As filed with the Securities and Exchange Commission on October 24, 2014

Registration No. 333-199069

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

Amendment No. 3
to
Form S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

FibroGen, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**77-0357827**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

409 Illinois St.
San Francisco, CA 94158
(415) 978-1200
(Address, including zip code, and telephone number, including area code, of registrant’s principal executive offices)

Thomas B. Neff
Chief Executive Officer
FibroGen, Inc.
409 Illinois Street
San Francisco, CA 94158
(415) 978-1200
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Glen Sato **Michael E. Tenta** **Cooley LLP** **3175 Hanover Street** **Palo Alto, CA 94304** **(650) 843-5000**	**Michael Lowenstein** **Vice President, Legal Affairs** **FibroGen, Inc.** **409 Illinois Street** **San Francisco, CA 94158** **(415) 978-1200**	**John L. Savva** **Sullivan & Cromwell LLP** **1870 Embarcadero Road** **Palo Alto, CA 94303** **(650) 461-5600**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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(1) Estimated solely for the purpose of computing the amount of registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
(2) Includes shares the underwriters have the option to purchase.
(3) Calculated pursuant to Rule 457(o) under the Securities Act of 1933, as amended, based on an estimate of the proposed maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion. Dated October 24, 2014.

Shares

FIBROGEN

Common Stock

This is an initial public offering of shares of common stock of FibroGen, Inc. All of the shares of common stock are being sold by the company.

Prior to this offering, there has been no public market for the common stock. It is currently estimated that the initial public offering price per share will be between $ and $. We intend to list our common stock on the NASDAQ Global Select Market under the symbol “FGEN”.

We are an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, may elect to comply with certain reduced public company reporting requirements in future reports after the completion of this offering.

AstraZeneca, one of our collaboration partners, has agreed to purchase from us concurrently with the closing of this offering in a private placement shares of our common stock with an aggregate purchase price of $20 million at a price per share equal to the initial public offering price.

See “Risk Factors” on page 18 to read about factors you should consider before buying shares of the common stock.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$	$
Underwriting discount[1]	$	$
Proceeds, before expenses, to us	$	$

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[1] See “Underwriting” for a description of the compensation payable to the underwriters.

To the extent that the underwriters sell more than shares of common stock, the underwriters have the option to purchase up to an additional shares from FibroGen at the initial price to public less the underwriting discount.

The underwriters expect to deliver the shares against payment in New York, New York on , 2014.

Goldman, Sachs & Co. **Citigroup** **Leerink Partners**

RBC Capital Markets **Stifel** **William Blair**

Prospectus dated , 2014.

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Prospectus

Through and including   , 2014 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer’s obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes thereto and the information set forth under the sections "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Unless the context otherwise requires, we use the terms "FibroGen," "company," "we," "us" and "our" in this prospectus to refer to FibroGen, Inc. and, where appropriate, our consolidated subsidiaries.

Company Overview

We are a research-based biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics to treat serious unmet medical needs. We have capitalized on our extensive experience in fibrosis and hypoxia-inducible factor, or HIF, biology to generate multiple programs targeting various therapeutic areas. Our most advanced product candidate, roxadustat, or FG-4592, is an oral small molecule inhibitor of HIF prolyl hydroxylases, or HIF-PHs, in Phase 3 clinical development for the treatment of anemia in chronic kidney disease, or CKD. Our second product candidate, FG-3019, is a monoclonal antibody in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis, or IPF, pancreatic cancer and liver fibrosis. We have taken a global approach to the development and future commercialization of our product candidates, and this includes development and commercialization in the People's Republic of China, or China.

Roxadustat, the first HIF-PH inhibitor to enter Phase 3 clinical development, acts by stimulating the body's natural pathway of erythropoiesis, or red blood cell production. Roxadustat represents a new paradigm for the treatment of anemia in CKD patients, and has the potential to offer a safer, more effective, more convenient and more accessible therapy than the current standard of care, injectable erythropoiesis stimulating agents, or ESAs. 1,449 subjects have participated in 26 completed Phase 1 and 2 clinical studies for roxadustat in North America, Europe and Asia. These studies have demonstrated roxadustat's potential for a favorable safety and efficacy profile in anemic CKD patients, both those who are dialysis-dependent, or DD-CKD, and those who are not dialysis-dependent, or NDD-CKD. We, along with our collaboration partners Astellas Pharma Inc., or Astellas, and AstraZeneca AB, or AstraZeneca, have designed a global Phase 3 program to support regulatory approval of roxadustat in both NDD-CKD and DD-CKD patients in multiple geographies. Based on its multiple potential advantages, we believe there is a significant opportunity for roxadustat to address markets currently served by injectable ESAs. According to IMS Health, 2013 global ESA sales in all anemia indications totaled $8.6 billion. Further, roxadustat could expand access to anemia treatment for the growing global CKD population that is not adequately served by ESAs, and over time, address other anemia indications.

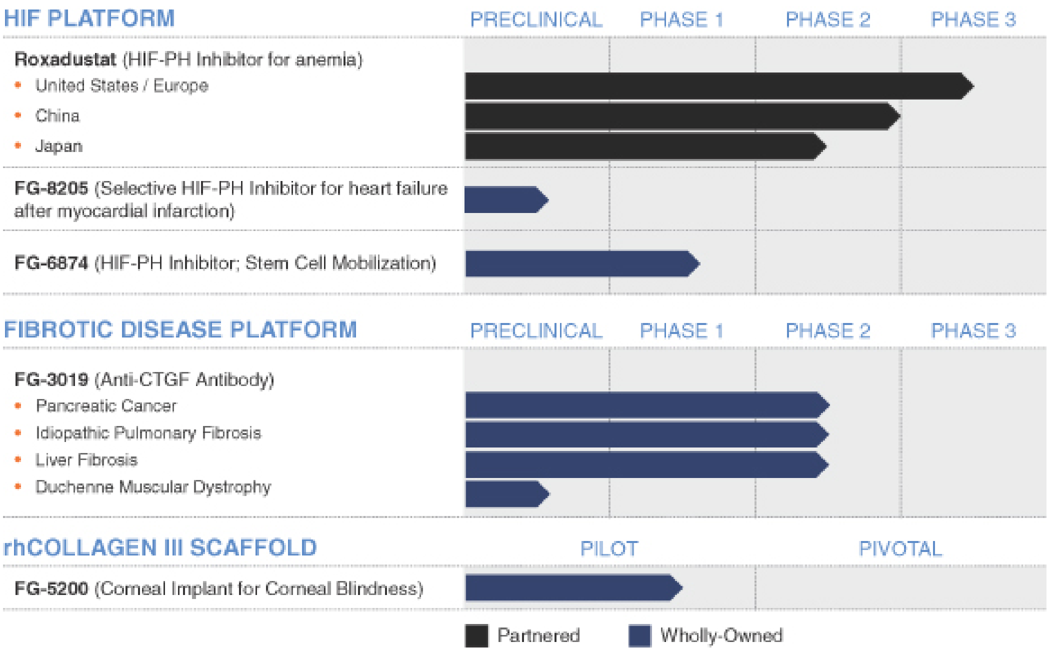
FG-3019 is our fully-human monoclonal antibody that inhibits the activity of connective tissue growth factor, or CTGF, a critical common element in the progression of fibrosis and associated serious diseases. In an animal model of lung fibrosis, FG-3019 reversed fibrosis. In Phase 2 IPF clinical studies, FG-3019 demonstrated the potential for stabilization of disease and, for the first time in human studies, reversal of lung fibrosis in some patients. In an open-label Phase 2 pancreatic cancer study of FG-3019 plus gemcitabine and erlotinib, FG-3019 demonstrated a dose-dependent improvement in one year survival rate. In ten Phase 1 and Phase 2 clinical studies of FG-3019 to date involving over 340 subjects, FG-3019 has been well tolerated across a wide range of doses studied, and there have been no dose-limiting toxicities observed to date.

In IPF, average life expectancy at the time of confirmatory diagnosis is estimated to be between 3 to 5 years, with approximately two-thirds of IPF patients dying within five years of diagnosis. Decision Resources Group estimates that there will be approximately $4.6 billion in U.S. and European sales of IPF drugs in 2020. There is one drug that has been approved in Europe, Canada, Japan and the United States, and a second drug that has been approved in the United States and submitted for accelerated approval in the European Union. However, we believe that FG-3019 could be the first product with disease-modifying activity.

In pancreatic ductal adenocarcinoma, or pancreatic cancer, the fourth leading cause of cancer deaths in the United States, average life expectancy with currently available anti-cancer agents is approximately six to nine months and 94% of patients die within five years of diagnosis. Decision Resources Group estimates that there will be approximately $1.3 billion in sales of pancreatic cancer drugs in 2022.

If FG-3019 can be shown in future clinical studies to safely and effectively address either IPF or pancreatic cancer, we believe that the commercial potential for this product candidate can be significant. To date, we have retained worldwide rights for FG-3019.

The chart below is a summary of our most advanced product candidates:



We are also currently pursuing the use of our proprietary type III recombinant human collagens in our biosynthetic corneal implant product candidate, FG-5200, for treatment of corneal blindness resulting from partial thickness corneal damage in China, and potentially other territories. FG-5200 is designed to serve as a temporary scaffold to allow for regeneration of the native corneal tissue. Our China subsidiary, FibroGen (China) Medical Technology Development Co., Ltd., or FibroGen China, has submitted a device classification application to the China Food and Drug Administration, or CFDA, to designate FG-5200 as a Domestic Class III medical device.

Overview of Roxadustat—Treatment of Anemia in CKD

Roxadustat is an orally administered small molecule that corrects anemia by a mechanism of action different from that of ESAs. Roxadustat activates a response that is naturally activated when the body responds to reduced oxygen levels in the blood, such as when a person adapts to high altitude. The response activated by roxadustat involves the regulation of multiple, complementary processes to promote erythropoiesis and increase the blood's oxygen carrying capacity. This coordinated erythropoietic response includes both the stimulation of red blood cell progenitors by increasing the body's production of erythropoietin, or EPO, and an increase in iron availability for hemoglobin, or Hb, synthesis. Patients taking roxadustat typically have EPO levels within or near the physiologic range naturally experienced by people 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 red blood cell progenitors without a corresponding increase in iron availability, and are typically dosed well above the natural physiologic range of EPO. We believe these high ESA doses are a main cause of the significant safety issues that have been attributed to ESAs. Accordingly, the differentiated pharmacologic action of roxadustat has the potential to provide a safer and more effective treatment of anemia in CKD and potentially in other disorders.

Anemia is a serious medical condition in which patients have insufficient red blood cells and low levels of Hb, a protein in red blood cells that carries oxygen to cells throughout the body. Anemia is associated with increased risks of hospitalization, cardiovascular complications, need for blood transfusion, exacerbation of other serious medical conditions and death. In addition, anemia frequently leads to significant fatigue, cognitive dysfunction and decreased quality of life. The more severe the anemia, as measured by lower Hb levels, the greater the health impact on patients. Severe anemia is common in patients with CKD, cancer, myelodysplastic syndrome, or MDS, inflammatory diseases and other serious illnesses. Even when it accompanies these prevalent and serious diseases, anemia is often not effectively treated.

Anemia is particularly prevalent in patients with CKD, which is a critical healthcare problem that affects over 200 million people worldwide, and anemia significantly increases healthcare costs for those patients. CKD is generally a progressive disease characterized by the gradual loss of kidney function that may eventually lead to kidney failure, also known as end stage renal disease, or ESRD. Patients with ESRD require renal replacement therapy – either dialysis treatment or kidney transplantation. More advanced stages of kidney disease are associated with greater rates of anemia and more severe anemia. However, patients typically do not receive treatment for their anemia until they initiate dialysis, and as a result there is a significant need for a safe and effective therapy for patients with anemia in less advanced stages of CKD.

Currently available therapies to treat anemia in CKD include ESAs and blood transfusions. ESAs are currently the standard of care for effectively treating anemia in patients with CKD and must be administered intravenously or subcutaneously. ESAs are all synthetic recombinant versions of human EPO, a hormone that binds to receptors on red blood cell precursors in the bone marrow, thereby stimulating erythropoiesis and increasing Hb levels. Intravenous, or IV, iron is often required to supplement ESAs in dialysis patients in an effort to achieve adequate Hb response and to avoid iron depletion in the course of anemia therapy.

While injectable ESAs have been one of the most commercially successful drug classes, significant safety concerns have emerged from studies published in 2006 to 2009, resulting in several changes to ESA labeling. The package insert for ESAs currently includes a "Black Box" warning, which was mandated by the U.S. Food and Drug Administration, or FDA, and states that ESAs increase the risk of death and major adverse cardiovascular events, such as myocardial infarction, stroke, venous thromboembolism and thrombosis of vascular access. Tumor progression or recurrence in patients with cancer has also been associated with ESAs and is reflected in the Black Box warning. Secondary analyses of these studies suggest that the safety concerns associated with ESAs, particularly the increased cardiovascular risk, may result from the high ESA doses or circulating levels of ESAs, rather than the achieved Hb levels.

Potential Advantages of Roxadustat Over the Current Standard of Care

Cardiovascular Safety Advantages

In addition to being linked to an increased incidence of major adverse cardiovascular events as described above, ESAs are associated with an increased risk for new onset hypertension and exacerbation of pre-existing hypertension, increased platelet counts and thromboembolic events, including stroke, vascular access thrombosis (where the dialysis access shunt is blocked due to clotting) and blood clots in the leg.

Safety analyses of our Phase 2 trials did not reveal any association between the roxadustat dose or the associated rate of Hb rise or Hb level and the rates of cardiovascular events, new onset hypertension, exacerbation of pre-existing hypertension, increased platelet counts or thrombosis. In addition, we observed a reduction in average total cholesterol and an improvement in average HDL / LDL ratio versus baseline.

Correcting Anemia within or near Physiologic EPO Levels

In order to be effective, ESAs typically require doses well above physiologic range. By contrast, our clinical trials to date have shown that roxadustat can treat anemia in CKD by causing an increase of blood EPO levels that are typically within or near the physiologic range observed in people who are adapting to high altitude, following blood donation or impaired lung function, such as pulmonary edema. The ability of roxadustat to treat anemia without causing supraphysiologic blood levels of EPO may provide significant safety benefits over ESAs.

Anemia Correction for Patient Populations That are Hyporesponsive to ESAs

CKD patients receive a wide range of ESA doses. Higher doses, and thus higher circulating levels of ESAs, are typically required for patients within the first four months of initiating dialysis, or incident dialysis, suffering from chronic inflammation, undergoing surgery or with acute illness. These higher doses are not only associated with increased safety risks, but also may not be sufficient to effectively raise Hb levels to target in some patients.

In our Phase 2 studies, doses of roxadustat that corrected anemia in incident dialysis patients and patients with elevated markers for inflammation were similar to doses that corrected anemia in non-incident, or stable, dialysis patients and patients without elevated markers for inflammation. We believe effective doses of roxadustat are likely to be comparable in these CKD patient subsets because roxadustat can overcome the direct suppressive effects of inflammatory cytokines on erythropoiesis, can increase iron availability through an increase in iron absorption from the gastrointestinal, or GI, tract, and can increase the release of iron from intracellular stores and the transport of iron to the bone marrow.

Anemia Correction Without the Need for IV Iron

Our Phase 2 studies have shown roxadustat to correct anemia without the need for concomitant administration of IV iron. We believe this benefit results from roxadustat’s effects on iron metabolism described above. In these studies, roxadustat corrected anemia without IV iron in stable and incident dialysis patients and patients with elevated markers for inflammation. In contrast, IV iron supplementation is required to support anemia correction in a majority of U.S. dialysis patients receiving ESAs, and IV iron is associated with a variety of risks, including hypersensitivity (which can be life-threatening), infection, skin problems, hypotension and gastrointestinal symptoms.

Reimbursement and Convenience Advantages

ESAs and oral equivalents of ESAs are included in the bundled payment system in the DD-CKD setting and reimbursed under Medicare Part B in the NDD-CKD setting. Based on roxadustat’s differentiated mechanism of action and therapeutic effects, it is not known whether it will be included in or excluded from the bundle in the DD-CKD setting. Agents that have no IV equivalent in the bundle are currently expected to be excluded from the bundle until 2024.

In the NDD-CKD setting, we expect that roxadustat, an oral treatment, should be subject to Medicare Part D, which would allow physicians to prescribe roxadustat without the financial and reimbursement risk associated with purchasing and storing injectable ESAs. We believe that this should encourage significantly greater usage outside of the dialysis setting.

In addition to safety, labeling, reimbursement and efficacy limitations, ESAs must be administered intravenously or subcutaneously, often with IV iron in order to be effective at treating to target Hb levels. Roxadustat, in contrast, is a small molecule administered orally and is therefore more convenient, particularly for the NDD-CKD population, the peritoneal dialysis population and other non-CKD anemia patients who are not already regularly visiting hospitals or dialysis centers.

We also believe that roxadustat's potential pharmacoeconomic advantages over ESAs may include safety (due to a potential decrease in cardiovascular events and consequently lower associated treatment costs), lower administrative cost, and reduction or elimination of the cost of IV iron and potentially other medications. These pharmacoeconomic advantages may help support reimbursement worldwide, including in Europe and China.

Overview of Roxadustat Clinical Studies and Development Strategy

In our completed Phase 2 studies, we accomplished the following critical objectives:

- Identified optimal roxadustat dosing regimens for anemia correction and maintenance of Hb response.
- Demonstrated roxadustat's potential efficacy in the treatment of anemia in both NDD-CKD and DD-CKD patients, including incident dialysis patients, the most unstable and high risk CKD patient population.
- Generated substantial safety data indicating that roxadustat is well tolerated, appears safe and could offer an improved cardiovascular profile relative to ESAs. Including our Phase 1, 2 and 3 studies, 1,503 subjects have been exposed to roxadustat.

In support of our initial efforts for regulatory approval in the United States and Europe, we have initiated with our partners our global Phase 3 clinical program for roxadustat in North America, Europe and Asia Pacific, with plans for expanding to other regions. We currently expect FibroGen China to begin a separate Phase 3 program in China in the first half of 2015, and Astellas is responsible for Phase 3 studies upon completion of Phase 2 studies in Japan. We believe that our ongoing global Phase 3 program, with a combined target enrollment of approximately 7,000 – 8,000 patients, is the largest Phase 3 program ever conducted for an anemia product candidate. Most of the primary and secondary efficacy measures that we plan to evaluate in our Phase 3 studies were evaluated previously in our Phase 2 studies. Our Phase 3 program will study multiple patient populations, including stable dialysis and incident dialysis, and will include multiple NDD-CKD studies comparing roxadustat against placebo. Our Phase 3 program is also designed and sized for, and will incorporate, major adverse cardiac events, or MACE, composite safety endpoints that we believe will be required for approval in the United States for all new anemia therapies. Additionally, our Phase 3 studies will incorporate dosing regimens that were extensively tested in our six Phase 2 studies.

Our Collaboration Partnerships for Roxadustat

We are currently developing and commercializing roxadustat for anemia globally in collaboration with our partners. We have two agreements under which we provided Astellas the right to develop and commercialize roxadustat and other compounds for anemia in Japan, Europe, the Commonwealth of Independent States, or CIS, the Middle East and South Africa.

We also have two agreements under which we provided AstraZeneca the right to develop and commercialize roxadustat for anemia, one for China, and one for the United States and all other countries not previously licensed to Astellas, or the U.S. / RoW. 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 United States approval, excluding development cost reimbursement.

So long as the collaboration agreements remain in effect, we expect our CKD anemia program to be fully funded through launch of roxadustat through the payment of upfront, non-contingent and milestone payments, and development cost reimbursement. The total payments to us under these agreements are summarized in the following table:

	Astellas	**AstraZeneca**
Territories	Japan, Europe, CIS, Middle East, South Africa	U.S., China, RoW
Upfront and Milestone Payments		
Upfront and other non-contingent payments	$360.1M	$402.2M*
Potential Milestone Payments:		
Development and Regulatory	$542.5M	$571.0M*
Commercial-based	$15.0M	$652.5M
Total	$557.5M	$1,223.5M
Total Potential Upfront, Non-contingent and Milestone Payments	$917.6M	$1,625.7M
Development Cost Reimbursement		
(for territorial approval)	*Japan*: 100% *Europe:* 50%**	*China*: 50% *U.S.:* 50% up to FibroGen cap of $116.5M*** 100% above $116.5M *RoW:* 100%***
Consideration for Product Sales		
Transfer Price Payments	Low 20% of net sales	*U.S. / RoW:* Low-mid single digit % of net sales
Royalty Payments	N/A	*U.S. / RoW:* Low 20% of net sales
Profit Share		*China:* 50/50 profit share
Equity Investment		$20.0M****

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* *A $62 million time-based development milestone became non-contingent as of July 30, 2014*

** *Includes 50% of U.S. costs under agreed development plan*

*** *Includes U.S. and Europe costs not borne by Astellas; $116.5 million is less than 50% of the expected CKD anemia development costs*

**** *Concurrent private placement of our common stock with an aggregate purchase price of $20 million at a price per share equal to the initial public offering price*

In addition, Astellas has separately invested a total of $80.5 million in the preferred stock of FibroGen, Inc. to date.

Roxadustat for Treatment of Anemia in China

We believe there is a particularly significant unmet medical need for the treatment of anemia in CKD in China. Anemia is undertreated in the rapidly growing DD-CKD population due in part to the significant safety concerns relating to the high doses of ESAs required to treat some patients to target Hb levels, the lack of IV iron use and reimbursement limitations. Anemia is largely not treated in the NDD-CKD population, which includes patients who are eligible for dialysis but are not dialyzed, due in part to logistical and financial barriers to treatment with ESAs, as well as the insufficient dialysis infrastructure.

In the context of the rapidly growing Chinese pharmaceutical market, we believe that the demand for anemia therapy will continue to grow as a result of an expanding CKD population, and the central government's mandate to make dialysis, which is still in the early stages of infrastructure development, more available through expansion of government reimbursement and build-out of dialysis facilities. We believe that roxadustat is a particularly promising product candidate for this market.

We plan to seek product approval from the CFDA as a Domestic "Class 1.1" Drug through our China subsidiary, Fibrogen (China) Medical Technology Development Co., Ltd., or Fibrogen China. We believe the domestic pathway represents the fastest route for bringing roxadustat to market.

We have completed our Phase 1 and Phase 2 clinical trials in China and expect to start our Phase 3 clinical trials in China in the first half of 2015. These Phase 3 trials are expected to continue to be conducted in parallel with, but independently of, the other trials conducted in the global development program, although all available safety data from the global program will be submitted for the China NDA. We plan to perform two Phase 3 trials in China to support approval of roxadustat for the treatment of anemia in DD-CKD and NDD-CKD patients. Based on discussions with the CFDA, the Phase 3 trials are designed to confirm Phase 2 results and have similar trial design and endpoints, except that they are expected to include more patients and longer dosing durations.

Overview of FG-3019

FG-3019 was developed by FibroGen to inhibit the activity of CTGF and its central role in the progression of serious diseases associated with fibrosis. Our data to date indicate that FG-3019 is a promising and highly differentiated product candidate with broad potential to treat a number of fibrotic diseases and cancers. FG-3019 has received orphan drug designation in IPF in the United States.

We are currently conducting an extension study for an open-label Phase 2 trial in IPF, a randomized, double-blind, placebo-controlled Phase 2 trial in IPF, a randomized, open-label Phase 2 trial in pancreatic cancer and a randomized trial in liver fibrosis. We have completed the initial one-year treatment portion of our open-label Phase 2 trial in IPF and an open-label, dose escalation Phase 2 trial in pancreatic cancer. In ten Phase 1 and Phase 2 clinical studies involving FG-3019 to date, including more than 340 patients who were treated with FG-3019 (146 patients dosed for more than 6 months), FG-3019 has been well tolerated across the range of doses studied, and there have been no dose-limiting toxicities seen thus far.

To date, we have retained exclusive worldwide rights for FG-3019. We plan to retain commercial rights to FG-3019 in North America and will also continue to evaluate the opportunities to establish co-development partnerships for FG-3019 as well as commercialization collaborations for territories outside of North America.

Idiopathic Pulmonary Fibrosis

Idiopathic pulmonary fibrosis, or IPF, is a form of progressive pulmonary fibrosis, or abnormal scarring, which destroys the structure and function of the lungs. Current approved therapies are unable to reverse this fibrotic process. Over a period of just a few years, 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 rapid weight loss. Average life expectancy at the time of confirmatory diagnosis of IPF is estimated to be between 3 to 5 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 United States prevalence and incidence of IPF are estimated to be 44,000 to 135,000 cases and 21,000 new cases per year, respectively. We believe that with the availability of technology to enable more accurate diagnoses, the number of individuals diagnosed with IPF annually will continue to increase.

Pirfenidone has been approved to treat IPF in Europe, Canada, Japan and the United States. According to the FDA advisory committee submission by its sponsor, pirfenidone has been shown to have a modest effect on slowing down the progression of the disease as measured by forced vital capacity, or FVC, in a minority (less than 15%) of patients. Nintedanib has also been approved in the United States and has been submitted for accelerated approval in the EU. We believe there remains an unmet need for a product like FG-3019 which has the potential to stabilize or reverse lung fibrosis and thus slow or stop the deterioration of, or improve, lung function in patients with IPF.

We have completed one year of dosing in two dose-cohorts in an open-label Phase 2 study of FG-3019 in patients with IPF. In addition to monitoring changes in pulmonary function, we incorporated the use of quantitative high resolution computed tomography, or HRCT, to assess changes in fibrosis over the course of the study. Recent publications based on similar quantitative HRCT methods have identified an association between worsening pulmonary fibrosis (as measured by HRCT) and mortality in IPF. The data from the open-label Phase 2 FG-3019 trial show that fibrosis was reversed or stabilized in a substantial subset of IPF patients (38%) after 48 weeks of treatment. To our knowledge, this is the first demonstration of pulmonary fibrosis reversal in any clinical study of IPF.

We are currently conducting a randomized, double-blind, placebo-controlled Phase 2 study to evaluate the safety and efficacy of FG-3019 in approximately 136 IPF patients with mild to moderate disease. As with our ongoing open-label Phase 2 trial, the primary efficacy endpoint is change in FVC from baseline. Secondary endpoints are extent of pulmonary fibrosis as measured by quantitative HRCT, other pulmonary function assessments and measures of health-related quality of life. The study is currently enrolling.

Pancreatic Cancer

Pancreatic cancer has a historic median survival of approximately six to nine months when treated with currently approved drugs. In desmoplastic, or fibrotic, cancers such as pancreatic cancer, we believe that CTGF expression in tumor-associated fibrous tissue promotes abnormal proliferation of stromal cells and tumor cells, induces extracellular-matrix, or ECM, deposition that provides a substrate for tumor cell adherence, promotes angiogenesis and promotes metastasis by enhancing cell motility, invasion and survival. Studies in a transgenic mouse model of pancreatic cancer indicate that treatment with FG-3019 in combination with chemotherapy can enhance the efficacy of chemotherapy and significantly improve survival.

Pancreatic cancer is the fourth leading cause of cancer deaths in the United States. In the United States, the prevalence of pancreatic cancer is estimated to be 44,000 and there are projected to be approximately 46,000 new cases of pancreatic cancer and approximately 39,000 deaths from the disease in 2014. Pancreatic cancer is aggressive and typically not diagnosed until it is incurable. Most patients are diagnosed after the age of 45, and 94% of patients die within five years from diagnosis.

The majority of pancreatic cancer patients are treated with chemotherapy, but this cancer is highly resistant to chemotherapy. Approximately 20% are treated with surgery; however, even for those with successful surgical resection, the median survival is approximately 2 years. Radiation may be used for locally advanced tumors, but it is not curative.

Several anti-cancer agents have been approved to treat pancreatic cancer. However, the duration of effect of these treatments is limited. In 1996, gemcitabine was approved for pancreatic cancer based on the demonstrated improvement in median overall survival from four to six months. Erlotinib was approved in 2005 after demonstrating an additional 10 days of survival. Nab-paclitaxel in combination with gemcitabine was recently approved by the FDA for the treatment of pancreatic cancer, having demonstrated median survival of 8.5 months. The limitations of these drugs illustrate that progress in pancreatic cancer has been slow and incremental, and there remains a need for substantial improvement in patient survival and quality of life.

We have completed an open-label Phase 2 dose finding trial of FG-3019 combined with gemcitabine plus erlotinib in patients with previously untreated locally advanced (stage 3) or metastatic (stage 4) pancreatic cancer. FG-3019 demonstrated a dose-dependent improvement in one year survival rate. We have recently begun an open-label, randomized Phase 2 trial of FG-3019 combined with gemcitabine plus nab-paclitaxel chemotherapy versus the chemotherapy regimen alone in patients with marginally inoperable pancreatic cancer that has not been previously treated. Approximately 40 patients are expected to be treated and the number may be increased based on preliminary results. The overall goal of the trial is to determine whether FG-3019 in combination with other drug treatments can convert inoperable pancreatic cancer to operable cancer. Tumor removal is the only chance for cure of pancreatic cancer, but only 15% to 20% of patients are eligible for surgery. The use of an anti-fibrotic agent in combination with chemotherapy may shrink the tumor size enough to enable surgical removal without compromising major blood vessels or other important anatomic structures.

We also plan to perform a randomized Phase 2 trial of FG-3019 combined with gemcitabine and nab-paclitaxel compared to the chemotherapy regimen alone to assess disease progression and survival in patients with previously untreated metastatic pancreatic cancer. The overall goal is to confirm our open-label Phase 2 data that suggest combinations of FG-3019 and chemotherapy may increase survival. We plan to open the study for enrollment in the first half of 2015.

Our Strategy

We intend to leverage our extensive experience in fibrosis and HIF biology to build a successful biopharmaceutical company with a strong pipeline of products and product candidates for the treatment of anemia, fibrosis, cancer, corneal blindness and other serious unmet medical needs. Our near-term and long-term strategies include:

- Develop and, if approved, commercialize roxadustat with the assistance of our collaboration partners in the United States, Europe, China and Japan and the rest of the world, including enrolling and completing our global Phase 3 program in CKD anemia and seeking regulatory approval for roxadustat in multiple geographies, including as a Domestic Class 1.1 therapeutic in China.
- Enroll and complete our Phase 2 clinical studies of FG-3019 in IPF and pancreatic cancer, and initiate, enroll, and complete subsequent Phase 3 pivotal studies of FG-3019 in IPF and pancreatic cancer in the United States and potentially outside of the United States.
- Continue to pursue an extensive and multi-layered patent portfolio to protect our technologies and product candidates.
- Explore potential partnering opportunities for the development and commercialization of FG-3019 in certain territories.
- Develop FG-5200 for treatment of corneal blindness resulting from partial thickness corneal damage in China and elsewhere in the world.
- Strategically invest in the research and development of additional anemia indications for roxadustat, which may include chemotherapy-induced anemia, anemia relating to inflammatory diseases, myelodysplastic syndrome and surgical procedures requiring transfusions.
- Use our extensive HIF platform to increase our pipeline by exploring proof-of-concept with our HIF-PH selective inhibitors, such as FG-8205, and our other HIF-PH inhibitors, including FG-6874 (which has completed single and multiple ascending dose Phase 1 clinical studies in Singapore), in indications

such as hematopoietic stem cell mobilization, peri-operative anemia, heart failure post-myocardial infarction, inflammatory bowel disease, diabetes, cancer and wound healing.

- Expand our efforts in fibrosis by pursuing additional indications for FG-3019, which may include Duchenne muscular dystrophy, scleroderma lung disease, liver fibrosis associated with graft injection, non-alcoholic steatohepatitis, diabetic nephropathy, focal segmental glomerular sclerosis, congestive heart failure, pulmonary arterial hypertension and cancers such as melanoma, ovarian, breast, and squamous cell lung carcinoma.

Financial Overview

Our revenue to date has been generated primarily from collaboration and license revenue pursuant to our collaboration agreements with Astellas and AstraZeneca. We have not generated any commercial product revenue. As of June 30, 2014, we had $202.1 million of cash, cash equivalents and short-term investments and an accumulated deficit of $232.2 million.

Risk Factors Summary

Our business is subject to numerous risks and uncertainties, including those highlighted in the section entitled “Risk Factors” immediately following this prospectus summary. These risks include, among others, the following:

- We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future; we may require additional financings in order to fund our operations;
- All of our recent revenue has been received from our roxadustat collaboration partners; if any of the agreements with these collaboration partners were to terminate we would require substantial additional funding;
- If we are unable to achieve development and regulatory milestones under our collaboration agreements, our revenues may decrease and our activities may fail to lead to commercialized products;
- We are substantially dependent on the success of our lead product candidate, roxadustat, and our second compound in development, FG-3019, and their clinical and commercial success will depend on a number of factors, many of which are beyond our control;
- We may be unable to obtain regulatory approval for our product candidates, or such approval may be delayed or limited, due to a number of factors, many of which are beyond our control;
- Our Phase 2 results to date for roxadustat and FG-3019 may not be indicative of the results that may be obtained in larger clinical studies required for approval;
- We do not know whether our ongoing or planned Phase 3 clinical studies in roxadustat or Phase 2 clinical studies in FG-3019 will need to be redesigned based on interim results, be able to achieve sufficient enrollment or be completed on schedule, if at all;
- Our product candidates may cause, or have attributed to them, undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential;
- If we or third party manufacturers on which we rely cannot manufacture our product candidates and/or products at sufficient yields, we may experience delays in development, regulatory approval and commercialization;
- If our collaborations with Astellas or AstraZeneca were terminated, or if Astellas of AstraZeneca were to prioritize other initiatives over their collaborations with us, whether as a result of a change of control or otherwise, our ability to successfully develop and commercialize our lead product candidate, roxadustat, would suffer;

- We currently rely, and expect to continue to rely, on third parties to conduct many aspects of our clinical studies, and these third parties may not perform satisfactorily;
- Certain of the components of our product candidates are acquired from single-source suppliers and have been purchased without long-term supply agreements;
- If our efforts to protect our proprietary technologies are not adequate, we may not be able to compete effectively in our market;
- Intellectual property disputes with third parties and competitors may be costly and time consuming, and may negatively affect our competitive position;
- We are establishing international operations and seeking approval to commercialize our product candidates outside of the United States, in particular in China, and a number of risks associated with international operations could materially and adversely affect our business;
- We are building our own manufacturing facility in China to produce roxadustat and clinical trial material for our corneal program; as an organization, we have limited experience in the construction or operation of a manufacturing plant; accordingly, we cannot assure you we will be able to meet regulatory requirements to operate our plant and to sell our products;
- Our decision to seek approval in China for roxadustat as a domestic new drug may not be accepted, which would result in additional delay and expense; and
- The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above the initial public offering price.

Concurrent Private Placement

AstraZeneca, one of our collaboration partners, has agreed to purchase from us concurrently with the closing of this offering in a private placement shares of our common stock with an aggregate purchase price of $20 million at a price per share equal to the initial public offering price.

Our Corporate Information

We were incorporated in 1993 in Delaware. Our headquarters are located at 409 Illinois Street, San Francisco, CA 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 prospectus.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year (a) following the fifth anniversary of this offering, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means we have been public for at least twelve months and the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

"FibroGen," the FibroGen logo and other trademarks or service marks of FibroGen, Inc. appearing in this prospectus are the property of FibroGen, Inc. This prospectus 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.

The Offering

Common stock offered by us	shares
Common stock sold in the concurrent private placement	AstraZeneca, one of our collaboration partners, has agreed to purchase from us concurrently with the closing of this offering in a private placement shares of our common stock with an aggregate purchase price of $20 million at a price per share equal to the initial public offering price, or shares assuming an initial public offering price of $ per share, which is the midpoint of the range set forth on the cover page of this prospectus. We will receive the full proceeds from the sale and will not pay any underwriting discounts or commissions with respect to the shares that are sold in the private placement. The sale of these shares to AstraZeneca will not be registered in this offering and these shares will be subject to a 180-day lock-up agreement with the underwriters in this offering as well as restrictions on sale for two years pursuant to AstraZeneca's agreement with us. We refer to the private placement of these shares of common stock as the "concurrent private placement".
Common stock to be outstanding after this offering and the concurrent private placement	shares
Underwriters' option to purchase additional shares of common stock offered by us	shares
Use of proceeds	We estimate the net proceeds to us from this offering, excluding the proceeds from the concurrent private placement, to be approximately $ million, assuming an initial public offering price of $ per share, which is the midpoint of the range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Our proceeds from the sale of common stock sold in the concurrent private placement will be $20 million. See the section of the prospectus captioned "Use of Proceeds." The principal purposes of this offering are to create a public market for our common stock and thereby facilitate access to the public equity markets, increase our visibility in the marketplace and obtain additional capital. We believe our existing cash and cash equivalents, short-term and long-term investments and payments due under our license and collaboration agreements will be sufficient to meet our anticipated working capital and capital expenditure needs for at least the next 12 months. Additionally, if roxadustat is successful in further clinical development, based on our current development plans, expected payments under our existing license and collaboration agreements may be sufficient to fund our development of roxadustat through commercialization. We intend to use a portion of the net proceeds

	from this offering and the concurrent private placement to commercialize our unpartnered product candidates such as FG-3019, corneal implants and other HIF-PH inhibitors, as well as for general corporate purposes. These uses include meeting any short term liquidity needs pending receipt of amounts due or subject to reimbursement under our license and collaboration agreements. If the development cost of roxadustat were to exceed our expectations and not be funded by our collaboration partners, or collaboration receipts were less than we anticipate, or if a portion of our existing cash and cash equivalents are used to develop other product candidates, we may use a more substantial portion of the net proceeds from this offering and the concurrent private placement to fund our roxadustat development costs through commercialization. We may also use a portion of the net proceeds to acquire complementary businesses, products or technologies, although we have no present commitments or agreements for any specific acquisitions. Accordingly, we will have broad discretion over the uses of the net proceeds from this offering and the concurrent private placement.
Risk factors	See the section of the prospectus captioned “Risk Factors” beginning on page 16 and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Proposed Listing and Trading symbol	We intend to list our common stock on the NASDAQ Global Select Market under the symbol “FGEN”.

The number of shares of our common stock to be outstanding after this offering and the concurrent private placement is based on 118,514,511 shares of common stock outstanding as of June 30, 2014, which reflects and assumes the conversion of all shares of convertible preferred stock (Senior Preferred Stock and Junior Preferred Stock) and excludes the following shares:

- 26,922,433 shares of common stock issuable upon the exercise of outstanding stock options issued as of June 30, 2014 pursuant to our 1999 and 2005 Stock Plans at a weighted average exercise price of $1.48 per share;
- 5,661,682 shares of common stock issuable upon the exercise of stock options pursuant to our 2005 Stock Plan at a weighted average exercise price of $5.82 that were subject to shareholder approval as of June 30, 2014, 26,552 of which were cancelled as of shareholder approval (which approval was obtained in July 2014);
- 4,000,000 shares of common stock to be reserved for future issuance under our 2014 Employee Stock Purchase Plan, or ESPP, as of the date the registration statement of which this prospectus forms a part if declared effective by the SEC, as well as any automatic increases in the number of shares of common stock reserved for future issuance under ESPP;
- 18,942,169 shares of common stock to be reserved for future issuance under our 2014 Plan, as of the date the registration statement of which this prospectus forms a part is declared effective by the SEC (which shares are as of June 30, 2014 and are currently reserved for future grant under our 2005 Plan and will cease to be reserved under our 2005 Plan immediately prior to the time our 2014 Plan becomes effective) as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2014 Plan;

- 432,790 shares of common stock issuable upon exercise of common stock warrants outstanding as of June 30, 2014 at a weighted-average exercise price of $3.03 per share; and
- 2,397,505 shares of common stock issuable upon the exchange of outstanding preferred stock issued by our European subsidiary, FibroGen Europe Oy, or FibroGen Europe.

Unless otherwise indicated, all information in this prospectus reflects and assumes the following:

- the conversion of all outstanding shares of our convertible preferred stock (Senior Preferred Stock and Junior Preferred Stock) into an aggregate of 84,800,239 shares of our common stock, which will occur immediately prior to the completion of this offering;
- no exercise by the underwriters of their option to purchase up to additional shares of our common stock in this offering; and
- the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the completion of this offering.

Summary Financial Data

The following tables summarize our financial data and should be read together with the sections in this prospectus entitled "Selected financial data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

We have derived the consolidated statement of operations data for the years ended December 31, 2012 and 2013 from our audited financial statements included elsewhere in this prospectus. We have derived the statement of operations data for the six months ended June 30, 2013 and 2014 and the balance sheet data as of June 30, 2014 from our unaudited interim consolidated financial statements included elsewhere in this prospectus. We have prepared the unaudited interim consolidated financial statements on the same basis as the audited financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair statement of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that should be expected in the future, and our unaudited interim results are not necessarily indicative of the results that should be expected for the full year or any other period.

	Years ended December 31,		Six Months ended June 30,	
	2012	2013	2013	2014
	(in thousands, except per share data)			
Result of Operations				
Revenue:				
License and milestone revenue	$ 62,845	$ 94,961	$ 16,895	$ 97,148
Collaboration services and other revenue	3,088	7,209	1,637	10,686
Total revenue	65,933	102,170	18,532	107,834
Operating expenses:				
Research and development (1)	74,222	85,710	33,092	58,919
General and administrative (1)	18,934	24,409	9,610	13,948
Total operating expenses	93,156	110,119	42,702	72,867
Income (loss) from operations	(27,223)	(7,949)	(24,170)	34,967
Total interest and other, net	(5,448)	(6,994)	(3,303)	(4,376)
Income (loss) before income taxes	(32,671)	(14,943)	(27,473)	30,591
Benefit from income taxes	100	—	—	—
Net income (loss)	$(32,571)	$ (14,943)	$(27,473)	$ 30,591
Net income (loss) per share—basic (2)	$ (0.99)	$ (0.45)	$ (0.83)	$ 0.30
Net income (loss) per share—diluted (2)	$ (0.99)	$ (0.45)	$ (0.83)	$ 0.18
Weighted-average number of common shares used in net income (loss) per share—basic (2)	32,820	32,964	32,938	33,198
Weighted-average number of common shares used in net income (loss) per share—diluted (2)	32,820	32,964	32,938	53,970
Pro forma net income (loss) per share—basic (unaudited) (3)		$ (0.13)		$ 0.26
Pro forma net income (loss) per share—diluted (unaudited) (3)		$ (0.13)		$ 0.22
Pro forma weighted-average number of common shares used in net income (loss) per share—basic (unaudited) (3)		117,764		117,998
Pro forma weighted-average number of common shares used in net income (loss) per share—diluted (unaudited) (3)		117,764		140,164

(1) Stock-based compensation expense is included in our results of operations as follows (in thousands):

	Years Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
Research and development	$2,277	$1,925	$ 953	$ 883
General and administrative	2,284	1,519	802	582
Total stock-based compensation expense	$4,561	$3,444	$1,755	$1,465

(2) See Note 10 to our consolidated financial statements appearing elsewhere in this prospectus for a description of the method used to calculate basic and diluted net income (loss) per share of common stock.

(3) Pro forma basic net income (loss) per share has been calculated assuming the conversion of all outstanding shares of convertible preferred stock, using the as-if converted method, into shares of common stock as of the beginning of the applicable period or the original issuance if later. Pro forma diluted net income (loss) per share includes the dilutive effect of employee stock options and warrants using the treasury stock method, as well as the effect of the conversion of preferred stock held by investors in FibroGen Europe into a maximum total of 2,397,505 shares of FibroGen, Inc. common stock.

The pro forma balance sheet data set forth below give effect to an assumed conversion as of June 30, 2014 of all outstanding shares of our Senior Preferred Stock and Junior Preferred Stock into 84,800,239 shares of our common stock. See Note 10 to our consolidated financial statements appearing elsewhere in this prospectus for a description of the method used to calculate pro forma basic and diluted net income (loss) per share.

