective Date. Within five (5) days following the Release Effective Date, the Company will pay Executive the Severance Benefits Executive would otherwise have received on or prior to such date but for the delay in payment related to the effectiveness of the Release, with the balance of the benefits being paid as originally scheduled. Unless a Change in Control has occurred, the Board, in its sole discretion, may modify the form of the required Release to comply with applicable law and shall determine the form of the required Release, which may be incorporated into a termination agreement or other agreement with Executive. Notwithstanding the foregoing, if the Company (or, if applicable, the successor entity thereto) determines that any of the Severance Benefits constitute "deferred compensation" under Section 409A (defined below), then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, no Severance Benefits will be paid prior to the sixtieth (60th) day following Executive's Separation from Service. On the sixtieth (60th) day following the date of Separation from Service, the Company will pay to Executive in a lump sum the applicable Severance Benefits that Executive would otherwise have received on or prior to such date, with the balance of the Severance Benefits being paid as originally scheduled.

15. Limitation on Payments. If any payment or benefit (including payments and benefits pursuant to this Agreement) that Executive would receive in connection with a Change in Control from the Company or otherwise ("Transaction Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Company shall cause to be determined, before any amounts of the Transaction Payment are paid to Executive, which of the following two alternative forms of payment would result in Executive's receipt, on an after-tax basis, of the greater amount of the Transaction Payment notwithstanding that all or some portion of the Transaction Payment may be subject to the Excise Tax: (1) payment in full of the entire amount of the Transaction Payment (a "Full Payment"), or (2) payment of only a part of the Transaction Payment so that Executive receives the largest payment possible without the imposition of the Excise Tax (a "Reduced Payment") . For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall cause to be taken into account all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes). If a Reduced Payment is made, (x) Executive shall have no rights to any additional payments and/or benefits constituting the Transaction Payment, and (y) reduction in payments and/or benefits will occur in the following order: (1) reduction of cash payments; (2) cancellation of accelerated vesting of equity awards other than stock options; (3) cancellation of accelerated vesting of stock options; and (4) reduction of other benefits paid to Executive. In the event that acceleration of vesting of equity award compensation is to be reduced, such acceleration of vesting will be cancelled in the reverse order of the date of grant of Executive's equity awards. In no event will the Company or any stockholder be liable to Executive for any amounts not paid as a result of the operation of this Section 5.

(a) The professional firm engaged by the Company for general tax purposes as of the day prior to the effective date of the Change in Control shall make all determinations required to be made under this Section 5. If the professional firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint a nationally recognized independent registered public accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such professional firm required to be made hereunder.

(b) The professional firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive within fifteen (15) calendar days after the date on which Executive's right to a Transaction Payment is triggered or such other time as reasonably requested by the Company or Executive. If the professional firm determines that no Excise Tax is payable with respect to the Transaction Payment, either before or after the application of the Reduced Amount, it shall furnish the Company and Executive with detailed supporting calculations of its determinations that no Excise Tax will be imposed with respect to such Transaction Payment. Any good faith determinations of the professional firm made hereunder shall be final, binding and conclusive upon the Company and Executive.

16. Successors.

(a) Company's Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the Company's, or ensure that the Company fully performs its, obligations under this Agreement and shall perform the Company's, or ensure that the Company performs its, obligations, under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under this Agreement, the term "Company" shall include any such successor.

(b) Executive's Successors. Without the written consent of the Company, Executive shall not assign or transfer any right or obligation under this Agreement to any other person or entity. Notwithstanding the foregoing, the terms of this Agreement and all rights of Executive hereunder shall inure to the benefit of, and be enforceable by, Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

17. Notices.

(a) General. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. In the case of Executive, mailed notices shall be addressed to him at the home address which he most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

(b) Notice of Termination. Any termination by the Company with or without Cause or by Executive as a result of a voluntary resignation for any reason shall be communicated by a notice of termination to the other party hereto given in accordance with this Agreement.