The pro forma as adjusted balance sheet data set forth below give further effect to our issuance and sale of   shares of our common stock in this offering and the concurrent private placement at an assumed initial public offering price of $ per share, which is the midpoint of the range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	As of June 30, 2014		
	Actual	**Pro forma**	**Pro forma as adjusted**
		(in thousands)	
Balance Sheet Data:			
Cash and cash equivalents	$ 182,662	$ 182,662	$
Short-term and long-term investments	27,159	27,159	
Working capital	171,683	171,683	
Total assets	372,657	372,657	
Deferred revenue	72,936	72,936	
Lease financing obligations	96,914	96,914	
Product development obligations	18,291	18,291	
Senior Preferred Stock	168,436	—	
Junior Preferred Stock	136,313	—	
Accumulated deficit	(232,188)	(232,188)	
Total stockholders’ equity (deficit)	(56,446)	111,990	
Non-controlling interests	27,875	27,875	
Total equity (deficit)	(28,571)	139,865	

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our 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 clinical-stage biopharmaceutical company with two lead product candidates in clinical development, roxadustat, or FG-4592 in anemia in CKD, and FG-3019 in idiopathic pulmonary fibrosis, or IPF, pancreatic cancer and liver fibrosis. Pharmaceutical product development is a highly risky undertaking. To date, we have focused our efforts and most of our resources on hypoxia-inducible factor, or HIF, and fibrosis biology research, as well as developing our lead product candidates. We are not profitable and, other than in 2006 and 2007 due to income received from our Astellas collaboration, have incurred losses in each year since our inception. We have not generated any significant revenue based on product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. Our net loss for the years ended December 31, 2012 and 2013 was approximately $32.6 million and $14.9 million, respectively. For the six months ended June 30, 2014 we achieved net income of $30.6 million due principally to a significant contractual time-based payment and the resulting revenue recognized from our AstraZeneca collaboration agreement. As of June 30, 2014, we had an accumulated deficit of $232.2 million. As of June 30, 2014, we had capital resources consisting of cash, cash equivalents and short-term investments of $202.1 million. Despite contractual development and cost coverage commitments from our collaboration partners, AstraZeneca AB, or AstraZeneca, and Astellas Pharma Inc., or Astellas, and the potential to receive milestone and other payments from these partners, we anticipate we will continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, and seek regulatory approval for our product candidates. If we do not successfully develop and obtain regulatory approval for our existing or any future product candidates and effectively manufacture, market and sell any product candidates that are approved, we may never generate product sales, and even if we do generate product sales, 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 FG-3019, seek regulatory approval and prepare for the 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. In particular, in our planned Phase 3 clinical trial program for roxadustat, which we believe will be the largest Phase 3 program ever conducted for an anemia product candidate, we are expecting to enroll approximately 7,000 to 8,000 patients worldwide. We are conducting this Phase 3 program in conjunction with Astellas and AstraZeneca, and we are substantially dependent on Astellas and AstraZeneca for the funding of this large program. 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 this offering and the concurrent private placement, together with our expected third party collaboration revenues and existing cash, cash equivalents and short-term investments, 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, which are discussed in more detail below, 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.

Our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress in the development of our product candidates;
- the costs of development efforts for our product candidates, such as FG-3019, that are not subject to reimbursement from our collaboration partners;
- the costs necessary to obtain regulatory approvals, if any, for our product candidates in the United States, China and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where approval is obtained;
- the continuation of our existing collaborations and entry into new collaborations;
- the time and unreimbursed costs necessary to commercialize products in territories in which our product candidates are approved for sale;
- the revenues from any future sales of our products as well as revenue earned from profit share, royalties and milestones;
- the level of reimbursement or third party payor pricing available to our products;
- the costs of establishing and maintaining manufacturing operations and obtaining third party commercial supplies of our products, if any, manufactured in accordance with regulatory requirements;
- the costs we incur in maintaining domestic and foreign operations, including operations in China;
- the costs associated with being a public company; and
- the costs we incur in the filing, prosecution, maintenance and defense of our extensive patent portfolio and other intellectual property rights.

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.

All of our recent revenue has been received from collaboration partners for our product candidates under development.

During the past two years, substantially all of our revenues were from our collaboration partners, including $90.8 million received under our current collaborations with Astellas and $76.5 million received under our current collaborations with AstraZeneca, constituting 99% and 100% of our revenues for 2012 and 2013, respectively.

We will require substantial additional capital to achieve our development and commercialization goals, which for our lead product candidate, roxadustat, is currently contemplated to be provided under our existing third party collaborations with Astellas and AstraZeneca.

If either or both of these collaborations were to be terminated, we could require significant additional capital in order to proceed with development and commercialization of our product candidates, 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 research and development efforts or other operations.

If we are unable to continue to progress our development efforts and achieve milestones under our collaboration agreements, our revenues may decrease and our activities may fail to lead to commercial products.

Substantially all of our revenues to date have been, and a significant portion of our future revenues are expected to be, derived from our existing collaboration agreements. Revenues from research and development collaborations depend upon continuation of the collaborations, reimbursement of development costs, the achievement of milestones and royalties and profits from our product sales, if any, derived from future products developed from our research. If we are unable to successfully advance the development of our product candidates or achieve milestones, revenues under our collaboration agreements will be substantially less than expected.

Risks Related to the Development and Commercialization of Our Product Candidates

We are substantially dependent on the success of our lead product candidate, roxadustat, and our second compound in development, FG-3019.

To date, we have invested a substantial portion of our efforts and financial resources in the research and development of roxadustat, which is currently our lead product candidate. Roxadustat is our only product candidate that has advanced into a potentially pivotal trial, and it may be years before the studies required for its approval are completed, if ever. Our other product candidates are less advanced in development and may never enter into pivotal studies. We have completed 26 Phase 1 and 2 clinical studies with roxadustat in North America, Europe and Asia, in which 1,449 subjects have participated and for which we reported favorable primary and secondary safety and efficacy endpoint results. Based on our discussions with the United States Food and Drug Administration, or FDA, we believe that we have an acceptable plan for the conduct of our global Phase 3 clinical trial program. We have also had discussions with China regulatory authorities regarding the conduct of Phase 3 clinical trials in China, which are part of our global Phase 3 clinical trial program for safety data. We have also discussed our Phase 3 clinical development program with three national health authorities in the EU and obtained scientific advice from the European Medicines Agency. Our near-term prospects, including maintaining our existing collaborations with Astellas and AstraZeneca, will depend heavily on successful Phase 3 development and commercialization of roxadustat.

Our other lead product candidate, FG-3019, is currently in clinical development for IPF, pancreatic cancer and liver fibrosis. FG-3019 requires substantial further development and investment. In ten Phase 1 and 2 clinical trials, over 340 subjects have been treated with FG-3019 to date. We do not have a collaboration partner for support of this compound, and, while we have promising open-label safety data and potential signals of efficacy, we would need to complete larger and more extensive controlled clinical trials to validate the results to date in order to continue further development of this product candidate. In addition, although there are many potentially promising indications beyond IPF, pancreatic cancer and liver fibrosis, we are still exploring indications for which further development of, and investment for, FG-3019 may be appropriate. Accordingly, the costs and time to complete development and related risks are currently unknown. Moreover, FG-3019 is a monoclonal antibody, which may require experience and expertise that we may not currently possess as well as financial resources that are potentially greater than those required for our small molecule lead compound, roxadustat.

The clinical and commercial success of roxadustat and FG-3019 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 FG-3019.

The clinical and commercial success of roxadustat and FG-3019 will depend on a number of factors, including the following:

- the timely initiation, continuation and completion of our Phase 3 clinical trials for roxadustat, which will depend substantially upon requirements for such trials imposed by the FDA and other regulatory agencies and bodies and the continued commitment and coordinated and timely performance by our third party collaboration partners, AstraZeneca and Astellas;
- the timely initiation and completion of our Phase 2 clinical trials for FG-3019, including in IPF and pancreatic cancer;
- our ability to demonstrate the safety and efficacy of our product candidates to the satisfaction of the relevant regulatory authorities;
- whether we are required by the 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 timely receipt of necessary marketing approvals from the FDA and foreign regulatory authorities, including pricing and reimbursement determinations;
- the ability to successfully commercialize our product candidates, if approved, for marketing and sale by the FDA or foreign regulatory authorities, whether alone or in collaboration with others;
- 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 and patients 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 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;
- our ability to obtain and sustain an adequate level of pricing or reimbursement for our products by third party payors;
- our ability to enforce successfully our intellectual property rights for our product candidates and against the products of potential competitors; and
- our ability to avoid or succeed in third party patent interference or patent infringement claims.

Many of these factors are beyond our control. Accordingly, we cannot assure you that we will ever be able to achieve profitability through the sale of, or royalties from, our product candidates. If we or our collaboration partners are not successful in obtaining approval for and commercializing our product candidates, or are delayed in completing those efforts, our business and operations would be adversely affected.

We may be unable to obtain regulatory approval for our product candidates, 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 United States 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. Accordingly, we may be unable to successfully develop or commercialize roxadustat or FG-3019 or any of our other product candidates.

We have not obtained regulatory approval for any of our product candidates and it is possible that roxadustat and FG-3019 will never receive regulatory approval in any country. Regulatory authorities may delay, limit or deny approval of roxadustat or FG-3019 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 chronic kidney disease, or CKD, or that FG-3019 is safe and effective in treating IPF, pancreatic cancer or liver fibrosis;
- our failure to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- the determination by regulatory authorities that additional clinical trials are necessary to demonstrate the safety and efficacy of roxadustat or FG-3019, 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 contract research organizations, or 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, or 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;
- collaboration partners may not perform or complete their clinical programs in a timely manner, or at all; or
- principal investigators may determine that one or more serious adverse events, or SAEs, is related or possibly related to roxadustat, and any such determination may adversely affect our ability to obtain regulatory approval, whether or not the determination is correct.

Any of these factors, many of which are beyond our control, could jeopardize our or our collaboration partners’ abilities to obtain regulatory approval for and successfully market roxadustat. Because our business and operations in the near-term are almost entirely dependent upon roxadustat, any significant delays or impediments to regulatory approval could have a material adverse effect on our business and prospects.

Furthermore, in both the United States and China, we also expect to be required to perform additional clinical trials in order to obtain approval or as a condition to maintaining approval due to post-marketing requirements. If the FDA requires a risk evaluation and mitigation strategy, or REMS, for any of our product candidates if approved, the substantial cost and expense of complying with a REMS or other post-marketing requirements may limit our ability to successfully commercialize our product candidates.

Our Phase 2 clinical trial results to date for roxadustat 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 may not be predictive of similar results in larger, controlled clinical trials, and successful results from early or small clinical trials may not be replicated or show as favorable an outcome, even if successful. For example, in the past we developed an earlier generation product candidate aimed at treating anemia in CKD that resulted in a clinical hold for a safety signal seen in that product in Phase 2 clinical trials. The clinical hold applied to that product candidate and roxadustat and was lifted for both product candidates after submission of the requested data to the FDA. While we have not seen similar safety concerns involving roxadustat to date, our Phase 2 clinical trials have involved a relatively small number of patients exposed to roxadustat for a relatively short period of time compared to the Phase 3 clinical trials that we will be conducting, and only a fraction of the patients in the Phase 2 clinical trials were randomized to placebo. Accordingly, the Phase 2 clinical trials that we have conducted may not have uncovered safety issues, even if they exist. In addition, some of the safety concerns associated with the treatment of patients with anemia in CKD using erythropoiesis stimulating agents, or ESAs, did not emerge for many years until placebo-controlled studies had been conducted in large numbers of patients. The biochemical pathways that we believe are affected by roxadustat are implicated in a variety of biological processes and disease conditions, and it is possible that the use of roxadustat to treat larger numbers of patients will demonstrate unanticipated adverse effects, including possible drug interactions, which may negatively impact the safety profile, use and market acceptance of roxadustat. We studied the potential interaction between roxadustat and three statins (atorvastatin, rosuvastatin and simvastatin), which are used to lower levels of lipids in the blood. An adverse effect associated with increased statin plasma concentration is myopathy, which typically presents in a form of myalgia. The studies indicated the potential for increased exposure to those statins when roxadustat is taken simultaneously with those statins and suggested the need for statin dose reductions for patients receiving higher statin doses. We are planning additional clinical pharmacology studies to evaluate if the effect of any such interaction can be minimized or eliminated by a modification of the dosing schedule that would separate the administration of roxadustat and the statin. It is possible that the potential for interaction between roxadustat and statins could lead to label provisions for statins or roxadustat relating, for example, to dose scheduling or recommended statin dose limitations. In CKD patients statin therapy is often initiated earlier than treatment for anemia, and risks of myopathy have been shown to decrease with increased time on drug. While we believe the prior statin treatment history of such patients at established doses may reduce the risk of adverse effects from any interaction with roxadustat and facilitate any appropriate dose adjustments, we cannot be sure that this will be the case.

The FDA has informed us that our Phase 3 trials must include, as a safety endpoint, a major adverse cardiac events, or MACE, endpoint, which is a composite endpoint designed to identify major safety concerns, in particular relating to cardiovascular events such as cardiovascular death, myocardial infarction and stroke. In addition, we expect that our Phase 3 clinical trials supporting approval in Europe will be required to include MACE+ as a safety endpoint which, in addition to the MACE endpoints, also incorporates measurements of hospitalization rates due to heart failure or unstable angina. As a result, our ongoing and planned Phase 3 clinical trials may identify unanticipated safety concerns in the patient population under study. The FDA has also informed us that the MACE endpoint will need to be evaluated separately for our Phase 3 trials in non-dialysis dependent-CKD patients and our Phase 3 trials in dialysis dependent-CKD patients. The MACE endpoint will be evaluated in pooled analysis across phase 3 studies of similar study populations and requires demonstration of non-inferiority relative to comparator, which means that the MACE event rate in roxadustat-treated patients must have less than a specified probability of exceeding the rate in the comparator trial by a specified hazard ratio. The number of patients necessary in order to permit a statistical analysis with adequate ability to detect the relative risk of MACE or MACE+ events in different arms of the trial, referred to as statistical power, depends on a number of factors, including the rate at which MACE or MACE+ events occur per patient-year in the trial, treatment duration of the patients, the required hazard ratio, and the required statistical power and confidence intervals.

In addition, we cannot be sure that the potential advantages that we believe roxadustat may have for treatment of patients with anemia in CKD as compared to the use of ESAs will be substantiated by our Phase 3 clinical trials or that we will be able to include a discussion of such advantages in our labeling should we obtain approval. We believe that roxadustat may have certain benefits as compared to ESAs based on the data from our Phase 2 clinical trials conducted to date, including safety benefits, the absence of a hypertensive effect, the potential to lower cholesterol levels and the potential to correct anemia without the use of IV iron. However, our belief that roxadustat may offer those benefits is based on a limited amount of data from our Phase 2 clinical trials and our understanding of the likely mechanisms of action for roxadustat. Some of these benefits, such as those associated with the apparent effects on blood pressure and cholesterol, are not fully understood and, even if roxadustat receives marketing approval, we do not expect that it will be approved for the treatment of high blood pressure or high cholesterol based on the data from our Phase 3 trials, and we may not be able to refer to any such benefits in the labeling. While the data from our Phase 2 trials suggests roxadustat may reduce LDL, or low-density lipoprotein, and reduce the ratio of LDL to HDL, or high-density lipoprotein, the data show it may also reduce HDL, which may be a risk to patients. In addition, causes of the safety concerns associated with the use of ESAs to achieve specified target Hb levels have not been fully elucidated. While we believe that the issues giving rise to these concerns with ESAs are likely due to factors other than the Hb levels achieved, we cannot be certain that roxadustat will not be associated with similar, or more severe, safety concerns.

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. In addition, the CKD patient population has many afflictions that may cause severe illness or death, which may be attributed to roxadustat in a manner that negatively impacts the safety profile of our product candidate. If the results of our ongoing or future clinical trials for roxadustat are inconclusive with respect to efficacy, if we do not meet our clinical endpoints with statistical significance, or if there are unanticipated safety concerns or adverse events that emerge during clinical trials, we may be prevented from or delayed in obtaining marketing approval for roxadustat, and even if we obtain marketing approval, any sales of roxadustat may suffer.

Our Phase 2 results to date for FG-3019 may not be indicative of the results that may be obtained in larger, controlled Phase 2 clinical trials or Phase 3 clinical trials required for approval.

We have conducted only a limited number of Phase 2 clinical trials with FG-3019. We have conducted an open-label Phase 2 dose escalation study of FG-3019 for IPF in 89 patients and a Phase 2 dose finding trial of FG-3019 combined with gemcitabine plus erlotinib in 75 patients with pancreatic cancer. We cannot be sure that the results of these trials will be substantiated in double-blinded trials with larger numbers of patients, that larger trials will demonstrate the efficacy of FG-3019 for these or other indications or that safety issues will not be uncovered in further trials. In the Phase 2 clinical trial for IPF, we used quantitative high resolution computed tomography, or HRCT, to measure the extent of lung fibrosis. While we believe that quantitative HRCT is an accurate measure of lung fibrosis, it is a novel technology that has not yet been accepted by the FDA as a primary endpoint in pivotal clinical trials. In addition, while we believe that the animal studies that we have conducted to date demonstrate that FG-3019 has the potential to arrest or reverse fibrosis and reduce tumor mass, we cannot be sure that these results will be indicative of the effects of FG-3019 in human trials. In addition, the IPF and pancreatic cancer patient populations are extremely ill and routinely experience SAEs, including death, which may be attributed to FG-3019 in a manner that negatively impacts the safety profile of our product candidate. If the additional Phase 2 clinical trials that we are planning for FG-3019 in IPF and pancreatic cancer do not show favorable efficacy results or result in safety concerns, or if we do not meet our clinical endpoints with statistical significance, or demonstrate an acceptable risk-benefit profile, we may be prevented from or delayed in obtaining marketing approval for FG-3019 in one or both of these indications.

We do not know whether our ongoing or planned Phase 3 clinical trials in roxadustat or Phase 2 clinical trials in FG-3019 will need to be redesigned based on interim results, be able to achieve sufficient enrollment or be completed on schedule, if at all.

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, or IRB, 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 addition, we could encounter delays if a clinical trial is suspended or terminated by us, by the relevant IRBs 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. Adverse events and SAEs that emerge during treatment with our product candidates or other compounds acting through similar biological pathways may be deemed to be related to our product candidate and 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. See "Business—Our Development Program for Roxadustat" and "Business—FG-3019 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 FG-3019.

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, may a more complete safety profile be 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 ESAs, that have been approved by the regulatory authorities but for which safety concerns have been uncovered following approval. Such safety concerns have led to labelling changes or withdrawal of ESA products from the market, and any of our product candidates may be subject to similar risks. For example, roxadustat for use in anemia in CKD is being developed to address a very diverse patient population expected to have many serious health conditions at the time of administration of roxadustat, including diabetes, high blood pressure and declining kidney function.

Although to date we have not seen evidence of significant safety concerns with our product candidates currently in clinical trials, 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.

We may fail to enroll a sufficient number of patients in our clinical trials in a timely manner, which could delay or prevent clinical trials of our product candidates.

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:

- 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 as to the potential advantages of our product candidates being studied in relation to available therapies or other products under development;
- our, 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.

Patients may be unwilling to participate in our clinical trials for roxadustat due to adverse events observed in other drug treatments of anemia in CKD, and patients currently controlling their disease with existing ESAs may be reluctant to participate in a clinical trial with an investigational drug. We may not be able to successfully initiate or continue clinical trials if we cannot rapidly enroll a sufficient number of eligible patients to participate in the clinical trials required by regulatory agencies. 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, any of which could have a material and adverse effect on our business and prospects.

If we or third party manufacturers on which we rely cannot manufacture our product candidates and/or products at sufficient yields, we may experience delays in development, regulatory approval and commercialization.

Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture our product candidates at sufficient yields and at commercial scale. 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. Our efforts to establish these capabilities may not meet our requirements as to scale-up, yield, cost, potency or quality in compliance with cGMP. 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. Even an experienced third party manufacturer may encounter difficulties in production, which difficulties may include:

- costs and challenges associated with scale-up and attaining sufficient manufacturing yields, in particular for biologic products such as FG-3019, which is a monoclonal antibody;
- supply chain issues, including the timely availability and shelf life requirements of raw materials and supplies;
- quality control and 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 limitations and scheduling availability in contracted facilities; and
- natural disasters that affect facilities and possibly limit production.

Any delay or interruption in the supply of our product candidates or products could have a material adverse effect on our business and operations.

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, we expect that regulatory approvals, if obtained at all, will limit the approved indicated uses for which roxadustat may be marketed, as ESAs have been subject to significant safety limitations on usage as directed by the “Black Box” warnings included in their labels. See “Business—Roxadustat For the Treatment of Anemia in Chronic Kidney Disease—Limitations of the Current Standard of Care for Anemia in CKD”. In addition, in the past, an approved ESA was voluntarily withdrawn due to serious safety issues discovered after approval. 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 that limit the market opportunity for roxadustat. These warnings could include warnings against exceeding specified Hb targets and other warnings that derive from the lack of clarity regarding the basis for the safety issues associated with ESAs, even if our Phase 3 clinical trials do not themselves raise safety concerns.

As an organization, we have never completed a Phase 3 clinical trial or submitted a New Drug Application, or NDA, before, and may be unable to do so efficiently or at all for roxadustat or any product candidate we are developing.

We are currently conducting Phase 2 clinical trials for FG-3019 and we may need to conduct additional Phase 2 clinical trials before initiating our Phase 3 clinical trials for FG-3019. We intend to conduct Phase 3 clinical trials of roxadustat, and if our Phase 2 clinical trials are successful for FG-3019, we intend to conduct Phase 3 clinical trials for FG-3019. The conduct of Phase 3 clinical trials and the submission of a successful NDA is a complicated process. As an organization, we have not completed a Phase 3 clinical trial before, have limited experience in preparing, submitting and prosecuting regulatory filings, and have not submitted an NDA before. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to NDA submission and approval of roxadustat or for any other product candidate we are developing, even if our earlier stage clinical trials are successful. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials would prevent us from or delay us in commercializing roxadustat or any other product candidate we are developing.

If we are unable to establish sales, marketing and distribution capabilities or enter into or maintain agreements with third parties to market and sell our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.

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 either 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.

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 such as EPOGEN® and Aranesp®, commercialized by Amgen Inc., Procrit® and Eprex®, commercialized by Johnson & Johnson Inc., and Mircera®, which has received marketing approval in the United States, has been commercialized by Hoffmann-La Roche, or Roche, outside of the United States, and which Roche is able to commercialize in the United States beginning in mid-2014 if it chooses to do so. ESAs currently comprise the standard of care in the treatment of anemia in CKD, serving a significant majority of dialysis patients on

Medicare. It may be difficult to encourage treatment providers and patients to switch from products with which they have become familiar to roxadustat. We may also face competition from potential new anemia therapies currently in clinical development. For example, there are several other HIF product candidates in various stages of active development for anemia indications that may be in competition with roxadustat for patient recruitment and enrollment for clinical trials and may be in direct competition with roxadustat if and when it is approved and launched commercially. These candidates are being developed by such companies as Akebia Pharmaceuticals, Inc., or Akebia, Bayer Corporation, GlaxoSmithKline plc and Japan Tobacco Inc. Some of these product candidates may enter the market prior to roxadustat. There may 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.

The introduction of biosimilars for ESAs into the market in the United States will likely also increase the competition for roxadustat if approved. A biosimilar product is a follow-on version of an existing, branded biologic product. Under current laws, an application for a biosimilar product should not be approved by the FDA until 12 years after the existing, patent-protected product was approved under a Biologics License Application, or BLA. The patents for the existing, branded product must expire in a given market before biosimilars may enter that market with limited or no risk of being sued for patent infringement. The patents for epoetin alfa, a version of EPOGEN, expired in 2004 in the European Union, and the remaining patents have expired or will expire between 2012 and 2015 in the United States. Several biosimilar versions of currently marketed ESAs are available for sale in the EU and other biosimilars are currently under development, including in the United States.

Furthermore, in the case of roxadustat, many of our existing and potential competitors have distribution relationships with leading dialysis providers and customers as well as brand recognition and reimbursement. Two of the largest operators of dialysis clinics in the United States, DaVita Healthcare Partners Inc., or DaVita, and Fresenius SE & Co. KGaA, or Fresenius, represent more than 60% of the dialysis market in the United States and have entered into long-term sales agreements with Amgen that began in January 2012, which in the case of Fresenius, includes an exclusive relationship. As a result, successful penetration of this market would require AstraZeneca to reach a significant agreement with Fresenius or DaVita, the two largest dialysis clinics in the United States, on favorable terms and on a timely basis.

If FG-3019 is approved and launched commercially to treat IPF, competing drugs are expected to include Intermune’s pirfenidone, which is approved for marketing in Europe, Canada, Japan and the United States, and Boehringer Ingelheim’s nintedanib which has been approved in the United States and has been submitted for accelerated approval in the EU. Nintedanib is also in development for non-small cell lung cancer and ovarian cancer. Other potential competitive product candidates in various stages of Phase 2 development for IPF include Gilead Sciences, Inc.’s simtuzumab, Celgene Corporation’s CC-4047 and CC-930, Janssen Biotech, Inc. and Johnson & Johnson Inc.’s CNTO-888, Sanofi’s GC-1008, Novartis’ QAX-576 and Biogen Idec’s STX-100.

If FG-3019 is approved and launched commercially to treat pancreatic cancer, we expect it to be used in combination instead of as monotherapy; and, likely competition for FG-3019 would be from other agents also seeking approval in combination with gemcitibine and nab-paclitaxel from companies such as Threshold Pharmaceuticals, Inc., Gilead Sciences, Inc. and Halozyme Therapeutics, Inc. 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, respectively, and was the first drug approved in this disease in nearly a decade. Other chemotherapies include capecitabine (Xeloda®), oxaliplatin (Eloxatin®), fluorouracil or leucovorin. There are a number of product candidates in clinical trials for pancreatic cancer, many of which are in combination with existing chemotherapies, as both first-line and second-line therapy for metastatic pancreatic cancer. In a recent Phase 3 clinical trial in first-line metastatic pancreatic cancer comparing gemcitabine with the regimen known as FOLFIRINOX, which is a combination of oxaliplatin, irinotecan, fluorouracil and leucovorin. Merrimack Pharmaceuticals, Inc. is currently conducting a pivotal Phase 3 clinical trial of MM-398 for the treatment of patients with metastatic pancreatic cancer who have previously failed treatment with gemcitabine.

The success of any or all of these potential competitive products may negatively impact the development and potential for success of FG-3019. In addition, any competitive products that are on the market or in development may compete with FG-3019 for patient recruitment and enrollment for clinical trials or may force us to change our clinical trial comparators, whether placebo or active, in order to compare FG-3019 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, these companies have greater experience and expertise 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 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 into 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.

Our future commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, third party payors and others in the health care community.

Even if we obtain marketing approval for roxadustat, FG-3019 or any other product candidates that we may develop or acquire in the future, these product candidates may not gain market acceptance among physicians, third party payors, patients and others in the health care community. Market acceptance of any approved product depends on a number of other factors, including:

- 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;
- acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new therapies and of physicians to prescribe new therapies;
- the cost, safety, efficacy and convenience of treatment in relation to alternative treatments;
- the restrictions on the use of our products together with other medications, if any;
- the availability of adequate coverage and reimbursement or pricing by third party payors and government authorities;
- the ability of treatment providers, such as dialysis clinics, to enter into relationships with us without violating their existing agreement; and
- the effectiveness of our sales and marketing efforts.

For example, in the case of roxadustat, two of the largest operators of dialysis clinics in the United States, DaVita and Fresenius, represent more than 60% of the dialysis market in the United States and have entered into long-term sales agreements with Amgen that began in January 2012, which in the case of Fresenius, includes an exclusive relationship.

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 third party payors and may be affected by existing and future healthcare reform measures or the prices of related products for which reimbursement third party applies. Coverage and reimbursement by a third party payor may depend upon a number of factors, including the third party 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. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our products.

In countries outside of the United States, price controls may limit the price at which products such as roxadustat, if approved, are sold. For example, reference pricing is used by various European Union 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 Astellas or AstraZeneca were terminated, or 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, our ability to successfully develop and commercialize our lead product candidate, roxadustat, would suffer.

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

Our agreements with Astellas and AstraZeneca provide each of them with the right to terminate their respective agreements with us, upon the occurrence of negative clinical results, delays in the development and commercialization of our product candidates or adverse regulatory requirements or guidance. 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.

Conflicts with our collaboration partners could jeopardize our collaboration agreements and our ability to commercialize product candidates.

Our collaboration partners 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, 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 Phase 3 development program. 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 planned Phase 3 clinical studies.

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, and we should be precluded from such internal activities. 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 contract research organizations, or 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 good clinical practices, or 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 are 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. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements.

If CROs and other third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is be compromised due to their failure to adhere to trial protocols or to regulatory requirements, or if they otherwise fail to comply with regulations and trial protocols or meet expected standards or deadlines, 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, or the results may not be acceptable. If any of these events occur, we may not be able to obtain regulatory approval of 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 these third parties may not perform satisfactorily.

We do not have any operating manufacturing facilities at this time, and our current manufacturing facility plans in China are not expected to satisfy the requirements necessary to support roxadustat 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. 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 for all aspects of manufacturing activities, including regulatory compliance and quality control and assurance;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that 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 or suppliers unrelated to our product, including the bankruptcy of the manufacturer or supplier or a catastrophic event affecting our manufacturers 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 specifications and the regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure and/or maintain regulatory approval for our product candidates. 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.

Any of our 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 active pharmaceutical ingredient or drug product. 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., or 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, 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.

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 our Phase 3 clinical trials or, if roxadustat is approved and marketed, a failure to satisfy patient demand.

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. To date, we have used purchase orders for the supply of materials that we use in our product candidates. We may be unable to enter into long-term commercial supply arrangements with our vendors, 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. Moreover, we currently do not have any agreements for the commercial production of those materials.

The logistics of our supply chain, which includes shipment of materials and intermediates from countries such as China and India adds additional time and risk to the manufacture of our product candidates. While we have in the past maintained sufficient inventory of materials, active pharmaceutical ingredient, or 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 United States increases 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 and initiated by third parties, 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 active pharmaceutical ingredient 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 United States and other countries are typically not published until 18 months after 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 United States 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 United States, the first to file a patent application encompassing the invention is entitled to patent protection for the invention. The United States moved to a “first to file” system under the Leahy-Smith America Invents Act, or AIA, effective March 16, 2013. The effects of this change and other elements of the AIA are currently unclear, as the United States Patent and Trademark Office, or USPTO, is still implementing associated regulations, and the applicability of the AIA and associated regulations to our patents and patent applications have not been fully determined. This new system also includes new 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 United States. 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 a 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 FG-3019. 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 intend, if necessary, to vigorously enforce our intellectual property in order to protect the proprietary position of our product candidates, including roxadustat and FG-3019. Active efforts to enforce our patents 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. 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. Moreover, third parties may continue to initiate new proceedings in the U.S. and foreign jurisdictions to challenge our patents from time to time.

We may consider administrative proceedings and other means for challenging third party patents and patent applications. Third parties may also challenge our patents and patent applications, through interference, reexamination, *inter partes* review, and post-grant review proceedings before the USPTO or through other comparable proceedings, such as oppositions or invalidation proceedings, before foreign patent offices. 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. Even if we are successful, participation in administrative proceedings before the USPTO or a foreign patent office may result in substantial costs and time on the part of our management and other employees. For example, on December 5, 2013, Akebia filed an opposition to our European Patent No. 1463823, or the ‘823 patent, with the European Patent Office, and Akebia and other third parties may initiate or pursue similar proceedings with the European Patent Office or other corresponding foreign jurisdictions. The granted claims of the ‘823 patent encompass the use of roxadustat for the treatment of anemia. While we believe the ‘823 patent will be upheld in its entirety, the ultimate outcome of the opposition remains uncertain, and ultimate resolution of the proceeding may take a number of years and result in substantial costs to us.

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 United States 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 United States, and we may encounter significant problems in securing and defending our intellectual property rights outside the United States.

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 granting, 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 United States 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 damage 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 under the same or very similar brand names and/or having a similar appearance to genuine products, but which are sold without proper licenses or approvals. Such products divert sales from genuine products, often are of lower cost, often are of lower quality (having different ingredients or formulations, for example), and have the potential to damage the reputation for quality and effectiveness of the genuine product. If counterfeit pharmaceuticals illegally sold under our brand name result in adverse side effects to consumers, we may be associated with any negative publicity resulting from such incidents. In addition, 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. 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. We have not obtained regulatory approval for any product candidate, and it is possible that neither roxadustat nor FG-3019, nor any future product candidates we may discover, in-license or acquire and seek to develop in the future, will ever obtain regulatory approval.

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 United States where the standard of care is potentially different from that in the United States;

- 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, 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 current or planned 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.

If our product candidates obtain marketing approval, we will be subject to more extensive healthcare laws, regulation and enforcement and our failure to comply with those laws could have a material adverse effect on our results of operations and financial condition.

If we obtain approval 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 United States 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 federal Health Insurance Portability and Accountability Act of 1996, or 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 the Health Information Technology and Clinical Health Act, or HITECH, 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 PPACA, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare and Medicaid Services, or 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, or 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.

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 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.

The impact of recent United States healthcare reform 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, if any, could be affected by changes in healthcare spending and policy in the United States 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 United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the 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, or 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 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 will be included in the payment bundle. If roxadustat is included in the bundle, it may reduce the price that could be charged for roxadustat, and therefore potentially limit our profitability. On the other hand, it is possible that exclusion from the bundle may limit or delay market penetration of roxadustat.

More recently, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively PPACA, was enacted in 2010 with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers. The PPACA, among other things, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D. In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013.

It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing healthcare legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any products that may be approved for sale;
- the price and profitability of our products;
- pricing, coverage and reimbursement applicable to our products;
- the ability to successfully position and market any approved product; and
- the taxes applicable to our pharmaceutical product revenues.

We may not be able to conduct, or contract others to conduct, animal testing in the future, which could harm our research and development activities.

Certain laws and regulations relating to drug development require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted or delayed.

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 failures 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 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 will adopt a code of conduct for our directors, officers and employees, or the Code of Business Conduct and Ethics, which will be effective as of consummation of this offering, but it is not always possible to identify and deter employee misconduct, 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. 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 United States 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 United States, 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 risks related with our international operations, many of which may be beyond our control. These risks include:

- different regulatory requirements for drug approvals in foreign countries;
- different standards of care in various countries that could complicate the evaluation of our product candidates;
- different United States and foreign drug import and export rules;
- reduced protection for intellectual property rights in certain countries;
- unexpected 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;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating 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 United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- 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. See “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. Any 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. Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry, in some cases launching industry-wide investigations, oftentimes appearing to focus on foreign companies. The costs and time necessary to respond to an investigation can be material. 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.

Patients’ use of traditional Chinese medicine in violation of study protocols in our China studies may lead the CFDA and regulators in other jurisdictions in which are seeking approval to suspend our studies, reject our study data and withhold approval for roxadustat.

A common issue encountered in conducting clinical studies in China is patients’ use of traditional Chinese medicine in violation of study protocols. We believe that many patients with anemia in CKD are currently being treated with traditional Chinese medicine, and it is possible that such patients may continue their use of traditional Chinese medicine after enrollment in our studies and in violation of study protocols. If the patients participating in our China clinical studies do not comply with study protocols and continue to use traditional Chinese medicine, adverse events may emerge in our studies that are due to such traditional Chinese medicine or the interaction between such traditional Chinese medicine and roxadustat. In addition, the use of traditional Chinese medicine by patients in our studies may confound our study results. The occurrence of such adverse events or the confounding our study results may lead the China Food and Drug Administration, or CFDA, and regulators in other jurisdictions in which we are seeking approval to, among other things, suspend our studies, reject our study data and withhold approval for roxadustat.

We are building our own manufacturing facility in China to produce roxadustat and clinical trial material for our corneal implant program. As an organization, we have limited experience in the construction or 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 recently received a Pharmaceutical Production Permit, a general manufacturing license, for our facility in China in which we intend to manufacture roxadustat and FG-5200 in support of the clinical development and potential commercialization of these product candidates in China. However, we have not yet received a license to commercially manufacture either roxadustat or FG-5200. As an organization, we have limited experience building a manufacturing facility in the past and our facility must be constructed, licensed and operated in conformity with applicable cGMP requirements. We will be obligated to comply with continuing cGMP requirements and there can be no assurance that we will receive and 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 facility meet applicable specifications and other requirements for product safety, efficacy and quality and there can be no assurance that our efforts will succeed for licensure or continue to be successful in meeting these requirements. Moreover, our facility, even if approved for the manufacture of roxadustat, would require separate approval for the separate suite being constructed for the manufacture of FG-5200, whether it is categorized as a medical device or other product under CFDA guidelines. For FG-5200, we expect to convert our existing manufacturing process to an automated process which would require us to show that implants from our new manufacturing process are comparable to the implants from our existing manufacturing process. There can be no assurance that we will successfully receive licensure and maintain approval for the manufacture of either or both of roxadustat or FG-5200, either of which would be expected to delay or preclude our ability to develop and commercialize those product candidates in China and may materially adversely affect our business and operations and prospects in China.

Manufacturing facilities in China are subject to periodic unannounced inspections by the CFDA 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, earthquakes, terrorist attacks, government appropriation of our facility, and wars, could significantly impair our ability to operate our manufacturing facility and certain equipment, records and other materials located in these facilities would be difficult to replace or 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.

Our decision to seek approval in China for roxadustat as a domestic new drug may not be accepted, which would result in additional delay and expense.

Our Chinese subsidiary, FibroGen (China) Medical Technology Development Co., Ltd., or FibroGen China plans to seek approval for roxadustat in China as a Domestic Class 1.1 Drug, which is not a typical route to approval in China for enterprises with headquarters outside of China. Our submission for review of a New Drug Application under domestic drug regulations rather than under the imported drug regulations may not result in approval, or the regulatory authorities may determine that we are not eligible for approval as a domestic drug, which would require us to obtain approval for roxadustat first in the United States or in Europe and then to prepare and submit a new application for approval of roxadustat in China as an imported drug. This would result in significant delay in our commercialization plans for roxadustat. While we plan to provide the China-only clinical trial data required of a domestic drug, the size of our trial in China and the additional safety data from our global roxadustat Phase 3 program may not be deemed sufficient to receive approval. Elements of our plan for approval of roxadustat and other product candidates in China are based on communications with the CFDA and not on formal written regulations, findings or determinations. Accordingly, while we believe we have understandings with the CFDA regarding the domestic drug approval process and the clinical data currently required for approval, the regulatory authorities may later determine that changes are required in the drug approval process, that additional or different clinical data must be generated, or that the domestic drug route may not be available to FibroGen China, any of which could significantly delay approval of roxadustat or any of our other product candidates, and materially and adversely affect our plans and operations in China.

Even if roxadustat is approved in China, 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. Even if roxadustat is approved for sale in China, we and AstraZeneca may experience difficulties in our marketing, commercialization and sales efforts in China, and our business and operations could be adversely affected. In particular, sales of roxadustat in China may be limited due to the complex nature of the healthcare system, low average personal income, lack of patient cost reimbursement, pricing controls, poorly developed infrastructure and potentially rapid competition from other products.

The market for treatments of anemia in CKD in China is highly competitive.

Even if roxadustat is approved in China, it will face intense competition in the market for treatments of anemia in CKD. Roxadustat would compete with ESAs, which are offered by established multinational pharmaceutical companies such as Kirin Brewery Company Limited and Roche and Chinese pharmaceutical companies such as 3SBio Inc. and Di’ao Group Chengdu Diao Jiuhong Pharmaceutical Factory. Many of these competitors have substantially greater name recognition, scientific, financial and marketing resources as well as established distribution capabilities than we do. Many of our competitors have more resources to develop or acquire, and more experience in developing or acquiring, new products and in creating market awareness for those products. Many of these competitors have significantly more experience than we have in navigating the Chinese regulatory framework regarding the development, manufacturing and marketing of drugs in China, as well as in marketing and selling anemia products in China. Additionally, we believe that most patients with anemia in CKD in China are currently being treated with traditional Chinese medicine, which is widely accepted and highly prevalent in China. Traditional Chinese medicine treatments are often oral and thus convenient and low-cost, and practitioners of traditional Chinese medicine are numerous and accessible in China. As a result, it may be difficult to persuade patients with anemia in CKD to switch from traditional Chinese medicine to roxadustat.

There is no assurance that roxadustat will be included in the Medical Insurance Catalogs.

Eligible participants in the national basic medical insurance program in China, which consists of mostly urban residents, are entitled to reimbursement from the social medical insurance fund for up to the entire cost of medicines that are included in the Medical Insurance Catalogs. See “Business—Government Regulation—Regulation in China.” We believe that the inclusion of a drug in the Medical Insurance Catalogs can substantially improve the sales of a drug. The Ministry of Labor and Social Security in China, or the MLSS, together with other government authorities, select medicines to be included in the Medical Insurance Catalogs based on a variety of factors, including treatment requirements, frequency of use, effectiveness and price. The MLSS also occasionally removes medicines from such catalogs. There can be no assurance that roxadustat will be included, and once included, remain in the Medical Insurance Catalogs. The exclusion or removal of roxadustat from the Medical Insurance Catalogs may materially and adversely affect sales of roxadustat.

We may not be successful in the tender processes for the purchase of medicines by state-owned and state-controlled hospitals.

Most hospitals in China participate in collective tender processes for the purchase of medicines listed in the Medical Insurance Catalogs and medicines that are consumed in large volumes and commonly prescribed for clinical uses. During a collective tender process, the hospitals will establish a committee consisting of recognized pharmaceutical experts. The committee will assess the bids submitted by the various participating pharmaceutical manufacturers, taking into consideration, among other things, the quality and price of the drug product and the service and reputation of the manufacturer. Only drug products that have been selected in the collective tender processes may be purchased by participating hospitals. If we are unable to win purchase contracts through the collective tender processes in which we decide to participate, there will be limited demand for roxadustat, and sales revenues from roxadustat will be materially and adversely affected.

We plan to seek approval for FG-5200 as a medical device, with respect to which we have no development and manufacturing experience. Even if FG-5200 can be manufactured successfully and achieve regulatory approval, we may not achieve commercial success.

We plan to seek regulatory approval for FG-5200 as a medical device, with respect to which we have no development and manufacturing experience. There can be no assurance that we will achieve medical device designation or receive approval for FG-5200. In addition, we have not yet used the material planned for our clinical trials of FG-5200 in any previous clinical trials and because we have not yet received a license to manufacture FG-5200 in our China manufacturing facility or at scale, we will have to show that FG-5200 from our China manufacturing facility meets the applicable regulatory requirements. There can be no assurance that we can meet these requirements or that FG-5200 can be approved for development, manufacture and sale in China.

Even if we are able to manufacture and develop FG-5200 as a medical device in China, the size and length of any potential clinical trials required for approval are uncertain and we are unable to predict the time and investment required to obtain regulatory approval. Moreover, even if FG-5200 can be successfully developed for approval in China, our product candidate would require extensive training and investment in assisting physicians in the use of FG-5200.

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 which 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 China Catalog for Guidance for Foreign Investment, we will need to operate in China through a variable interest entity structure.

The China Catalog for Guidance for Foreign Investment sets forth the industries and sectors that the Chinese government encourages and restricts foreign investment and participation. The Catalog for Guidance for Foreign Investment is subject to revision from time to time by 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 variable interest entity, or 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 China 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 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 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. We may rely on dividends and royalties paid by FibroGen China for a portion of our cash needs, including the funds necessary to service any debt we may incur and to pay our operating expenses. The payment of dividends by FibroGen China 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 China 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 China 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 reach 50.0% of its registered capital. Statutory reserves are not distributable as cash dividends. In addition, if FibroGen China 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.

Any capital contributions from us to FibroGen China 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 China.

The Ministry of Commerce in China or its local counterpart must approve the amount and use of any capital contributions from us to FibroGen China, 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 China 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.

If roxadustat is approved for sale in China, 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, China 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 China 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, or 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 China 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 China's funds are held in banks that do not provide insurance, the failure of any bank in which FibroGen China deposit 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 China may not have access to funds on deposit. Depending upon the amount of money FibroGen China 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 United States and other jurisdictions in which we operate are extremely complex and subject to change. New laws, new interpretations of existing laws, or limitations on our ability to structure our operations and intercompany transactions may lead to inefficient tax treatment of our revenue, profits, royalties and distributions, if any are achieved. For example, under the Internal Revenue Code, certain types of income derived by our foreign subsidiaries that are controlled foreign corporations could give rise to a current inclusion of income to FibroGen, Inc., for U.S. tax purposes.

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 of the tax treaties we could be subject to additional taxes, which could adversely affect our financial condition and results of operations.

The enactment of legislation implementing changes in the U.S. taxation of international business activities or the adoption of other tax reform policies could materially impact our financial position and results of operations.

The current Administration has proposed, and Congress has introduced, legislation to reform the U.S. taxation of international business activities, including, but not limited to, limiting the ability of taxpayers to claim and utilize foreign tax credits, limiting the check-the-box regime, revising the rules applicable to transfers of intangible property, and deferring certain tax deductions until non-U.S. earnings are repatriated to the United States. The current Administration has made public statements indicating that it has made the issue a priority, and key members of the U.S. Congress have conducted hearings and proposed legislation. Accordingly, depending on the final form of legislation enacted, if any, the consequences of changes to the U.S. taxation of international business activities may be significant for our China Business and other offshore activities. If any of these proposals are enacted into legislation, they could have material adverse consequences on our effective tax rate, the amount of tax we pay and our financial position and results of operations.

We have implemented a corporate structure taking into consideration our international operations and potentially applicable tax impact on our worldwide operations, and any changes in applicable tax laws and regulations may negatively impact our financial condition and operating results.

We have developed our corporate structure to be closely aligned with the international nature of our business. There can be no assurance that the applicable tax laws and regulations will continue in effect or that the taxing authorities in any or all of the applicable jurisdictions will not challenge one or more aspects or characterizations of our corporate structure and the treatment of transactions or agreements within our corporate structure, or determine that the manner in which we operate our business is not consistent with our corporate structure. Any unfavorable changes in laws and regulations or positions by tax authorities could harm our financial position and results of operations.

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 filing China and international patent applications, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. We currently have 3 granted patents and 15 pending patent applications relating to roxadustat in China. See “Business—Intellectual Property.” However, 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 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 United States 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 Chinese 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 Chinese 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.

We are subject to laws and regulations governing corruption, which will require us to develop 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 and anti-bribery and anti-corruption laws in other countries, particularly China. The creation and implementation of international business practices compliance programs is costly and such programs are 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 United States 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 to 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, or DOJ. The Securities and Exchange Commission, or 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 and have led to vigorous anti-bribery law enforcement actions imposing heavy fines in multiple jurisdictions, particularly in the United States 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, encompass provisions relating to books and records that will apply to us as we become 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 violations of the FCPA's accounting provisions. Even if we are not ultimately punished by government authorities, the costs of investigation and review, the distraction of company 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.

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 became effective in 2008 and provides stronger protections for employees and imposes more 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.

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 China judicial system have significant discretion in interpreting and implementing statutory and contractual terms, which may render it difficult for FibroGen China 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 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.

The Chinese economy and Chinese society continue to undergo significant change. Adverse changes in the political 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 structure of foreign investment in this industry. We are unable to predict the frequency and scope of such policy changes, any of which could materially and adversely affect FibroGen China's liquidity and 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.

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 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 and manage any future growth effectively. Our failure to accomplish any of them could prevent us from successfully implementing our strategy and maintaining the confidence of investors in our company.

If we fail to attract and keep senior management and key personnel, in particular our chief executive officer, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

We are highly dependent on our chief executive officer, Thomas Neff, and other members of our senior management team. The loss of the services of Mr. Neff or any of these other individuals would be expected to significantly negatively impact the development and commercialization of our product candidates, our existing collaborative relationships and our ability to successfully implement our business strategy.

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

There is also significant competition, in particular in the San Francisco Bay area, for the hiring of experienced and qualified personnel, which increases the importance of retention of our existing personnel. 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. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption 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. To the extent that any disruption or security breach 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 the further development of our product candidates could be delayed.

Our headquarters and data storage facilities 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, such as data storage, 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, such as our data storage facilities, enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that 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 currently are limited and are unlikely to prove adequate 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 and This Offering

We do not know whether a market will develop for our common stock or what the market price of our common stock will be, and as a result, it may be difficult for you to sell your shares of our common stock.

Before this offering, there was no public trading market for our common stock. If a market for our common stock does not develop or is not sustained, it may depress the market price of our common stock and make it difficult for you to sell your shares of common stock at an attractive price, or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors and, as a result of these and other factors, the price of our common stock may fall.

The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above the initial public offering 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 FG-3019;
- 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 publication of research reports by securities analysts about us or our competitors or our industry or negative recommendations or withdrawal of research coverage by securities analysts;
- 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;
- the ineffectiveness of our internal controls;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- announced strategic decisions by us or our competitors;
- 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;
- sales of our common stock by us, our insiders or our other stockholders;
- speculation in the press or investment community;
- announcement or expectation of additional financing efforts;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- changes in accounting principles;
- activities of the government of China, including those related to the pharmaceutical industry as well as industrial policy generally;
- performance of other United States publicly traded companies with significant operations in China;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters such as earthquakes and other calamities;
- changes in market conditions for biopharmaceutical stocks;
- changes in general market and economic conditions; 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 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 our company 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 June 30, 2014, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 27.8% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after such date, and we expect that upon completion of this offering and the concurrent private placement that same group will continue to hold at least   % of our outstanding common stock. Accordingly, even after this offering and the concurrent private placement, 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 are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act and for so long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. Specifically, the JOBS Act:

- permits us to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- eliminates the requirement to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- removes the requirement to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board;
- reduces disclosure obligations regarding executive compensation; and

- exempts from the requirements of holding a non-binding stockholder advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

This prospectus is based upon the reduced reporting burdens under the JOBS Act and we expect to continue at these reduced levels for so long as we are permitted under the JOBS Act. Specifically, we could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including any of the following: if the market value of our common stock held by non-affiliates exceeds $700 million as of June 30 in any calendar year before that time or if we have total annual gross revenue of $1 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the end of such year or, if we issue more than $1 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately. If any investors find our common stock less attractive as a result, there may be a less active market for our common stock and our stock price may be more volatile.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. However, we chose to “opt out” of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates that adoption of such standards is required for non-emerging growth companies. Our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

A significant portion of our total outstanding shares may be sold into the public market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time after the expiration of the lock-up agreements described in the “Underwriting” section of this prospectus. These sales, or the market perception that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering and the concurrent private placement, we will have   shares of common stock outstanding. This includes the   shares that we are selling in this offering, which may be resold in the public market immediately subject to any restrictions imposed on our affiliates under Rule 144. The remaining shares, or   % of our outstanding shares after this offering and the concurrent private placement, are currently or will be restricted as a result of securities laws or lock-up agreements but will be able to be sold, subject to any applicable volume limitations under federal securities laws with respect to affiliate sales, in the near future as set forth below.

In addition, as of December 31, 2013, there were 27,710,067 shares subject to outstanding options and 432,790 shares subject to outstanding warrants to purchase common stock that will become eligible for sale in the public market to the extent permitted by any applicable vesting requirements, the lock-up agreements and Rules 144 and 701 under the Securities Act. We also intend to register all shares of common stock that we may issue under our employee benefit plans, including our 2005 Equity Incentive Plan and 2014 Equity Incentive Plan. Once we register these shares and they are issued in accordance with the terms of the plans, they can be freely sold in the public market upon issuance, subject to the lock-up agreements and the restrictions imposed on our affiliates under Rule 144. For more information, see “Shares Eligible for Future Sale—Rule 144”.

Proceedings instituted by the SEC against five China based accounting firms, including the Chinese affiliate of our independent registered public accounting firm, could result in our financial statements being determined to not be in compliance with the requirements of the Exchange Act.

In late 2012, the SEC commenced administrative proceedings under Rule 102(e) of its Rules of Practice and also under the Sarbanes-Oxley Act of 2002 against the Chinese affiliates of the “big four” accounting firms, including PricewaterhouseCoopers Zhong Tian CPAs Limited, the Chinese affiliate of our independent registered public accounting firm. The Rule 102(e) proceedings initiated by the SEC relate to these firms' failure to produce documents, including audit work papers, in response to the request of the SEC pursuant to Section 106 of the Sarbanes-Oxley Act of 2002, as the auditors located in China are not in a position lawfully to produce documents directly to the SEC because of restrictions under Chinese law and specific directives issued by the China Securities Regulatory Commission. The issues raised by the proceedings are not specific to our auditors or to us.

In January 2014, an administrative law judge reached an initial decision that the Chinese affiliates of the "big four" accounting firms should be barred from practicing before the SEC for a period of six months. However, it is currently impossible to determine the ultimate outcome of this matter as the accounting firms have filed a petition for review of the initial decision, and, pending that review, the effect of the initial decision is suspended. It will, therefore, be for the commissioners of the SEC to make a legally binding order specifying the sanctions, if any, to be placed on these audit firms. Once such an order was made, the accounting firms would have a right to appeal to U.S. Federal courts, and the effect of the order might be further suspended pending the outcome of that appeal.

Although it does not play a substantial role (as defined under PCAOB standards) in the audit of our consolidated financial statements, if PricewaterhouseCoopers Zhong Tian CPAs Limited were denied, temporarily, the ability to practice before the SEC, our ability to produce audited consolidated financial statements for our company could be affected and we could be determined not to be in compliance with the requirements of the Securities Exchange Act of 1934. Such a determination could ultimately lead to the delisting of our shares from or deregistration from the SEC, or both, which would substantially reduce or effectively terminate the trading of our stock.

You will incur immediate and substantial dilution as a result of this offering.

The initial public offering price of our common stock will be substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase common stock in this offering, you will pay a price per share that substantially exceeds our pro forma adjusted net tangible book value per share after this offering. To the extent shares subsequently are issued under options, you will incur further dilution. Based on an initial assumed public offering price of $, the midpoint of the range set forth on the cover page of this prospectus, you will incur immediate and substantial dilution of $ per share, representing the difference between our pro forma net tangible book value per share, after giving effect to this offering and the concurrent private placement, and the assumed initial public offering price. In addition, purchasers of common stock in this offering and the concurrent private placement will have contributed approximately % of the aggregate price paid by all purchasers of our stock but will own approximately % of our common stock outstanding after this offering and the concurrent private placement.

In addition, as of June 30, 2014, we had outstanding stock options to purchase an aggregate of 32,584,115 shares of common stock, of which 26,552 were cancelled upon shareholder approval (which approval was obtained in July 2014), at a weighted average exercise price of $2.23 per share and warrants to purchase an aggregate of 432,790 shares of common stock at a weighted average exercise price of $3.03 per share. As of June 30, 2014, shares of preferred stock held by investors of FibroGen Europe were exchangeable into an aggregate of 2,397,505 shares of our common stock. To the extent these outstanding options, warrants or shares of FibroGen Europe preferred stock are exercised to purchase or are exchanged for shares of our common stock, there will be further dilution to investors in the offering and the concurrent private placement. Further, because we may need to raise additional capital to fund our clinical development programs, we may in the future sell substantial amounts of common stock or securities convertible into or exchangeable for common stock.

We have broad discretion in the use of net proceeds from this offering and the concurrent private placement and may not use them effectively.

We currently intend to use the net proceeds from this offering and the concurrent private placement to further development of our product candidates in additional indications and for general corporate purposes. Investors are directed to see the section of this prospectus entitled “Use of Proceeds.” Although we currently plan to use the net proceeds from this offering and the concurrent private placement as described, we will have broad discretion in the application of the net proceeds. Our failure to apply these funds effectively could affect our ability to continue to develop, manufacture and commercialize our product candidates.

We will incur increased costs as a result of operating as a public company and we expect to devote substantial resources to public company compliance programs.

As a public company, we will incur significant legal, insurance, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the listing requirements of The NASDAQ Stock Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management’s time and attention from product development activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. In the future, it will be more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

Specifically, in order to comply with the requirements of being a public company, we may need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our ordinary shares could decline. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on The NASDAQ Stock Market.

We are not currently required to comply with the SEC’s rules that implement Section 404 of the Sarbanes-Oxley Act, or Section 404, and are therefore not yet required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we will be required to comply with certain of these rules, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report. This assessment will need to include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will need to continue to dedicate internal resources, outside consultants and continue to execute a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements and we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls in the future.

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 our company. 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 that will become effective upon the closing of this offering 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.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits, or NOLs or credits, to offset future taxable income. Our existing NOLs or credits may be subject to substantial limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after this offering, our ability to utilize NOLs or credits could be further limited by

Section 382 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating United States federal and state taxable income. As described above under "—Risks Related to our Financial Position and History of Operating Losses," we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the United States federal or state taxable income necessary to utilize our NOLs or credits. A full valuation allowance has been provided for the entire amount of our NOLs and credits.

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 that will become effective upon the closing of this offering 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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, particularly in the sections captioned “Prospectus Summary,” “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 prospectus, all statements other than statements of historical or present facts contained in this prospectus, 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 prospectus 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, FG-3019 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 this offering and the concurrent private placement, 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 prospectus captioned “Risk Factors” and elsewhere in this prospectus, regarding, among other things:

- We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future; we may require additional financings in order to fund our operations;
- All of our recent revenue has been received from our roxadustat collaboration partners; if any of the agreements with these collaboration partners were to terminate, we would require substantial additional funding;
- If we are unable to achieve development and regulatory milestones under our collaboration agreements, our revenues may decrease and our activities may fail to lead to commercialized products;
- We are substantially dependent on the success of our lead product candidate, roxadustat, and our second compound in development, FG-3019, and their clinical and commercial success will depend on a number of factors, many of which are beyond our control;
- We may be unable to obtain regulatory approval for our product candidates, or such approval may be delayed or limited, due to a number of factors, many of which are beyond our control;
- Our Phase 2 results to date for roxadustat and FG-3019 may not be indicative of the results that may be obtained in larger clinical studies required for approval;
- We do not know whether our ongoing or planned Phase 3 clinical studies in roxadustat or Phase 2 clinical studies in FG-3019 will need to be redesigned based on interim results, be able to achieve sufficient enrollment or be completed on schedule, if at all;
- Our product candidates may cause, or have attributed to them, undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential;
- If we or third party manufacturers on which we rely cannot manufacture our product candidates and/or products at sufficient yields, we may experience delays in development, regulatory approval and commercialization;

- If our collaborations with Astellas or AstraZeneca were terminated, or if Astellas of AstraZeneca were to prioritize other initiatives over their collaborations with us, whether as a result of a change of control or otherwise, our ability to successfully develop and commercialize our lead product candidate, roxadustat, would suffer;
- We currently rely, and expect to continue to rely, on third parties to conduct many aspects of our clinical studies, and these third parties may not perform satisfactorily;
- Certain of the components of our product candidates are acquired from single-source suppliers and have been purchased without long-term supply agreements;
- If our efforts to protect our proprietary technologies are not adequate, we may not be able to compete effectively in our market;
- Intellectual property disputes with third parties and competitors may be costly and time consuming, and may negatively affect our competitive position;
- We are establishing international operations and seeking approval to commercialize our product candidates outside of the United States, in particular in China, and a number of risks associated with international operations could materially and adversely affect our business;
- We are building our own manufacturing facility in China to produce roxadustat and clinical trial material for our corneal program; as an organization, we have limited experience in the construction or operation and licensure of a manufacturing plant; accordingly, we cannot assure you we will be able to meet regulatory requirements to operate our plant and to sell our products;
- Our decision to seek approval in China for roxadustat as a domestic new drug may not be accepted, which would result in additional delay and expense; and
- The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above the initial public offering price.

These risks are not exhaustive. Other sections of this prospectus 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 prospectus 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 prospectus or to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part 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. You should also read carefully the factors described in the section of this prospectus captioned “Risk Factors” and elsewhere to better understand the risks and uncertainties inherent in our business and underlying and forward-looking statements.

This prospectus 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.

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering, excluding the proceeds from the concurrent private placement, will be approximately $ million, assuming an initial public offering price of $ per share, which is the midpoint of the range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Our proceeds from the sale of the common stock sold in the concurrent private placement will be $20 million.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) the net proceeds to us from this offering by $, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us. Each increase or decrease of shares by shares in the number of shares offered by us would increase or decrease the net proceeds to us from this offering by approximately $, assuming that the assumed initial price to public remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the initial price to the public or the number of shares by these amounts would have a material effect on uses of the proceeds from this offering and the concurrent private placement, although it may accelerate the time at which we will need to seek additional capital.

The principal purposes of this offering are to create a public market for our common stock and thereby facilitate access to the public equity markets, increase our visibility in the marketplace and obtain additional capital. We believe our existing cash and cash equivalents, short-term and long-term investments and payments due under our license and collaboration agreements will be sufficient to meet our anticipated working capital and capital expenditure needs for at least the next 12 months. Additionally, if roxadustat is successful in further clinical development, based on our current development plans, expected payments under our existing license and collaboration agreements may be sufficient to fund our development of roxadustat through commercialization. We intend to use a portion of the net proceeds from this offering and the concurrent private placement to commercialize our unpartnered product candidates such as FG-3019, corneal implants and other HIF-PH inhibitors, as well as for general corporate purposes. These uses include meeting any short term liquidity needs pending receipt of amounts due or subject to reimbursement under our license and collaboration agreements. If the development cost of roxadustat were to exceed our expectations and not be funded by our collaboration partners, or collaboration receipts were less than we anticipate, or if a portion of our existing cash and cash equivalents are used to develop other product candidates, we may use a more substantial portion of the net proceeds from this offering and the concurrent private placement to fund our roxadustat development costs through commercialization. We may also use a portion of the net proceeds to acquire complementary businesses, products or technologies, although we have no present commitments or agreements for any specific acquisitions. Accordingly, we will have broad discretion over the uses of the net proceeds from this offering and the concurrent private placement. Pending these uses, we plan to invest these net proceeds in short-term and long-term interest bearing obligations, investment grade instruments, certificates of deposit or direct or guaranteed obligations of the United States.

We will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering and the concurrent private placement.

DIVIDEND POLICY

We have never declared or paid dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay cash dividends on our capital stock in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors subject to applicable laws, and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. Our future ability to pay cash dividends on our stock may be limited by the terms of any future debt or preferred securities.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and investments and capitalization as of June 30, 2014:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all outstanding shares of our convertible preferred stock (Senior Preferred Stock and Junior Preferred Stock) into an aggregate of 84,800,239 shares of common stock immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to give further effect to the sale of shares of our common stock offered in this offering and the concurrent private placement, based on an assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information together with our unaudited interim consolidated financial statements and related notes appearing elsewhere in this prospectus and the information set forth under the heading "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations".

	As of June 30, 2014		
	Actual	Pro Forma (unaudited, in thousands)	Pro Forma, as Adjusted
Cash, cash equivalents and investments (1)	$ 209,821	$ 209,821	$
Current and long-term lease financing obligations	96,914	96,914	
Product development obligations	18,291	18,291	
Series E and F redeemable convertible preferred stock (Senior Preferred Stock); par value $0.01 per share, 38,340,182 shares authorized, 38,340,182 shares issued and outstanding at June 30, 2014 (unaudited), and no shares authorized, issued or outstanding pro forma and pro forma as adjusted at June 30, 2014 (unaudited)	168,436	—	
Stockholders' equity (deficit):			
Series A, B, C, D, G and royalty acquisition convertible preferred stock (Junior Preferred Stock); par value $0.01 per share, 86,659,818 shares authorized, 46,460,057 shares issued and outstanding at June 30, 2014 (unaudited), and no shares authorized, issued or outstanding pro forma and pro forma as adjusted at June 30, 2014 (unaudited)	136,313	—	
Common stock; par value of $0.01, 225,000,000 shares authorized, 33,714,272 shares issued and outstanding at June 30, 2014 (unaudited), respectively, and 118,514,511 and shares outstanding pro forma and pro forma as adjusted at June 30, 2014 (unaudited)	337	1,185	
Additional paid-in capital	43,225	347,126	
Accumulated other comprehensive loss	(4,133)	(4,133)	
Accumulated deficit	(232,188)	(232,188)	
Total stockholders' equity (deficit)	(56,446)	111,990	
Non-controlling interests	27,875	27,875	
Total equity (deficit)	(28,571)	139,865	
Total capitalization	$ 255,070	$ 255,070	$

(1) Includes $7.7 million classified as long-term investments.

If the underwriters' option to purchase additional shares of our common stock from us were exercised in full, pro forma as adjusted cash and cash equivalents and investments, additional paid-in capital, total stockholders' equity and shares outstanding as of June 30, 2014 would be $, $, $ and shares, respectively.

The actual, pro forma and pro forma as adjusted information set forth in the table above are based on 33,714,272 shares of our common stock outstanding as of June 30, 2014, and excludes the following:

- 26,922,433 shares of common stock issuable upon the exercise of outstanding stock options issued as of June 30, 2014 pursuant to our 1999 and 2005 Stock Plans at a weighted average exercise price of $1.48 per share;
- 5,661,682 shares of common stock issuable upon the exercise of stock options pursuant to our 2005 Stock Plan at a weighted average exercise price of $5.82 that were subject to shareholder approval as of June 30, 2014, 26,552 of which were cancelled as of shareholder approval (which approval was obtained in July 2014).
- 4,000,000 shares of common stock to be reserved for future issuance under our 2014 Employee Stock Purchase Plan, or ESPP, as of the date the registration statement of which this prospectus forms a part is declared effective by the SEC, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.
- 18,942,169 shares of common stock to be reserved for future issuance under our 2014 Plan, as of the date the registration statement of which this prospectus forms a part is declared effective by the SEC (which shares are as of June 30, 2014 and are currently reserved for future grant under our 2005 Plan and will cease to be reserved under our 2005 Plan immediately prior to the time our 2014 Plan becomes effective) as well as any automatic increases in the number of shares of common stock reserved for future issuance under this the 2014 Plan;
- 432,790 shares of common stock issuable upon exercise of common stock warrants outstanding as of June 30, 2014 at a weighted-average exercise price of $3.03 per share; and
- 2,397,505 shares of common stock issuable upon the exchange of outstanding preferred stock issued by FibroGen Europe.

DILUTION

Dilution in net tangible book value per share to new investors is the amount by which the offering price paid by the purchasers of the shares of common stock sold in the offering exceeds the pro forma net tangible book value per share of common stock after the offering. Net tangible book value per share is determined at any date by subtracting our total liabilities from the total book value of our tangible assets and dividing the difference by the number of shares of common stock deemed to be outstanding at that date.

The historical net tangible book value of our common stock as of June 30, 2014 was $(28.6) million, or $(0.85) per share. Our pro forma net tangible book value as of June 30, 2014 was $139.9 million, or $1.18 per share, which gives effect to the conversion of all outstanding shares of our preferred stock into an aggregate of 84,800,239 shares of our common stock immediately prior to the completion of this offering. After giving effect to the receipt and our intended use of approximately $ million of estimated net proceeds from our sale of shares of common stock in this offering and the concurrent private placement at an assumed offering price of $ per share, which is the midpoint of the range set forth on the cover page of this prospectus, our pro forma as adjusted net tangible book value as of June 30, 2014 would have been $ million, or $ per share. This represents an immediate increase in net tangible book value of $ per share to existing stockholders and an immediate dilution of $ per share to new investors purchasing shares of common stock in the offering. The following table illustrates this substantial and immediate per share dilution to new investors.

Assumed initial public offering price per share (the midpoint of the range set forth on the cover page of this prospectus)		$
Pro forma net tangible book value per share at June 30, 2014	$	
Pro forma increase per share attributable to new investors	$	
Pro forma as adjusted net tangible book value per share after giving effect to this offering		$
Dilution in net tangible book value per share to new investors		$

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value by $, the pro forma as adjusted net tangible book value per share by $ and the dilution per share to new investors in this offering by $, or $ if the underwriters exercise their option to purchase additional shares in full, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us.

Similarly, each increase or decrease of   shares in the number of shares offered by us would increase or decrease, as applicable, our pro forma as adjusted net tangible book value by approximately $, the pro forma as adjusted net tangible book value per share by $ and the dilution per share to new investors by $, or $ if the underwriters exercise their option to purchase additional shares in full, assuming the assumed initial public offering price remains the same and after deducting underwriting discounts and commissions and estimated expenses payable by us.

The following table summarizes, as of June 30, 2014:

- the total number of shares of common stock purchased from us by our existing stockholders and by new investors purchasing shares in this offering and the concurrent private placement;
- the total consideration paid to us by our existing stockholders and by new investors purchasing common stock in this offering and the concurrent private placement, assuming an initial public offering of $ per share, which is the midpoint of the range set forth on the cover page of this prospectus (before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us in connection with this offering); and

- the average price per share paid by existing stockholders and by new investors purchasing shares in this offering and the concurrent private placement.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%	$	%	$
Concurrent private placement investor					
New investors					
Total		100%	$	100%	$

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, as applicable, total consideration paid by existing stockholders, total consideration paid by new investors and the average price per share by $, $ and $, respectively, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and without deducting the estimated underwriting discounts and commissions and estimated expenses payable by us.

If the underwriters exercise their option to purchase additional shares in full, the number of shares held by the existing stockholders after this offering and the concurrent private placement would be reduced to , or % of the total number of shares of our common stock outstanding after this offering and the concurrent private placement, and the number of shares held by new investors would increase to , or %, of the total number of shares of our common stock outstanding after this offering and the concurrent private placement.

The tables and calculations above are based on the number of shares of our common stock outstanding as of June 30, 2014, but do not include, as of June 30, 2014, the following shares:

- 26,922,433 shares of common stock issuable upon the exercise of outstanding stock options issued as of June 30, 2014 pursuant to our 1999 and 2005 Stock Plans at a weighted average exercise price of $1.48 per share;
- 5,661,682 shares of common stock issuable upon the exercise of stock options pursuant to our 2005 Stock Plan at a weighted average exercise price of $5.82 that were subject to shareholder approval as of June 30, 2014, 26,552 of which were cancelled as of shareholder approval (which approval was obtained in July 2014).
- 4,000,000 shares of common stock to be reserved for future issuance under our ESPP, as of the date the registration statement of which this prospectus forms a part is declared effective by the SEC, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.
- 18,942,169 shares of common stock to be reserved for future issuance under our 2014 Plan, as of the date the registration statement of which this prospectus forms a part is declared effective by the SEC (which 18,942,169 shares are as of June 30, 2014 and are currently reserved for future grant under our 2005 Plan and will cease to be reserved under our 2005 Plan immediately prior to the time our 2014 Plan becomes effective) as well as any automatic increases in the number of shares of common stock reserved for future issuance under this the 2014 Plan;
- 432,790 shares of common stock issuable upon exercise of common stock warrants outstanding as of June 30, 2014 at a weighted-average exercise price of $3.03 per share; and
- 2,397,505 shares of common stock issuable upon the exchange of outstanding preferred stock issued by FibroGen Europe.

SELECTED CONSOLIDATED FINANCIAL DATA

You should read the following selected financial data together with the section of this prospectus entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included in this prospectus. The statement of operations data for the years ended December 31, 2012 and 2013 and the balance sheet data as of December 31, 2012 and 2013 are derived from our consolidated financial statements included elsewhere in this prospectus. The statement of operations data for the six months ended June 30, 2013 and 2014 and the balance sheet data as of June 30, 2014 are derived from our unaudited interim consolidated financial statements included elsewhere in this prospectus. We have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair statement of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results to be expected in the future, and our unaudited interim results are not necessarily indicative of the results to be expected for the full year or any other period.

	Years ended December 31,		Six Months ended June 30,	
	2012	**2013**	**2013**	**2014**
	(in thousands, except per share data)			
Result of Operations				
Revenue:				
License and milestone revenue	$ 62,845	$ 94,961	$ 16,895	$ 97,148
Collaboration services and other revenue	3,088	7,209	1,637	10,686
Total revenue	65,933	102,170	18,532	107,834
Operating expenses:				
Research and development (1)	74,222	85,710	33,092	58,919
General and administrative (1)	18,934	24,409	9,610	13,948
Total operating expenses	93,156	110,119	42,702	72,867
Income (loss) from operations	(27,223)	(7,949)	(24,170)	34,967
Total interest and other, net	(5,448)	(6,994)	(3,303)	(4,376)
Income (loss) before income taxes	(32,671)	(14,943)	(27,473)	30,591
Benefit from income taxes	100	—	—	—
Net income (loss)	$(32,571)	$ (14,943)	$(27,473)	$ 30,591
Net income (loss) per share—basic (2)	$ (0.99)	$ (0.45)	$ (0.83)	$ 0.30
Net income (loss) per share—diluted (2)	$ (0.99)	$ (0.45)	$ (0.83)	$ 0.18
Weighted-average number of common shares used in net income (loss) per share—basic (2)	32,820	32,964	32,938	33,198
Weighted-average number of common shares used in net income (loss) per share—diluted (2)	32,820	32,964	32,938	53,970
Pro forma net income (loss) per share—basic (unaudited) (3)		$ (0.13)		$ 0.26
Pro forma net income (loss) per share—diluted (unaudited) (3)		$ (0.13)		$ 0.22
Pro forma weighted-average number of common shares used in net income (loss) per share—basic (unaudited) (3)		117,764		117,998
Pro forma weighted-average number of common shares used in net income (loss) per share—diluted (unaudited) (3)		117,764		140,164

(1) Stock-based compensation expense is included in our results of operations as follows (in thousands):

	Years Ended December 31,		Six Months Ended June 30,	
	2012	**2013**	**2013**	**2014**
Research and development	$2,277	$1,925	$ 953	$ 883
General and administrative	2,284	1,519	802	582
Total stock-based compensation expense	$4,561	$3,444	$1,755	$1,465

(2) See Note 10 within the notes to our consolidated financial statements appearing elsewhere in this prospectus for a description of the method used to calculate basic and diluted net income (loss) per share of common stock.

(3) Pro forma basic net income (loss) per share has been calculated assuming the conversion of all outstanding shares of convertible preferred stock, using the as-if converted method, into shares of common stock as of the beginning of the applicable period or the original issuance if later. Pro forma diluted net income (loss) per share includes the dilutive effect of employee stock options and warrants using the treasury stock method, as well as the effect of the conversion of preferred stock held by investors in FibroGen Europe into a maximum total of 2,397,505 shares of FibroGen, Inc. common stock.

	As of December 31,		As of June 30,
	2012	2013	2014
	(in thousands)		
Balance Sheet Data:			
Cash and cash equivalents	$ 38,872	$ 76,332	$ 182,662
Short-term and long-term investments	82,630	61,833	27,159
Working capital	29,125	106,164	171,683
Total assets	265,588	296,952	372,657
Deferred revenue	5,764	36,649	72,936
Lease financing obligations	92,902	96,809	96,914
Product development obligations	17,152	18,257	18,291
Senior Preferred Stock	168,436	168,436	168,436
Junior Preferred Stock	136,313	136,313	136,313
Accumulated deficit	(247,836)	(262,779)	(232,188)
Non-controlling interests	27,700	27,875	27,875
Total deficit	$ (46,252)	$ (60,833)	$ (28,571)

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 appearing in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, 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 prospectus beginning on page 16 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.

Overview

We are a research-based, biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics to treat serious unmet medical needs. We have capitalized on our extensive experience in fibrosis and hypoxia-inducible factor, or HIF, biology to generate multiple programs targeting various therapeutic areas. Roxadustat, or FG-4592, is an oral small molecule inhibitor of HIF prolyl hydroxylases, or HIF-PHs, in Phase 3 clinical development for the treatment of anemia in chronic kidney disease, or CKD. FG-3019 is our monoclonal antibody in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis, or IPF, pancreatic cancer and liver fibrosis. We have taken a global approach with respect to our product candidates, and this includes development and commercialization of product candidates in the People's Republic of China, or China.

Roxadustat, the first HIF-PH inhibitor to enter Phase 3 clinical development, acts by stimulating the body's natural pathway of erythropoiesis, or red blood cell production. Roxadustat represents a new paradigm for the treatment of anemia in CKD patients, and has the potential to offer a safer, more effective, more convenient and more accessible therapy than the current standard of care, injectable erythropoiesis stimulating agents, or ESAs. We, along with our collaboration partners Astellas Pharma Inc., or Astellas, and AstraZeneca AB, or AstraZeneca, have designed a global Phase 3 program to support regulatory approval of roxadustat in both NDD-CKD and DD-CKD patients in multiple geographies.

FG-3019 is our fully-human monoclonal antibody that inhibits the activity of connective tissue growth factor, or CTGF, a critical common element in the progression of fibrosis and associated serious diseases. We are currently conducting an open-label Phase 2 trial in IPF; a randomized, double-blind placebo-controlled Phase 2 trial in IPF; an open-label Phase 2 trial in pancreatic cancer; and a randomized, double-blind, placebo-controlled Phase 2 trial in liver fibrosis. To date, we have retained exclusive worldwide rights for FG-3019.

We are also currently pursuing our corneal implant FG-5200 for treatment of corneal blindness resulting from partial thickness corneal damage in China.

To date, our operations have been primarily funded by net proceeds from the sale of convertible preferred stock of FibroGen, Inc. and sales of preferred stock in our majority-owned subsidiaries as well as equity investments from our collaboration partners and upfront payments, milestone payments and net research and development payments from our collaboration partners.

Since inception and through June 30, 2014, we have incurred a total of $826.8 million in research and development expenses, a majority of which relates to the development of roxadustat, FG-3019 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 continue to increase in the future as we advance our product candidates through clinical trials and expand our product candidate portfolio. We will not generate revenue based on product sales unless and until we or one of our partners successfully complete development of and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. In addition, we expect to incur significant expenses relating to seeking regulatory approval for our product candidates. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with operating as a public reporting company. We consider the active management and development of our clinical pipeline to be crucial to our long-term success. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time consuming. Except for $116.5 million, all currently planned development and commercialization costs for roxadustat for the treatment of anemia in CKD in the United States, Europe, Japan and all other markets outside of China are paid by Astellas and AstraZeneca. All development and commercialization costs for roxadustat in China will be shared equally, and AstraZeneca will pay for all of our commercialization costs until profitability and AstraZeneca will recoup such costs out of product sales, if any. Any termination of any of our collaboration agreements would require us to fund 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.

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, see "Risk Factors".

Financial Operations Overview

Revenue

Our revenue to date has been generated primarily from our collaboration agreements with Astellas Pharmaceuticals Inc., or Astellas, and AstraZeneca AB, or AstraZeneca. The following tables summarize the sources of our revenue for the years ended December 31, 2012 and 2013, and the six months ended June 30, 2013 and 2014:

	Year Ended December 31,		**Six Months Ended June 30,**	
	2012	**2013**	**2013**	**2014**
	(in thousands)		**(unaudited, in thousands)**	
Astellas-Related party:				
License	$ 12,845	$ 9,826	$ 4,395	$ 6,460
Milestone	50,000	12,500	12,500	—
Collaboration Services	2,275	3,335	1,628	1,618
Total Astellas	$ 65,120	$ 25,661	$ 18,523	$ 8,078
AstraZeneca:				
License	$ —	$ 72,635	$ —	$ 90,688
Milestone	—	—	—	—
Collaboration Services	—	3,843	—	9,025
Total AstraZeneca	$ —	$ 76,478	$ —	$ 99,713
Other	$ 813	$ 31	$ 9	$ 43
Total Revenue	$ 65,933	$ 102,170	$ 18,532	$ 107,834

Under our revenue recognition policy, license revenue includes amounts from upfront, non-refundable license payments and amounts allocated pursuant to the relative selling price method from other consideration received (other than substantive milestone payments) during the periods. This revenue is generally recognized as deliverables are met and services are performed. Milestone revenue includes payments from milestones which are deemed to be substantive in nature and is recognized in its entirety in the period in which the milestone is achieved. License and milestone revenues represented 95% and 93% of total revenues for the years ended December 31, 2012 and 2013, respectively, and 91% and 90% for the six months ended June 30, 2013 and 2014, respectively.

Collaboration services include co-development services, manufacturing of clinical supplies, committee services and information sharing. Collaboration services revenues are recognized over the non-contingent performance period, ranging from 36 to 65 months. Other revenues consist of royalty payments received, which are recorded on a monthly basis as they are reported to us, and have been included with collaboration services and other revenue in the Consolidated Statements of Operations, as they have not been material for each of the years ended December 31, 2012 and 2013 and the six months ended June 30, 2013 and 2014. Collaboration services and other revenues represented 5% and 7% of total revenues for the years ended December 31, 2012 and 2013, respectively, and 9% and 10% for the six months ended June 30, 2013 and 2014, respectively.

We have not generated any revenues based on the sale of products. In the future, we may generate revenue from product sales and from collaboration agreements in the form of license fees, milestone payments, reimbursements for collaboration services and royalties on product sales. We expect that any revenues we generate will fluctuate from quarter to quarter as a result of the uncertain timing and amount of such payments and sales.

Collaboration Agreements

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.

In June 2005, we entered into a collaboration agreement with Astellas for roxadustat for the treatment of anemia in Japan (“Japan Agreement”).

In April 2006, we entered into a collaboration agreement with Astellas for roxadustat for the treatment of anemia in Europe, the Commonwealth of Independent States, the Middle East, and South Africa (“Europe Agreement”).

In July 2013, we entered into a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in the U.S. and all territories not previously licensed to Astellas, except China (“US/RoW Agreement”).

In July 2013, through our China subsidiary and related affiliates, we entered into a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in China (“China Agreement”).

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

Total cash consideration received through June 30, 2014 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 June 30, 2014	Additional Potential Cash Payments	Total Potential Cash Payments
		(in thousands)	
Astellas-Related party:			
Japan Agreement	$ 52,593	$ 120,000	$ 172,593
Europe Agreement	410,000	335,000	745,000
Total Astellas	$ 462,593	$ 455,000	$ 917,593
AstraZeneca:			
US/RoW Agreement	$ 192,000	$ 1,057,000	$ 1,249,000
China Agreement	28,200	348,500	376,700
Total AstraZeneca	$ 220,200	$ 1,405,500	$ 1,625,700
Total	$ 682,793	$ 1,860,500	$ 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.

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, or CROs, 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, 2012 and 2013, and for the six months ended June 30, 2013 and 2014:

		Year Ended December 31,		Six Months Ended June 30,	
		2012	2013	2013	2014
Product Candidate	Phase of Development	(in thousands)		(in thousands)	
Roxadustat	Phase 3	$36,631	$43,620	$16,897	$34,468
FG-3019	Phase 2	16,607	20,103	7,282	10,286
FG-6874	Phase 1	3,410	1,979	1,018	1,915
FG-5200	Preclinical	2,428	3,154	1,115	1,866
Other research and development expenses		15,146	16,854	6,780	10,384
Total research and development expenses		$74,222	$85,710	$33,092	$58,919

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. The largest component of our total operating expenses has historically been our investment in research and development activities, including the clinical development of our product candidates. Since inception and through June 30, 2014, we have incurred a total of $826.8 million in research and development expenses, a majority of which relates to the development of roxadustat, FG-3019 and other HIF-PH inhibitors. 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. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time consuming. We consider the active management and development of our clinical pipeline to be crucial to our long-term success. The actual probability of success for each product candidate and clinical program may be affected by a variety of factors, including the safety and efficacy data of the product candidate, investment in the program, competition, manufacturing capability and commercial viability. Furthermore, we have entered into collaborations with third parties to participate in the development and commercialization of our product candidates, and we may enter into additional collaborations in the future. In situations in which third parties have control over the preclinical development or clinical study process for a product candidate, the estimated completion dates are largely outside of our control. We are unable to forecast with any degree of certainty which of our product candidates, if any, will be subject to collaborations in the future or how such arrangements would affect our development plans or capital requirements. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects, or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

The duration, costs and timing of clinical studies and development of our product candidates will depend on a variety of factors. For example, if the FDA, EMA or another regulatory authority were to require us to conduct clinical studies beyond those that we currently anticipate will be required, or if we experience significant delays in enrollment in any of our clinical studies, we could be required to expend significant additional financial resources and the time to the completion of clinical development would be extended.

We intend to identify additional partnerships to further develop product candidates other than roxadustat, which may offset a portion of our research and development expenses through reimbursement from potential partners. Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of expenses incurred or when, or if, we will be able to achieve sustained profitability.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses for executive, operational, finance, legal, compliance and human resource functions. Other general and administrative expenses include facility-related costs and professional fees, accounting and legal services, other outside services, recruiting fees and expenses associated with obtaining and maintaining patents.

For the years ended December 31, 2012 and 2013, and for the six months ended June 30, 2013 and 2014, we incurred $18.9 million, $24.4 million, $9.6 million and $13.9 million, respectively, in general and administrative expenses.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. We also anticipate increased expenses, including exchange listing and Securities and Exchange Commission requirements, director and officer insurance premiums, legal, audit and tax fees, regulatory compliance programs and investor relations costs associated with being a public company. Additionally, if and when we believe the first regulatory approval of one of our product candidates appears likely, 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.

Interest and Other, Net

Interest Expense

In connection with our long-term lease for our corporate headquarters in San Francisco, California, which was entered into in September 2006, and the lease for our pilot plant located in Beijing Yizhuang Biomedical Park, or BYBP, which was entered into in February 2013, we recognized an asset for costs of constructing the building shells of $50.8 million and $3.1 million, respectively for these facilities and recorded a corresponding lease financing obligation. In addition, we recorded $32.5 million in reimbursements for tenant improvements in the San Francisco location and $0.5 million in rent reimbursements for BYBP.

As the monthly lease payments are made, we record interest expense and an increase or reduction in the corresponding lease financing obligation for any amounts allocated to or deficiencies being applied to the principal value of these obligations.

Interest expense includes payments made for imputed interest related to the facility lease financing obligations for the San Francisco and China properties (see Note 8 to the consolidated financial statements) and interest related to The Technology Development Center of the Republic of Finland, or TEKES, product development obligations (see Note 6 to the consolidated financial statements).

Interest Income

Interest income represents interest earned on our cash, cash equivalents and investments.

Other Income (Expense)

Other income (expense) relates to foreign currency transaction gains (losses) and remeasurement of certain monetary assets and liabilities in non-functional currency of our subsidiaries using exchange rates in effect at the end of the period into the functional currency as well as realized gains (losses) on sales of investments.

Sublease Income

We sublease approximately 34,400 square feet of space within our corporate headquarters facility to certain subtenants on a short-term basis. These subleases include invoices for base rent and reimbursement of various expenses. Sublease income is included as an offset to our facilities expenses for both general and administrative and research and development expenses. For the years ended December 31, 2012 and 2013, and the six months ended June 30, 2013 and 2014, we had sublease income of $4.3 million, $4.5 million, $2.2 million and $2.4 million, respectively.

Critical Accounting Policies and Significant Judgments 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 U.S. generally accepted accounting principles. 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. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. 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 prospectus, 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 deliverables, and we follow the guidance in Accounting Standards Codification Topic 605-25, “Revenue Recognition—Multiple-Element Arrangements,” or ASC Topic 605-25 (“ASC 605-25”). ASC 605-25:

- provides guidance on how revenue arrangements with multiple deliverables should be separated and how the arrangement consideration should be allocated among the separate units of accounting;
- requires an entity to determine the selling price of a separate deliverable using a hierarchy of (i) vendor-specific objective evidence, or VSOE, (ii) third-party evidence, or TPE, or (iii) best estimate of selling price, or BESP; and
- requires the allocation of the arrangement consideration, at the inception of the arrangement, to the separate units of accounting based on relative selling price.

We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. Based on this evaluation, the deliverables are separated into units of accounting. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. Significant judgment may be required in determining whether a deliverable provides stand-alone value, determining the amount of arrangement consideration that is fixed or determinable, and estimating the stand-alone selling price of each unit of accounting.

To date, we have determined that the selling price for the deliverables within our collaboration agreements should be determined using BESP, as neither VSOE nor TPE is available. The process for determining BESP involves significant judgment on our part 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.

For each unit of accounting identified within an arrangement, we determine the period over which the deliverables are provided and the performance obligation is satisfied. Service revenue is recognized using a proportional performance method. Direct labor hours or full time equivalents are used as the measurement of performance. Revenue may be recognized using a straight line method when performance is expected to occur consistently over a period of time.

Payments or reimbursements resulting from our research and development efforts for those arrangements where such efforts are considered as deliverables are recognized as the services are performed and are presented on a gross basis. To the extent payments are required to be made to our collaboration partners pursuant to research and development efforts, those costs are charged to research and development using the guidance pursuant to ASC 605-250, Customer Payments and Incentives, which states that cash consideration given by a vendor to a customer is presumed to be a reduction of the selling prices unless the vendor receives an identifiable benefit in exchange for the consideration that is sufficiently separable from the recipient’s purchase of the vendor’s products, and the vendor can reasonably estimate the fair value of the benefit.

Each of our collaboration agreements includes milestones for which we follow ASC Topic 605-28, Revenue Recognition—Milestone Method (“ASC 605-28”). ASC 605-28 establishes the milestone method as an acceptable method of revenue recognition for certain contingent event-based payments under research and development arrangements. Under the milestone method, a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event (i) that can only be achieved based in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to us. Determining whether a milestone is substantive is a matter of judgment and that assessment must be made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the milestone (i) is commensurate with either our performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) relates solely to past performance and (iii) is reasonable relative to all deliverables and payment terms in the arrangement. Payments for achieving milestones which are not considered substantive are treated as additional arrangement consideration and are allocated following the relative selling price method previously described.

Clinical Trial Accruals

Clinical trial costs are a component of research and development expenses. We accrue and expense clinical trial activities performed by third parties based upon actual work completed in accordance with agreements established with clinical research organizations and clinical sites. We determine the actual costs through external service providers as well as confirmation with internal personnel as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services.

Income Taxes

We account for income taxes using an asset and liability approach. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Operating loss and tax credit carryforwards are measured by applying currently enacted tax laws. Valuation allowances are provided when necessary to reduce net deferred tax assets to an amount that is more likely than not to be realized. As of December 31, 2012 and 2013, we provided a full valuation allowance against our net deferred tax assets.

We recognize the tax effects of an uncertain tax position only if it is more likely than not to be sustained based solely on its technical merits as of the reporting date and only in an amount more likely than not to be sustained upon review by the tax authorities. We consider many factors when evaluating and estimating our tax positions and tax benefits, which may require periodic adjustments and which may not accurately reflect actual outcomes.