18. Arbitration. The Company and Executive shall attempt to settle any disputes arising in connection with this Agreement through good faith consultation. In the event that Executive and the Company are not able to resolve any such disputes within fifteen (15) days after notification in writing to the other, any dispute or claim arising out of or in connection with this Agreement will be finally settled by binding arbitration in San Francisco, California in accordance with the rules of the American Arbitration Association by one arbitrator mutually agreed upon by the parties. The arbitrator will apply California law, without reference to rules of conflicts of law or rules of statutory arbitration, to the resolution of any dispute. Except as set forth in Section 10(h) below, the arbitrator shall not have authority to modify the terms of this Agreement. The Company shall pay the costs of the arbitration proceeding. Each party shall, unless otherwise determined by the arbitrator, bear its or his or her own attorneys' fees and expenses, provided however that if Executive prevails in an arbitration proceeding, the Company shall reimburse Executive for his or her reasonable attorneys' fees and costs. Judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. Notwithstanding the foregoing, the Company and Executive may apply to any court of competent jurisdiction for preliminary or interim equitable relief, or to compel arbitration in accordance with this paragraph, without breach of this arbitration provision.

19. Definition of Terms. The following terms referred to in this Agreement shall have the following meanings:

(a) Cause. "Cause" for termination of Executive's employment will exist if Executive is terminated by the Company for any of the following reasons: (i) Executive's willful failure substantially to perform his or her duties and responsibilities to the Company or deliberate violation of a Company policy; (ii) Executive's commission of any act of fraud, embezzlement, dishonesty or any other willful misconduct that has caused or is reasonably expected to result in material injury to the Company; (iii) unauthorized use or disclosure by Executive of any proprietary information or trade secrets of the Company or any other party to whom Executive owes an obligation of nondisclosure as a result of his or her relationship with the Company; or (iv) Executive's willful breach of any of his or her obligations under any written agreement or covenant with the Company. The determination as to whether Executive is being terminated for Cause shall be made in good faith by the Company and shall be final

and binding on Executive. The foregoing definition does not in any way limit the Company's ability to terminate Executive's employment relationship at any time as provided in Sections 1 and 10(d) of this Agreement, and the term "Company" will be interpreted to include any subsidiary, parent or affiliate of the Company, as appropriate.

(b) Change in Control. "Change in Control" means the first to occur of any of the following transactions that also constitutes a change in the ownership or effective control of the Company, or a change in the ownership of a substantial portion of the Company's assets, as described in Treasury Regulation Section 1.409A-3(i)(5): (A) a merger or consolidation in which the Company is not the surviving entity, except for a transaction the principal purpose of which is to change the state in which the Company is incorporated; (B) the sale, transfer or other disposition of all or substantially all of the assets of the Company (including the capital stock of the Company's subsidiary corporations); (C) any reverse merger in which the Company is the surviving entity but in which securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from those who held such securities immediately prior to such merger; or (D) an acquisition in a single or series of related transactions by any person or related group of persons (other than the Company or by a Company-sponsored employee benefit plan) of beneficial ownership (within the meaning of Rule 13d-3 of the Exchange Act) of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities.

(c) Good Reason. "Good Reason" for Executive's resignation of his or her employment shall exist following the occurrence of any of the following without Executive's written consent: (i) a material reduction in job duties or responsibilities inconsistent with the Executive's position with the Company; provided, however, that any such reduction or change after a Change in Control will not constitute Good Reason if Executive retains reasonably comparable duties, and responsibilities with respect to the Company's business within the successor entity following a Change of Control; (ii) a material reduction of Executive's then current base salary or target bonus; (iii) the relocation of Executive's principal place of employment to a place that increases Executive's one-way commute by more than forty (40) miles as compared to Executive's then current principal place of employment immediately prior to such relocation; (iv) any material breach by the Company of the Plan or any other written agreement between the Company and the Executive; or (v) the failure by any successor to the Company to assume the Plan and any obligations under the Plan; provided, that the Executive gives written notice to the Company of the event forming the basis of the termination for Good Reason within sixty (60) days after the date on which the Company gives written notice to the Executive of the Company's affirmative decision to take an action set forth in clause (i), (ii), (iii), (iv) or (v) above, the Company fails to cure such basis for the Good Reason resignation within thirty (30) days after receipt of Executive's written notice and Executive terminates his or her employment within thirty (30) days following the expiration of the cure period.