As of December 31, 2013, we had net operating loss carryforwards available to offset future taxable income of approximately $115.4 million and $171.7 million for federal and state tax purposes, respectively. These carryforwards will begin to expire in 2024 for federal purposes and in 2014 for state purposes, if not utilized before these dates. We also had foreign net operating loss carryforwards of approximately $17.3 million that expire between 2014 and 2023 if not utilized.

As of December 31, 2013, we had approximately $18.4 million of federal and $13.8 million of state research and development tax credit carryforwards available to offset future taxable income. The federal credits will begin to expire in 2018 and the California research credits have no expiration dates.

Utilization of net operating losses and tax credit carryforwards may be limited by the “ownership change” rules, as defined in Section 382 of the Internal Revenue Code (any such limitation, a “Section 382 limitation”). Similar rules may apply under state tax laws. We have performed an analysis to determine whether an “ownership change” occurred from inception to December 31, 2013. Based on this analysis, management determined that we did experience historical ownership changes of greater than 50% during this period. Therefore, the utilization of a portion of our net operating losses and credit carryforwards is currently limited. However, these Section 382 limitations are not expected to result in a permanent loss of the net operating losses and credit carryforwards. As such, a reduction of our gross deferred tax asset for our net operating loss and tax credit carryforwards is not necessary prior to considering the valuation allowance. In the event we experience any subsequent changes in ownership, the amount of net operating losses and research and development credit carryforwards useable in any taxable year could be limited and may expire unutilized.

Stock-Based Compensation

We measure and recognize compensation expense for all stock options granted to our employees, directors and non-employees based on the estimated fair value of the award on the grant date. We use 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. We believe 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 as of each reporting date. The resulting increase in value, if any, is recognized as expense during the requisite service period on a straight-line basis. The determination of the grant date fair value of options using an option pricing model is affected by our 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.

Historically, for all periods prior to this initial public offering, the fair values of the shares of common stock underlying our stock-based awards were estimated on each grant date by our board of directors. In order to determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, contemporaneous valuations of our common stock prepared by unrelated third-party valuation firms in accordance with the guidance provided by the American Institute of Certified Public Accountants 2004 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or the Practice Aid. Given the absence of a public trading market of our common stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including:

- contemporaneous valuations of our common stock performed by unrelated third-party valuation firms as of February 29, 2012, August 31, 2012, February 15, 2013, July 31, 2013, October 31, 2013 and February 28, 2014;
- our stage of development;
- our operational and financial performance;
- the nature of our services and our competitive position in the marketplace;
- the value of companies that we consider peers based on a number of factors, including similarity to us with respect to industry and business model;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale given prevailing market conditions, and the nature and history of our business;
- issuances of preferred stock and the rights, preferences and privileges of our preferred stock relative to those of our common stock;
- current business conditions and projections;
- the history of our company and our introduction of new solutions; and
- the lack of marketability of our common stock.

Common Stock Valuation Methodology

The valuations were performed in accordance with applicable elements of the Practice Aid. The Practice Aid prescribes several valuation approaches for estimating the value of an enterprise, such as the cost, market and income approaches, and various methodologies for allocating the value of an enterprise to its common stock.

The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date. In accordance with the Practice Aid, our board determined that the Probability-Weighted Expected Return Method (or PWERM) was the most appropriate method for determining the fair value of our common stock for the above noted valuation dates based on our stage of development and other relevant factors. The PWERM is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.

For valuations after the completion of this initial public offering, our board of directors will determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported on   on the date of grant.

Results of Operations

	Years ended December 31,		Six Months ended June 30,	
	2012	2013	2013	2014
			(unaudited)	
	(in thousands)			
Revenue:				
License and milestone revenue	$ 62,845	$ 94,961	$ 16,895	$ 97,148
Collaboration services and other revenue	3,088	7,209	1,637	10,686
Total revenue	65,933	102,170	18,532	107,834
Operating expenses:				
Research and development	74,222	85,710	33,092	58,919
General and administrative	18,934	24,409	9,610	13,948
Total operating expenses	93,156	110,119	42,702	72,867
Income (loss) from operations	(27,223)	(7,949)	(24,170)	34,967
Total interest and other, net	(5,448)	(6,994)	(3,303)	(4,376)
Income (loss) before income taxes	(32,671)	(14,943)	(27,473)	30,591
Benefit from income taxes	100	—	—	—
Net income (loss)	$(32,571)	$ (14,943)	$(27,473)	$ 30,591

Comparison of the six months ended June 30, 2013 and 2014 (unaudited)

Revenue

	Six Months Ended June 30,					
	2013	% of Revenue	2014	% of Revenue	Change	% Change
	(dollars in thousands)					
Revenue:						
License and milestone revenue	$16,895	91%	$ 97,148	90%	$80,253	475%
Collaboration services and other revenue	1,637	9%	10,686	10%	9,049	553%
Total revenue	$18,532	100%	$107,834	100%	$89,302	482%

Total revenue increased by $89.3 million, or 482% for the six months ended June 30, 2014 compared to the six months ended June 30, 2013 for the reasons as more fully discussed in the sections below.

License and Milestone Revenue

	Six Months Ended June 30,					
	2013	% of License and Milestone Revenue	2014	% of License and Milestone Revenue	Change	% Change
	(dollars in thousands)					
License and milestone revenue:						
Astellas—Related party	$16,895	100%	$ 6,460	7%	$(10,435)	(62)%
AstraZeneca	—	—	90,688	93%	90,688	NM
Total license and milestone revenue	$16,895	100%	$97,148	100%	$ 80,253	475%

NM - Not Meaningful

License and milestone revenue increased by $80.3 million for the six months ended June 30, 2014 compared to the six months ended June 30, 2013. This increase was primarily driven by license revenue recognized in connection with our collaboration agreements signed in July 2013 with AstraZeneca. The amount of license revenue recognized was due principally to the receipt of a $110 million time-based payment in June 2014 and the application of the relative selling price method to each of the deliverables underlying the AstraZeneca agreement. As a result of applying the relative selling price method and assessing the timing of the provision of various deliverables (as more fully discussed in the notes to the consolidated financial statements), at June 30, 2014, approximately $19.3 million (which relates to the co-development, information sharing and committee services unit of accounting) and $14.9 million (which relates to the China unit of accounting) of this payment were deferred. The amounts related to the co-development, information sharing and committee services unit of accounting will be recognized as revenue as these services are performed through the remainder of the non-contingent development period (which was estimated as 65 months from the date the AstraZeneca agreement was signed). The amount relating to the China unit of accounting has been deferred until commercialization commences in the China market.

Collaboration Services and Other Revenue

Collaboration services revenue increased $9.0 million for the six months ended June 30, 2014, compared to the six months ended June 30, 2013, primarily due to an increase in expenses subject to reimbursement following our entry into our agreements with AstraZeneca.

Operating Expenses

	Six Months Ended June 30,					
	2013	% of Revenue	2014	% of Revenue	Change	% Change
	(dollars in thousands)					
Operating expenses:						
Research and development	$33,092	179%	$58,919	55%	$25,827	78%
General and administrative	9,610	52%	13,948	13%	4,338	45%
Total operating expenses	$42,702	231%	$72,867	68%	30,165	71%

Research and development expenses increased by $25.8 million, or 78% for the six months ended June 30, 2014 compared to the six months ended June 30, 2013. The increase was primarily due to an increase in personnel related costs of $6.6 million, of which $3.9 million related to an increase in headcount and related expenses, $1.8 million related to increased expenses under our corporate bonus program and $0.9 million related to the establishment of a 401(k) employee contribution matching program. We also experienced an increase in outside services expenses of $10.3 million as we utilized third parties for scientific contract work for increased regulatory submissions for roxadustat and certain other of our product candidates and an increase in drug development expenses of $3.5 million due to increased supply required for roxadustat and FG-3019 trials. In addition, our overall clinical trials expenses increased $4.6 million, as a result of our increased use of CROs as well as costs for data management.

General and administrative expenses increased $4.3 million, or 45%, for the six months ended June 30, 2014 compared to the six months ended June 30, 2013. The increase was primarily due to an increase in personnel related costs of $2.1 million, of which $1.2 million related to an increase in headcount and related expenses, $0.6 million related to increased expenses under our corporate bonus program and $0.3 million related to the establishment of a 401(k) match program. In addition, professional fees increased $1.5 million due to increase in legal, audit, tax and other outside services costs. Furthermore, facilities expense increased $0.3 million due to the costs associated with our newly leased facility in China.

Interest Expense and Other, Net

	Six Months Ended June 30, 2013	Six Months Ended June 30, 2014	Change	% Change
	(dollars in thousands)			
Interest expense and other, net:				
Interest expense	$ 5,307	$ 5,451	$ 144	3%
Interest income	(1,840)	(1,080)	760	(41)%
Foreign currency and other (gain) loss	(164)	5	169	(103)%
Total interest expense and other, net	$ 3,303	$ 4,376	$1,073	32%

Interest expense and other, net increased $1.1 million, or 32%, for the six months ended June 30, 2014, compared to the six months ended June 30, 2013. Interest expense includes payments made for imputed interest related to the facility lease financing obligations for the San Francisco and the China properties as well as interest related to the TEKES product development obligations. Interest expense increased $0.1 million, primarily due to the newly-leased facility in China.

Interest income consists primarily of interest earned on bonds held. Interest income decreased $0.8 million for the six months ended June 30, 2014, compared to the six months ended June 30, 2013, due to a decrease in bond interest related to the maturity and call of bonds. Foreign currency and other decreased $0.2 million for the six months ended June 30, 2014, compared to the six months ended June 30, 2013, as a result of nonrecurring realized gains on the sale of investments for the six months ended June 30, 2013.

Comparison of the years ended December 31, 2012 and 2013

Revenue

	Year Ended December 31, 2012	% of Revenue	2013	% of Revenue	Change	% Change
	(dollars in thousands)					
Revenue:						
License and milestone revenue	$62,845	95%	$ 94,961	93%	$32,116	51%
Collaboration services and other revenue	3,088	5%	7,209	7%	4,121	133%
Total revenue	$65,933	100%	$102,170	100%	$36,237	55%

Total revenue increased by $36.2 million, or 55% for the year ended December 31, 2013 compared to the year ended December 31, 2012 for the reasons as more fully discussed in the sections below.

License and Milestone Revenue

	Year Ended December 31,					
	2012	% of License and Milestone Revenue	2013	% of License and Milestone Revenue	Change	% Change
	(dollars in thousands)					
License and milestone revenue:						
Astellas—Related party	$62,845	100%	$22,326	24%	$(40,519)	(64)%
AstraZeneca	—	—	72,635	76%	72,635	NM
Total license and milestone revenue	$62,845	100%	$94,961	100%	$ 32,116	51%

NM - Not Meaningful

License and milestone revenue increased by $32.1 million, or 51% for the year ended December 31, 2013 compared to the year ended December 31, 2012. This increase was primarily driven by license and milestone revenue recognized in connection with our collaboration agreements signed in July 2013 with AstraZeneca. Under our collaboration agreements with Astellas, we recognized revenue related to two substantive milestones in 2012 and 2013 of $50.0 million and $12.5 million, respectively.

Collaboration Services and Other Revenue

Collaboration services and other revenue increased $4.1 million, or 133% for the year ended December 31, 2013 compared to the year ended December 31, 2012, primarily due to an increase in expenses subject to reimbursement of $3.8 million following our entry into our agreements with AstraZeneca.

Operating Expenses

	Year Ended December 31,					
	2012	% of Revenue	2013	% of Revenue	Change	% Change
	(dollars in thousands)					
Operating expenses:						
Research and development	$74,222	113%	$ 85,710	84%	$11,488	15%
General and administrative	18,934	29%	24,409	24%	5,475	29%
Total operating expenses	$93,156	141%	$110,119	108%	16,963	18%

Research and development expenses increased by $11.5 million, or 15% for the year ended December 31, 2013 compared to the year ended December 31, 2012. The increase was primarily due to an increase in personnel related costs of $8.6 million, of which $3.2 million related to an increase in headcount and related expenses and $5.4 million related to increased expenses under our corporate bonus program, primarily due to the agreements signed with AstraZeneca in July 2013. We also experienced an increase in outside services expenses of $3.2 million as we utilized third parties to support increased regulatory efforts for roxadustat, and certain other of our product candidates and an increase in drug development expenses of $1.9 million due to increased supply required for roxadustat and FG-3019 trials. These increases were partially offset by a decrease in overall clinical trials expenses of $2.1 million, primarily related to the decrease in clinical investigator site costs and decreased activity for CROs.

General and administrative expenses increased $5.5 million, or 29% for the year ended December 31, 2013 compared to the year ended December 31, 2012. The increase was primarily due to an increase in personnel expenses of $3.9 million, of which $0.8 million related to an increase in headcount and related expenses and $3.1 million related to increased expenses under our corporate bonus program, primarily due to the agreements signed with AstraZeneca in July 2013. In addition, professional fees increased $1.6 million due to increased legal and outside services costs related to the execution of the AstraZeneca agreements as well as other general corporate legal expenses. Furthermore, facilities expense increased $0.2 million due to the costs associated with the newly leased facility in China.

Interest Expense and Other, Net

	Year Ended December 31,			
	2012	2013	Change	% Change
	(dollars in thousands)			
Interest expense and other, net:				
Interest expense	$10,026	$10,702	$ 676	7%
Interest income	(4,397)	(3,552)	845	(19)%
Foreign currency and other	(181)	(156)	25	(14)%
Total interest expense and other, net	$ 5,448	$ 6,994	$1,546	28%

Interest expense and other, net increased $1.5 million, or 28%, for the year ended December 31, 2013, compared to the year ended December 31, 2012. Interest expense includes payments made for imputed interest related to the facility lease financing obligations for the headquarters and China facilities as well as interest related to the TEKES product development obligations, which increased $0.7 million, primarily due to the newly-leased facility in China.

Interest income consists primarily of interest earned on bonds held. Interest income decreased $0.8 million, or 19%, for the year ended December 31, 2013, compared to the year ended December 31, 2012, due to a decrease in bond interest related to the maturity and call of bonds.

Liquidity and Capital Resources

We have historically funded our operations principally from the sale of convertible preferred stock and from the execution of certain collaboration agreements involving license payments, milestones and reimbursement for development services. To date, we have raised net proceeds of $302.7 million through the sale of FibroGen, Inc. convertible preferred stock and $27.9 million in sales of convertible preferred stock in our majority-owned subsidiaries. We have also received approximately $13.0 million of loans from TEKES. As of June 30, 2014, we had cash and cash equivalents of approximately $182.7 million. Cash is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting principally of corporate and government debt securities and stated at fair value, are also available as a source of liquidity. As of June 30, 2014, we had short-term and long-term investments of approximately $19.4 million and $7.7 million, respectively.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Years ended December 31,		Six Months ended June 30,	
	2012	2013	2013	2014
			(unaudited)	
	(in thousands)			
Net cash provided by (used in):				
Operating activities	$ (5,605)	$25,918	$(25,255)	$ 77,238
Investing activities	19,152	10,778	5,726	29,594
Financing activities	6,807	680	459	(537)
Effect of exchange rate changes on cash	(66)	84	13	35
Net change in cash and cash equivalents	$20,288	$37,460	$(19,057)	$106,330

Operating Activities

Net cash provided by operating activities was $77.2 million for the six months ended June 30, 2014, and consisted primarily of net income of $30.6 million adjusted for non-cash items including stock-based compensation expense of $1.5 million, depreciation expense of $1.8 million, amortization of bond premium/discount of $0.3 million and a net increase in operating assets and liabilities of $43.0 million. The significant items in the change in operating assets and liabilities include an increase in deferred revenue of $36.3 million and an increase in accounts payable and accrued expenses of $5.0 million. The increase in deferred revenue relates to the timing of upfront payments and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca. The increase in accrued expenses is driven by the increase in clinical trial activity related to upcoming Phase 3 trials for roxadustat.

Net cash used in operating activities was $25.3 million for the six months ended June 30, 2013, and consisted primarily of a net loss of $27.5 million adjusted for non-cash items including stock-based compensation expense of $1.8 million, depreciation expense of $2.6 million, investment gain of $0.2 million, amortization of bond premium/discount of $0.4 million and a net decrease in operating assets and liabilities of $2.3 million. The change in operating assets and liabilities includes a decrease in accounts payable and accrued expenses of $4.9 million that was driven by a decrease in accrued clinical trial related expenses. This decrease was partially offset by changes in accounts receivable and deferred revenues related to our collaboration agreement with Astellas.

Net cash provided by operating activities was $25.9 million for the year ended December 31, 2013, and consisted primarily of a net loss of $14.9 million adjusted for non-cash items including stock-based compensation expense of $3.4 million, depreciation expense of $5.1 million, investment gains of $0.3 million, amortization of bond premium/discount of $0.8 million and a net increase in operating assets and liabilities of $31.8 million. The change in operating assets and liabilities include increases in accounts payable and accrued expenses of $9.3 million, an increase in deferred revenue of $30.9 million, a decrease in prepaid expenses and other current assets of $0.8 million, offset by increases of $0.5 million in other assets and $8.7 million in accounts receivable. The increase in accounts payable and accrued expenses was primarily due to increased accrued payroll expenses and accrued clinical trial related expenses. The increase in accounts receivable and deferred revenue relate to the timing of milestone payments and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca.

Net cash used in operating activities was $5.6 million for the year ended December 31, 2012, and consisted primarily of a net loss of $32.6 million adjusted for non-cash items including stock-based compensation expense of $4.6 million, depreciation expense of $5.6 million, investment gains of $0.4 million, amortization of bond premium or discount of $0.9 million and a net decrease in operating assets and liabilities of $16.3 million. The change in operating assets and liabilities include an increase in accounts payable and accrued expenses of

$2.2 million and a decrease of $14.1 million in accounts receivable, offset by increases of $0.5 million in prepaid expenses and other current assets and $0.4 million in other assets. The increase in accounts receivable relate to the timing of milestone payments under our collaboration agreements with Astellas.

Investing Activities

Net cash provided by investing activities consisted of purchases of fixed assets, purchases of investments, and proceeds from the maturity and sale of investments.

Net cash provided by investing activities for the six months ended June 30, 2014 was $29.6 million and consisted of proceeds from maturities of investments of $33.5 million offset by $4.0 million in purchases of fixed assets. Net cash provided by investing activities for the six months ended June 30, 2013 was $5.7 million and consisted of $7.6 million in proceeds from sales and maturities of investments, offset by $1.9 million in purchases of fixed assets.

Net cash provided by investing activities for the year ended December 31, 2013 was $10.8 million and consisted primarily of proceeds from sales and maturities of investments of $17.6 million offset by $6.8 million purchases of fixed assets. Net cash provided by investing activities for the year ended December 31, 2012 was $19.2 million and consisted primarily of $22.1 million in proceeds from sales and maturities of investments, offset by $2.2 million in purchases of investments and $0.7 million in purchases of fixed assets.

Financing Activities

Net cash used in financing activities for the six months ended June 30, 2014 was $0.5 million and consisted of $1.2 million in payments in equity issuance costs (costs paid associated with the planned public offering of our securities) and $0.2 million of payments on our lease option liability, partially offset by $0.8 million in proceeds from issuance of common stock upon exercise of stock options. Net cash provided by financing activities for the six months ended June 30, 2013 was $0.5 million and consisted of $0.6 million in proceeds from a convertible promissory note and $0.2 million in proceeds from non-controlling interests, partially offset by $0.2 million of repayments on equipment loans and $0.2 million for payments on our lease option liability.

Net cash provided by financing activities for the year ended December 31, 2013 was $0.7 million and consisted of $0.6 million from our lease financing liability rent subsidy, $0.6 million in proceeds from a convertible promissory note and $0.2 million in proceeds from non-controlling interests. These amounts were partially offset by $0.3 million of repayments on equipment loans and $0.4 million on our option lease liability. Net cash provided by financing activities for the year ended December 31, 2012 was $6.8 million and consisted of $6.6 million proceeds from non-controlling interests, $0.8 million proceeds from notes receivable, and $0.2 million from issuance of common stock, offset by $0.3 million of repayments on equipment loans, and $0.4 million on our lease option liability.

During the years ended December 31, 2012 and 2013, we also drew down and fully repaid amounts on our credit facility of $17.3 million and $11.5 million, respectively.

Operating Capital Requirements

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one or more of our current or future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. 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. Upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We believe our existing cash and cash equivalents, short-term and long-term investments and payments due under our license and collaboration agreements will be sufficient to meet our working capital and capital expenditure needs for at least the next 12 months. Our longer term liquidity requirements may require us to raise additional capital, such as through additional equity or debt financings. Our future capital requirements will depend on many factors, including our ability to meet milestones under our current collaboration agreements, and the timing of our expenditures related to clinical trials.

In addition, we may require additional capital sooner for the further development of our existing product candidates and may also need to raise additional funds sooner to pursue other development activities related to additional product candidates.

Until we can generate a sufficient amount of revenue from our product candidates, if ever, we expect to finance future cash needs through public or private equity or debt offerings. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional equity or debt securities, it could result in dilution to our existing stockholders or increased fixed payment obligations, and any such securities may have rights senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

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 funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the rate of progress in the development of our product candidates;
- the costs of development efforts for our product candidates, such as FG-3019, that are not subject to reimbursement from our collaboration partners;
- the costs necessary to obtain regulatory approvals, if any, for our product candidates in the United States, China and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where approval is obtained;
- the continuation of our existing collaborations and entry into new collaborations;
- the time and unreimbursed costs necessary to commercialize products in territories in which our product candidates are approved for sale;
- the revenues from any future sales of our products for which we are entitled to a profit share, royalties and milestones;
- the level of reimbursement or third party payor pricing available to our products;
- the costs of establishing and maintaining manufacturing operations and obtaining third party commercial supplies of our products, if any, manufactured in accordance with regulatory requirements;
- the costs we incur in maintaining domestic and foreign operations, including operations in China;
- the costs associated with being a public company; and

- the costs we incur in the filing, prosecution, maintenance and defense of our extensive patent portfolio and other intellectual property rights.

If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

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.

Contractual Obligations and Commitments

Cease-Use Liability

In April 2009, in conjunction with the move of our headquarters to a new facility, we exited from one of the two buildings we formerly occupied. This facility closure was accounted for in accordance with accounting guidance related to costs associated with exit or disposal activities. Based upon this guidance, we recorded a cease-use liability equal to the net present value of the future minimum lease payments, net of expected future sublease payments, through the end of the remaining lease term. Any adjustments to the cease-use liability, due to factors such as expected future sublease payments, will be recorded in general and administrative expenses in the period those adjustments occur. A rollforward of the cease-use liability is shown below:

	Years Ended December 31, 2012	Years Ended December 31, 2013	Six Months Ended June 30, 2014 (unaudited)
	(in thousands)		
Beginning liability balance	$ 2,868	$ 1,861	$ 894
Payments made	(885)	(967)	(370)
Adjustments to estimates	(122)	—	—
Ending liability balance	$ 1,861	$ 894	$ 524

Contractual Obligations

At December 31, 2013, our contractual obligations were as follows:

	Payments due by period: Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
			(in thousands)		
Contractual obligations:					
Operating lease obligations	$ 3,917	$ 555	$ —	$ —	$ 4,472
Lease financing obligations	13,286	41,356	43,562	41,382	139,586
Total contractual obligations	$17,203	$41,911	$43,562	$ 41,382	$144,058

The contractual obligations table excludes uncertain tax benefits of approximately $13.5 million that are disclosed in Note 12 in the notes to our consolidated financial statements because these uncertain tax positions, if recognized, would be an adjustment to the deferred tax assets.

Clinical Trials

As of December 31, 2013, we have several on-going clinical studies in various stages. Under agreements with various clinical research organizations, or 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, 2013, our FibroGen Europe subsidiary had $13.0 million of principal outstanding and $5.3 million of interest accrued related to the TEKES loans, respectively, which have been included as product development obligations in 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.

Off-Balance Sheet Arrangements

During the year ended December 31, 2013, 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.

JOBS Act Accounting Election

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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 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.

In February 2013, we 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 of BDA. The lease financing obligation of approximately $3.1 million is payable in Renminbi and subject to fluctuation in the exchange rate with the U.S. dollar. During the year ended December 31, 2013, the effect of a hypothetical 10% change in foreign currency exchange rates would have resulted in a gain or loss on foreign currency of approximately $0.3 million.

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 in high quality and highly liquid U.S. government money market funds and in other money market funds in stable economies. A portion of our investments are invested in high quality corporate bonds and may be subject to interest rate risk and could fall in value if market interest rates increase. However, because we generally hold our bonds to maturity, we believe that our exposure to interest rate risk is not significant and a 1% change in market interest rates would not have a material impact on the total fair value of our portfolio. 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.

Recent Accounting Pronouncements

In April 2014, the FASB issued Accounting Standards Update (“ASU”) No. 2014-08, *Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity*.” The ASU amendment changes the requirements for reporting discontinued operations in Subtopic 205-20. The amendment is effective on a prospective basis for financial statements issued for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2014. Early adoption is permitted for disposals that have not been reported in financial statements previously issued. We will apply the provisions of this ASU to any future transactions after the effective date which qualify for reporting discontinued operations.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which supersedes the revenue recognition requirements in ASC 605, *Revenue Recognition*. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The ASU’s effective date will be the first quarter of fiscal year 2017 (for a public entity) or the first quarter of 2018 (for a non-public entity, but with earlier adoption permitted) using one of two retrospective application methods. We have not determined the potential effects of this ASU on our consolidated financial statements.

In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income* (ASU 2013-02). This accounting standard update requires an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. This ASU is effective for reporting periods beginning after December 15, 2012. We adopted this guidance in the first quarter of 2013 and the adoption of this guidance did not have an impact on our consolidated financial statements or results of operations.

In July 2013, the FASB issued ASU No. 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a Consensus of the FASB Emerging Issues Task Force)* (ASU 2013-02). This newly issued accounting standard update requires a liability related to an unrecognized tax benefit to be presented as a reduction of a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward if such settlement is required or expected in the event the uncertain tax position is disallowed. We adopted this guidance in the first quarter of 2014 and the adoption of this guidance did not have an impact on our consolidated financial statements.

BUSINESS

OVERVIEW

We are a research-based, biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutic agents to treat serious unmet medical needs. We have capitalized on our extensive experience in fibrosis and hypoxia inducible factor, or HIF, biology to generate multiple programs targeting various therapeutic areas. Our most advanced product candidate, roxadustat, or FG-4592, is an oral small molecule inhibitor of HIF prolyl hydroxylases, or HIF-PHs, in Phase 3 clinical development for the treatment of anemia in chronic kidney disease, or CKD. Our second product candidate, FG-3019, is a monoclonal antibody in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis, or IPF, pancreatic cancer and liver fibrosis. We have taken a global approach to the development and future commercialization of our product candidates, and this includes development and commercialization in the People’s Republic of China, or China.

We intend to leverage our extensive experience in fibrosis and HIF biology to build a successful biopharmaceutical company with a strong pipeline of products and product candidates for the treatment of anemia, fibrosis, cancer, corneal blindness and other serious unmet medical needs. Our near-term and long-term strategies include:

- Develop and, if approved, commercialize roxadustat with the assistance of our collaboration partners in the United States, Europe, China and Japan and the rest of the world, including enrolling and completing our global Phase 3 program in CKD anemia and seeking regulatory approval for roxadustat in multiple geographies, including as a Domestic Class 1.1 therapeutic in China.
- Enroll and complete our Phase 2 clinical studies of FG-3019 in IPF and pancreatic cancer, and initiate, enroll, and complete subsequent Phase 3 pivotal studies of FG-3019 in IPF and pancreatic cancer in the United States and potentially outside of the United States.
- Continue to pursue an extensive and multi-layered patent portfolio to protect our technologies and product candidates.
- Explore potential partnering opportunities for the development and commercialization of FG-3019 in certain territories.
- Develop FG-5200 for treatment of corneal blindness resulting from partial thickness corneal damage in China and elsewhere in the world.
- Strategically invest in the research and development of additional anemia indications for roxadustat, which may include chemotherapy-induced anemia, anemia relating to inflammatory diseases, myelodysplastic syndrome, or MDS, and surgical procedures requiring transfusions.
- Use our extensive HIF platform to increase our pipeline by exploring proof-of-concept with our HIF-PH selective inhibitors, such as FG-8205, and our other HIF-PH inhibitors, including FG-6874 (which has completed single and multiple ascending dose Phase 1 clinical studies in Singapore), in indications such as hematopoietic stem cell mobilization, peri-operative anemia, heart failure post-myocardial infarction, inflammatory bowel disease, diabetes, cancer and wound healing.
- Expand our efforts in fibrosis by pursuing additional indications for FG-3019, which may include Duchenne muscular dystrophy, scleroderma lung disease, liver fibrosis associated with graft rejection, non-alcoholic steatohepatitis, or NASH, diabetic nephropathy, focal segmental glomerular sclerosis, congestive heart failure, pulmonary arterial hypertension and cancers such as melanoma, ovarian, breast, and squamous cell lung carcinoma.

ROXADUSTAT FOR THE TREATMENT OF ANEMIA IN CHRONIC KIDNEY DISEASE

Roxadustat is an internally discovered HIF-PH inhibitor that acts by stimulating the body's natural pathway of erythropoiesis, or red blood cell production. Roxadustat, the first HIF-PH inhibitor to enter Phase 3 clinical development, represents a new paradigm for the treatment of anemia in CKD patients, with the potential to offer a safer, more effective, more convenient and more accessible therapy than the current standard of care, injectable erythropoiesis stimulating agents, or ESAs.

Roxadustat is currently in Phase 3 global development for the treatment of anemia in patients with chronic kidney disease, or CKD. 1,449 subjects have participated in 26 completed Phase 1 and 2 clinical studies for roxadustat in North America, Europe and Asia. These studies have demonstrated roxadustat's potential for a favorable safety and efficacy profile in anemic CKD patients, both those who are dialysis-dependent, or DD-CKD, and those who are not dialysis-dependent, or NDD-CKD. According to IMS Health, 2013 global ESA sales in all anemia indications totaled $8.6 billion. While the use of ESAs to treat anemia in CKD has largely been limited to use in DD-CKD patients, we and our partners believe that, as an oral agent with a potentially more favorable safety profile, roxadustat could increase accessibility and expand the market for anemia treatment by penetrating the NDD-CKD market. In the longer term, we believe roxadustat has the potential to address non-CKD anemia markets, including chemotherapy-induced anemia, anemia related to inflammation (such as inflammatory diseases), myelodysplastic syndrome, or MDS, and surgical procedures requiring transfusions.

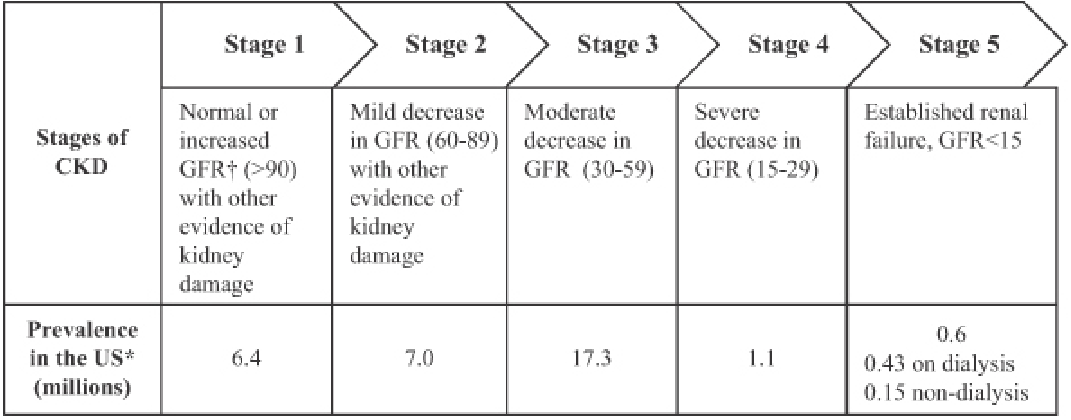
We, along with our collaboration partners Astellas Pharma Inc., or Astellas, and AstraZeneca AB, or Astra Zeneca, have designed a global Phase 3 program to support regulatory approval of roxadustat in both NDD-CKD and DD-CKD patients in the United States, the European Union, Japan and China. Our US and EU Phase 3 program has an aggregate target enrollment of approximately 7,000 to 8,000 patients worldwide and is the largest Phase 3 clinical program ever conducted for an anemia product candidate. Our Phase 3 program is also designed and sized for, and will incorporate major adverse cardiac events, or MACE, composite safety endpoints that we believe will be required for approval in the United States for all new anemia therapies. Our Phase 3 program will study multiple patient populations, including patients within the first four months of initiating dialysis, or incident dialysis, and non-incident, or stable, dialysis patients and will include multiple NDD-CKD studies comparing roxadustat against placebo control.

Background of Anemia in CKD

Anemia is a serious medical condition in which patients have insufficient red blood cells and low levels of hemoglobin, or Hb, a protein in red blood cells that carries oxygen to cells throughout the body. Anemia is associated with increased risks of hospitalization, cardiovascular complications, need for blood transfusion, exacerbation of other serious medical conditions and death. In addition, anemia frequently leads to significant fatigue, cognitive dysfunction, and decreased quality of life. The more severe the anemia, as measured in lower Hb levels, the greater the health impact on patients. Severe anemia is common in patients with CKD, cancer, MDS, inflammatory diseases, and other serious illnesses. Even when it accompanies prevalent and serious diseases, anemia is often not effectively treated.

Anemia is particularly prevalent in patients with CKD, which is a critical healthcare problem and is most commonly caused by diabetes and hypertension in the United States and Europe. CKD affects over 200 million people worldwide and anemia significantly increases healthcare costs for those patients. CKD is generally a progressive disease characterized by the gradual loss of kidney function that may eventually lead to kidney failure, also known as end stage renal disease, or ESRD. Patients with ESRD require renal replacement therapy—either dialysis treatment or kidney transplantation. CKD accompanied by anemia is associated with worse health outcomes than CKD alone, including more rapid progression of CKD and increased death rate. There are 5 stages of CKD which are primarily defined by a measure of the filtration function of the kidney (GFR).

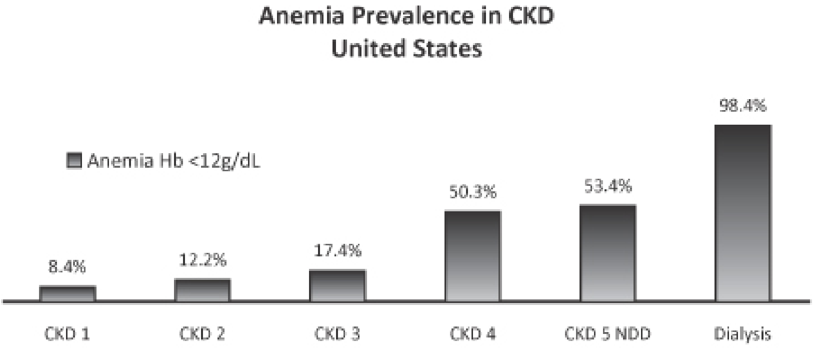
Stages of CKD and Prevalence in the United States



	Stage 1	**Stage 2**	**Stage 3**	**Stage 4**	**Stage 5**
Stages of CKD	Normal or increased GFR† (>90) with other evidence of kidney damage	Mild decrease in GFR (60-89) with other evidence of kidney damage	Moderate decrease in GFR (30-59)	Severe decrease in GFR (15-29)	Established renal failure, GFR<15
Prevalence in the US* (millions)	6.4	7.0	17.3	1.1	0.6 0.43 on dialysis 0.15 non-dialysis

* US prevalence is estimated for adults 20 years of age or older
† GFR: Glomerular Filtration Rate (ml/min/$1.73m^2$)
Sources: The prevalence of stage 1 through stage 4 CKD was calculated based on estimates by Kidney Disease Improving Global Outcomes (2012 guideline), 2011 estimates by the U.S. Renal Data System (USRDS) using data from the National Health and Nutrition Examination Survey (NHANES) 2005-2010 and 2011 data from the U.S. Census Bureau. The prevalence of stage 5 CKD was calculated based on 2011 data from the USRDS using data from NHANES 2005-2010 and 2011 data from the U.S. Census Bureau.

The prevalence rate of anemia in patients with Hb<12 g/dL is set forth below.



Sources: The prevalence of anemia in stage 1 through stage 4 CKD and stage 5 NDD-CKD were derived from Stauffer and Fan, Prevalence of Anemia in Chronic Kidney Disease in the United States, PLoS ONE (2014). The prevalence of anemia in patients undergoing dialysis was derived from Goodkin et al, Naturally Occurring Higher Hemoglobin Concentration Does Not Increase Mortality among Hemodialysis Patients, J Am Soc Nephrol (2011).

In the United States, according to the USRDS, a majority of dialysis eligible CKD patients are currently on dialysis. According to USRDS data as of 2011, approximately 430,000 patients were receiving dialysis in the United States, of whom approximately 80% were being treated with ESAs for anemia. Despite the presence of anemia in stages 3 and 4 CKD patients, in clinical practice, patients typically do not receive ESA treatment for their anemia until they initiate dialysis. In many CKD patients, the disease progresses gradually over decades, and, therefore, patients can spend years suffering from the symptoms and negative health impacts of anemia before they receive treatment. Many of these patients die from cardiovascular events before they initiate dialysis.

Limitations of the Current Standard of Care for Anemia in CKD

Current therapies to treat anemia in CKD include injectable ESAs, intravenous iron, or IV iron, oral iron and blood transfusions. ESAs are the current standard of care for effectively treating anemic CKD patients and are administered intravenously or subcutaneously, typically in conjunction with IV iron. ESAs currently on the market are all synthetic recombinant versions of human erythropoietin, or EPO, a hormone that stimulates erythropoiesis and increases Hb levels by binding to receptors on red blood cell precursors in the bone marrow.

The introduction of the first ESA in 1989 was viewed as a major advance in the treatment of anemia in CKD because it significantly decreased the need for blood transfusions. Since then, ESAs have become one of the most commercially successful drug classes. However, because ESAs were never studied relative to placebo in large randomized clinical trials prior to approval, it was not until years later that their safety profile became better elucidated. Studies published in 2006 to 2009 demonstrated the safety risks of higher ESA doses used to target Hb levels of 13 to 15 g/dL, prompting physicians to balance serious safety concerns against the efficacy of ESAs. The safety concerns observed with injectable ESAs in these studies included an increased risk of cardiovascular adverse events and death as well as a potentially increased rate of tumor recurrence in patients with cancer.

The emergence of the safety issues resulted in several changes to ESA drug labeling. This combination of safety concerns and labeling changes, in addition to the subsequent reimbursement changes, described below, was followed by a decline in ESA sales revenues beginning in 2007. While we believe this decline in ESA sales is primarily due to complete suspension of use of ESAs in anemias associated with cancer, and restrictions on use in chemotherapy induced anemia, we believe the decline in sales is also partly due to the progressive decline in ESA dose administered to CKD patients. Compared to the average ESA dose at the end of 2006, the mean monthly ESA dose in patients on hemodialysis dropped by 6%, 19% and 37% by the end of 2009, 2010 and 2011, respectively (USRDS ESRD Atlas 2013).

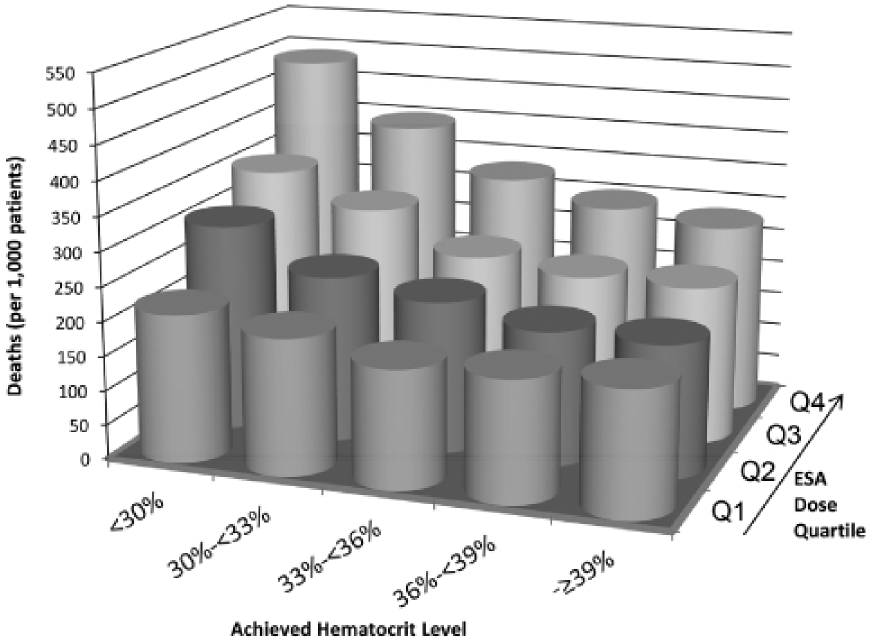
Safety Issues of ESAs

Several large clinical trials were designed to demonstrate that targeting higher as opposed to lower Hb levels results in better outcomes. However, they instead generated data showing that targeting higher Hb levels with ESAs resulted in an increase in adverse events, including cardiovascular adverse events. These adverse events were initially observed in 1998 in the NHCT (Normal Hematocrit Cardiac Trial) in CKD patients on dialysis, where the high Hb level treatment arm targeted Hb levels of 13 to 15 g/dL. Additional safety concerns emerged following the CHOIR (Correction of Hemoglobin in Outcomes and Renal Insufficiency), CREATE (Cardiovascular Risk Reduction by Early Anemia Treatment with Epoetin Beta), and TREAT (Trial to Reduce Cardiovascular Events with Aranesp Therapy) studies in NDD-CKD patients, which were published between 2006 and 2009.

Secondary analyses of NHCT, CHOIR and TREAT, as well as subsequent observational studies in dialysis patients, suggest that these safety concerns, particularly the increased cardiovascular risk associated with ESAs, may result from the high ESA doses used to target higher Hb levels rather than the achieved Hb levels themselves. For example, a secondary analysis of CHOIR showed that patients who achieved the desired Hb level with the lowest amounts of ESA have the lowest risk of adverse cardiovascular outcomes as measured by composite endpoints consisting of hospitalization for heart failure, heart attack, stroke, and death. Patients who were treated with the highest ESA doses and, particularly those who achieved the lowest Hb levels, had the greatest risk for these events. In addition, observational studies in patients undergoing dialysis highlighted these risks with high ESA doses and also indicated that higher Hb levels achieved with lower ESA doses were associated with better outcomes.

For example, in an analysis of data from the USRDS of 94,569 hemodialysis patients, increased mortality was found in patients with increased epoetin alfa dose. Patients who achieved the highest hematocrit level (which is a measure of the percentage of volume of whole blood made up of red blood cells; under typical conditions, Hb level can be estimated as one-third the hematocrit level) and received the lowest ESA doses (lowest dose quartile, Q1) had the lowest mortality rate, and, at any particular ESA dose quartile, patients with higher hematocrit levels tended to have lower mortality levels, according to Zhang et al (Am J Kidney Dis 44:866-876) as illustrated in the chart below.

Unadjusted 1-Year Mortality Rates (per 1000)
by Hematocrit and ESA dosing quartile



Warnings about these risks have been incorporated into guidelines and position papers from major kidney societies and thought leaders. Kidney Disease: Improving Global Outcomes, or KDIGO, a non-profit foundation established in 2003 and operated by the National Kidney Foundation, committed to improving global clinical guidelines for kidney patients, for example, states that, “[t]here may be toxicity from high doses of ESA, as suggested, though not proven, by recent post-hoc analyses of major ESA randomized controlled trials, especially in conjunction with the achievement of high Hb levels. Therefore, in general ESA dose escalation should be avoided.” In addition, the European Renal Best Practices Group specified in a recent position statement that caution should be used in ESA therapy in patients with specific risk factors.

Limited Effectiveness of ESAs in Certain Patient Populations

Hb responses to ESA doses are on a continuum with some patients responding with a satisfactory Hb increase to a small ESA dose and others responding very poorly to very high doses. In addition, patients’ responsiveness to ESAs can change over time and as a result of circumstances such as acute illness or surgery. In an attempt to reach target Hb level, ESA doses are increased in treatment-resistant patients, or hyporesponders, which can result in up to a 40-fold difference in ESA doses between the most ESA-resistant and the most ESA-responsive DD-CKD patients. Even with high doses of ESAs and concomitant IV iron, some of these hyporesponders are unable to reach target Hb levels.

Hyporesponsiveness is a significant problem in incident dialysis patients, for whom ESA doses are typically high, and is associated with a combination of critically low kidney function and accompanying illnesses, such as infections and chronic inflammation. Incident dialysis patients are generally more anemic, and have a higher risk of death, than patients who have been on dialysis for many months.

A major cause of ESA hyporesponsiveness is an underlying chronic inflammatory state that exists in many CKD patients. Chronic inflammation has a suppressive effect on erythropoiesis in CKD via two main mechanisms. Firstly, pro-inflammatory cytokines such as tumor necrosis factor alpha, or TNF-alpha, and interleukin-6, or IL-6, have been implicated in the suppression of erythropoiesis through inhibition of the response of erythroid progenitor cells to EPO. Secondly, pro-inflammatory cytokines such as IL-6 elevate the levels of hepcidin, the major hormone that regulates iron metabolism. The consequence of elevated hepcidin levels is a reduction in iron absorption from the gastrointestinal tract, or GI tract, and the trapping of iron in cellular stores. Together this leads to inadequate availability of iron to keep pace with the demands of the bone marrow for erythropoiesis, despite adequate total body iron stores. This condition is referred to as functional iron deficiency.

In the presence of inflammation, even high doses of ESAs may be ineffective to achieve target Hb levels, and to the extent Hb levels are raised, the risks associated with the higher ESA doses required may outweigh the benefits of any increased Hb levels.

Requirement for IV Iron to Support ESA Activity and Associated Safety Risks

IV iron supplementation is used to support anemia correction in a majority of hemodialysis patients treated with ESAs in the United States. ESA labeling indicates that physicians should evaluate the iron status in all patients before and during CKD anemia treatment and maintain iron repletion. Many CKD patients have deficient iron stores, or absolute iron deficiency, and cannot absorb enough iron from diet or oral iron supplements to correct this deficiency. Physicians administer IV iron to ensure patients are iron replete prior to initiating ESA treatment and continue IV iron to mitigate iron depletion caused by ESA-mediated erythropoiesis.

Additionally, many CKD patients who have adequate iron stores suffer from functional iron deficiency. IV iron is administered in an attempt to address this shortage of available iron in these CKD patients, resulting in many patients having elevated body iron stores. While IV iron can help correct anemia when used with ESAs, published studies have suggested acute and chronic risks of both morbidity and mortality associated with the use of IV iron. The acute risks of IV iron supplementation include hypersensitivity reactions (which can be life-threatening and the warning of anaphylaxis risk appears in every IV iron product package insert in the United States), infection, as well as less severe but more common side-effects, such as skin problems, hypotension and GI tract symptoms. In addition to acute side-effects, there may also be chronic adverse effects on organ systems related to the cumulative deposits of iron resulting from the volume of iron administered.

Using data from 12 countries obtained over the past twelve years, Bailie et al. demonstrated a direct dose risk relationship between the amount of IV iron administered per month to dialysis patients and the risk of hospitalization and death (Kidney International (2014)). The study identified that, even after controlling for other risk factors and adjusting for different practice patterns globally, dialysis patients receiving greater than 300 mg of IV iron per month had a greater risk of hospitalization or death than those receiving less than 300 mg. Mortality was 13% greater among those receiving between 300 and 400 mg of IV iron per month and 18% greater among those receiving greater than 400 mg of IV iron per month. Furthermore, hospitalization risk was 12% greater among those who received greater than 300 mg per month. The current paradigm of administrating greater doses of IV iron to decrease ESA doses in light of this recently described associated risk underscores the significant unmet need in the treatment of anemia.

Elevated Blood Pressure

ESAs have long been associated with increased blood pressure, including new onset hypertension and exacerbation of pre-existing hypertension. As a result, ESA labeling carries a warning for the potential for increased blood pressure with ESA usage. Hypertension has been shown to accelerate CKD progression and significantly increase the risk of death in CKD patients due to the increased risk of heart attack or stroke.

Increased Thromboembolism and Vascular Access Thrombosis

ESA use has been associated with thromboembolic events, including stroke, vascular access thrombosis (where the dialysis access shunt is blocked due to blood-clotting), blood clots in the leg, which may in part be due to increases in circulating platelet levels. As a result, ESA labeling carries a warning for an increased risk of thromboembolic events.

FDA Restrictions on ESA Usage

In response to safety concerns elucidated in the large clinical studies described above, the US Food and Drug Administration, or the FDA, steadily increased restrictions on the use of injectable ESAs from 2007 through 2011. During 2007, following the NHCT, CHOIR and CREATE studies and several oncology studies, the FDA mandated the inclusion of a boxed warning, or "Black Box" warning, in the package insert for ESAs. A Black Box warning is the strongest warning that the FDA can require in the package insert of prescription drugs. In June 2011, the FDA required further modification to the package insert for ESAs. The current boxed warning states that ESAs increase the risk of death, myocardial infarction, or heart attack, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence. In addition, the package insert changes include more conservative dosing guidelines for the use of injectable ESAs in anemic CKD patients. Specifically, the FDA removed the prior target Hb range of 10 to 12 g/dL and recommends that physicians initiate treatment of CKD patients when the Hb level is less than 10 g/dL and reduce or interrupt ESA dosing if the Hb level approaches or exceeds 10 g/dL for NDD-CKD patients and 11 g/dL for DD-CKD patients. In addition, physicians are advised to use only the lowest dose needed to avoid red blood cell transfusions.

Reimbursement Challenges Associated with ESAs

In addition to the safety concerns and labeling changes for ESAs, the reimbursement applicable to dialysis, including associated drugs such as ESAs, has also changed significantly in recent years, which made ESAs less economically attractive for providers to administer. Prior to January 2011, CMS reimbursed dialysis centers and other healthcare providers for use of ESAs at average selling price plus a premium to their cost, which enabled providers to realize a profit on the administration of ESAs, regardless of the quantity dosed. Under the Medicare Improvements for Patients and Providers Act, or 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 CMS based on the average cost per treatment, including the cost of ESAs and IV iron doses, typically without adjustment for usage.

ESAs administered to NDD-CKD patients have long been reimbursed under Medicare Part B, which requires providers to purchase and store ESAs in advance of being reimbursed, and in many healthcare practices, the amount reimbursed does not cover the cost of ESA administration. For many of these providers, including in nephrology practices where purchase and storing is most common, due to label changes and related reduction in patients available for treatment, ESA administration in NDD-CKD has become economically unattractive. Furthermore, non-nephrologists generally have elected not to provide ESAs. Accordingly, ESA treatment has been limited outside of dialysis centers.

Inconvenience of ESAs

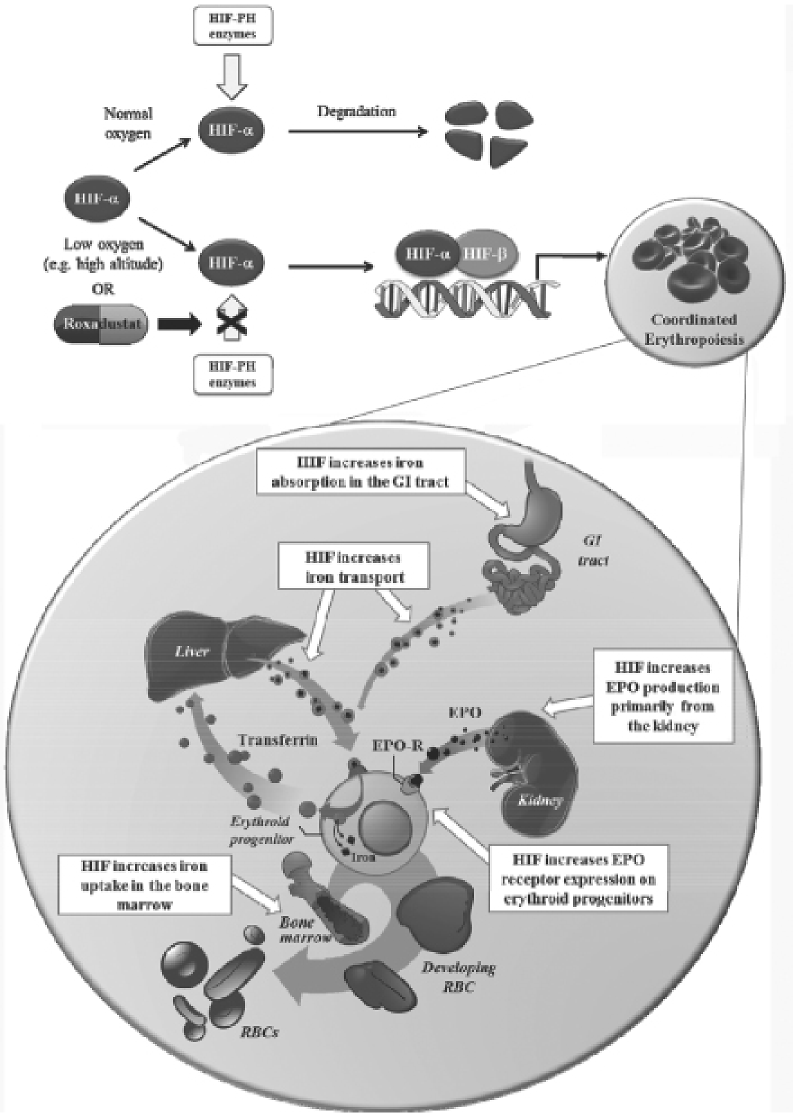
In addition to safety, labeling, reimbursement and efficacy limitations, ESAs must be administered intravenously or subcutaneously, often with IV iron in order for ESAs to be effective at treating to target Hb levels. ESAs are therefore inconvenient for the NDD-CKD population, the peritoneal dialysis population, for whom treatment is often administered at home, and other non-CKD anemia patients who are not already regularly visiting a hospital or dialysis center.

Our Solution

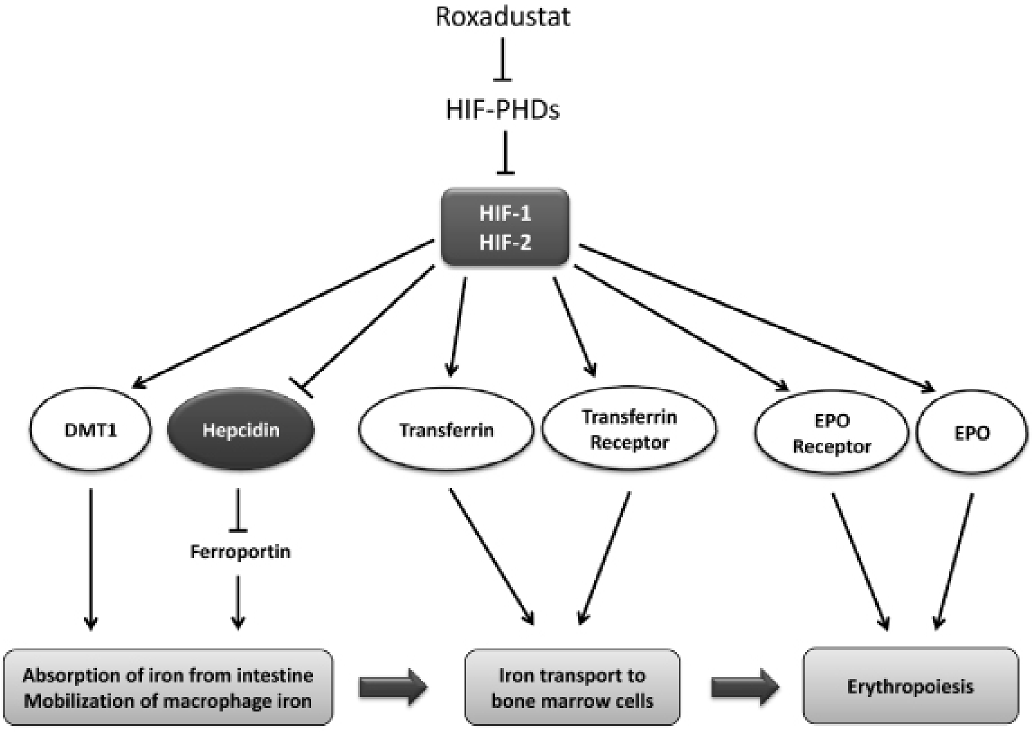
We believe that there is a significant need for a safer, more effective, more convenient and more accessible alternative to injectable ESAs for the treatment of anemia in CKD patients. In addition, we believe there is a significant opportunity for treatment of anemia in markets not effectively addressed by ESAs, such as in the NDD-CKD population and non-CKD anemia markets.

Roxadustat—A Novel, Orally Administered Treatment for Anemia

Roxadustat is an orally administered small molecule that corrects anemia by a different mechanism of action from that of ESAs. As a HIF-PH inhibitor, roxadustat activates a response that is naturally activated when the body responds to reduced oxygen levels in the blood, such as when a person adapts to high altitude. The response activated by roxadustat involves the regulation of multiple, complementary processes to promote erythropoiesis and increase the blood's oxygen carrying capacity. This coordinated erythropoietic response includes both the stimulation of red blood cell progenitors, by increasing the body's production of EPO, and an increase in iron availability for Hb synthesis. Patients taking roxadustat typically have EPO levels within or near the physiologic range naturally experienced by people 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 red blood cell progenitors 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 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.



Our HIF-PH inhibitor technology 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 transcribing the proteins shown below involved in iron absorption, mobilization and transport as well as stimulation of red blood cell progenitors.



Adapted from Prabhakar & Semenza. Physiological Reviews (2012) 92: 967-1003

Our discovery and development of roxadustat resulted from years of experience working with prolyl hydroxylase enzymes, such as those that regulate HIF, and a deep understanding of the complexities of HIF biology. We have explored therapeutic activation of HIF to treat anemia from an integrated perspective with a focus on applying our HIF-PH inhibitor technology to produce coordinated effects on erythropoiesis and iron homeostasis and metabolism. As part of these progressive efforts, we have explored the ability of our HIF-PH inhibitor technology to increase sensitivity to endogenous EPO by increasing EPO receptor expression on red blood cell progenitors. We have investigated multiple effects of HIF-PH inhibitors on iron metabolism, including their ability to regulate genes that can increase iron bioavailability. We have also shown that administration of HIF-PH inhibitors can decrease expression of hepcidin, the key hormone that regulates iron metabolism. Hepcidin is elevated under conditions of chronic inflammation, leading to reduced iron availability for erythropoiesis. Based on our gene expression and hepcidin data, we believe HIF-PH inhibitors can increase intestinal iron absorption and enhance the mobilization and uptake of iron. In addition, we have shown that HIF-PH inhibitors can improve transferrin saturation (a measure of circulating iron available for erythropoiesis) and can correct anemia associated with chronic inflammation by overcoming the hepcidin-mediated sequestration of iron that cannot be overcome by ESA therapy.

Based on our knowledge of HIF biology, we selected roxadustat from our extensive library of compounds from various chemical classes of HIF-PH inhibitors, including heterocyclic carboxamides and 2-oxoglutarate mimetics. Roxadustat was selected based on our belief that stabilizing the two main forms of HIF in the cell, HIF-1 and HIF-2, leads to a more complete erythropoietic response.

Although HIF-PH inhibitor programs have been subsequently initiated at several other companies, we expect to remain the leader in the development of HIF-PH inhibitors for anemia, with more patients dosed and more studies conducted with roxadustat than with any other HIF-PH inhibitor.

Potential Advantages of Roxadustat for Treatment of Anemia in CKD

We believe that roxadustat has the potential to offer several safety, efficacy, reimbursement, and convenience advantages over ESAs.

Potential Safety and Efficacy Advantages

Our clinical trials to date have shown that roxadustat can treat anemia in CKD with much lower circulating EPO levels than with treatment by ESAs, mitigate the need for IV iron and treat anemia in the presence of inflammation, thereby offering potential safety and efficacy benefits over ESAs. We have incorporated several endpoints into our Phase 3 studies to further elucidate and demonstrate these and other potential clinical benefits of roxadustat.

Potential Cardiovascular Benefits

The CKD patient population is at high risk for cardiovascular events such as heart attacks and strokes. One known side effect of ESAs is elevation of blood pressure, which is particularly dangerous in this high risk patient population. In contrast, we did not observe increases in blood pressure in patients treated with roxadustat beyond the background levels observed for the comparable placebo-treated patients in a NDD-CKD Phase 2 trial. However, these data should be cautiously assessed due to the limited number of patients exposed. The NDD-CKD patients treated with roxadustat three times weekly for more than 12 weeks had a modest decrease in blood pressure in a subgroup analysis of our Phase 2 NDD-CKD study.

In our Phase 2 studies, we did not observe a safety signal for thromboembolic risk. In contrast to the platelet increase with ESA treatment, platelet counts reported in roxadustat-treated patients did not increase, as those with platelet levels in the top 25th percentile at baseline saw their platelet levels decrease towards normal levels while those with platelet levels in the lower 75th percentile at baseline saw their platelet levels remain stable. This finding supports our belief in a potential safety benefit over ESAs since the platelet increase with ESAs could be a contributing factor in the thromboembolic risk associated with ESAs.

In addition, in our Phase 2 clinical trials, we observed reductions in total cholesterol and an improvement in average HDL / LDL ratio. Since many CKD patients have high cholesterol levels, which contribute to cardiovascular-related morbidity and mortality, the improvement in the average HDL / LDL ratio observed with roxadustat treatment could confer a benefit to patients.

Based on our preclinical and clinical data generated to date, we believe roxadustat could offer cardiovascular benefits to a CKD patient population that typically has cardiovascular-related co-morbidities and is at a high risk for cardiovascular events.

Potential for Anemia Correction with Moderate EPO Levels

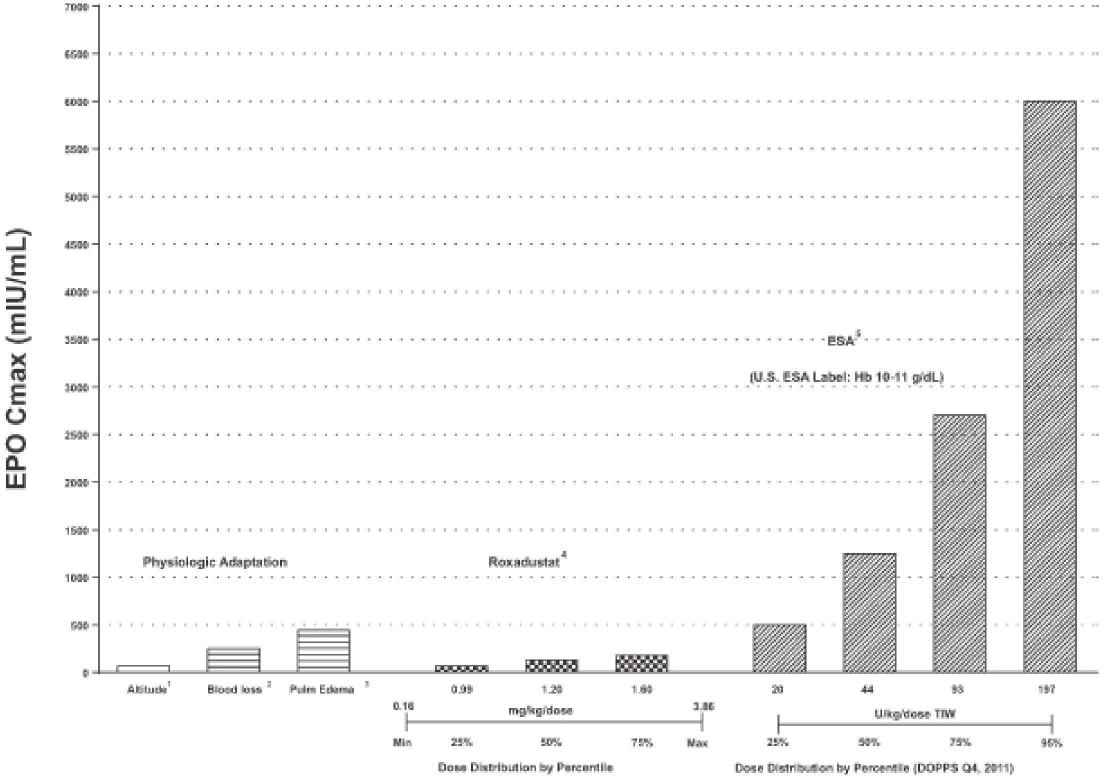
Randomized trials have suggested that high doses of ESAs administered in an attempt to achieve a target Hb level may cause the safety issues associated with ESA therapy. These high doses result in serum EPO levels much higher than physiological range. In contrast, the level of endogenous EPO elevation among patients treated with roxadustat is typically within or near the range observed when ascending to a higher elevation or giving blood. Treating anemia while maintaining lower circulating EPO levels may mitigate, or even avoid, the risks from ESA therapy, including cardiovascular events and death.

The following graph depicts:

1) the circulating endogenous EPO levels in natural physiologic adaptations, such as adjustment to high altitude, blood loss, or pulmonary edema [left, ▤];

2) transient peak endogenous EPO levels estimated for CKD patients who achieved a Hb response to therapeutic doses of roxadustat in our phase 2 clinical studies [middle, ▦];

3) the estimated peak circulating recombinant EPO levels resulting from IV ESA doses in distributions reported by the Dialysis Outcomes and Practice Patterns Study, or DOPPS, for the fourth quarter of 2011 in the United States (after bundling was initiated and when the Hb target in ESA labeling was in the range of 10-11 g/dL [right, ▨]).



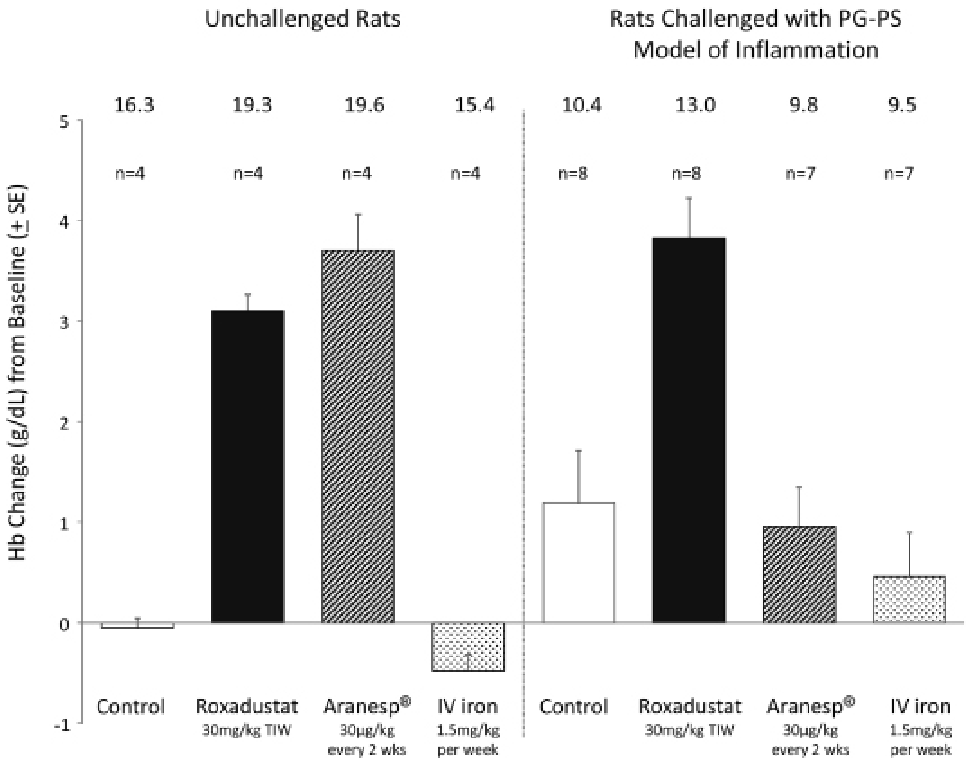
[1] Milledge & Cotes (1985) J Appl Physiol 59:360; [2] Goldberg et al. (1993), Clin Biochem 26:183, Maeda et al. (1992) Int J Hematol 55:111; [3] Kato et al. (1994) Ren Fail 16:645; [4] The transient peak endogenous EPO concentrations, or Cmax, data for roxadustat was derived from a subset of 243 patients who achieved a Hb response to roxadustat in our Phase 2 studies for whom we believe doses depicted approximated therapeutic doses. Hb target ranges for these patients were above the Hb levels specified in the current ESA package insert for CKD patients. Only doses in those patients whose Hb responded in Phase 2 studies are reflected in the figure. The subset of patients included 134 NDD-CKD patients treated to thrice-weekly, twice-weekly, or weekly doses of roxadustat for >16 weeks. The subset also included 109 DD-CKD patients, including incident dialysis patients whose anemia was corrected with therapeutic doses, and stable dialysis patients who received maintenance doses. EPO levels were not measured in all patients; instead EPO Cmax levels were estimated based on data derived from a more limited number of patients in whom EPO levels were measured at various roxadustat doses and among whom there was substantial variation in measured EPO levels. Accordingly, individual patients who received roxadustat may have realized EPO Cmax levels significantly above or below these estimated levels. Moreover, the estimates reflected in the graph may not be reflective of actual EPO Cmax levels or ranges that will be realized in larger populations of patients receiving roxadustat in our Phase 3 clinical trials. [5] EPO C_{max} was computed from ESA dose distributions based on Flaherty et al. (1990) Clin Pharmacol Ther 47:557.

Potential for Anemia Correction for Patient Populations that are Hyporesponsive to ESAs

Incident dialysis patients and patients who have chronic inflammation are often hyporesponsive to ESAs, which necessitates the use of higher doses of ESAs to increase Hb levels, thus increasing both safety risk and treatment cost. In contrast, the dose of roxadustat may not need to be increased in incident dialysis patients or to overcome the suppressive effects of inflammation on erythropoiesis, which we believe may confer significant safety and efficacy benefits.

As a result of roxadustat’s different mechanism of action, the ability of roxadustat to stimulate erythropoiesis does not appear to be impaired by chronic inflammation. In a preclinical model of inflammation induced by peptidoglycan-polysaccharide (PG-PS) polymers, roxadustat increased Hb levels and mean corpuscular volume (MCV), whereas Aranesp®, an ESA, and IV iron did not increase Hb or MCV. In contrast, the same doses of roxadustat and Aranesp® were both effective at raising Hb levels in the unchallenged rats (without inflammation). In addition, the ESA actually decreased MCV in the unchallenged rats, as compared to the control.

Increase in Hb after 2 Weeks in Preclinical Model of Inflammation



Our preclinical studies indicate that roxadustat can overcome the direct suppressive effects of inflammatory cytokines on erythropoiesis. In addition, roxadustat can reduce hepcidin levels, thus increasing absorption of iron from the GI tract and the release of iron from intracellular stores and mitigating the functional iron deficiency associated with chronic inflammation.

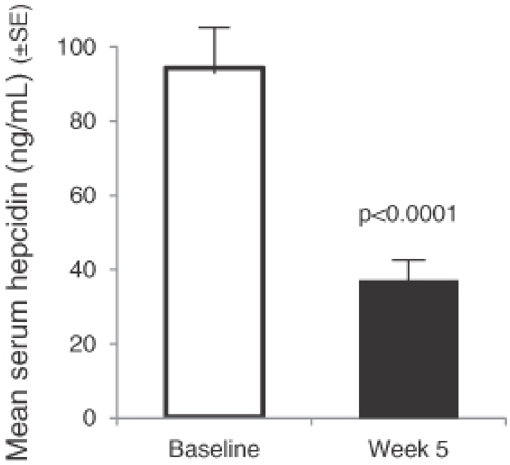
Furthermore, in our Phase 2 studies, patients’ Hb response to roxadustat was independent of the degree of underlying inflammation, as assessed by circulating levels of C-reactive protein, or CRP, a well-recognized marker of inflammation. Incident dialysis patients have the highest levels of mortality of all dialysis patients. The incident dialysis period is also the period during which mean ESA doses are generally highest. To the extent the increased levels of mortality are associated with high ESA doses, roxadustat may offer a benefit to incident dialysis patients. The median roxadustat dose in our dialysis Study 053 was 1.3 mg/kg; the endogenous EPO levels usually associated with this dose level are comparable to the physiologic range naturally experienced by people adapting to high altitude or following blood donation. See additional information on endogenous EPO levels under the heading “Potential for Anemia Correction with Moderate EPO Levels”.

Potential for Reduced Hepcidin Levels and Anemia Correction Without IV Iron

An important differentiator of roxadustat from ESAs is that roxadustat is expected to correct anemia and maintain Hb without IV iron supplementation. Patients with chronic illness, such as CKD, often suffer from absolute iron deficiency or functional iron deficiency. We believe that elevated levels of hepcidin, the major hormone that regulates iron metabolism, contributes to both absolute and functional iron deficiency.

Our Phase 2 clinical trials have shown that roxadustat can significantly reduce hepcidin levels in patients with DD-CKD and NDD-CKD. The following figure shows a reduction in serum hepcidin level of approximately two thirds, observed at week 5, in 52 incident dialysis patients treated with roxadustat.

Reduction of Serum Hepcidin Levels (Study 053) in Incident Dialysis Patients



In addition, we believe roxadustat increases the levels of proteins involved in iron uptake, release and transport. Data from our Phase 2 clinical trials indicate that oral iron supplementation alone is adequate to correct anemia during treatment with roxadustat, in contrast to ESAs which typically require IV iron supplementation. Additionally, our data indicate that unlike ESAs, roxadustat treatment does not require that patients be iron replete before initiating therapy.

Avoiding IV iron helps to avoid the significant safety risks associated with IV iron described above, and, because the cost of oral iron is significantly less than the cost of IV iron, could also confer significant costs savings.

Potential Reimbursement and Convenience Advantages

Potentially Differentiated Reimbursement Framework

ESAs are included in the MIPPA bundled payment system in the DD-CKD setting and reimbursed under Medicare Part B in the NDD-CKD setting. Based on our roxadustat data to date, we believe roxadustat has the potential to correct anemia through a differentiated mechanism of action and different therapeutic effects that create the potential to displace multiple drugs in current use (such as ESAs and IV iron), or those in development (such as agents for suppression of hepcidin). Although the bundle currently covers ESAs or oral equivalents of ESAs or other IV products encompassed by the bundle, due to the differentiated nature of roxadustat and a lack of definition in the regulations on oral equivalency, for which there may be a CMS determination later this year, it is unclear whether roxadustat will be included in or excluded from the bundle. Under MIPPA, agents that have no IV equivalent in the bundle are currently expected to be excluded from the bundle until 2024. We believe that there may be commercial benefits in either event but are unable to predict the potential benefits until further guidance from CMS becomes available.

In the NDD-CKD setting, we expect that roxadustat, an oral treatment, should be subject to Medicare Part D, which would allow physicians to prescribe roxadustat without the financial and reimbursement risk associated with purchasing and storing injectable ESAs. We believe that this should encourage significantly greater usage outside of the dialysis setting.

Potential Reduction of Other Medications

In addition to potentially eliminating the need for IV iron, based on our Phase 2 clinical trial results to date, we believe that roxadustat has the potential to reduce the use of other medications frequently required in some CKD anemia patients, such as anti-hypertensives, anti-coagulants, and statins.

Oral Administration

Many physicians that treat CKD patients, particularly cardiologists, endocrinologists, and internists, do not typically stock or administer ESAs. An easily accessible oral agent that is dispensed by pharmacies could significantly increase the number of physicians treating anemia in patients with CKD and therefore the number of patients receiving treatment.

In addition, the oral administration of roxadustat potentially offers a significant convenience advantage for CKD patients who have yet to initiate dialysis and are therefore not regularly visiting a dialysis center. Patients can more easily self-administer medicine in any setting, rather than being subject to the inconvenience and restrictions of regular visits to physicians’ offices or infusion centers for treatment with ESAs.

Potential Pharmacoeconomic Advantages

Based on our Phase 2 clinical trial results to date, we believe that roxadustat’s potential pharmacoeconomic advantages over ESA therapy may include safety (with a potential decrease in cardiovascular events and consequently lower associated treatment costs), lower administrative cost, reduction or elimination of IV iron and potentially other medications. If we can demonstrate any of these pharmacoeconomic advantages in our Phase 3 studies, they may help support reimbursement worldwide, including Europe and China.

The Market Opportunity for Roxadustat

We believe that there is a significant opportunity for roxadustat to address markets currently served by injectable ESAs. According to IMS Health, 2013 global ESA sales in all indications totaled $8.6 billion, driven primarily by $6.2 billion in the United States and Europe. We believe that a substantial portion of ESA sales are for CKD anemia. For example, in the U.S., EPOGEN, which is primarily used in the DD-CKD patient population, had 2013 sales of approximately $2 billion. 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.

Furthermore, we believe that there is a significant opportunity for roxadustat to address patient segments that are currently not effectively served by ESAs, such as anemia in the NDD-CKD patient population, which is substantially larger than the DD-CKD patient population. Diabetes and hypertension are the leading causes of secondary CKD. Although we estimate approximately 36% of diabetic and 20% of hypertensive CKD patients are anemic (Hb<12g/dL), we believe the majority of these patients are currently untreated for anemia since they are under the care of non-nephrology specialists, such as endocrinologists, diabetologists, cardiologists and internists, where ESA therapies are not readily available.

We also believe that roxadustat may provide a safer option to re-establish the chemotherapy induced anemia market, which was once a market of comparable size to the DD-CKD anemia market. Other non-CKD anemias, including anemia related to inflammatory diseases, MDS and surgical procedures requiring transfusions, which are not addressed adequately with currently available therapies, could form another opportunity.

OUR DEVELOPMENT PROGRAM FOR ROXADUSTAT

As of October 22, 2014, there have been 1,932 subjects enrolled in more than 32 roxadustat clinical studies in North America, Latin America, Europe, and Asia, of which 1,503 subjects have been exposed to roxadustat. We have treated some of these patients for 24 weeks in Phase 2 studies, and several patients for 3 years in a safety extension study.

We along with our partners, Astellas and AstraZeneca, have designed our global Phase 3 program to support regulatory approval of roxadustat in both NDD-CKD and DD-CKD patients in the United States, the European Union, Japan and China. Our US and EU Phase 3 program has an aggregate target enrollment of approximately 7,000 to 8,000 patients worldwide and is the largest Phase 3 clinical program ever conducted for an anemia product candidate. Our U.S. Phase 3 program is also designed and sized for demonstrating non-inferiority to comparators for the MACE composite safety endpoints in two separate patient pools, NDD-CKD and DD-CKD. We believe this will be required for approval in the United States for all new anemia therapies. Our Phase 3 program will study multiple patient populations, including incident dialysis patients and stable dialysis patients and will include multiple NDD-CKD studies comparing roxadustat against placebo controls. Five of the six Phase 3 studies supporting approval in the EU use the same patients that are intended to support approval in the United States. However, the EU requires shorter treatment duration and less overall patient exposure. We currently expect to complete patient enrollment in our U.S. studies by or in the first half of 2016, and that data for U.S. Phase 3 NDD-CKD studies will be reported in 2017.

We have a separate roxadustat clinical development program for China and we currently plan to initiate Phase 3 studies in the first half of 2015 through FibroGen China. In addition, Astellas is developing roxadustat in Japan as part of a Japan-specific development program and is currently conducting Phase 2 studies there.

Our Phase 2 Program

We have completed and analyzed six roxadustat Phase 2 studies, three in NDD-CKD patients and three in DD-CKD patients, to assess the efficacy of roxadustat to both correct anemia (“correction”) and maintain the Hb response (“maintenance”). Data from these studies have been published and presented at various medical conferences. Two of the six completed Phase 2 studies were conducted in China. The efficacy and safety data generated from our China studies were consistent with our U.S. Phase 2 studies and further contributed to the promising efficacy and safety results to date. Our collaboration partner Astellas’ Japan Phase 2 dialysis study in patients with CKD anemia has been completed, and data reconciliation and analysis are in process.

The data from our completed Phase 2 studies demonstrated that roxadustat achieved a clinically meaningful increase in Hb levels in anemic NDD-CKD and DD-CKD patients and maintained Hb levels in DD-CKD patients who were converted from ESA therapy. Roxadustat corrected anemia without the need for IV iron supplementation and exhibited an acceptable safety profile. Specifically, our Phase 2 studies achieved the following objectives:

- Identified optimal roxadustat dosing regimens for anemia correction and maintenance of Hb response.
- Demonstrated roxadustat’s potential to treat anemia in both NDD-CKD and DD-CKD patients, including incident dialysis patients, the most unstable and high risk CKD patient population.
- Generated substantial safety data, indicating that roxadustat is well tolerated, appears safe and could offer an improved cardiovascular profile relative to ESAs. Including our Phase 1, 2 and 3 studies 1,503 subjects have been exposed to roxadustat.
- Demonstrated that roxadustat may be able to treat anemia without the need for IV iron supplementation.
- Demonstrated that roxadustat can reduce hepcidin levels and potentially treat anemia in a significant subset of patients with inflammation.

The following chart summarizes the design of our completed studies in DD-CKD and NDD-CKD patients and indicates the primary objectives of each study.

Completed Phase 2 Studies

Study Number, Study Location	CKD Patient Population	Study Objective	Number of Roxadustat Patients	Number of Comparator Patients		Total Number of Patients in Study	Treatment Duration (Weeks)	Dose Frequencies
				Placebo	ESA			
FGCL-4592-017 US	Non-dialysis	Correction, PK	88	28		116	4	TIW, BIW
FGCL-4592-041 US	Non-dialysis	Correction & Maintenance	145			145	16;24	TIW, BIW, QW
FGCL-4592-047 China	Non-dialysis	Correction	61	30		91	8	TIW
FGCL-4592-040 US	Stable Dialysis	Conversion & Maintenance	117	4	40	161	6;19	TIW
FGCL-4592-053 Russia, US, Hong Kong	Incident Dialysis	Correction	60			60	12	TIW
FGCL-4592-048 China	Stable Dialysis	Conversion, PK	74		22	96	6	TIW
Total			**545**			**669**		

QW = weekly; BIW = twice weekly; TIW = three times weekly

The following chart summarizes the design of our ongoing Phase 2 studies and indicates the primary objectives of each study.

Ongoing Phase 2 Studies

Study Number, Location	CKD Patient Population	Study Objective	Number of Roxadustat Patients	Number of Comparator Patients		Total Target Number of Patients in Study	Treatment Duration (weeks)	Dose Frequencies
				Placebo	ESA			
1517-CL-0303* Japan	Non-dialysis	Correction	75	25		100	24	TIW, QW
1517-CL-0304* Japan	Dialysis	Maintenance	90		30	120	24	TIW
FGCL- 4592-059 US	Non-dialysis & Dialysis	Long Term Safety & Maintenance	15			15	260+	TIW, BIW, QW

*Studies1517-CL-303 and -304 are being conducted by Astellas

QW = weekly; BIW = twice weekly; TIW = three times weekly

Study 017: Dose Escalating Study in NDD-CKD patients

Study 017 established proof of concept for roxadustat by showing a significant increase in Hb in a dose-dependent manner, and provided data on the relationship between roxadustat dose and Hb response. This formed the basis for the dosing rules that we applied in subsequent studies of longer duration and in a larger number of patients.

This study, a randomized, single-blind, placebo-controlled, dose-escalation study, was the first Phase 2 study to assess the safety and efficacy of a range of roxadustat doses in the correction of anemia in NDD-CKD stage 3 and 4 patients, over four weeks of treatment, and a 12-week safety follow-up period. A total of 116 patients (of which 96 were evaluable) were randomized sequentially into four weight-based dose cohorts: 1 mg/kg, 1.5 mg/kg, 2 mg/kg, and 0.7 mg/kg, respectively. Roxadustat was administered either twice weekly or three times weekly.

Weight Based, Three Times Weekly and Twice Weekly Dosing Leads to Hb Improvement. We tested 4 different roxadustat weight-based doses administered for four weeks with Hb measurements over a six week period. As shown in the table below, all of the patients in the highest weight-based dose cohort met the criteria for response in that they achieved Hb rise ≥ 1 g/dL in four weeks. As roxadustat achieved 100% Hb response at the 2 mg/kg dose, higher doses were not pursued in this study despite the absence of dose limiting toxicity. Roxadustat was well tolerated without any safety concerns.

Significant, Dose Dependent Increases in Hb. As shown in the table below, the dose-dependent change in Hb from baseline in roxadustat patients was statistically significant from placebo by Day 8 (p=0.025) and remained so at each assessment through Week 6 (p=0.0001 at Day 22; p<0.0001 at Day 26–29/end of treatment).

A p-value is a statistical measure of the probability that the difference in two values could have occurred by chance. The smaller the p-value, the greater the statistical significance and confidence in the result. Typically, results are considered statistically significant if they have a p-value less than 0.05, meaning that there is less than a one-in-20 likelihood that the observed results occurred by chance. The FDA requires that sponsors demonstrate the effectiveness and safety of their product candidates through the conduct of adequate and well-controlled studies in order to obtain marketing approval. Typically, the FDA requires a p-value of less than 0.05 to establish the statistical significance of a clinical trial, although there are no laws or regulations requiring that clinical data be statistically significant, or that require a specific p-value, in order for the FDA to grant approval.

Hb Responses to a Range of Roxadustat Doses in FGCL-4592-017

		0.7 mg/kg		**1 mg/kg**		**1.5 mg/kg**		**2 mg/kg**	
	Placebo	**BIW**	**TIW**	**BIW**	**TIW**	**BIW**	**TIW**	**BIW**	**TIW**
N	23	10	12	5	5	10	11	9	11
Mean Maximum Change in Hb	0.44	0.82	1.22	1.12	0.81	1.74	2.03	1.93	2.16
Standard Error of the Mean	0.11	0.28	0.37	0.26	0.45	0.32	0.26	0.22	0.25
% Hb Responder	13%	30%	58%	60%	40%	80%	91%	100%	100%
Median Time to Response (Days)	NA	NA	26.5	42	NA	24.5	14	21	14

BIW = twice weekly; TIW = three times weekly

Standard error of the mean, or SE, is a statistical measure of the amount that an observed mean may be expected to differ by chance from the true mean. For a population that follows a normal distribution, 68% of observed means will be within one standard error of the mean.

Dose-Dependent Reduction in Hepcidin Levels. Roxadustat reduced serum hepcidin levels in a dose-dependent fashion.

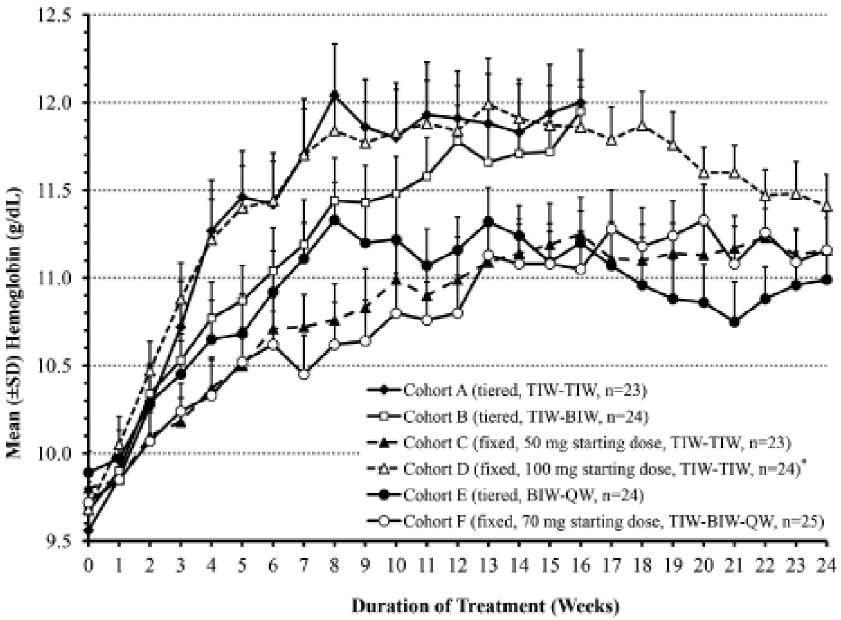
Study 041: Study for Optimization of Starting Dose and Dose Titration in NDD-CKD Patients

Study 041 demonstrated that both tier-weight and fixed starting doses can initiate anemia correction. In tier-weight based dosing for this study, we used starting doses based on the patient's body weight category: high, middle or low. This randomized, open-label Phase 2 study was designed to evaluate the efficacy and safety of roxadustat over 16 to 24 weeks in 145 NDD-CKD patients (of which 143 were efficacy evaluable), and to evaluate the effects of dosing regimens in order to determine an optimized approach to anemia correction. In this trial, we tested six different starting dose regimens: three fixed doses, and three tier-weight doses. In fixed dosing, all patients in the same cohort were given the same starting dose.

We tested both three times weekly and twice weekly dosing frequencies for anemia correction, similar to Study 017, and further demonstrated that Hb levels can be maintained using 3 dosing frequencies (three times weekly, twice weekly and weekly) once target Hb ³ 11 g/dL was achieved. We also studied various dose adjustment rules, with dose adjustment decisions made from 5 weeks onward, and every 4 weeks thereafter, to seek the best dose titration scheme.