(d) Plan. "Plan" collectively refers to (i) Company's Amended and Restated 2005 Stock Plan, adopted by the Board on February 17, 2005, as amended from time to time, (ii) Company's 2014 Equity Incentive Plan, adopted by the Board on September 9, 2014, as amended from time to time, and (iii) any preceding and succeeding plans thereto.

(e) Stock Awards. "Stock Award(s)" means any right to receive or purchase equity of the Company or other equity based award or compensation as granted under the Plan, including without limitation an Incentive Stock Option, a Nonstatutory Stock Option, a Stock Purchase Award, a Stock Bonus Award, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Unit Award, a Stock Appreciation Right, a Performance Stock Award or any Other Stock Award, each of the foregoing as defined under the Plan; *provided, however,* that a Stock Award shall not include any of the foregoing awards to the extent that the grant documentation evidencing such award explicitly provides that the terms of this Agreement shall be superseded by the provisions of such grant documentation.

20. Miscellaneous Provisions.

(a) Executive Obligations. Notwithstanding anything to the contrary contained herein, payment of any of the Severance Benefits will be conditioned upon (i) Executive continuing to comply with his or her obligations under his or her Confidential Information, Secrecy and Invention Agreement during the period of time in which Executive is receiving the Severance Benefits; and (ii) if Executive is a member of the Board, Executive's resignation from the Board, to be effective no later than the date of Separation from Service (or such other date as requested by the Board).

(b) Effect of Statutory Benefits. To the extent that any severance benefits are required to be paid to Executive upon termination of employment with the Company as a result of any requirement of law or any governmental entity in any applicable jurisdiction, the aggregate amount of severance benefits payable pursuant to Section 3 hereof shall not be reduced by such amount.

(c) No Duty to Mitigate. Executive shall not be required to mitigate the amount of any payment contemplated by this Agreement, nor shall any such payment be reduced by any earnings that Executive may receive from any other source.

(d) At-Will Employment Status. Nothing in this Agreement modifies Executive's at-will employment status. Either Executive or the Company can terminate the employment relationship at any time, with or without Cause.

(e) Waiver. No provision of this Agreement may be waived or discharged unless the waiver or discharge is agreed to in writing and signed by the Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(f) Integration. This Agreement supersedes all prior or contemporaneous agreements, whether written or oral, with respect to this Agreement; provided that, for clarification purposes, this Agreement shall not affect any agreements between the Company and Executive regarding intellectual property matters, non-solicitation or non-competition restrictions or confidential information of the Company. This Agreement expressly supersedes and terminates all Change in Control and Severance Agreements entered into by and between Company and Executive prior to the Effective Date.

(g) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the internal substantive laws, but not the conflicts of law rules, of the State of California.

(h) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(i) Income and Employment Taxes. Executive is responsible for any applicable taxes of any nature (including any penalties or interest that may apply to such taxes) that the Company reasonably determines apply to any payment made hereunder. Executive's receipt of any benefit hereunder is conditioned on his or her satisfaction of any applicable withholding or similar obligations that apply to such benefit and any cash payment owed hereunder will be reduced to satisfy any such withholding or similar obligations that may apply.

(j) Code Section 409A. It is intended that each installment of the payments and benefits provided for in this Agreements constitute a separate "payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, it is intended that payments of the amounts set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code") (Section 409A of the Code, together, with any state law of similar effect, "Section 409A") provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, if the Company (or, if applicable, the successor entity thereto) determines that the severance payments and benefits provided under this Agreement(the "Agreement Payments") constitute "deferred compensation" under Section 409A and Executive is, on the date of his or her Separation from Service, a "specified employee" of the Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code (a "Specified Employee"), then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Severance Benefits described in Section 4(b) shall be delayed as follows: on the earlier to occur of (i) the date that is six months and one day after Executive's Separation from Service or (ii) the date of Executive's death (such earlier date, the "Delayed Initial Payment Date"), the Company (or the successor entity thereto, as applicable) shall pay to Executive a lump sum amount equal to the applicable benefit that Executive would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the benefit had not been so delayed pursuant to this Section 10(j). If a release

revocation period spans two calendar years, then amounts will not be paid until the second of the two years to the extent necessary to avoid taxation under Section 409A.

(k) Legal Fees and Expenses. The parties shall each bear their own expenses, legal fees and other fees incurred in connection with the execution of this Agreement.

(l) Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

[*Signature Page Follows*]

In Witness Whereof, the parties have executed this Agreement as of the date first set forth above.

[EXECUTIVE NAME]

Name: _____

Date: _____

FIBROGEN, INC.

By: _____

Name: Michael D. Lowenstein

Title: Chief Legal Officer

Date: _____

EXHIBIT A

RELEASE AGREEMENT

In consideration of receiving certain benefits under my Change in Control and Severance Agreement with FibroGen, Inc. (the "Company") dated _____ (the "Agreement"), I have agreed to sign this Release. I understand that I am not entitled to benefits under the Agreement unless I sign this Release.

I understand that this Release, together with the Agreement, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company, affiliates of the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company that is not expressly stated therein. Certain capitalized terms used in this Release are defined in the Agreement.

I hereby confirm my obligations under my Confidential Information, Secrecy and Invention Agreement with the Company.

Except as otherwise set forth in this Release, I hereby generally and completely release the Company and its current and former directors, officers, executives, shareholders, shareholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, affiliates, and assigns (collectively, the "Released Parties") from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to my signing this Release (collectively, the "Released Claims"). The Released Claims include, but are not limited to: (1) all claims arising out of or in any way related to my employment with the Company or its affiliates, or the termination of that employment; (2) all claims related to my compensation or benefits, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, Stock Awards, or any other ownership interests in the Company or its affiliates; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (4) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (5) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) ("ADEA"), the federal Employee Retirement Income Security Act of 1974 (as amended), and the California Fair Employment and Housing Act (as amended)[2]. Notwithstanding the foregoing, the following are not included in the Released Claims (the "Excluded Claims"): (1) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company to which I am a party, the charter or bylaws of the Company, or under applicable law; (2) any rights related to vested securities of the Company that were granted to me during the course of my employment with the Company or any shares of capital stock or other securities of the Company that I purchased other than pursuant to Company's Plan; or (3) any rights which are not waivable

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2 Will need to revise for other states, as applicable.

as a matter of law. In addition, nothing in this Release prevents me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, the California Department of Fair Employment and Housing, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company, except that I hereby waive my right to any monetary benefits in connection with any such claim, charge or proceeding. I hereby represent and warrant that, other than the Excluded Claims, I am not aware of any claims I have or might have against any of the Released Parties that are not included in the Released Claims.

I acknowledge that I am knowingly and voluntarily waiving and releasing any rights I may have under the ADEA. I also acknowledge that the consideration given for the Released Claims is in addition to anything of value to which I was already entitled. I further acknowledge that I have been advised by this writing, as required by the ADEA, that: (a) the Released Claims do not apply to any rights or claims that arise after the date I sign this Release; (b) I should consult with an attorney prior to signing this Release (although I may choose voluntarily not to do so); (c) I have forty-five (45) days to consider this Release (although I may choose to voluntarily sign it sooner); (d) I have

seven (7) days following the date I sign this Release to revoke the Release by providing written notice to an officer of the Company; and (e) the Release will not be effective until the date upon which the revocation period has expired unexercised, which will be the eighth day after I sign this Release ("Effective Date").

I have received with this Release all of the information required by the ADEA, including without limitation a detailed list of the job titles and ages of all employees who were terminated in this group termination and the ages of all employees of the Company in the same job classification or organizational unit who were not terminated, along with information on the eligibility factors used to select employees for the group termination and any time limits applicable to this group termination program.

I acknowledge that I have read and understand Section 1542 of the California Civil Code which reads as follows: **"A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor."** I hereby expressly waive and relinquish all rights and benefits under that section and any law of any jurisdiction of similar effect with respect to my release of any claims hereunder.