Hb Correction. We met the primary efficacy endpoint of cumulative number (%) of patients with a Hb response, defined as an increase in Hb ³ 1.0 g/dL from baseline and Hb ³ 11.0 g/dL at the end of treatment. Regardless of the starting dose or dose titration scheme, 92% of patients collectively from all cohorts achieved an Hb increase of at least 1 g/dL from baseline. These data suggest the doses studied are of adequate range for anemia correction. The following figure shows mean Hb levels for the six dose groups.

FGCL-4592-041 Hb Response Over Various Dosing Regimens

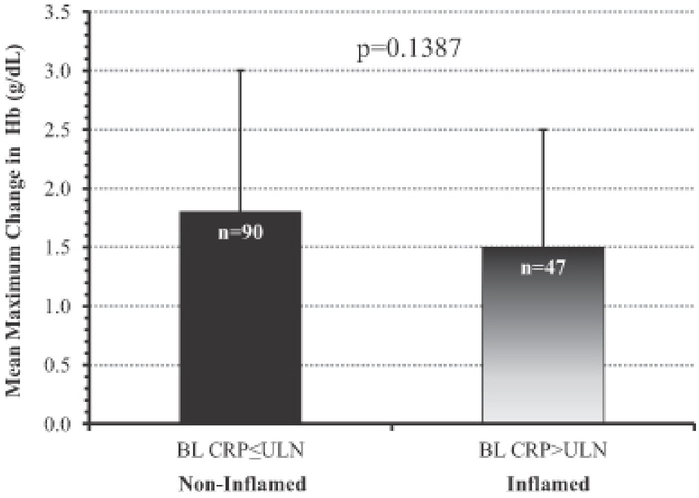


*** n at baseline**

TIW = three times weekly; BIW = twice weekly; QW= once weekly

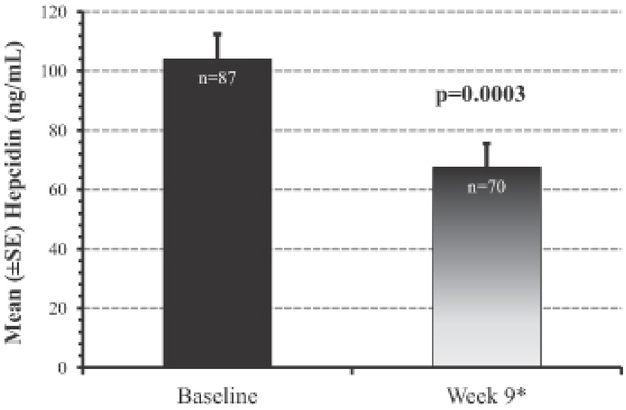
Hb Correction was Independent of Inflammation Status. In this study, in a post-hoc analysis, we observed that the magnitude of increases in Hb in response to roxadustat treatment was comparable for both patients with inflammation (elevated CRP levels) and without inflammation (normal CRP levels).

FGCL-4592-041 Mean (± SE) Maximum Change in Hb (g/dL) in 12 Weeks



This stands in contrast to treatments with ESAs, where elevated CRP is frequently associated with lower Hb response to ESAs. We observed a 30% reduction in mean hepcidin level from baseline with eight weeks of roxadustat treatment (p=0.0003), which supports our belief in roxadustat’s ability to overcome inflammation and to maintain iron availability for erythropoiesis.

FGCL-4592-041 Mean (± SE) Serum Hepcidin Level (ng/mL)



Hb Correction Without IV Iron and in Patients Who Have Low Iron Levels at Study Initiation. In connection with the conduct of the study, we also evaluated several iron parameters to assess roxadustat’s ability to improve Hb without the use of IV iron. At baseline, 49% of the efficacy evaluable patients did not have sufficient iron levels in the body to qualify for initiation of ESA treatment under current practice guidelines and would have been excluded from participation in all prior ESA Phase 3 trials. These patients would not be considered iron replete and are typically first treated with IV iron prior to ESA treatment initiation in an effort to ensure an adequate response to ESA and to minimize the risk of iron depletion. Of all patients in this study receiving roxadustat, only 38% were taking oral iron supplements. A mean Hb increase of 1.8 g/dL was achieved in the first 16 weeks of treatment without IV iron supplementation. There was no evidence for iron depletion as CHr, reticulocyte hemoglobin content or the amount of Hb in newly formed red blood cells, was maintained. Furthermore, there was evidence for improved iron utilization with increases in the MCV and increase in mean corpuscular hemoglobin concentration (MCHC) over the first 16 weeks of treatment with roxadustat from baseline ($p=0.0018$ and $p<0.0001$, respectively); both MCV and MCHC typically decrease when there is iron deficiency.

Despite the minimal use of oral iron and lack of IV iron usage, patients who were not iron replete had similar Hb responses at Week 16 as patients who were iron replete.

Reduction in Cholesterol Levels. In a post-hoc analysis of all cohorts, total cholesterol decreased during treatment with roxadustat. Mean reductions in total cholesterol were greater for patients with abnormally high cholesterol levels (> 200mg/dL). Decreases in cholesterol levels were independent of whether patients were taking statins or other lipid lowering agents. Furthermore, the HDL/LDL ratio improved with roxadustat treatment in the subgroup of patients in whom lipid profiles were conducted.

Improvement in Quality of Life. Finally, in an analysis of exploratory endpoints we observed improved quality of life in patients treated with roxadustat using a standard questionnaire called the SF-36 HRQOL. The largest positive changes from baseline occurred in the Vitality subscale (>4 points, $p<0.0001$) and Physical Component (>1.6 points, $p<0.005$) subscales of the questionnaire. We believe these data demonstrate that by correcting patients' anemia, roxadustat may improve quality of life.

Study 040: ESA Conversion Study in DD-CKD Patients

Study 040 was designed to evaluate the short- and long-term dosing of roxadustat in patients on hemodialysis, or HD, treatment. These results established a conversion dose relationship between ESAs and roxadustat that will be used for Phase 3 trials. Roxadustat maintained Hb without the use of IV iron, which is generally required for the treatment of anemia by ESAs.

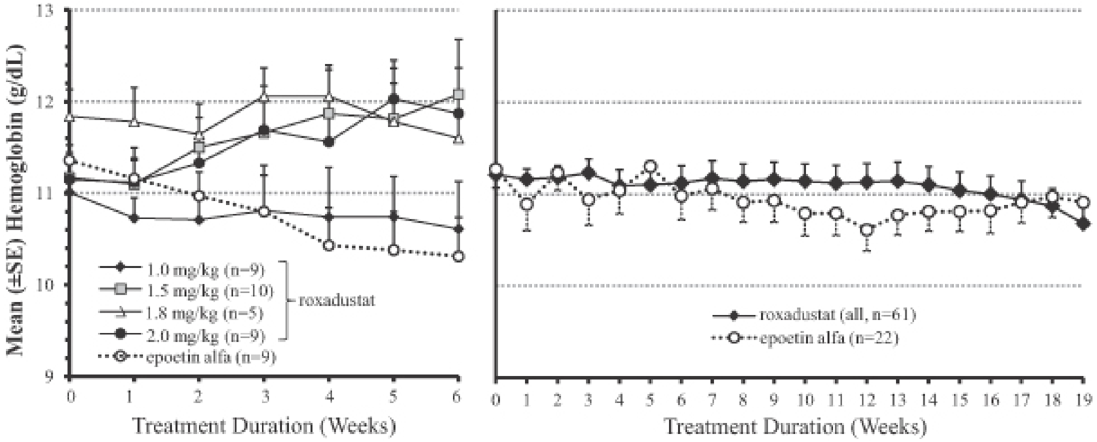
This randomized, single-blind study was the first roxadustat study in patients on HD treatment. Part 1 was a six week open-label Phase 2 dose ranging study in 54 patients (of which 42 were efficacy evaluable) to evaluate the impact of 4 sequential doses of roxadustat on dialysis patients' Hb levels over six weeks upon switching from epoetin alfa, in comparison to those continuing prior epoetin alfa doses. Part 2 was a 19 week treatment study in 90 patients (of which 83 were efficacy evaluable) to establish optimal conversion doses and dose adjustments. Patients included had previously demonstrated a wide range of ESA-responsiveness. Study 040 met its primary endpoint in Part 1 of maintaining Hb in patients previously treated with epoetin alfa at Week 6, indicating that roxadustat can replace ESAs in DD-CKD. Study 040 also met its primary endpoint in Part 2 of maintaining Hb at Week 19, indicating that roxadustat may be effective at long-term maintenance of Hb. IV iron was prohibited in both roxadustat treated patients and ESA treated control patients during this study.

Maintenance of Hb Levels Following Conversion from ESAs. In Part 1 of this study (six week treatment), 41 patients were randomized to one of four roxadustat dose cohorts, and 13 were randomized to continue on epoetin alfa treatment. The primary endpoint was maintaining an Hb level equal to or above 0.5 g/dL below baseline Hb by the end of six weeks. As shown in the figure below, roxadustat had a dose-response effect for maintaining Hb levels. The lowest roxadustat dose cohort of 1.0 mg/kg was comparable to epoetin alfa with maintenance in 44% of roxadustat patients and 33% of the control arm, patients who continued treatment with epoetin alfa (but who were required to stop concomitant treatment with IV iron). Roxadustat doses of 1.5 mg/kg or higher were better than epoetin alfa at maintaining Hb, with 79.2% overall maintenance and with 80% maintenance at the 1.5 mg/kg roxadustat dose, 80% maintenance at the 1.8 mg/kg roxadustat dose and 77.8% maintenance at 2 mg/kg roxadustat dose.

In Part 2 of the study (19 week treatment), 67 patients (with baseline ESA dose requirements ranging from 7 to 164.5 U/kg three times weekly) were randomized to seven cohorts of roxadustat (with various starting doses) and 23 patients were randomized to continue on epoetin alfa. Hb correction in the roxadustat treated patients pooled across all treatment cohorts was maintained over the 19 week treatment period and was comparable to epoetin alfa. The average roxadustat dose requirement for Hb maintenance was approximately 1.70 mg/kg three times weekly.

In Part 1, which was dose ranging, we observed an increase in Hb level at doses of 1.5 to 2.0 mg/kg TIW as shown in the figures below. In Part 2, which was to establish the optimal conversion dose, we observed similar Hb maintenance between roxadustat and epoetin alfa.

FGCL-4592-040 Mean: (± SE) Hemoglobin Over Time During Anemia Treatment with Roxadustat or Epoetin Alfa in Dialysis Patients

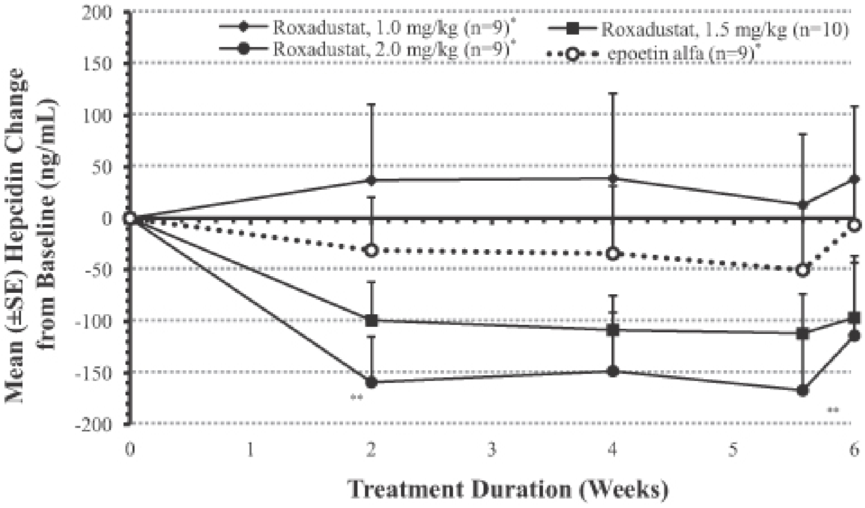


Part 1 (6 Weeks Dosing)

Part 2 (19 Weeks Dosing)

In addition, in an exploratory analysis of this study we observed a dose dependent decrease in hepcidin in Part 1 of this study.

FGCL-4592-040: Change in Hepcidin Level from Baseline (ng/mL)

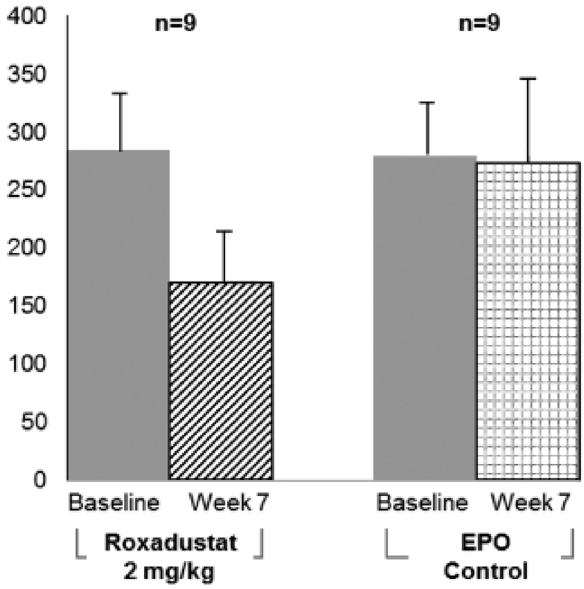


* n at baseline

** p<0.05 (comparing hepcidin change from baseline between the 2.0 mg/kg roxadustat group and the epoetin alfa group).

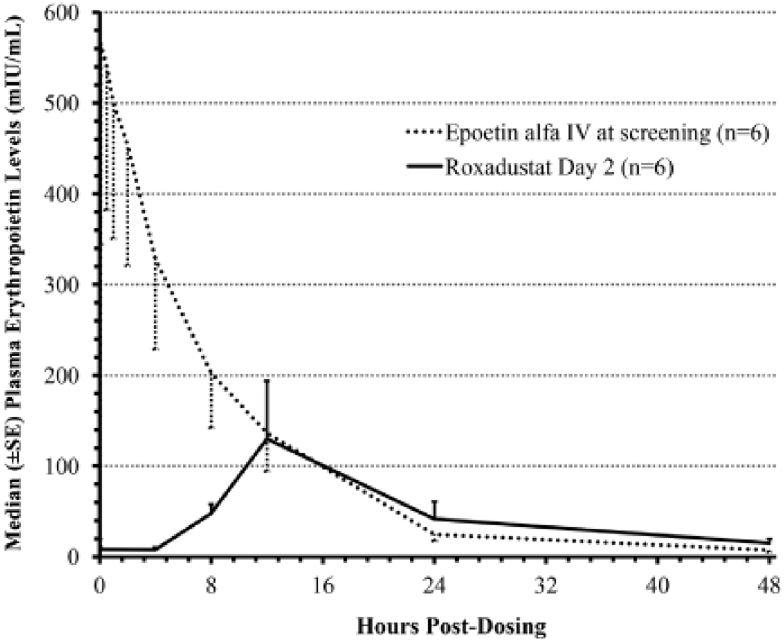
DD-CKD patients who switched from ESA treatment to treatment with 2.0 mg/kg roxadustat had significantly greater reduction in serum hepcin level than those who continued ESA treatment (p=0.038).

FGCL-4592-040 Mean (± SE) Serum Hepcidin Level (ng/mL)



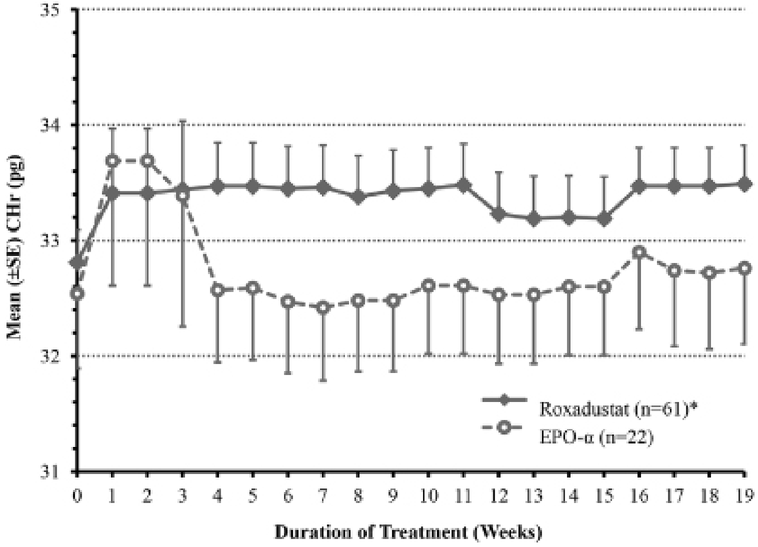
Roxadustat Doses are Associated with Lower Circulating EPO Levels than Epoetin Alfa. The following chart shows the result of six patients who were highly responsive to epoetin alfa and participated in a substudy in which their EPO levels during treatment with roxadustat were compared to EPO levels when the patients were receiving epoetin alfa prior to randomization. Their mean peak EPO concentration after an average dose of 44 U/kg was significantly higher when patients were receiving epoetin alfa relative to when they were receiving a mean roxadustat dose of 1.3 mg/kg as illustrated below. This observation is consistent with the mechanisms of action of ESA and roxadustat, respectively, and we believe the lower EPO exposure observed with roxadustat offers potential safety benefits.

FGCL-4592-040: Median (+SE) Plasma Erythropoietin Levels During Treatment With Roxadustat Compared With Prior Epoetin Alfa Dosing In the Same Patients (n=6)



Maintenance of Adequate Iron Supply. The concentrations of Hb within newly formed red blood cells, or CHr, is a measure of iron availability for erythropoiesis. In an exploratory analysis of this study, without IV iron supplementation (which was prohibited in this study), CHr was maintained during roxadustat treatment but declined in patients who continued treatment with epoetin alfa. This finding indicates that unlike epoetin alfa, roxadustat allows endogenous stores of iron to provide an adequate supply to newly forming red blood cells without any IV iron supplementation.

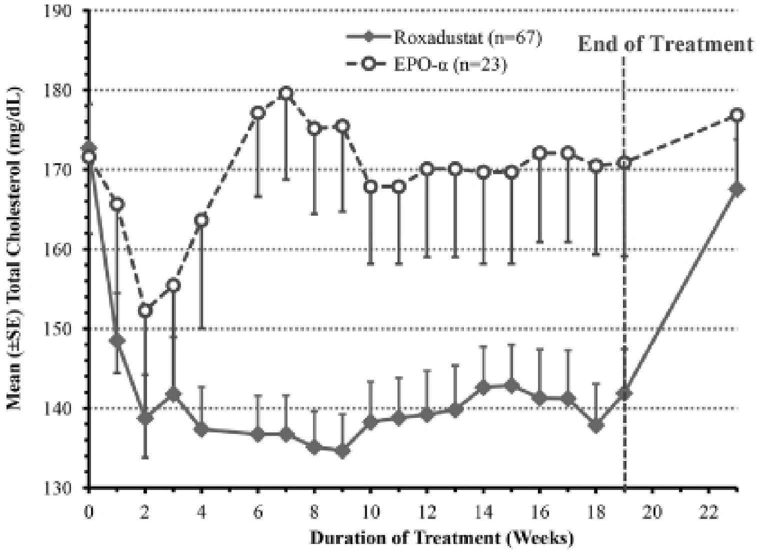
FGCL-4592-040: Mean Reticulocyte Hb Content (CHr) Over Time in Subjects Treated with Roxadustat and Epoetin Alfa



* n at baseline

Reduction in Total Cholesterol. Consistent with our Phase 2 studies in NDD-CKD patients, we observed in a post-hoc analysis that roxadustat reduced total cholesterol levels in stable dialysis patients, and this effect appeared durable throughout the 19 week treatment period as depicted below.

FGCL-4592-040: Mean (±SE) Total Cholesterol Over Time During Treatment of Dialysis Patients with Roxadustat or epoetin alfa-Treated



Study 053: Correction of Anemia in Incident Dialysis Patients

Incident dialysis patients are at increased risk of serious cardiovascular events and death as compared to stable dialysis patients. The mortality rate among dialysis patients is highest during the first few months of dialysis initiation, and on average, patients also require the highest doses of ESA in this period. These patients typically have high levels of systemic inflammation and require IV iron supplementation for ESA to be effective.

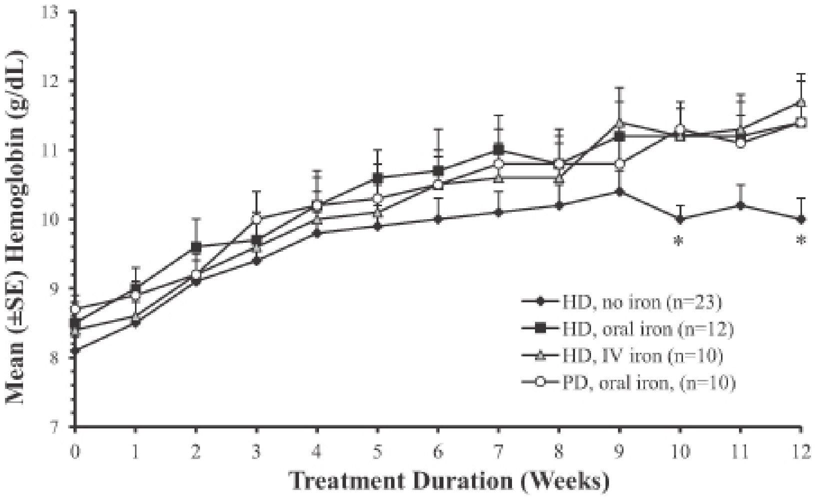
This randomized, open-label study was designed to evaluate the safety and efficacy of roxadustat for correction of anemia in 60 incident dialysis patients (of which 55 were efficacy evaluable) who were on dialysis for at least two weeks and not more than four months and had not been treated with ESAs, and to compare the treatment responses to roxadustat under the different iron supplementation conditions. All treatment groups in Study 053 met their primary endpoint in increasing Hb level during treatment: each cohort achieved maximum mean Hb increases from baseline, ranging between 2.8 g/dL to 3.5 g/dL, resulting from 12 weeks of roxadustat treatment. While roxadustat corrected anemia without iron supplementation, oral iron enabled an optimal Hb response. More importantly, oral iron was as effective as IV iron for Hb correction by roxadustat. In contrast, ESA therapy requires IV iron supplementation in this patient population.

This study also showed that roxadustat can correct anemia regardless of the patient’s level of inflammation as measured by CRP. At Week 12, the median weekly dose of roxadustat was 4.0 mg/kg in this trial of incident dialysis patients and is similar to the median weekly dose of 4.45 mg/kg at Week 12 in Study 040, our trial of roxadustat in stable dialysis patients. In contrast, ESA therapy typically involves higher doses at the time of dialysis initiation.

The 48 HD patients were randomized to one of the three iron supplementation options: oral iron, IV iron or no iron. Included in the 60 patients were 12 peritoneal dialysis, or PD, patients who received oral iron. This study incorporated the same tier-weight based dosing regimen utilized in Study 041.

Hb Correction in Incident Dialysis Patients Without IV Iron Administration. All three cohorts of roxadustat treated HD patients (no iron, oral iron or IV iron supplementation) and PD patients (oral iron) achieved a significant increase in the maximum Hb change from baseline, the primary efficacy endpoint. Most importantly, the maximum increase in Hb was not significantly different between roxadustat treated HD patients supplemented with oral iron (3.4 g/dL) and those supplemented with IV iron (3.5 g/dL). In contrast, a published study of ESAs in this patient population showed that patients supplemented with oral iron achieved a Hb response comparable to no iron supplementation and significantly lower Hb response than those supplemented with IV iron. These Phase 2 data demonstrate that roxadustat, unlike ESAs, may eliminate the need for IV iron and thus avoid the side effects of IV iron in DD-CKD patients.

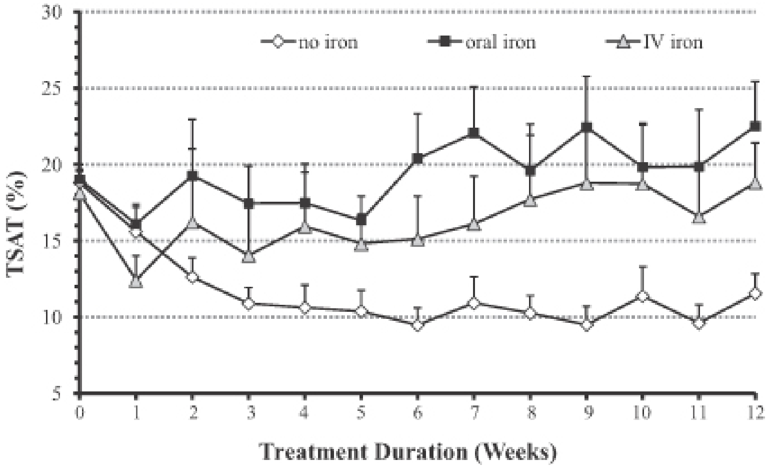
FGCL-4592-053: Hemoglobin Over Time During Anemia Correction with Roxadustat in Incident Dialysis Patients, with No Iron, Oral Iron, or IV Iron Supplementation



Note: Hb = hemoglobin; HD = hemodialysis; PD = peritoneal dialysis; n= number of patients
Note: *p<0.05 compared to IV iron and oral iron

Maintenance of Iron Stores. In an exploratory analysis of this study, transferrin saturation, or TSAT, a marker of iron stores, was well maintained during this period of intensive production of red blood cells with oral iron alone, indicating that iron stores can be maintained without IV iron.

FGCL-4592-053: TSAT Over Time During Anemia Correction With Roxadustat In Incident Dialysis Patients, With No Iron, Oral Iron, or IV Iron Supplementation



Hb Correction Independent of Inflammation Status. As is typical of incident dialysis patients, about half of all patients had elevated CRP levels at baseline. In a post-hoc analysis of this study, we observed that Hb responses following roxadustat treatment were independent of baseline CRP levels. These data demonstrate that, unlike the ESAs, roxadustat has the potential to overcome the suppressive effects of inflammation on Hb responsiveness to treatment.

Significant Reduction in Hepcidin. Consistent with our other studies, in an exploratory analysis of this study we observed that patients' hepcidin levels were significantly reduced, most notably in the no iron and oral iron cohorts, by $\geq$ 50% from baseline, and to a lesser extent in the IV iron cohort. At follow-up (4 weeks after stopping roxadustat), hepcidin levels returned towards baseline values. Hepcidin reduction may be one of the mechanisms for overcoming the Hb suppressive effects of inflammation by making iron more available for roxadustat-induced erythropoiesis.

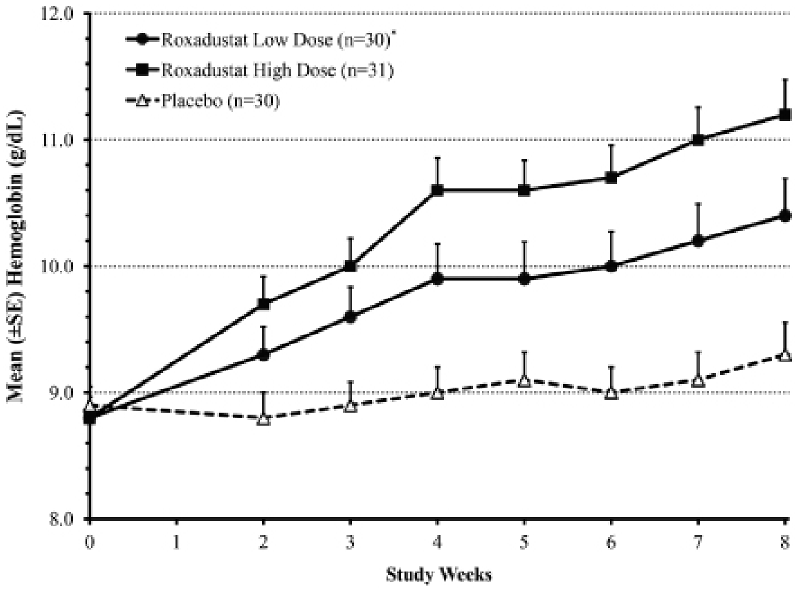
China Phase 2 Studies

In China, roxadustat is known as FG-4592. We performed two Phase 2 studies in China, one trial in NDD-CKD patients, and another trial in DD-CKD patients. In these trials, Hb correction in NDD-CKD patients and Hb maintenance in DD-CKD patients replicated the results seen in the US trials.

Study 047: Week Placebo-Controlled NDD-CKD

In this multi-center, double-blind, placebo-controlled study, 91 anemic CKD patients were randomized 2:1 to roxadustat or placebo treatment groups, respectively, in two sequential dose cohorts or placebo. Iron repletion at baseline was not required and IV iron supplementation was prohibited during the trial; oral iron supplementation was allowed during the trial, similar to the corresponding US Study 041. The study used tier-weight starting dose for four weeks after which the roxadustat dose was adjusted, depending upon the initial response to treatment. Study 047 met its primary endpoint of a mean maximum increase from baseline in Hb at the end of Week 8. The mean maximum Hb increases at the end of eight weeks of treatment were 1.6 g/dL and 2.4 g/dL in the low-dose and the high dose cohort, respectively, compared to 0.4 g/dL for placebo, p < 0.0001 for each cohort compared to placebo.

FGCL-4592-047: Hb Over Time (g/dL) in Chinese NDD-CKD Patients

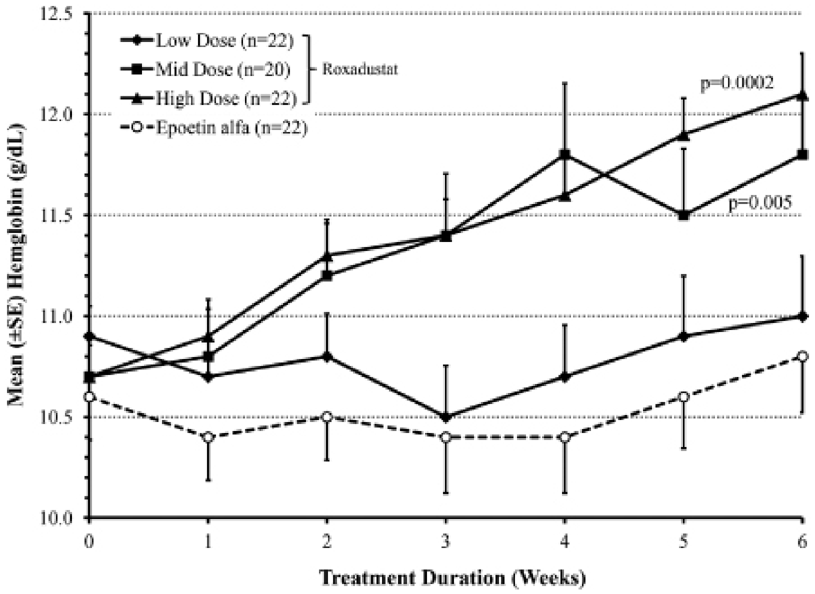


* n at baseline

Study 048: Stable Dialysis Conversion in China

In this multi-center, open-label, ESA-controlled study, 84 HD patients (of which 82 were efficacy evaluable) with Hb 9 to 12 g/dL previously maintained with ESAs were randomized 3:1 to roxadustat or epoetin alfa treatment groups, respectively, in three sequential dose cohorts of increasing starting doses of roxadustat. This study design was similar to Part 1 of Study 040. Study 048, an exploratory study, achieved its objective of number (%) of patients with successful dose conversion whose Hb levels are maintained at no lower than 0.5 g/dL below their mean baseline value at the end of Weeks 5 and 6 (as shown in the figure below). The Hb responses to the roxadustat treatment of Chinese dialysis patients, with the low dose cohort were numerically similar to epoetin alfa, while the mid-dose and the high-dose cohorts each had a statistically significantly higher Hb response rate than epoetin alfa. Hb responses to the roxadustat treatment of Chinese dialysis patients (as shown in the figure below) were similar to Part 1 of Study 040 in the United States.

FGCL-4592-048: Hb Over Time in Chinese Stable Dialysis Patients



Safety Summary

As of October 22, 2014, 1,503 subjects have received roxadustat in our clinical development program, including 537 healthy volunteers and 966 CKD patients (both dialysis and non-dialysis). The longest treatment exposure (10 participants in an ongoing open-label extension study) is over 2 years. A range of roxadustat doses, up to 3.0 mg/kg in DD-CKD patients and up to 5.0 mg/kg in healthy volunteers, have been administered and all roxadustat doses have been well-tolerated. The following summarizes the safety findings of our preclinical, Phase 1 and Phase 2 studies:

- *No Overall Safety Signals.* An independent data monitoring committee consisting of external experts in nephrology, hepatology, and biostatistics reviewed safety data from all US and Europe Phase 2 studies, and determined there were no safety signals. The overall frequency and type of treatment-emergent adverse events and serious adverse events, or SAEs, observed in these clinical studies reflect events that would be expected to occur in each of the NDD-CKD and DD-CKD patient populations. Safety analyses did not reveal any association between the rates of occurrence of cardiovascular events with roxadustat dose, rate of Hb rise or Hb level. The SAEs experienced in our studies identified by the principal investigator as possibly related to roxadustat were a stroke in a patient with a prior history of multiple strokes, one incident of vomiting, and one incident of deep venous thrombosis. The most commonly reported treatment emergent adverse events in the Phase 2 studies were diarrhea, nausea, urinary tract infection, nasopharyngitis, peripheral edema, hyperkalemia, headache, hypertension and upper respiratory tract infection.

- *No Liver Enzyme Safety Signal.* Liver enzymes were monitored closely in the roxadustat Phase 2 clinical development program. No evidence of hepatotoxicity was observed in any of the roxadustat clinical trials, and the independent data monitoring committee concluded that there was no concern for hepatotoxicity to date. Liver enzymes are being monitored in Phase 3 according to current FDA guidelines, without any special requirements.
- *Extensive Evaluation of Cancer Risk.* Furthermore, to assess the potential cancer risk of roxadustat, we conducted 12 tumor studies in rodents. These studies included xenograft, syngeneic, or spontaneous tumors of lung, colon, breast, pancreas, melanoma, ovarian, renal, prostate and leukemic origin, several of which are reported to be dependent on vascular endothelial growth factor, or VEGF, a protein that can be regulated by HIF for which increased levels have potentially been linked to increased tumor growth. No effect on tumor promotion was observed with roxadustat in any of the studies. In addition, roxadustat had no effect on tumor initiation or metastasis in the studies in which these end-points were also measured. Five other HIF-PH inhibitors from our library have been evaluated in many of the same rodent tumor models as roxadustat, as well as some additional ones (35 studies of six HIF-PH inhibitors in 18 models total), with no observed effect on tumor initiation, promotion or metastasis. Finally, no significant increases in plasma VEGF levels have been observed in any of our nonclinical studies at clinically relevant erythropoietic doses of roxadustat.

  Results from two-year rat and mouse carcinogenicity studies with roxadustat have been completed. Roxadustat treatment had no adverse effect on survival and did not cause carcinogenic effect in either species. Final reports are expected in Q4 2014 or early 2015. Two-year rodent carcinogenicity studies that were conducted with one of the other HIF-PH inhibitors evaluated in the tumor models, showed no effect on mortality or incidence of tumors.

  In clinical studies to date, we and our independent data monitoring committee have not identified any evidence to suggest tumor risk in the use of roxadustat.
- *No QT Prolongation.* We conducted a Thorough QT study evaluating roxadustat doses up to 5 mg/kg (approximately four times the average maintenance dose studied in the NDD-CKD patient population). A lengthened QT interval is a biomarker for certain ventricular arrhythmias and a risk factor for sudden death. Our results demonstrate that roxadustat did not affect the QT interval in this study. Based on the extensive safety data collected to date, we believe that roxadustat has a favorable safety profile that supports its further development in Phase 3 clinical studies.

Our Global Phase 3 Program for Roxadustat

In support of our initial efforts for regulatory approval in the United States and Europe, we have initiated with our partners our global Phase 3 clinical program for roxadustat in North America, South America, Europe and Asia Pacific, with plans for expanding to other regions. As of October 22, 2014, there have been approximately 436 patients enrolled in this Phase 3 clinical program. FibroGen China will begin a separate Phase 3 program in China in the first half of 2015, and Astellas is responsible for Phase 3 studies upon completion of Phase 2 studies in Japan. Roxadustat is the first HIF-PH inhibitor to enter Phase 3 clinical trials. We believe that our ongoing global Phase 3 program will be the largest Phase 3 program ever conducted for an anemia agent. This broad Phase 3 program is designed to meet regulatory approval requirements of multiple regions, and is being jointly implemented with our partners, Astellas and AstraZeneca. The below chart summarizes our ongoing and planned Phase 3 clinical trials, all of which include Hb level maintenance as a study objective once correction or conversion is achieved.

Ongoing and Planned Roxadustat Phase 3 Clinical Trials

Study Number, Enrollment Start Date for Ongoing Trials	Company Sponsor	Dose Frequencies for Ongoing Trials	Comparator	Estimated # of Patients to be Enrolled	Random-ization	Study Objective
United States and Europe Trials						
NON-DIALYSIS						
FGCL-4592-060, November 2012	FibroGen	TIW, BIW, QW	Placebo	Up to 600	2:1	Correction
1517- CL-0608, October 2013	Astellas	TIW, BIW, QW	Placebo	450 to 600	2:1	Correction
D5740C00001, July 2014	AstraZeneca	TIW	Placebo	2,600	1:1	Correction
1517-CL-0610, April 2014	Astellas	TIW, BIW, QW	Darbepoetin alfa	570	2:1	Correction
			NDD-CKD Sub Total	**4,000 to 4,500**		
DIALYSIS						
			Stable and Incident Dialysis			
* FGCL-4592-063, February 2014	FibroGen	TIW	Epoetin alfa	Up to 750	1:1	Correction
1517- CL-0613	Astellas	TIW	Epoetin alfa or Darbepoetin alfa	750	376:200:174	Conversion
FGCL-4592-064	FibroGen	TIW	Epoetin alfa	750	1:1	Conversion
* D5740C00002, July 2014	AstraZeneca	TIW	Epoetin alfa	1,425	1:1	Correction & Conversion
			DD-CKD Sub Total	**3,000 to 3,700**		
			NDD and DD-CKD Total for the U.S. and EU	**7,000 to 8,000**		
			China Trials			
Non- Dialysis						
FGCL-4592-808	FibroGen	TIW	Placebo	150	2:1	Correction
Stable Dialysis						
FGCL-4592-806	FibroGen	TIW	Epoetin alfa	300	2:1	Correction & Conversion
			China Total	**450****		

TIW = three times weekly; BIW = twice weekly; QW = weekly

* Study ‘063 consists of only incident dialysis patients, Study ‘002 consists of both incident dialysis patients and conversion of stable dialysis patients. All other dialysis studies consist of only conversion of stable dialysis patients.

** Mandatory post approval safety study of approximately 2,000 patients expected to be required in China.

The below chart summarizes the planned and ongoing Phase 3 clinical trials by regulatory approval region, emphasizing the differences in estimated patients enrolled, minimum and average treatment durations, and resulting “patient years” (the product of estimated number of patients and average patient treatment duration). The studies supporting both U.S. and EU approval have extended treatment durations in the U.S. (52+ weeks) as compared with the EU (36+ weeks).

Regional Differences in Estimated Approval Requirements
Roxadustat Phase 3 Clinical Trials

			Estimated # of Patients to be Enrolled		
	Study Sponsor	**Study Number**	**United States**	**Europe**	**China**
Non-Dialysis					
	FibroGen	FGCL-4592-060	Up to 600*	Up to 600*	
	Astellas	1517- CL-0608	450-600*	450-600*	
	AstraZeneca	D5740C00001	2,600		
	Astellas	1517-CL-0610		570	
	FibroGen	FGCL-4592-808			150
NDD-CKD Sub Total by Region			Up to 3,800	Up to 1,770	150
Stable and Incident Dialysis					
	FibroGen	FGCL-4592-063**	Up to 750*	Up to 750*	
	Astellas	1517- CL-0613	750*	750*	
	FibroGen	FGCL-4592-064	750*	750*	
	AstraZeneca	D5740C00002**	1,425		
	FibroGen	FGCL-4592-806			300
DD-CKD Sub Total by Region			Up to 3,675	Up to 2,250	300
Total by Approval Region			**~7,500**	**~4,000**	**450*****
Combined U.S. and EU Total			**~7,000 – 8,000**		
Minimum Treatment Duration			52 Weeks	36 Weeks	26-52 Weeks
Average Patient Treatment Duration			~1.3-1.5 years	~1 year	~32 Weeks****
Patient Years by Approval Region			**~10,000+**	**~4,000**	**~275**
Estimated Time to Complete Patient Enrollment			1H 2016		2H 2015

* Same patients used for U.S. approval and Europe approval, with extended treatment durations for U.S. approval.

** Study ‘063 consists of only incident dialysis patients, Study ‘002 consists of both incident dialysis patients and conversion of stable dialysis patients. All other dialysis studies consist of only conversion of stable dialysis patients.

*** Mandatory post approval safety study of approximately 2,000 patients expected to be required in China.

**** 350 patients will be treated for a minimum of 26 weeks and 100 patients will be treated for a minimum of 52 weeks.

To maximize the commercial potential for roxadustat, we have incorporated several unique elements into our Phase 3 program. We are performing the first placebo-controlled Phase 3 studies in NDD-CKD patients to potentially demonstrate the benefits of anemia therapy and safety of roxadustat compared to placebo. We are also performing the largest Phase 3 study in incident dialysis anemia patients, who have the highest risk for death, and are the most difficult patients to stabilize and treat for anemia in CKD. Based on data from our Phase 2 studies, we believe that roxadustat may offer a safer alternative to ESAs for this particularly vulnerable patient population. We are also evaluating the cardiovascular safety of roxadustat compared to placebo in NDD-CKD patients to first demonstrate a lack of increased risk to qualify for marketing approval by the FDA, and in these patients we will have an opportunity to measure improvements in patient outcomes with anemia therapy. Separately, we are evaluating cardiovascular safety of roxadustat compared to ESA in DD-CKD patients.

Primary and Secondary Endpoints of Our Phase 3 Program

With our partners, we have designed our Phase 3 studies to evaluate the following endpoints, most of which were evaluated in our Phase 2 studies.

- Primary efficacy endpoints for anemia correction studies:
  - U.S.: Hb change from baseline to the average Hb level during weeks 28-52.
  - EU: Cumulative % patients with Hb response by week 24. Hb response is defined as Hb of 11 g/dL and an increase of at least 1 g/dL from baseline.
- Primary efficacy endpoints for conversion and maintenance studies:
  - U.S.: Hb change from baseline to the average Hb level during weeks 28-52.
  - EU: Hb change from baseline to the average Hb level during weeks 28-36.
- The primary safety endpoints for U.S. approval will be major adverse cardiac events, commonly referred to as MACE, which is a composite endpoint designed to identify major safety concerns, in particular relating to cardiovascular events such as cardiovascular death, myocardial infarction and stroke, and will be pooled across multiple studies and evaluated separately in our NDD-CKD trials and our DD-CKD trials.
- We expect that our Phase 3 clinical trials supporting approval in Europe will be required to include MACE+ as a safety endpoint which, in addition to the MACE endpoints, also incorporates measurements of hospitalization rates due to heart failure or unstable angina.
- We also plan to evaluate secondary endpoints, including the following:
  - IV iron usage in roxadustat-treated patients relative to ESA-treated patients with DD-CKD.
  - Red blood cell transfusion rate in roxadustat-treated relative to placebo treated patients with NDD-CKD.
  - Hypertension adverse events in roxadustat-treated patients relative to ESA-treated patients with DD-CKD, and blood pressure in roxadustat-treated patients relative to placebo-treated patients with NDD-CKD.
  - Total cholesterol, LDL-cholesterol and VLDL-cholesterol levels in roxadustat-treated patients relative to placebo-treated patients with NDD-CKD and relative to ESA-treated patients in all three anemic CKD patient populations.
  - Quality of life in roxadustat-treated patients relative to placebo-treated patients with NDD-CKD.
  - CKD progression in roxadustat-treated patients relative to placebo-treated patients with NDD-CKD.
  - Hospitalization rate in roxadustat-treated patients relative to placebo-treated patients with NDD-CKD and relative to ESA-treated patients in all three anemic CKD patient populations.
  - Rate of vascular access thrombosis in roxadustat-treated patients relative to ESA-treated patients in DD-CKD.

Dosing Regimen

Our Phase 3 studies incorporate dosing regimens that were extensively tested in our six Phase 2 studies.

- *Identified Dosing Regimen.* The dosing regimens for our Phase 3 studies are designed to achieve an appropriate rate and magnitude of Hb rise. In our Phase 2 studies, we explored ranges of therapeutic doses under several dosing regimens, including both tier-weight and fixed starting doses and conversion doses. Our Phase 3 program will use two tier-weight starting doses for ESA-naive patients (70 mg for patients between 45 and 70 kg and 100 mg for patients between 70 and 160 kg). Our Phase 3 dosing strategies are based on our understanding of effective approaches, derived from our Phase 2 studies, tested in modeling and simulation, and were designed to achieve Hb correction for patients with varying dose requirements in a manner that is optimal for both patients and physicians.
- *Dose Titration.* Our Phase 3 program will use a pre-determined sequence of dose steps to titrate to a patient’s particular response to roxadustat, which we found to be simple to use and sufficient to correct anemia in our Phase 2 studies. In our Phase 2 anemia correction studies, only one or two cycles of dose titration were necessary to achieve Hb correction in at least 80% of patients on average.
- *Dose Frequency.* In preclinical and Phase 1 studies, we observed that intermittent dosing yielded optimal responses to roxadustat. Our Phase 2 studies indicated that three times weekly, twice weekly and weekly dosing regimens achieved Hb maintenance. Our Phase 3 program will dose three times weekly for all studies except two (060 and 0608) which will dose some patients twice per week and some patients once per week. We believe that intermittent dosing may help ensure a consistent and durable treatment effect, and avoid the loss of effect that may be associated with more frequent dosing.
- *Dose Conversion for Dialysis Patients Previously Treated with ESAs.* In our Phase 2 conversion studies, we tested a variety of starting doses and developed a mathematical relationship between baseline ESA dose and roxadustat dose required to maintain Hb levels. We use dose conversion tables derived from these Phase 2 studies to formulate starting roxadustat doses in our Phase 3 trials for patients who switch to roxadustat from ESAs.

Our Phase 2 studies indicated that this dosing regimen enabled anemia correction up to 24 weeks and Hb maintenance up to 19 weeks when converting a patient from ESA.

Clinical Trial Eligibility, Iron Status, and Iron Supplementation During Treatment

Unlike ESA clinical trials where patient study eligibility criteria included a requirement of adequate iron availability (measured by ferritin ³ 100 ng/mL and TSAT ³ 20%) and encouraged IV iron use, roxadustat Phase 2 studies included anemic NDD-CKD patients with ferritin ³ 30 ng/mL and TSAT³ 5% and anemic DD-CKD patients with ferritin ³ 50 ng/dL and TSAT ³10%, which permits the inclusion of patients who are iron deficient. Hemoglobin response was generally achieved in iron deficient NDD-CKD and DD-CKD patients (ferritin <100 ng/dL and TSAT< 20%) despite the fact that IV iron was not allowed during roxadustat treatment.

Our placebo-controlled Phase 3 NDD-CKD studies will use iron eligibility criteria employed in our Phase 2 studies, allow oral iron, but prohibit the use of IV iron (except as a rescue medication). In our Phase 3 DD-CKD studies, since ESA serves as the comparator and similar treatment conditions are required for roxadustat and ESA, study eligibility criteria include ferritin ³ 100 ng/mL and TSAT ³ 20%. Patients will be randomized to roxadustat or ESA, and will be encouraged to take oral iron as a first line supplemental agent. IV iron is permitted if there is inadequate Hb response to treatment and if the patient is iron deficient (ferritin <100 ng/dL and TSAT< 20%).

Status with Regulatory Agencies

In the last two years, we and our collaboration partners have had interactions with regulatory agencies in multiple territories regarding the planned development and potential path to approval of roxadustat.

Most recently, we met with the FDA in May, June and July of 2014 to discuss the overall scope of our Phase 3 development program. In order to comply with FDA's recommendation, we have designed and sized our Phase 3 program for, and will incorporate MACE composite safety endpoints that we believe will be required for approval in the United States for all new anemia therapies.

We have also discussed our Phase 3 clinical development program with three National Health Authorities in the EU and obtained Scientific Advice from the European Medicines Agency, which was confirmed in writing in January 2014 with respect to the adequacy of our current clinical development program to support the indication for the treatment of anemia in NDD-CKD and DD-CKD patients. We expect the MAA submission in Europe to precede our NDA filing in the United States.

Investigational New Drug and Clinical Trial Applications

Roxadustat is being studied under one Investigational New Drug Application, or IND, and several Clinical Trial Applications, or CTAs, all with a specified indication of treatment of anemia in CKD. We submitted the IND in the United States to the FDA in April 2006. Our collaboration partner, Astellas, submitted the CTA in Japan to the Pharmaceuticals and Medical Devices Agency in June 2009. We and Astellas have submitted CTAs in Europe to the EMA, beginning in 2013.

Opportunities in Other Anemia Indications

Based on roxadustat's safety and efficacy profile to date and other potential advantages over ESAs, we believe that in addition to treating anemia in CKD, roxadustat has the potential to treat anemia associated with many other conditions, such as chemotherapy-induced anemia, anemia related to inflammatory diseases, MDS and surgical procedure requiring transfusions. We think that roxadustat, if successful, could potentially address the significant unmet need in these anemia markets.

HIF-PH Inhibitor Platform

We have been a world leader in prolyl hydroxylase inhibition since the mid-nineties. Over the past two decades, we have built a robust drug discovery platform based on our deep understanding of the inhibition of prolyl hydroxylase enzymes using small molecules. Our platform is supported not only by internal research but also by numerous academic collaborations, including a long-standing funded collaboration with a research group at the University of Oulu, Finland, headed for many years by our scientific co-founder, Dr. Kari I. Kivirikko. Dr. Kivirikko is one of the world's leading experts in collagen prolyl hydroxylases, and he remains an advisor to us.

Prior to the discovery of HIF regulation by prolyl hydroxylase activity, we had acquired compound collections from several pharmaceutical companies and assembled a diverse library of prolyl hydroxylase inhibitors to target collagen prolyl hydroxylase enzymes for fibrosis. Consequently, we were particularly well positioned to rapidly generate proof-of-concept for a number of aspects of HIF biology, and to direct medicinal chemistry efforts towards increasing potency and selectivity for the newly identified HIF-PH enzymes.

We have applied our expertise in the field of HIF-PH inhibition to develop an understanding, not only of the role of HIF in erythropoiesis, but also of other areas of HIF biology with important therapeutic implications. This consistent progression of discovery has led to findings relating to HIF-mediated effects associated with inflammatory pathways, various aspects of iron metabolism, insulin sensitivity and glucose and fat metabolism, neurological disease, and stroke. The extensive patent portfolio covering our discoveries represents an important competitive advantage.

The strength of our platform capitalizes on these internal discoveries, as well as some of the complexities of HIF biology that we and the scientific community have uncovered over the past decade. There are at least three different HIF-PH enzymes that are known to regulate the stability of HIF—these enzymes are commonly referred to in the scientific literature as PHD1, PHD2 and PHD3. Studies of genetically modified mice, in which the individual HIF-PH enzymes have been deleted, have revealed that PHD2 plays a major role in the regulation of erythropoiesis by HIF. In contrast, PHD1 and PHD3 appear to play less important roles in HIF-mediated erythropoiesis, but instead have been implicated in other important biological pathways.

We believe that inhibitors selectively targeting PHD1 or PHD3 could have important therapeutic applications beyond anemia. For example, as PHD1 has been implicated in ischemic tissue injury, it has been proposed that PHD1 inhibitors may provide a novel therapeutic approach to protect organs and tissues from ischemic damage. PHD3 on the other hand has been implicated in insulin signaling, raising the possibility that PHD3 inhibitors may have therapeutic utility in the treatment of diabetes. Despite the challenges associated with selectively inhibiting just one enzyme from a closely related family, we have made important advances in the identification of selective HIF-PH inhibitors. We currently have active research programs focused on exploring the therapeutic utility of PHD1 selective inhibitors and PHD3 selective inhibitors. A lead candidate from our PHD1 inhibitor program, FG-8205, is currently in preclinical evaluation for use as a cardioprotective agent to prevent the onset of heart failure following a heart attack.

In addition, FG-6874, another novel HIF-PH inhibitor selected from our proprietary compound library, has recently completed Phase 1 single dose and multiple dose studies in which it was found to be well tolerated. We are planning on exploring FG-6874 for hematopoietic stem cell mobilization and certain other indications.

In September 2011, we submitted a CTA in Singapore for our HIF-PH inhibitor FG-6874; however, no indication was specified under this CTA as it was for a Phase 1 trial. While we have other HIF-PH inhibitors in preclinical evaluation, such as FG-8205, we have not submitted any INDs or CTAs with respect to such compounds at this time.

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

We believe there is a particularly significant unmet medical need for the treatment of anemia in CKD in China. Specifically, anemia is undertreated in the rapidly growing number of dialysis stage patients and anemia is not treated in non-dialysis patients including patients who are eligible for dialysis but are not treated due to a shortage of dialysis facilities, and cannot easily obtain anemia treatment outside of the dialysis system. In the context of the rapidly growing Chinese 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, which is still in the early stages of infrastructure development, more available through expansion of government reimbursement and build-out of dialysis facilities. We believe that roxadustat is a particularly promising product candidate for this market.

Addressable Patient Populations in China

Based on a cross-sectional survey performed between September 2009 and September 2010 published in the *Lancet* (Zhang, et al. *Lancet* (2012)), there are an estimated 119.5 million CKD patients in China. There were approximately 19 million patients in CKD stage 3, stage 4 and stage 5 which we have grouped into three categories: dialysis dependent CKD patients, or DD-CKD; Dialysis Eligible patients who need dialysis under treatment guidelines but are not dialyzed, or Dialysis Eligible NDD-CKD; and stages 3 and 4 patients as well as stage 5 patients who are not eligible for dialysis, or Other NDD-CKD.

DD-CKD (Dialysis)

Dialysis can be delivered in the form of hemodialysis, or HD, or peritoneal dialysis, or PD. In China, HD is mostly performed at dialysis clinics within hospitals, not at freestanding dialysis centers outside of hospitals which is the common practice in the United States. PD is self-administered at home by patients, and they visit their nephrologists on a monthly basis at the hospital for monitoring and follow-up.

Dialysis Eligible NDD-CKD

Dialysis Eligible NDD-CKD refers to patients who need dialysis under Chinese treatment guidelines but are not dialyzed. The Chinese treatment guidelines recommend initiation of dialysis at eGFR<10 mL/min/1.73 m^2 (and eGFR<15 mL/min/1.73m^2 for diabetic nephropathy patients). The Minister of Health estimated that one to two million people in China were eligible for dialysis in 2011, and of those we believe that only 300,000 to 400,000 are on dialysis. While the size of dialysis population is large and approaches that of the United States, it nevertheless falls far short of the number who require dialysis treatment. We believe that this Dialysis Eligible NDD-CKD population is characteristic of developing markets like China and is at risk for severe anemia.

Other NDD-CKD

Other NDD-CKD refers to the other sub-groups of CKD patients within non-dialysis who are earlier stage: CKD patients in stage 3 and stage 4, as well as stage 5 who are not eligible for dialysis. Many of these patients receive medical care in endocrinology, cardiology or internal medicine clinics where they are treated for their primary disease.

Unmet Medical Need

DD-CKD Patients are Under-Treated for Anemia

We believe there is chronic under-treatment for anemia within the DD-CKD patient population, as many patients do not reach target Hb levels despite ESA therapy. The consensus opinion of the expert panel assembled by the Chinese Journal of Nephrology in 2013 advocated treating to Hb 11.0 g/dL to 13.0 g/dL, whereas we believe, based on our key opinion leader Advisory Board Meeting in Shanghai in March 2013 that in clinical practice, nephrologists generally use Hb 10.0 g/dL to 12.0 g/dL as the target. However, according to the 2012 Shanghai Dialysis Registry, approximately 50% of patients in Shanghai did not exceed a Hb level of 10.0 g/dL and approximately 75% did not exceed Hb 11.0 g/dL. Over 19% of dialysis patients failed to reach a severely low Hb level of 8.0 g/dL. The Chinese Renal Data System reported that in 2011, the most recently reported data, the average Hb level of DD-CKD patients in the registry was approximately 9.1 g/dL and the percentage of patients who reached Hb levels greater than or equal to 11.0 g/dL was only about 21%.

We believe there are a number of factors that have led to under-treatment of anemia in the dialysis population, including:

- The ESA doses used are generally not sufficient to treat to target Hb levels for certain patient populations. We believe that the reasons include constraints on reimbursement for anemia treatment and fixed hospital pharmacy budgets, as well as safety and efficacy limitations of these drugs. Lower dose levels are particularly ineffective in the hypo-responsive patient population.
- The use of IV iron, which is often needed to correct Hb to target levels with ESAs, is limited due to limited reimbursement and perceived clinical risk. According to the Shanghai Dialysis Registry, in 2011, less than 9% of dialysis patients in Shanghai were treated with IV iron.
- For the PD population, where patients are not already visiting the hospital for HD and are receiving ESA treatment during dialysis, similar logistical and financial issues that impede ESA use in the NDD-CKD population discussed below apply to these patients.

Dialysis Eligible NDD-CKD and Other NDD-CKD Patients are Largely Un-Treated for Anemia

Apart from the ESAs used by the dialysis patients in China, we believe that there is a low level of use of ESAs in the non-dialysis population. Based on our clinical trial experience in China, we believe use of ESAs in this population is generally limited to “CKD Clinics” at major research hospitals in top cities where CKD patients are admitted into programs for academic research purposes. We believe there are a number of significant impediments that inhibit the use of ESAs in the outpatient setting, for patients who are not already visiting the hospital for dialysis treatment on a regular basis.

- Generally, under the Chinese healthcare system, patients do not have a personal physician but rather are seen by the physician on the schedule on the day of the visit. This limited continuity of care makes managing the potential risks of ESAs and the titration of ESA treatment needed to maintain Hb within target range particularly difficult.

- Hypertension and associated co-morbidities are top risk factors for the CKD population. Many physicians in China believe that for the outpatient NDD-CKD population, the risk of developing new or exacerbating existing hypertension from ESA with the attendant risk of worsening renal failure outweigh the benefits of treating anemia.
- Injectable drugs like ESAs present a challenge in China because even subcutaneous administration is performed at hospitals and not in the home. Frequent hospital visits for injections, for the sole purpose of receiving ESA treatment, can present a substantial logistical and financial burden on patients.
- Nephrologists are the primary prescribers of ESAs. Those CKD patients with hypertension or diabetes who are treated by other physicians, such as cardiologists and endocrinologists, are generally not treated with ESAs.
- Non-dialysis patients are covered under outpatient reimbursement, unlike dialysis patients who are covered under Severe Disease reimbursement, when available. The lower level of reimbursement coverage means a higher patient co-pay, which further limits ESA use and compliance.

We believe that these impediments have contributed to a low rate of ESA use in the NDD-CKD population in China, and that roxadustat, as an oral agent triggering the HIF mechanism of action, has the potential to make this population accessible for effective anemia treatment in CKD.

Growing Market Opportunity

Healthcare expenditures in China have more than doubled over the past five years, from $156 billion in 2006 to $357 billion in 2011. China is projected by IMS Health to become the world’s second largest pharmaceutical market after the United States by 2016 (IMS Market Prognosis, May 2012). We believe several factors will continue to drive the growth of the overall pharmaceutical market in China as well as the market for the treatment of anemia in CKD. These factors include continuing urbanization, an aging population and the increasing prevalence of chronic diseases (particularly diabetes and hypertension which are common causes of CKD), and income growth. We also believe that the increasing standard of living will drive higher rates of disease awareness, leading to greater rates of diagnosis and treatment.

The strong growth in the China healthcare sector is a direct result of central government policy. In 2009, the Chinese government implemented healthcare reform that greatly expanded reimbursement coverage across population, scope, and level of coverage, and in 2011, the 12th Five Year Plan placed the biomedical industry and development of innovative medicines as a strategic priority for the country. The following table shows the growth and size of the China healthcare market:

	2006 ($US)	**2011 ($US)**
Total Healthcare Expenditures	$156 billion	$357 billion
Per Capita Healthcare Expenditures	$119	$261
Market Size for Pharmaceuticals	$27 billion	$71 billion
Percentage of Population with Health Insurance	43%	>95%
China in Global Ranking of Pharmaceutical Markets	9th	3rd

Source: Health care in China: Entering “uncharted waters”, McKinsey & Company, healthcare systems and services practice, November 2012

Current ESA Market Size and Drivers of Market Growth in China

Total ESA sales in China were approximately $145 million in 2013, and the ESA market in China has grown at a 25% compound annual growth rate between 2006 and 2013 based on data from IMS Health.

We believe that given the limited availability of dialysis in China, dialysis is still in the early stages of development relative to the United States, and has the potential for sustained long-term growth. We believe growth of dialysis will be driven by the expansion of reimbursement and expansion of dialysis facilities. We further believe that the growing pipeline of CKD patients and expansion of reimbursement will drive growth in demand for anemia treatment in CKD patients.

- *Expansion of Reimbursement.* Reimbursement exists for the use of ESAs in the treatment of anemia in CKD and the coverage levels are expanding. Under Basic Medical Insurance, the reimbursement program for the urban population, coverage for healthcare and drugs is categorized into one of three categories: outpatient, inpatient, and Severe Disease. Both the Dialysis Eligible and Other NDD-CKD patients are reimbursed under outpatient coverage. As an example, coverage levels for outpatient are in the 60-85% range in Shanghai, depending on level of hospital visited and patient age. Dialysis patients, on the other hand, receive reimbursement under the more generous Severe Disease coverage, which is reimbursement for catastrophic healthcare expenditures. Coverage levels are set at a minimum level of 50% by policy and are as high as 85% for employees and 92% for retirees in Shanghai. We expect the availability of Severe Disease reimbursement to significantly drive the utilization of dialysis services and ESAs in the coming years.
- *Expansion of Dialysis Infrastructure.* The number of DD-CKD patients increased from approximately 70,000 in 2007 to an estimated 300,000 to 400,000 in 2013 and has grown at a compound annual growth rate of 25% to 30% per year from 2007 to 2013. Despite this substantial rate of growth, the Ministry of Health and the Chinese Society of Nephrology have publicly recognized the need for further investment in dialysis infrastructure to accommodate the expected continued growth of the patient population requiring dialysis. PD is an alternative to HD and does not require the level of capital investment in facilities and equipment that is necessary to enable HD. At the end of 2012, PD was estimated to account for 10% of the current dialysis population.
- *Demographics-Driven Growth.* Diabetes and hypertension are common causes of CKD, the rates of which have been growing in China over past two decades. China is experiencing epidemiological changes in metabolic diseases due to economic development, urbanization and an aging population. We believe the increase in diabetes and hypertension prevalence will result in increasing numbers of patients with CKD in the future.

Our China Solution

We believe that roxadustat, if approved, has the potential to address the unmet medical need for the treatment of anemia in each of the three categories of CKD patients in China. Several of the safety, efficacy, reimbursement and convenience advantages that roxadustat, our oral therapeutic, potentially offers over ESAs (see "—Our Solution—Roxadustat—A Novel, Orally Administered Treatment for Anemia") are particularly applicable in the China market.

Roxadustat May Address Chronic Under-Treatment in DD-CKD Patients

We expect roxadustat to be viewed as more attractive than ESAs, and particularly attractive within certain categories of the dialysis population—patients who are not treated to target Hb levels for any reason, patients who are hyporesponsive to ESAs, patients on PD, which is home-based, and DD-CKD patients who have not previously received ESA treatment.

- *Roxadustat May Increase Rate of Successful Anemia Treatment.* We believe that the level of ESA dosing generally used in China is not adequate to achieve target Hb levels for many dialysis patients, especially with minimal use of IV iron. The dose levels used are within a very narrow range due to clinical concerns over ESA safety at higher doses. Moreover, reimbursement limits may cap ESA dose. In contrast, assuming roxadustat is approved, we believe we can price roxadustat so that reimbursable doses of roxadustat will be sufficient to treat most patients to target Hb levels.

- *Roxadustat May Address Hyporesponsiveness.* Hyporesponsive patients, who often fail to respond to ESA treatment, in particular are often inadequately treated due to need for significantly higher doses of ESAs. Our data suggest that roxadustat may be safe and effective in this patient population without the use of high doses.
- *Roxadustat May Reduce Requirements for IV Iron.* ESAs generally require IV iron for effective anemia treatment, and IV iron use is limited in China due to limited reimbursement and perceived clinical risk. Roxadustat potentially eliminates the need for IV iron to reach treatment target.

Roxadustat May Address Lack of Access of ESA Treatment in NDD-CKD Patients

We view NDD-CKD as the segment where roxadustat, with the benefits of the HIF mechanism of action and being an orally administered small molecule, could potentially represent the only viable treatment solution for this patient population.

- *Roxadustat May Make Treatment Accessible and Feasible*. As an oral agent, roxadustat eliminates the need for frequent hospital visits which are needed for ESA administration, decreasing the overall cost and inconvenience of treatment, particularly for DD-CKD patients undergoing PD who are otherwise treated in the home, as well as Dialysis Eligible NDD-CKD and Other NDD-CKD patients.
- *Roxadustat May Have an Improved Safety Profile.* ESA treatment is associated with an increased risk of severe adverse events including hypertension, stroke, myocardial infarction and death. Our data suggest that roxadustat may not increase the risk of these events and therefore may be safer than ESAs thereby potentially removing a significant deterrent to anemia therapy in China.

Roxadustat May Add Value in Both the NDD-CKD and DD-CKD Patient Populations

- *Roxadustat May Reduce Overall Cost of Treatment Associated With Anemia.* For the equivalent reimbursement cost to the government, we believe that roxadustat may deliver a higher potential clinical benefit compared to ESAs. Roxadustat, if approved, could treat patients to target Hb level. Roxadustat could also potentially lower the use of IV iron and anti-hypertensives. Moreover, the total cost of care would be reduced by lowering loss of time and cost of hospital-based ESA injections, and eliminating the infrastructure costs necessary to store ESAs in a cold storage environment. Finally, patients would benefit by reducing the cost of travel to the hospital and the potential lost wages for hospital visits.

Commercialization

Regulatory Strategy

We plan to seek product approval from the China Food and Drug Administration, or CFDA, as a Domestic Class 1.1 drug through our China subsidiary, FibroGen China. FibroGen China submitted a CTA to the CFDA for roxadustat for the treatment of anemia in CKD in March 2013. This Domestic Class 1.1 designation allows us to use the “green channel”, which may facilitate expedited approval with access to the regulatory authorities for formal and informal dialogue about development plans. We believe the domestic pathway represents the fastest route for bringing roxadustat to market and providing patients with access to a potentially safer, more effective, more convenient and more accessible therapy.

We believe the development of roxadustat is aligned with the Chinese government’s current policies. The Chinese government is building dialysis infrastructure to address the unmet need for dialysis. We believe that anemia treatment is a critical component of any national dialysis program, and the cost of anemia treatment is an important factor in the public health burden of CKD.

FibroGen China has completed Phase 1 and Phase 2 clinical trials in China and expects to start Phase 3 clinical trials in China in the first half of 2015, with Phase 3 data expected in the second half of 2016 and, assuming the

Phase 3 clinical trial is successful, possible NDA approval in China in mid-2017. However, actual dates depend on a variety of factors and are subject to numerous risks and uncertainties, including with respect to patient enrollment, safety results, manufacturing, third party contractors and government regulators, some of which are out of our control. See also “Risk Factors” beginning on page 16, and particularly those risk factors under the heading “Risk Related to the Development and Commercialization of Our Product Candidates.” These trials have been conducted, and will continue to be conducted, in parallel with but independently of the other trials conducted in the global roxadustat development program. All available safety data from the global program will be included in the China NDA submission.

Manufacturing Certification

FibroGen China plans to secure all New Drug and Manufacturing Licenses (including a Drug Approval Code) required for commercialization of roxadustat in China. A Manufacturing License is fundamental for production and sale of drugs in China, and it is the Manufacturing License, not the New Drug License which is granted at NDA approval, that gives FibroGen China the right to market roxadustat. With the Manufacturing License, FibroGen China will have the right to sell roxadustat (issue “fa-piaos”, or invoices, for the sale) into the highly regulated pharmaceutical distribution system, and recognize revenues for such sale. FibroGen China will also have the right to negotiate pricing with the government and the right to apply for reimbursement for roxadustat.

FibroGen China is completing construction and validation of its manufacturing facility in Beijing. We received a Pharmaceutical Production Permit, which is a general manufacturing license, for the manufacturing facility in August 2014, and we expect to receive the Manufacturing Licenses that will be necessary to manufacture roxadustat in the next few years after successful completion of the registration and GMP validation campaigns. *(See “—Manufacture and Supply” and “—Government Regulation—Regulation in China”).*

Market Segmentation

We believe DD-CKD market in China is readily addressable in the near term, and we believe roxadustat has the potential to deliver a compelling value proposition in particular to certain subgroups within DD-CKD: patients who are not treated to target Hb levels for any reason, patients who are hypo-responsive to ESAs, and patients on PD, which is performed at home. In addition, we believe that roxadustat, if approved, would have the potential to be the preferred anemia treatment for newly-initiated dialysis patients who have not been previously treated with ESA. With the expected expansion of Severe Disease reimbursement, we believe that the number of DD-CKD patients will increase steadily. We believe that it could require more than a decade for China to address the treatment gap between patients who need dialysis and those who are actually dialyzed.

If roxadustat is approved, we believe the Dialysis Eligible NDD-CKD population could represent another readily accessible and potentially new market segment for anemia therapy. There is an urgent and severe unmet medical need for these very sick patients, and the current low rate of treatment within this patient group could be addressed by an approved anemia treatment such as roxadustat. We view the Other NDD-CKD population as a longer term market opportunity where the potential number of patients could be substantial.

We believe the hospital-based nature of the China healthcare system is a very attractive feature of this market as it lends itself to rapid adoption of roxadustat within nephrology practices and across specialties, unlike in the United States where dialysis is performed separately at freestanding dialysis centers and CKD is treated at widely dispersed clinics and primary care offices across the country. In China, within nephrology, the same physicians care for dialysis, Dialysis Eligible NDD-CKD and Other NDD-CKD patients. Moreover, cardiologists and endocrinologists are located at the same hospitals as nephrologists, and prescriptions from all specialties are often filled at the same hospital pharmacy; as a result, the points of sale are highly concentrated.

Reimbursement

As roxadustat is potentially a chronic use drug that addresses an unmet medical need and is intended to benefit large numbers of Chinese patients, we intend to apply for reimbursement by the Chinese government. Pricing for drugs sold without reimbursement is determined by the drug manufacturer, whereas pricing for drugs under reimbursement is determined by the government. We believe the compelling pharmaco-economic value proposition will support fair pricing for roxadustat.

AstraZeneca

We have entered into an agreement with AstraZeneca relating to roxadustat in China. Under the agreement, FibroGen China will hold all of the regulatory licenses issued by China regulatory authorities and be primarily responsible for regulatory, clinical and manufacturing activities.

AstraZeneca will conduct commercialization activities as well as serve as the national distributor for roxadustat, sourcing the distribution of roxadustat to a network of regional and local distributors. FibroGen China will be responsible for medical affairs and physician education.

We believe that the collaboration will not only help to accelerate market access and patient adoption, but also reduce our risks associated with roxadustat launch in China, as AstraZeneca has significant experience with the China market and will be paying for launch-related commercialization costs in advance and recouping 50% of these expenses from initial roxadustat profits.

Clinical Trials

Our clinical development plan is based upon an agreement with the CFDA that our NDA package will include Phase 1, 2 and 3 trials performed exclusively in China, as well as reference data from Phase 1 and Phase 2 trials performed outside of China.

Clinical Trials of Roxadustat in China

We have successfully completed Phase 1 and Phase 2 trials in China. A summary of our data and comparison to data from our trials performed outside of China is as follows:

Phase 1 Trials

We completed Phase 1 trials of single and multiple ascending doses of roxadustat. Key findings were:

- Roxadustat pharmacokinetic parameters in Chinese are similar to those in Caucasians and Japanese.
- Stimulation of endogenous erythropoietin, a marker of roxadustat pharmacodynamics, in Chinese is similar to stimulation in Caucasians and Japanese.
- Roxadustat was well tolerated and there were no negative safety signals.

Phase 2 Trials

We completed a Phase 2 double-blind placebo controlled trial in NDD-CKD patients and a Phase 2 randomized trial of roxadustat compared to epoetin alfa in DD-CKD patients. Results of these trials are very similar to results from comparable trials performed in the United States. See “Business—Our Development Program for

Roxadustat.” The results of the DD-CKD trial were presented at the 2013 World Congress of Nephrology and the results of the NDD-CKD trial were presented at the 2013 American Society of Nephrology meeting. Key findings of these trials are as follows:

DD-CKD Trial Results

- Roxadustat achieved Hb maintenance in DD-CKD patients who discontinued treatment with epoetin alfa.
- In a post-hoc analysis, the data met the primary endpoint of our planned Phase 3 trial in China in this patient population.
- There were no serious adverse events after starting roxadustat and most common adverse events were muscle spasms, abdominal discomfort, decreased appetite and infections which were typical of those expected for DD-CKD patients. There were no dose-related trends or imbalances in the nature of adverse events between roxadustat and epoetin alfa groups.

NDD-CKD Trial Results

- By Week 9, roxadustat increased Hb levels significantly compared to placebo ($p<0.001$).
- In a post-hoc analysis, the data met the primary endpoint of our planned Phase 3 trial in China in this patient population.
- Serious adverse events were progression of CKD, infection and high potassium levels and the most common adverse events were infections, high potassium levels, nausea and dizziness. The percentage of patients with adverse events was similar for patients treated with roxadustat compared to patients treated with placebo. There were no imbalances in the nature of adverse events between the patient groups.

Strategy for Continued Development of Roxadustat in China

We plan to perform two Phase 3 trials in China to support approval of roxadustat for treatment of anemia in DD-CKD and NDD-CKD patients. Based on discussions with the CFDA, our planned Phase 3 trials are designed to confirm Phase 2 results. Consequently, these Phase 3 trials are similar in design and endpoints to our Phase 2 trials in DD-CKD and NDD-CKD, except that our Phase 3 trials will include a larger number of patients and will study longer dosing durations. The overall designs of our planned Phase 3 trials are as follows:

Phase 3 Trial in DD-CKD (FGCL-4592-806):

- Design: Randomized, multicenter, open-label, active control.
- Patients: CKD on dialysis.
- Number: 300.
- Control treatment: epoetin alfa.
- Randomization: 2:1 (roxadustat:epoetin alfa).
- Dosing duration: 26 weeks with option for some patients to continue dosing to Week 52.
- Primary endpoint: Hb mean change from baseline averaged over Weeks 23 to 27.

Phase 3 Trial in NDD-CKD (FGCL-4592-808):

- Design: Randomized, multicenter, double-blind, placebo controlled.

- Patients: CKD not on dialysis.
- Number: 150.
- Control treatment: placebo.
- Randomization: 2:1 (roxadustat:placebo).
- Dosing duration: 8 weeks followed by open-label treatment to week 26 and option for some patients to continue dosing to week 52.
- Primary endpoint: Proportion of patients who achieve a confirmed Hb response at any time up to and including Week 9.

In designing these trials, we had several important considerations:

- We had successful Phase 2 trials, and in post-hoc analyses our Phase 2 trial results met the primary endpoints of our planned Phase 3 trials.
- The dosing regimens in our planned Phase 3 trials are based on the dosing regimens in our China Phase 2 trials doses that met the primary endpoints.
- Dosing duration to meet the primary endpoint in the NDD-CKD Phase 3 trial is identical to the China Phase 2 trial dosing duration with additional dosing beyond eight weeks as part of this trial.
- Dosing duration to meet the primary endpoint in the DD-CKD Phase 3 trial is longer than the China Phase 2 trial dosing duration but similar to U.S. Phase 2 trial dosing duration.
- Increased number of patients in Phase 3 increases the trials' power, or ability to detect the primary endpoint.

The CFDA is currently reviewing our Phase 3 clinical trial application, and we expect to begin enrolling subjects in the first half of 2015.

Planned Phase 4 Studies

The CFDA imposes a five-year monitoring surveillance period after NDA approval on all Class 1.1 innovative drugs like roxadustat. Based on current CFDA guidelines, we believe we will need to conduct a 2,000 subject post-marketing observational study to demonstrate the long-term safety of roxadustat as well as provide additional information related to the quality and stability of the manufacturing process for roxadustat. The study design will be determined after Phase 3 data become available.

FG-5200 FOR THE TREATMENT OF CORNEAL BLINDNESS IN CHINA

Corneal blindness, defined as visual acuity of 3/60 or less, is caused by various factors, including scarring resulting from infections, such as herpes simplex, physical trauma, chemical injury and genetic diseases affecting the function of the cornea. In countries with sufficient tissue banks and skilled surgeons, the treatment for corneal blindness is the replacement of the damaged cornea with a corneal graft from donor corneas from human cadavers. Despite use of immunosuppressive drugs, graft rejection remains a serious problem, resulting in graft failure within five years in approximately 35% of cases in the United States. We are developing FG-5200 for the treatment of corneal blindness resulting from partial thickness corneal damage.

In China, there are ethical or religious beliefs, cultural norms and significant infrastructure barriers that limit organ donation or tissue banking possibilities, resulting in an extreme shortage of cadaver corneas. Alternatives to cadaver corneas, such as collagen derived from porcine tissue or fish scales, are experimental, and to our knowledge, have not yielded satisfactory results. In many cases of corneal blindness, infection and other factors lead to serious risks to the patient.

Market Opportunity

Approximately 40,000 corneal grafts were performed in the U.S. in 2011 using tissue from human cadavers. In contrast, while there are approximately 4 to 5 million patients in China with corneal blindness and an incidence of 100,000 cases of corneal blindness each year, there were only about 3,000 corneal grafts performed in China in 2007 using tissue from human cadavers. We believe the number of corneal grafts using cadaver tissue in China may decrease significantly due to recent changes in government policy.

FG-5200 as a Potential Solution to This Unmet Medical Need

FG-5200 Corneal Implant

Our expertise in fibrosis and extracellular matrix proteins has allowed us to develop processes for producing human collage types I, II and III, as well as coordinate expression of several enzymes involved in assembly of collagen. We have successfully produced a proprietary version of recombinant human collagen III that is suitable for use in cornea repair.

FG-5200, a corneal implant that we intend to apply for approval as a medical device in China, is designed to serve as an immediately functional replacement cornea as well as a temporary scaffold to allow for regeneration of the native corneal tissue. In contrast, cadaver graft tissue is never “turned over”; in fact, only limited integration occurs over the life of the graft. Our FG-5200 implant is made of recombinant human collagen that has been formed into a highly concentrated fibrillar matrix to provide physical characteristics optimal for corneal implantation.

In animal models, FG-5200 persists for less than one year, at which time native tissue has completely regrown, including both epithelium (the outer cell layer of the cornea) and stroma. The stroma in these animal models is seen to be infiltrated with nerve fibers, leading to the reacquisition of the touch response critical to the avoidance of additional corneal damage.

Corneal implants using human donor tissue are currently being reimbursed by the government, and similar to many other implantable Class III devices in China (including stents and bone grafts), we would expect that FG-5200 could be added to the reimbursement list for medical devices, if approved.

Clinical Testing of FG-5200

An initial clinical study outside of China has been conducted to test the safety and feasibility of using a biosynthetic implant composed of recombinant human collagen for the treatment of severe corneal damage as an alternative to human donor tissue. Ten patients with advanced keratoconus, or severe corneal scarring, were implanted with the recombinant collagen implants and have been followed for more than five years. Two-year follow-up data were reported in *Science Translational Medicine* (Fagerholm et al., (2010)) and four-year follow-up data were reported in *Biomaterials* (Fagerholm et al., *Biomaterials* (2014)). Key clinical findings include the following:

- Patients with biosynthetic implants had a 4-year mean corrected visual acuity of 20/54 and gained on average more than 5 Snellen lines of vision on an eye chart.
- Nerve re-growth and touch sensitivity was closer to that of healthy corneas and significantly better in corneas with biosynthetic implants than in human donor corneas.
- Corneas with biosynthetic implants maintained a stable shape and thickness without any need for a long course of immunosuppression therapy.
- There has been no recruitment of inflammatory dendritic cells into the biosynthetic implant area and no episodes of rejection, in contrast to the control arm of human donor cornea transplantation, where a rejection episode was observed.

Using our animal models, we tested FG-5200 against the original formulation of our implants used in the clinical study described above, which contained a lower collagen concentration. The animal studies showed no difference in safety but improved epithelialization with FG-5200 due to the less intrusive suturing technique possible with the new, higher collagen content formulation.

We plan to meet with the CFDA to reach agreement on design and patient size of our clinical program for FG-5200.

FG-5200 Strategy

FibroGen China has submitted a device classification application to the CFDA to designate FG-5200 corneal implants as a Domestic Class III medical device. We have not submitted an investigational device exemption or similar application for FG-5200. We are currently focused on planning, building and certifying our corneal implant manufacturing process in China prior to initiating a pivotal study.

Subject to CFDA designation, we currently plan to manufacture FG-5200 clinical trial material in an aseptic production suite built within the same Beijing manufacturing plant in which we will manufacture roxadustat for China.

We plan to develop FG-5200 in China first. If FG-5200 is successful in China, we believe there is a future opportunity to develop FG-5200 in other Asian countries where cadaver materials are in short supply, in part because cultural norms and infrastructure and other challenges in tissue banking limit tissue donations. We also believe there is an opportunity to obtain CE Marking to facilitate entry into other markets, such as Latin America. We may develop FG-5200 in the United States and Europe as well, where cadaver corneas are available but the required immunosuppressive therapy may make FG-5200 a potentially attractive alternative.

FG-3019 FOR THE TREATMENT OF FIBROSIS AND CANCER

We were founded to discover and develop therapeutics for fibrosis. We began studying connective tissue growth factor, or CTGF, shortly after its discovery. Our ongoing internal research, efforts with collaboration partners and the work of other investigators have consistently demonstrated elevated CTGF levels in pathologic fibrotic conditions characterized by sustained production of extracellular matrix, or ECM, elements that are key molecular components of fibrosis. 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 fully-human monoclonal antibodies that bind to different parts of the CTGF protein and block various aspects of CTGF biological activity, we selected FG-3019, for which we have exclusive worldwide rights. We believe that FG-3019 blocks CTGF and inhibits its central role in causing diseases associated with fibrosis. Our data to date indicate that FG-3019 is a promising and highly differentiated product with broad potential to treat a number of fibrotic diseases and cancers. We are currently conducting Phase 2 trials in idiopathic pulmonary fibrosis, or IPF, pancreatic cancer and liver fibrosis. FG-3019 has received orphan drug designation in IPF in the United States.

Based on its ability to block CTGF, FG-3019 may be a treatment for a broad array of fibrotic disorders of nearly every organ system. In animal studies of FG-3019, such as radiation-induced pulmonary fibrosis in mice, we have demonstrated that FG-3019 is capable of reversing fibrosis. In clinical trials, we have used advanced medical imaging technology to quantify changes in fibrosis throughout the lungs. Our data to date using these measures demonstrate that FG-3019 may stabilize and in some instances reverse pulmonary fibrosis and improve pulmonary function in IPF patients.

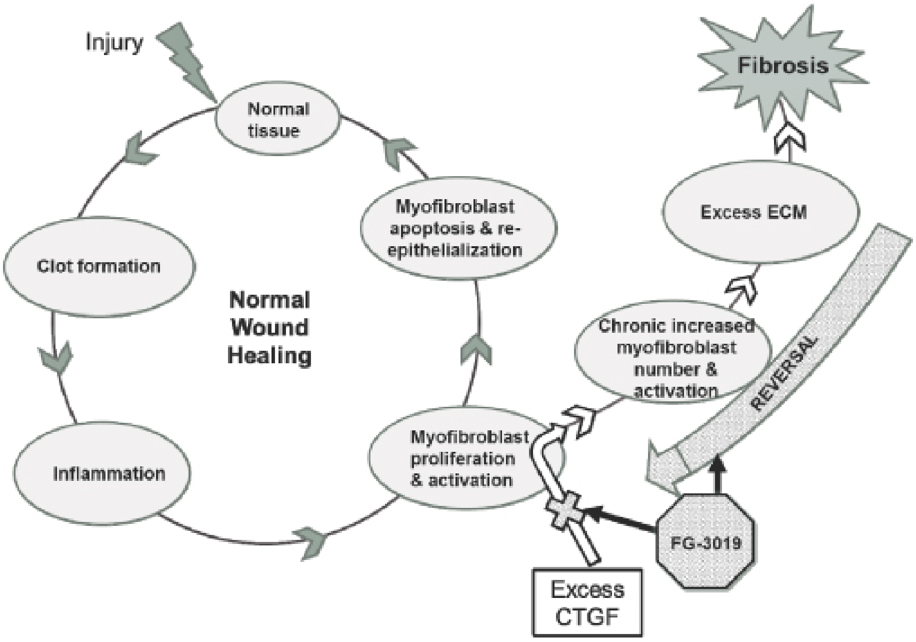
Certain cancers have a prominent ECM component that contributes to metastasis and progressive disease. Specifically, ECM is the connective tissue framework of an organ or tissue; all tumors have ECM. In the case of fibrotic tumors, ECM is more pronounced and there is more fibrosis than in other tumor types. In mouse models of pancreatic cancer, FG-3019 treatment has demonstrated reduction of tumor mass, slowing of metastasis and improvement in survival. In an open-label Phase 2 study of FG-3019 plus gemcitabine and erlotinib, FG-3019 demonstrated a dose-dependent improvement in one year survival rate.

Results to date indicate that FG-3019 has broad potential to address unmet needs for the treatment of fibrotic diseases and cancers. Specifically, given the preclinical and clinical data in pulmonary fibrosis and pancreatic cancer, our primary focus for clinical development of FG-3019 is additional Phase 2 clinical trials in metastatic pancreatic cancer and IPF. We are also conducting exploratory clinical trials with FG-3019 in liver fibrosis secondary to viral infection.

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 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.

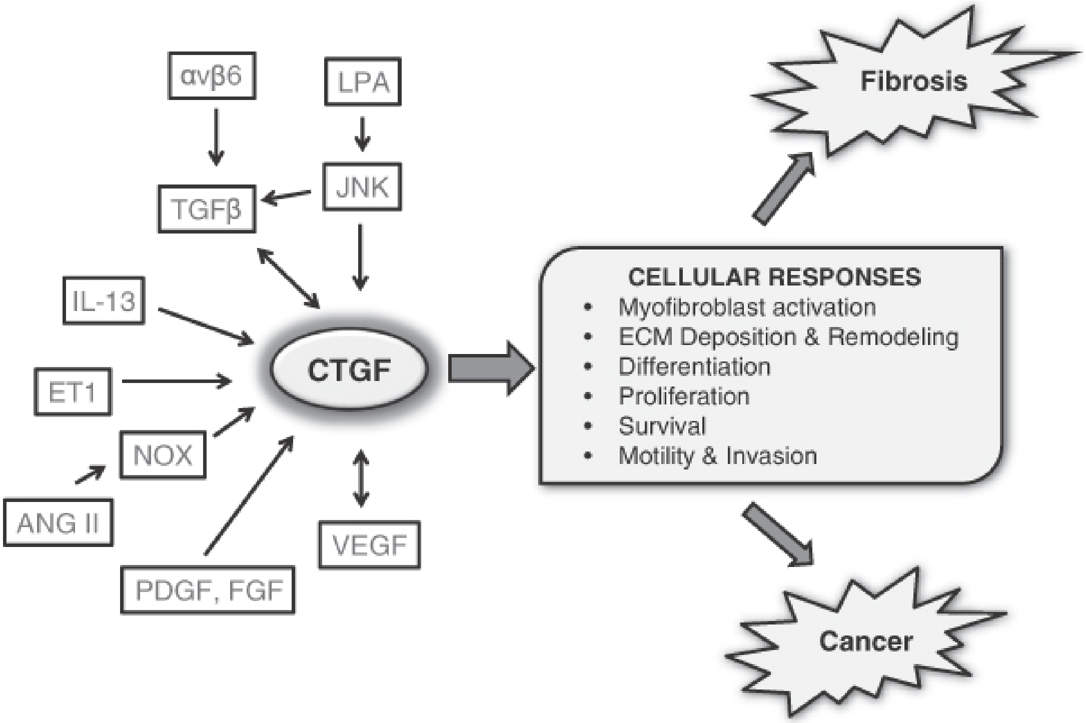
Excess CTGF Causes Fibrosis. FG-3019 Blocks CTGF and Reverses Fibrosis



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. In fibrotic conditions, excess CTGF results in chronic activation of myofibroblasts, which leads to chronic ECM deposition and fibrosis (see figure above).

Multiple biological agents and pathways have been implicated in the fibrotic process (Wynn J Pathol (2008)). Many fibrosis pathways converge on CTGF (see figure below), which the scientific literature demonstrates to be a central mediator of fibrosis (Oliver et al, J Inv Derm (2010)). In the case of cancer, the sustained tumor-associated fibrotic tissue promotes tumor cell survival and metastasis. The figure below shows the commonality of cellular mechanisms that may result in fibrosis and cancer.