I hereby represent that I have been paid all compensation owed and for all hours worked, I have received all the leave and leave benefits and protections for which I am eligible, and I have not suffered any on-the-job injury for which I have not already filed a workers' compensation claim.

I hereby agree not to disparage the Company, or its officers, directors, executives, shareholders or agents, in any manner likely to be harmful to its or their business, business reputation, or personal reputation; *provided, however,* that I will respond accurately and fully to any question, inquiry or request for information when required by legal process.

I acknowledge that to become effective, I must sign and return this Release to the Company so that it is received not later than forty-five (45) days following the date it is provided to me, and I must not revoke it thereafter.

[EXECUTIVE NAME]

Name: _____

Date: _____

EXHIBIT B

RELEASE AGREEMENT

In consideration of receiving certain benefits under my Change in Control and Severance Agreement with FibroGen, Inc. (the "Company") dated _____ (the "Agreement"), I have agreed to sign this Release. I understand that I am not entitled to benefits under the Agreement unless I sign this Release.

I understand that this Release, together with the Agreement, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company, affiliates of the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company that is not expressly stated therein. Certain capitalized terms used in this Release are defined in the Agreement.

I hereby confirm my obligations under my Confidential Information, Secrecy and Invention Agreement with the Company.

Except as otherwise set forth in this Release, I hereby generally and completely release the Company and its current and former directors, officers, executives, shareholders, shareholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, affiliates, and assigns (collectively, the "Released Parties") from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to my signing this Release (collectively, the "Released Claims"). The Released Claims include, but are not limited to: (1) all claims arising out of or in any way related to my employment with the Company or its affiliates, or the termination of that employment; (2) all claims related to my compensation or benefits, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, Stock Awards, or any other ownership interests in the Company or its affiliates; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (4) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (5) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) ("ADEA"), the federal Executive Retirement Income Security Act of 1974 (as amended), and the California Fair Employment and Housing Act (as amended). Notwithstanding the foregoing, the following are not included in the Released Claims (the "Excluded Claims"): (1) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company to which I am a party, the charter or bylaws of the Company, or under applicable law; (2) any rights related to vested securities of the Company that were granted to me during the course of my employment with the Company or any shares of capital stock or other securities of the Company that I purchased other than pursuant to Company's Plan; or (3) any rights which are not waivable as a matter of law. In addition, nothing in this Release prevents me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, the California Department of Fair Employment and Housing, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company, except that I hereby waive my right to any monetary benefits in connection with any such claim, charge or proceeding. I hereby represent and warrant that, other than the Excluded Claims, I am not aware of any claims I have or might have against any of the Released Parties that are not included in the Released Claims.

I acknowledge that I am knowingly and voluntarily waiving and releasing any rights I may have under the ADEA. I also acknowledge that the consideration given for the Released Claims is in addition to anything of value to which I was already entitled. I further acknowledge that I have been advised by this writing, as required by the ADEA, that: (a) the Released Claims do not apply to any rights or claims that arise after the date I sign this Release; (b) I should consult with an attorney prior to signing this Release (although I may choose voluntarily not to do so); (c) I have twenty-one (21) days to consider this Release (although I may choose to voluntarily sign it sooner); (d) I have seven (7) days following the date I sign this Release to revoke the Release by providing written notice to an officer of the Company; and (e) the Release will not be effective until the date upon which the revocation period has expired unexercised, which will be the eighth day after I sign this Release ("Effective Date").

I acknowledge that I have read and understand Section 1542 of the California Civil Code which reads as follows: **"A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor."** I hereby expressly waive and relinquish all rights and benefits under that section and any law of any jurisdiction of similar effect with respect to my release of any claims hereunder.

I hereby represent that I have been paid all compensation owed and for all hours worked, I have received all the leave and leave benefits and protections for which I am eligible, and I have not suffered any on-the-job injury for which I have not already filed a workers' compensation claim.

I hereby agree not to disparage the Company, or its officers, directors, executives, shareholders or agents, in any manner likely to be harmful to its or their business, business reputation, or personal reputation; *provided, however,* that I will respond accurately and fully to any question, inquiry or request for information when required by legal process.

I acknowledge that to become effective, I must sign and return this Release to the Company so that it is received not later than twenty-one (21) days following the date it is provided to me, and I must not revoke it thereafter.

[EXECUTIVE NAME]

Name: _____

Date: _____

EXHIBIT C

RELEASE AGREEMENT

In consideration of receiving certain benefits under my Change in Control and Severance Agreement with FibroGen, Inc. (the "Company") dated _____ (the "Agreement"), I have agreed to sign this Release. I understand that I am not entitled to benefits under the Agreement unless I sign this Release.

I understand that this Release, together with the Agreement, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company, affiliates of the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company that is not expressly stated therein. Certain capitalized terms used in this Release are defined in the Agreement.

I hereby confirm my obligations under my Confidential Information, Secrecy and Invention Agreement with the Company.

Except as otherwise set forth in this Release, I hereby generally and completely release the Company and its current and former directors, officers, executives, shareholders, shareholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, affiliates, and assigns (collectively, the "Released Parties") from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to my signing this Release (collectively, the "Released Claims"). The Released Claims include, but are not limited to: (1) all claims arising out of or in any way related to my employment with the Company or its affiliates, or the termination of that employment; (2) all claims related to my compensation or benefits, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, Stock Awards, or any other ownership interests in the Company or its affiliates; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (4) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (5) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Executive Retirement Income Security Act of 1974 (as amended), and the California Fair Employment and Housing Act (as amended). Notwithstanding the foregoing, the following are not included in the Released Claims (the "Excluded Claims"): (1) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company to which I am a party, the charter or bylaws of the Company, or under applicable law; (2) any rights related to vested securities of the Company that were granted to me during the course of my employment with the Company or any shares of capital stock or other securities of the Company that I purchased other than pursuant to Company's Plan; or (3) any rights which are not waivable as a matter of law. In addition, nothing in this Release prevents me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, the California Department of Fair Employment and Housing, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company, except that I hereby waive my right to any monetary benefits in connection with any such claim, charge or proceeding. I hereby represent and warrant that, other than the Excluded Claims, I am not aware of any claims I have or might have against any of the Released Parties that are not included in the Released Claims.

I acknowledge that I have read and understand Section 1542 of the California Civil Code which reads as follows: **"A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor."** I hereby expressly waive and relinquish all rights and benefits under that section and any law of any jurisdiction of similar effect with respect to my release of any claims hereunder.

I hereby represent that I have been paid all compensation owed and for all hours worked, I have received all the leave and leave benefits and protections for which I am eligible, and I have not suffered any on-the-job injury for which I have not already filed a workers' compensation claim.

I hereby agree not to disparage the Company, or its officers, directors, executives, shareholders or agents, in any manner likely to be harmful to its or their business, business reputation, or personal reputation; *provided, however,* that I will respond accurately and fully to any question, inquiry or request for information when required by legal process.

I acknowledge that to become effective, I must sign and return this Release to the Company so that it is received not later than fourteen (14) days following the date it is provided to me, and I must not revoke it thereafter.

[EXECUTIVE NAME]

Name: _____

Date: _____

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-200348, No. 333-213816, No. 333-216369, and No. 333-233204) of FibroGen, Inc. of our report dated March 2, 2020 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
March 2, 2020

Exhibit 31.1

CERTIFICATION

I, Enrique Conterno, certify that;

1. I have reviewed this annual report on 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 the 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: March 2, 2020

/s/ Enrique Conterno

Enrique Conterno
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Pat Cotroneo, certify that;

1. I have reviewed this annual report on 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 the 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: March 2, 2020

/s/ Pat Cotroneo

Pat Cotroneo
Senior Vice President, Finance 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 Pat Cotroneo, 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, 2019 (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 2nd day of March, 2020.

/s/ Enrique Conterno	/s/ Pat Cotroneo
Enrique Conterno	Pat Cotroneo
Chief Executive Officer	Senior Vice President, Finance 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.