Most Biological Factors Implicated in Fibrosis Work Through CTGF



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-b and vascular endothelial growth factor, or 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 stop or reverse tissue fibrosis. In addition, since CTGF is implicated in nearly all forms of fibrosis, we believe FG-3019 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 can be reversed in some instances upon treatment with FG-3019. We do not believe that there is clinical evidence that therapies currently on the market directly prevent or reverse fibrosis in human disease. While certain other companies are working on topical inhibition of CTGF, we are not aware of other products in development that target CTGF inhibition for deep organ fibrosis and cancer.

Clinical Development of FG-3019—Overview

We have performed clinical trials of FG-3019 in IPF, pancreatic cancer, liver fibrosis and diabetic kidney disease. We are currently conducting an extension study for an open-label Phase 2 trial in IPF; a randomized, double-blind placebo-controlled Phase 2 trial in IPF; an open-label Phase 2 trial in pancreatic cancer; and a randomized, double-blind, placebo-controlled Phase 2 trial in liver fibrosis. In ten Phase 1 and Phase 2 clinical studies involving FG-3019 to date, including more than 340 patients who were treated with FG-3019 (146 patients dosed for more than 6 months), FG-3019 has been well-tolerated across the range of doses studied, and there have been no dose-limiting toxicities seen thus far.

In IPF, we completed a Phase 1 single dose trial, and subsequently advanced the program to an ongoing open-label Phase 2 trial of FG-3019 in 89 patients, which has completed its one year treatment period and based on encouraging results is now in an extension phase. We are also conducting a randomized, double-blind, placebo-controlled Phase 2 trial. Both Phase 2 trials are designed to evaluate the effects of FG-3019 on pulmonary function, extent of fibrosis and health-related quality of life.

In pancreatic cancer, we performed an open-label, dose-finding Phase 2 trial in a total of 75 patients with advanced pancreatic cancer. We recently began a randomized, active-control, neoadjuvant Phase 2 trial combining FG-3019 with nab-paclitaxel plus gemcitabine in approximately 40 patients with locally advanced pancreatic cancer. We anticipate interim data from this study in the second half of 2015. We also expect to begin a randomized Phase 2 trial of FG-3019 in metastatic pancreatic cancer patients in the first half of 2015. However, actual dates depend on a variety of factors and are subject to numerous risks and uncertainties, including with respect to patient enrollment, safety results, manufacturing, third party contractors, and government regulators, some of which are out of our control. See also “Risk Factors” beginning on page 16, and particularly those risk factors under the heading “Risks Related to the Development and Commercialization of Our Product Candidates.”

We are conducting a Phase 2 clinical trial with FG-3019 in liver fibrosis associated with hepatitis B, or HBV, in Hong Kong and Thailand, where the prevalence of HBV is high. A small pilot clinical study in liver fibrosis associated with hepatitis C, or HCV, associated fibrosis is also being conducted in Hong Kong.

Early clinical development included studies in diabetic kidney disease. Although no adverse outcomes were observed, we decided not to pursue this indication at this time based on the difficulty of the regulatory path and the extensive clinical trials likely to be required for approval for the treatment of diabetic kidney disease.

The table below provides a summary of our clinical trials involving FG-3019:

Completed and Ongoing FG-3019 Clinical Trials

Study, Study #	Study Design	Dose (mg/kg)	Frequency	Treatment Duration (weeks)	Subjects
Phase 1—IPF, FGCL-MC3019-002	Open-label, dose-escalation	1, 3, or 10	Single		21
Phase 2—IPF, FGCL-3019-049	Open-label, dose-escalation	15 or 30	Every 3 weeks	45 weeks	89*
Phase 2—IPF, FGCL-3019-067	Double-blind, placebo-controlled (1:1)	30 mg/kg	Every 3 weeks	45 weeks	Target 136**
Phase 2—Pancreatic Cancer, FGCL-MC3019-028	Open-label, dose-escalation	3, 10, 15, 25, 35, or 45 17.5 or 22.5	Every other week Weekly	Until disease progression 1 to 89 weeks	75
Phase 2—Pancreatic Cancer, FGCL-3019-069	Open-label, active control (1:1)	35	Cycle 1 = Days 1, 8 and 15 Subsequent Cycles = Every other week	24 weeks	Target 40**
Phase 2—HBV- Liver Fibrosis, FGCL-3019-801	Double-blind, placebo-controlled (2:1)	15 or 45	Every 3 weeks	45 weeks	Target 120**
Phase 2—HCV- Liver Fibrosis, FGCL-3019-802	Open-label	30	Every 3 weeks	45 weeks	Target 15**
Phase 1—Diabetic Kidney Disease, FGCL-MC3019-003	Open-label, dose-escalation	3 or 10	Days 0, 14, 28 and 42	6 weeks	24
Phase 2—Diabetic Kidney Disease, FGCL-3019-029	Double-blind, placebo-controlled (1:1:1)	5 or 10	Every 2 weeks Every 4 weeks	12 weeks 12 weeks	38
Phase 2—Diabetic Kidney Disease, FGCL-3019-032	Double-blind, placebo-controlled	3 or 10	Biweekly	26 weeks	46

* Study 049 completed its one year treatment period and, based on encouraging results, is now in an ongoing extension phase.

** Currently enrolling.

Idiopathic Pulmonary Fibrosis

Understanding IPF and the Limitations of Current Therapies

IPF is a form of progressive pulmonary fibrosis, or abnormal scarring, that 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 confirmatory diagnosis of IPF is estimated to be between 3 to 5 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, or HRCT, imaging technology have enabled more reliable diagnosis of IPF and clearer distinction from other interstitial lung diseases.

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. In 2011, Decision Resources Group estimated that there will be approximately $4.6 billion in sales of IPF drugs in the United States and Europe in 2020.

Pirfenidone has been approved to treat IPF in Europe, Canada, Japan and the United States. According to the FDA advisory committee submission by its sponsor, pirfenidone has been shown to have a modest effect on slowing the progression of IPF as measured by forced vital capacity, or FVC, in a minority (less than 15%) of patients. Nintedanib has also been approved to treat IPF in the United States and has been submitted for accelerated approval in the EU. We believe that FG-3019 has the potential to stabilize or reverse lung fibrosis and if approved, improve the prognosis for patients with IPF.

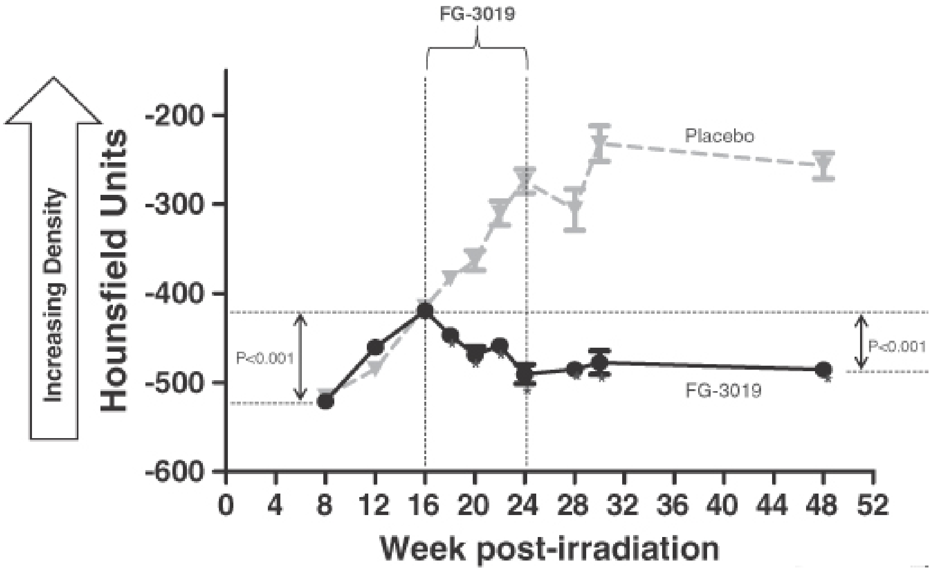
Reversal of Lung Damage in Preclinical Models with FG-3019 in Pulmonary Fibrosis

While there are no established animal models for IPF, we selected the mouse model of radiation-induced lung damage from a variety of other models because we believe that it most closely approximates the process of lung fibrosis seen in humans. We conducted a proof of concept study of FG-3019 using this model as summarized in the figures below.

In this model, a single irradiation of the thorax causes lung tissue damage that over time results in progressive fibrosis. Lung density, indicative of tissue damage, was monitored by HRCT and began to increase eight to 12 weeks after irradiation.

Sixteen weeks after irradiation, measured lung density was significantly elevated and continued to increase in the placebo-treated animals until reaching a plateau at Week 30. Therapeutic treatment with FG-3019 began at Week 16. Significant decreases in lung fibrosis were measurable at Week 18 and it continued to decrease over the eight weeks of FG-3019 treatment through Week 24.

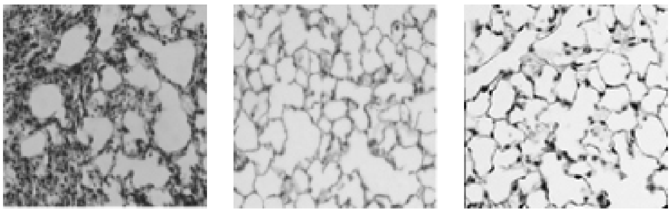
FG-3019 Treatment Starting 16 Weeks After Irradiation Reverses Lung Fibrosis in Mice as Measured by HRCT (Mean ± SE)



* indicates FG-3019-treated lung density is significantly different (p£ 0.05) from placebo-treated

Rapid reversal of lung damage was confirmed by examining tissue histology which showed substantial changes within two weeks of initiating treatment. Prior to FG-3019 treatment (Week 16) lung histology showed lung damage characterized by increased cellularity and tissue remodeling. After two weeks of treatment with FG-3019 (Week 18), damage had been reversed and the structure of the lung more closely resembled that of a non-irradiated or normal mouse. The figure below is representative of the typical pattern of structural changes observed in the mice in this study.

Two Weeks After FG-3019 Treatment: Structural Changes Could be Seen by Lung Histology in Mice



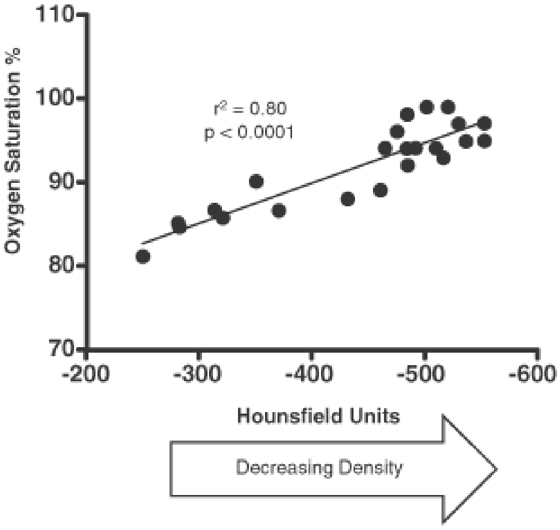
Week 16
Pre-Treatment

Week 18
2 Weeks after starting
FG-3019 Treatment

Normal

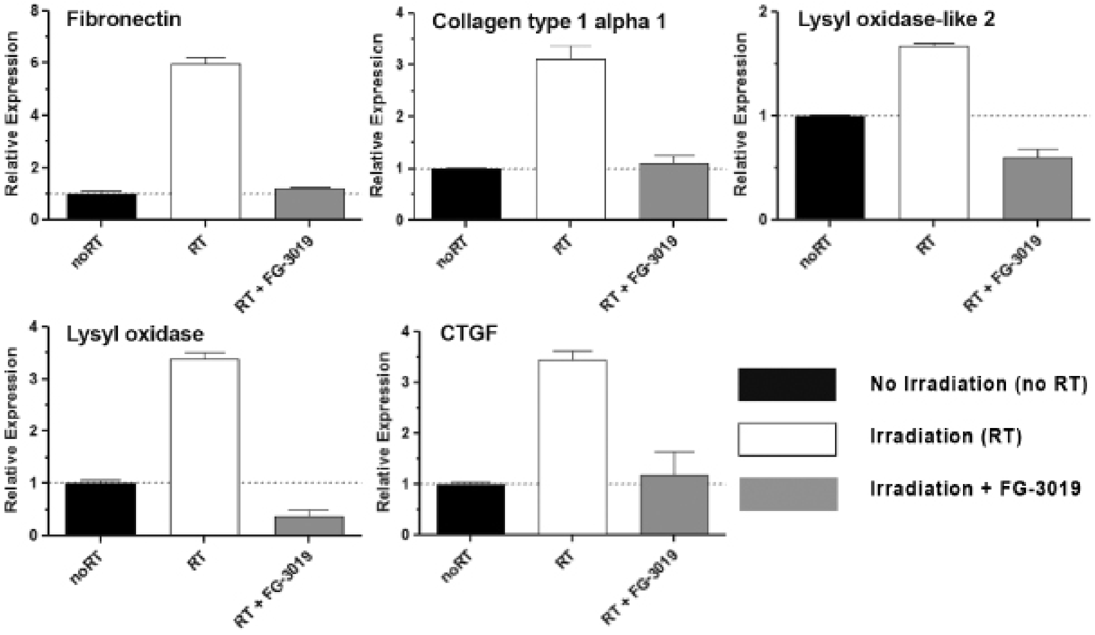
As shown below, reduced lung density consistently correlated with improved lung function, as measured by blood oxygenation.

Improvement of Lung Fibrosis Corresponds with Improvement in Lung Function in Mice



Gene expression changes were also examined at Week 18, two weeks after initiation of treatment with FG-3019. Irradiation induced increased expression of genes involved in ECM deposition, such as fibronectin, collagen type 1 alpha 1, lysyl oxidase, CTGF and lysyl oxidase-like 2. FG-3019 treatment was shown to reduce expression of these genes, as illustrated below.

Examples of Changes in Gene Expression by mRNA Microarray Analysis (mean ± SE) after FG-3019 Treatment in Mice



Clinical Trials of FG-3019 for IPF

Study 002 was a Phase 1 open-label study to determine the safety and PKs of escalating single doses of FG-3019. Patients with a diagnosis of IPF by clinical features and surgical lung biopsy received a single IV dose of FG-3019 at 1, 3, or 10 mg/kg. A total of 21 patients were enrolled in the study; 6 patients received a dose of 1 mg/kg, 9 patients received 3 mg/kg, and 6 patients received 10 mg/kg. FG-3019 was well tolerated across the range of doses studied; and there were no dose-limiting toxicities. Treatment emergent adverse events that were considered to be possibly related by the principal investigator to FG-3019 were mild and self-limited, consisting of pyrexia, cough and headache.

We completed the initial one-year treatment portion of Study 049, a Phase 2 open-label, dose-escalation study to evaluate the safety, tolerability, and efficacy of FG-3019 in 89 patients with IPF. FG-3019 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 3 weeks for 45 weeks. Nineteen patients from Cohort 1 participated in the current 1 year extension of dosing. Efficacy endpoints are pulmonary function assessments, extent of pulmonary fibrosis as measured by quantitative imaging and measures of health-related quality of life.

HRCT is typically used to diagnose IPF based on visual assessments of computed tomography, or CT, images of lung fibrosis. We used quantitative HRCT to measure changes in fibrosis in this Study 049. We used software to quantify whole lung fibrosis from the compilation of 1 mm HRCT sections of the entire lung. The computer algorithm, which our vendor validated, provides an overall determination of the percentage of the lung that contains individually the three characteristic forms of IPF fibrosis, including reticular IPF fibrosis which is expected to make the most dynamic contribution to overall lung fibrosis.

The extent of lung fibrosis as measured by quantitative HRCT has been shown to be accurate and reproducible (Kim et al. Eur Radiol (2011)). Recent publications based on similar quantitative HRCT methods have identified an association between worsening pulmonary fibrosis and mortality in IPF (Maldonado et al. Eur Resp J (2014); Oda et al. Respiratory Research (2014)). However, HRCT has not been used by the FDA to establish efficacy in IPF.

Eighty-nine patients in this Phase 2 open label study received at least one dose of FG-3019. We defined disease severity in terms of baseline pulmonary function, measured as the FVC percent of the predicted value for a healthy matched person of the same age, or FVC percent predicted. Severe disease was FVC percent predicted < 55%, moderate disease was FVC percent predicted between 55% and 80%, and mild disease was FVC percent predicted >80%.

In Cohort 1, we enrolled patients with a wide range of disease severity to assess safety and efficacy across the full spectrum. 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 ³ 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.

Disease Severity in Enrolled and Evaluated Patients Treated with FG-3019 in FGCL-3019-049

		Cohort 1				Cohort 2			
		Severe	Moderate	Mild		Severe	Moderate	Mild	
	FVC % Predicted	< 55%	55% to 80%	> 80%		< 55%	55% to 80%	> 80%	
		N			Total	N			Total
Total	**Enrolled**	16	34	3	53	4	22	10	36
	Complete	5	30	3	38	1	17	10	28
Evaluated	**Enrolled**		34	3	37		22	10	32
	Complete		30	3	33		17	10	27

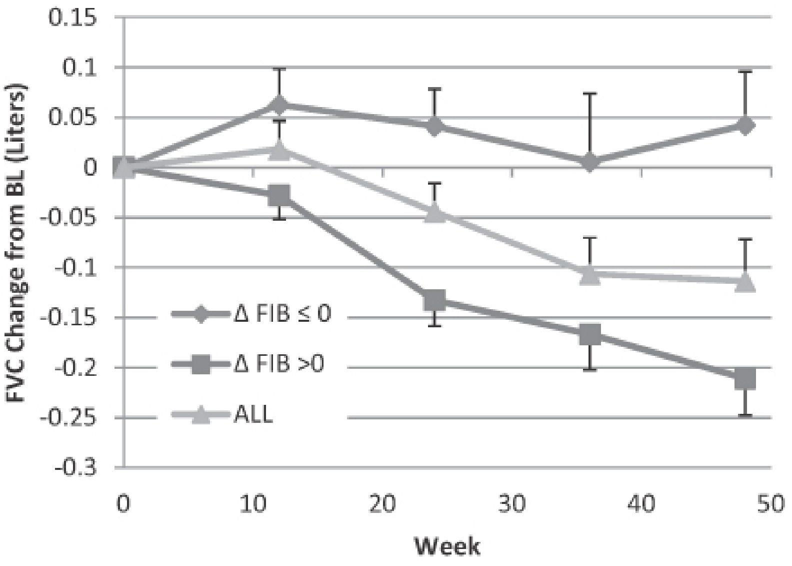
The table below provides a summary of the observed quantitative change in fibrosis for patients in Cohorts 1 and 2 as measured by HRCT. Twenty-four percent of these patients had improved fibrosis at Week 48. We believe that this is the first trial to demonstrate reversal of fibrosis in IPF. Stable fibrosis 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 FG-3019 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	33/74 (45%)	23/66 (35%)	17/74 (23%)	16/66 (24%)	16/64 (25%)

Fibrosis improvement or stabilization in patients with mild to moderate disease as measured by HRCT correlated with improvement or stabilization of pulmonary function measured by FVC ($p<0.0001$; $r=-0.59$ Cohorts 1 and 2 combined). The figure below shows FVC changes up to Week 48 for patients with stable or improved fibrosis versus patients with worsening fibrosis. Patients with stable or improved fibrosis showed improved pulmonary function, on average, which was significantly different or better than patients with worsening fibrosis who showed a substantial decline in FVC ($p= 0.0001$, Cohorts 1 and 2 combined). Patients with worsening fibrosis had pulmonary function that was similar to the annual decline in pulmonary function for typical IPF patients.

Categorical Analysis of FVC Change from Baseline (BL) (mean ±SE) in FGCL-3019-049



The FVC changes observed in Study 049 are compared to the changes reported in Phase 3 clinical trials for pirfenidone and nintedanib in the table below.

Comparison of FGCL-3019-049 Mean FVC Change in One year to Phase 3 Results for Pirfenidone and Nintedanib

	Mean Change of FVC in One Year				
	N Pbo/Active	Placebo	Active	Difference	%
Pirfenidone I*	174/176	-350	-181	169	48.2%
Pirfenidone II*	173/171	-274	-220	54	19.7%
Pirfenidone III†	238/223	-280	-164	116	41.5%
Nintedanib I	204/307	-205	-95	110	53.6%
Nintedanib II	217/327	-205	-95	110	53.6%
FG-3019	0/66	-	-140		

*Week48, FVC (rank ANCOVA w/ imputation)
† Linear slope analysis

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. To date, including the 1-year extension of dosing, there have been 45 SAEs in 31 patients, four of which were considered possibly related by the principal investigator to study treatment. During the first year of treatment there were 32 SAEs in 24 patients. Adverse events observed to date are consistent with typical conditions observed in this patient population.

In aggregate, the data from the Phase 2 open-label, dose-escalation study indicate that a subset of FG-3019 treated IPF patients experienced improvements in lung fibrosis with commensurate improvement in pulmonary function and a potential for prolonged benefit with continued treatment. These results are consistent with the mouse disease model results which showed that FG-3019 treatment can reverse lung fibrosis and result in improved pulmonary function. We believe that our patient data showing correlated improvements in both fibrosis and lung function in some patients have not been seen in previously published IPF clinical studies.

Clinical Development Plan for FG-3019 in IPF

Study 067 is an ongoing Phase 2, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of FG-3019 in approximately 136 IPF patients with mild to moderate disease (baseline FVC percentage predicted between 55% and 90%). Patients are being randomized (1:1) to 30 mg/kg of FG-3019 or placebo, every 3 weeks, for 45 weeks. As with our open-label Phase 2 trial, Study 049, the primary efficacy endpoint for Study 067 is change in FVC from baseline. Secondary endpoints are extent of pulmonary fibrosis as measured by quantitative HRCT, other pulmonary function assessments and measures of health-related quality of life. The study is currently enrolling and we plan to meet with the FDA to discuss the further development of FG-3019, including the potential to explore higher doses and more frequent dosing, which may further improve efficacy. We anticipate reporting data from this study in the second half of 2016. However, the actual date will depend on a variety of factors and are subject to numerous risks and uncertainties, including with respect to patient enrollment, safety results, manufacturing, third party contractors and government regulators, some of which are out of our control. See also “Risk Factors” beginning on page 16, and particularly those risk factors under the heading “Risks Related to the Development and Commercialization of Our Product Candidates.”

Pancreatic Cancer

Understanding Pancreatic Cancer and the Limitations of Current Therapies

Pancreatic ductal adenocarcinoma, or pancreatic cancer, is the fourth leading cause of cancer deaths in the United States. U.S. prevalence of pancreatic cancer is estimated to be 44,000. According to the National Cancer Institute, in 2014 there are projected to be approximately 46,000 new cases of pancreatic cancer and approximately 39,000 deaths from the disease in the United States. According to the World Health Organization, or WHO, and based on data from the United Nations Population Division, there were approximately 79,000 new cases of pancreatic cancer and approximately 78,000 deaths in the EU in 2012. The National Cancer Center of Japan estimated that in 2010 (latest year available) there were 32,330 new cases of pancreatic cancer. In 2013, Decision Resources Group estimated that there will be approximately $1.3 billion in sales of pancreatic cancer drugs in 2022.

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 recently approved by the FDA for the treatment of pancreatic cancer, having demonstrated median survival of 8.5 months. These drugs illustrate that progress in treatment for pancreatic cancer has been limited, 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, 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 FG-3019 indicate that it has the potential to inhibit tumor expansion through effects on tumor cell proliferation and apoptosis as well as reduce metastasis.

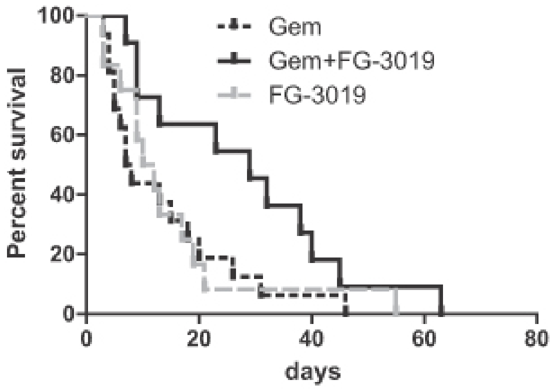
Preclinical Models of FG-3019 for Pancreatic Cancer

We tested FG-3019 in mouse models of pancreatic cancer, where it has demonstrated reduction of tumor mass and metastasis in several models, including the genetically engineered KPC mouse model. This is a preferred model for studying pancreatic cancer because all KPC mice spontaneously develop pancreatic cancer that closely approximates many features of the human disease, including similar genetic mutations, expression of CTGF, extensive stroma, metastases and ascites, or abdominal fluid, formation. KPC mouse tumors, like human pancreatic cancer tumors, are highly resistant to anti-cancer therapies. We performed two short-term studies of tumor responses to treatment and a long-term study of survival which were all conducted with staggered enrollment as mice developed tumors of sufficient size.

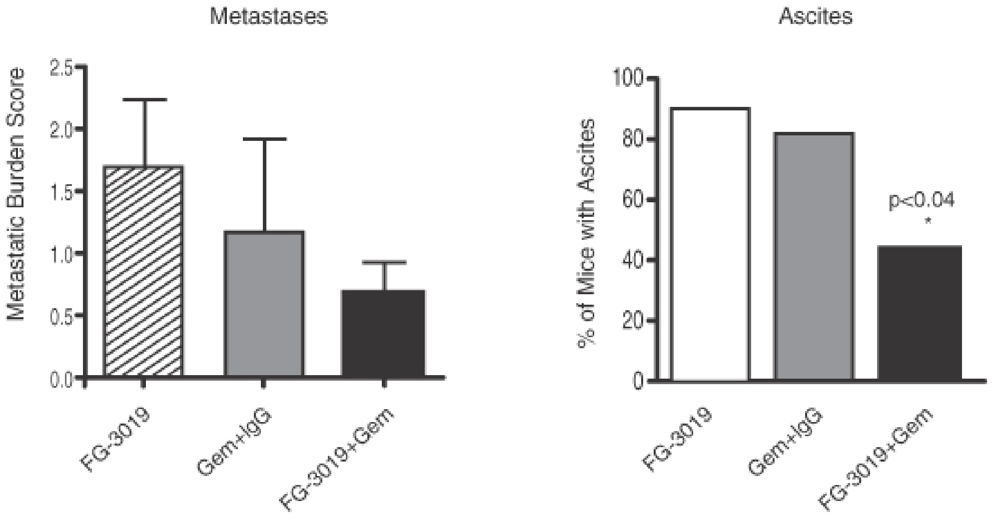
After initiation of treatment, mice randomized to FG-3019 alone survived for 11 days, which is comparable to the historical experience with gemcitabine alone of 7.5 days. The combination of FG-3019 plus gemcitabine increased survival to 29 days.

In additional studies, malignant hemorrhagic ascites were significantly reduced and liver metastases were reduced (although the reduction was not statistically significant) with the combination of FG-3019 plus gemcitabine. Both FG-3019 and FG-3019 plus gemcitabine increased tumor cell apoptosis significantly compared to gemcitabine alone. Our data suggest that FG-3019 may increase tumor cell apoptosis and improve survival in mice by inhibiting expression of XIAP, or X-linked inhibitor of apoptosis. XIAP is one of a family of proteins whose function is to inhibit apoptosis. Elevated expression of XIAP promotes cell survival and is one mechanism by which tumor cells can become resistant to chemotherapeutic agents. FG-3019 decreased XIAP levels significantly whereas gemcitabine did not decrease XIAP levels. The combination of FG-3019 and gemcitabine was even more effective as shown in the figure below.

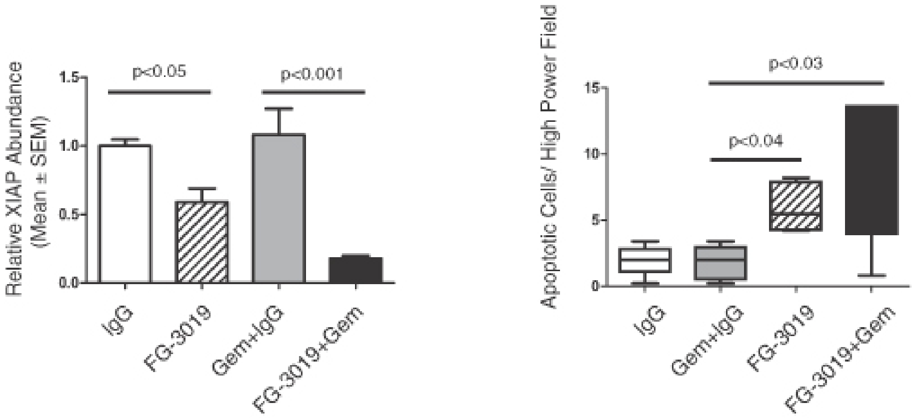
FG-3019 Plus Gemcitabine Treatment Increased Survival (11-13 Mice per Group) in the KPC Mouse Model



FG-3019 Plus Gemcitabine Treatment Reduced Metastasis and Ascites in the KPC Mouse Model (mean ±SE) (*Indicates Statistically Significant Difference from Gemcitabine + IgG)



FG-3019 Plus Gemcitabine Treatment Reduced Expression of Tumor Pro-Survival Gene XIAP and Increased the Number of Apoptotic Cells in the KPC Mouse Model



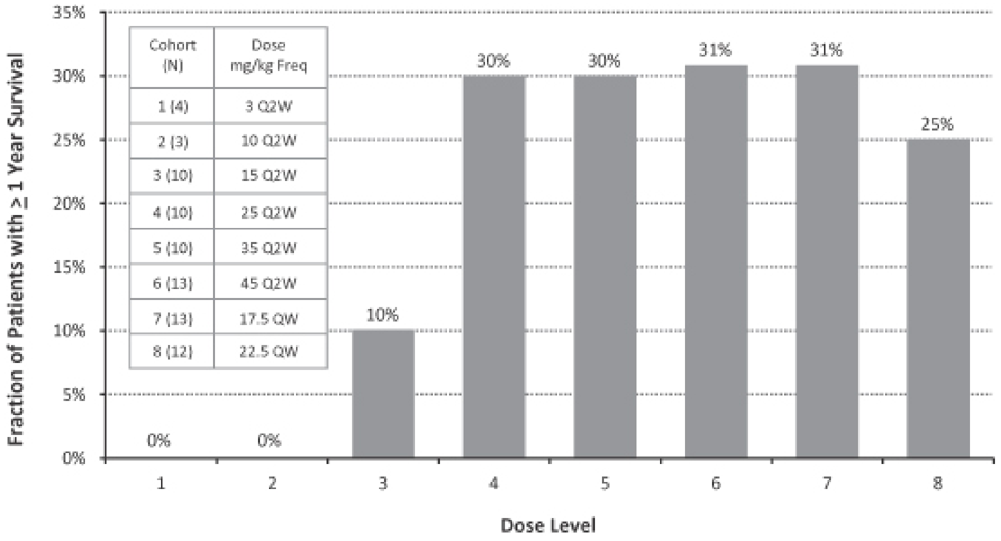
Median inter-quartile ranges and maximum and minimum observations

Clinical Trials of FG-3019 for Pancreatic Cancer

We completed an open-label Phase 2 (FGCL-MC3019-028) dose finding trial of FG-3019 combined with gemcitabine plus erlotinib in patients with previously untreated locally advanced (stage 3) or metastatic (stage 4) pancreatic cancer. The trial tested FG-3019 doses of 3 mg/kg, 10 mg/kg, 15 mg/kg, 25 mg/kg, 35 mg/kg and 45 mg/kg administered every two weeks, and FG-3019 doses of 17.5 mg/kg and 22.5 mg/kg administered weekly after a double loading dose. On Day 15, treatment began with gemcitabine 1000 mg/m^2 weekly for three weeks in a four week cycle and erlotinib 100 mg daily. Treatment continued until progression of the cancer or the patient withdrew for other reasons. Patients were then followed until death. Tumor status was evaluated by CT imaging every eight weeks until disease progression to assess changes in tumor mass.

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, as described in the figure below. At the lowest doses, no patients survived for even one year while at the highest doses up to 31% of patients survived one year.

Effect of FG-3019 Dose on One Year Survival in Pancreatic Cancer

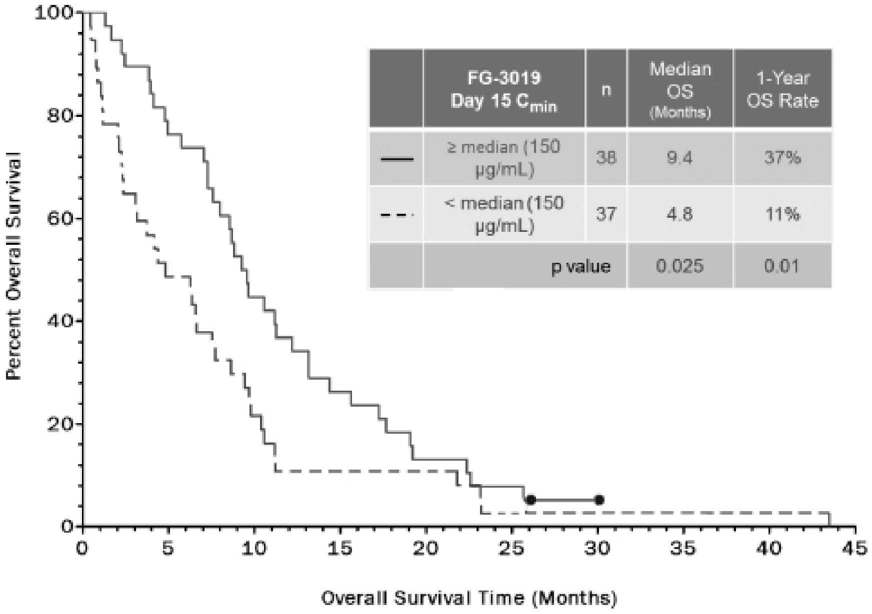


Cohort (N)	Dose mg/kg Freq
1 (4)	3 Q2W
2 (3)	10 Q2W
3 (10)	15 Q2W
4 (10)	25 Q2W
5 (10)	35 Q2W
6 (13)	45 Q2W
7 (13)	17.5 QW
8 (12)	22.5 QW

* QW = weekly; Q2W = twice weekly

A post-hoc analysis found that there was a significant relationship between survival and trough levels of plasma FG-3019 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) versus those patients with Cmin less than 150 µg/mL. For patients with Cmin ≥ 150 µg/mL median survival was 9.4 months compared to median survival of 4.8 months for patients with Cmin < 150 µg/mL. Similarly, 37% of patients with Cmin ≥ 150 µg/mL survived for longer than one year compared to 11% for patients with Cmin < 150 µg/mL. These data suggest that sufficient blockade of CTGF requires FG-3019 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 FG-3019



	FG-3019 Day 15 C_{min}	n	Median OS (Months)	1-Year OS Rate
—	≥ median (150 µg/mL)	38	9.4	37%
- - -	< median (150 µg/mL)	37	4.8	11%
	p value		0.025	0.01

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 FG-3019. There were 99 treatment emergent SAEs; six of which were assessed as possibly related by the principal investigator, and 93 as not related to study treatment. We did not identify any evolving dose-dependent pattern, and higher doses of FG-3019 were not associated with higher numbers of SAEs or greater severity of the SAEs observed.

In both the KPC mouse study and in this clinical trial, FG-3019 treatment had a substantial effect on survival with no apparent increase to the toxicity of the chemotherapeutic regimen.

Clinical Development Plan for FG-3019 in Pancreatic Cancer

For pancreatic cancer, we have recently begun enrolling an open-label, randomized (1:1) Phase 2 trial (FGCL-3019-069) of FG-3019 combined with gemcitabine plus nab-paclitaxel chemotherapy versus the chemotherapy regimen alone in patients with marginally inoperable pancreatic cancer that has not been previously treated. Approximately 40 patients are expected to be treated for up to 6 months and the number may be increased based on preliminary results. The overall goal of the trial is to determine whether the FG-3019 combination can convert inoperable pancreatic cancer to operable cancer. Tumor removal is the only chance for cure of pancreatic cancer, but only 15% to 20% of patients are eligible for surgery. The use of an anti-fibrotic agent in combination with chemotherapy may shrink the tumor size enough to enable surgical removal free from major blood vessels. The patients will then be followed for disease progression and overall survival. We will also perform numerous studies of the effects of treatment on gene and protein expression using pre-treatment and post-treatment tumor biopsies.

We also plan to perform a randomized (1:1) Phase 2 trial of FG-3019 combined with gemcitabine and nab-paclitaxel compared to the chemotherapy regimen alone to assess disease progression and survival in approximately 240 patients with previously untreated metastatic pancreatic cancer. The overall goal is to confirm our open-label Phase 2 data that suggest combinations of FG-3019 and chemotherapy may increase survival. We plan to open this study for enrollment in the first half of 2015.

Liver Fibrosis

Understanding Liver Fibrosis and the Limitations of Current Therapies

Fibrosis in the liver is caused primarily by hepatitis virus infection, obesity associated disorders such as non-alcoholic steatohepatitis, or NASH, and excessive consumption of alcohol. Repetitive injury to the liver from these causes leads to worsening fibrosis culminating in liver cirrhosis, organ failure and increased risk of hepatocellular carcinoma. There are no approved pharmaceutical treatments for liver fibrosis in the United States. Treating the underlying cause of disease may stabilize or reverse fibrosis, but only liver transplantation can treat fibrosis that has advanced to cirrhosis.

Despite advances in HBV and HCV antiviral therapy, reversal of fibrosis is slow, and largely observed in patients with mild to moderate fibrosis. Nonetheless, a significant proportion of hepatitis patients have pre-cirrhotic or cirrhotic liver fibrosis and treatments that address the fibrotic process itself would provide benefit for patients with approaching liver failure. Aside from weight loss, there are no available treatments for NASH. The American Liver Foundation estimates a prevalence of 0.9 to 2.5 million cases in the United States for advanced NASH. As in other forms of fibrosis, elevated tissue and plasma levels of CTGF have correlated with disease severity.

According to the World Health Organization, about 240 million people worldwide are chronically infected with HBV and approximately 130 to 150 million people are chronically infected with HCV. NASH and non-alcoholic fatty liver disease are associated with obesity and are becoming increasingly important causes of cirrhosis. NASH has been estimated to affect 5% to 7% of the general population (Starley et al. Hepatology (2010)).

Clinical Development of FG-3019 for Liver Fibrosis

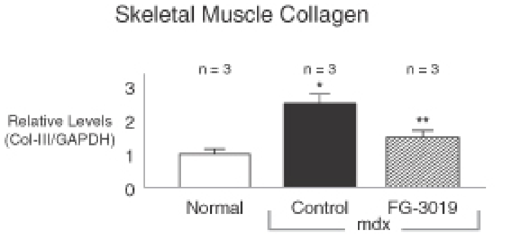
A randomized, placebo-controlled Phase 2 clinical trial is currently being conducted with FG-3019 in 120 patients with HBV-associated liver fibrosis in Hong Kong and Thailand, where the prevalence of HBV is high. The primary endpoint of the trial is change in fibrosis as assessed in liver biopsies. Efficacy data comparing low and high doses of FG-3019 compared to placebo are expected in 2015. A small pilot clinical study in HCV is also being conducted in Hong Kong.

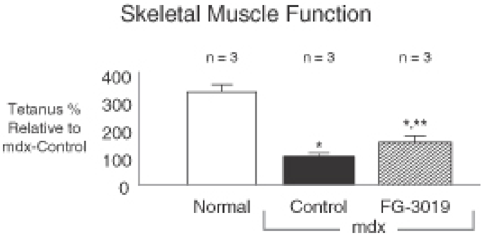
Our future clinical development strategy for liver fibrosis is under active consideration. The need and opportunity for an anti-fibrotic therapy to prevent cirrhosis associated with hepatitis and NASH patients are sizable. However, there is no regulatory consensus on study end-points because clinical manifestations of liver disease do not become apparent until fibrosis is advanced. As with HRCT for pulmonary fibrosis, the imaging technologies are improving for assessment of liver fibrosis, and we are evaluating their applicability to clinical trials for liver fibrosis. There are active efforts by the FDA and liver medical societies to focus on clinical trial design for liver fibrosis and address this challenge. Liver biopsies, the gold standard for measuring liver fibrosis, have significant risks and sample only a small portion of the liver. In a manner similar to our approach to IPF where we assess lung fibrosis by quantitative HRCT, we are currently exploring other non-invasive measurements of overall liver fibrosis, such as magnetic resonance elastography.

FG-3019 for Duchenne Muscular Dystrophy

In the United States, 1 in 3,500 boys have Duchenne muscular dystrophy, or DMD, and there are currently no approved disease-modifying treatments. Most children, despite taking steroids to mitigate progressive muscle loss, are wheelchair bound by age 12, and median survival is age 25. DMD is caused by absence of the dystrophin protein resulting in abnormal muscle structure and function and buildup of fibrosis in muscle, leading to diminished mobility, pulmonary function and cardiac function. 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.

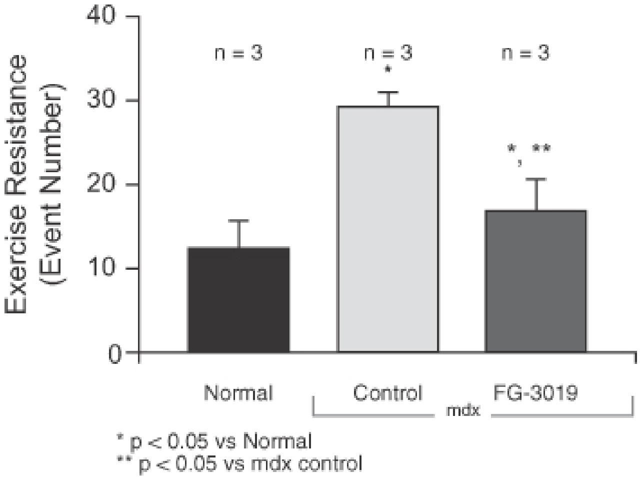
Higher CTGF levels correlate with more skeletal muscle fibrosis, and increased CTGF mRNA levels have been found in human DMD muscle and in the mdx mouse model, an accepted model of DMD (Pessina (2014)). It has also been shown in mdx mice that increased CTGF expression occurs concurrently with the progression of cardiac fibrosis, or cardiomyopathy (Au (2011)), and precedes the onset of overt cardiac dysfunction. Vial et al (2008) published results indicating that CTGF induced several ECM constituents and had an inhibitory effect on muscle cell differentiation by decreasing nuclear translocation of myogenin and myosin. CTGF treatment of myoblasts induced their de-differentiation, or failure to become mature muscle cells. These data suggest that in muscle tissue, CTGF directly impacts not just fibrosis but muscle cell phenotype. Morales (2011) showed that CTGF over-expression in tibialis anterior muscle of normal mice induced extensive skeletal muscle damage. CTGF over-expression induced fibrosis and caused a decrease of the specific isometric contractile force of the muscle. When CTGF over-expression stopped, the pathology was reversed. As compared with the mdx mouse model of DMD, both mdx mice with hemizygous CTGF gene deletion (causing a reduction of CTGF levels), and mdx mice treated with FG-3019 performed better in an exercise endurance test, had better muscle strength in isolated muscles and reduced skeletal muscle impairment, apoptotic damage and fibrosis. The figures below show decreased fibrosis (as measured by collagen) and increased muscle strength (as measured by relative tetanus %) in the FG-3019 treated mdx mice as compared to the mdx control mice.





* $p < 0.05$ vs Normal
** $p < 0.05$ vs mdx control
Morales et al. Human Molecular Genetics, 2013, Vol. 22, No. 24

The figure below shows the results in a 5-minute treadmill exercise tolerance test performed by Morales, Hum Mol Genet-Suppl Data (2013). The FG-3019-treated mdx mice stopped fewer times to rest than the untreated mdx mice (mdx-Control), and were more similar to normal mice.



In a 2009/2010 study, which we used in support of our patent titled "Methods for Treatment of Muscular Dystrophy" issued in 2014, Brandan et al. found that there was a tendency of FG-3019 to increase contraction of the diaphragm muscle in a limited number of FG-3019-treated mdx mice on an electromyographic test, as compared with untreated mdx mice. These results suggest the potential for improvement of respiratory function using this therapeutic approach.

We currently plan to conduct a clinical trial with FG-3019 to assess its ability to impact muscle pathology and improve muscle function in DMD patients. We have plans to work with the TREAT-NMD Advisory Committee for Therapeutics to refine clinical trial design and optimize target patients and appropriate endpoint measures.

FG-3019 for Radiation Countermeasures

The National Institute of Allergy and Infectious Diseases, or NIAID, has sponsored the consortium, Medical Countermeasures Against Radiological Threats, or MCART, to develop medical countermeasures to treat the key pathological conditions and delayed effects resulting from acute radiation exposure. MCART is mandated to develop animal models that adhere to all criteria of FDA's *Guidance for Industry Product Development Under the Animal Rule* (May 2014). Under this draft FDA guidance, the FDA may grant conditional marketing approval based on adequate and well-controlled animal efficacy studies when human challenge studies would not be ethical and field trials after accidental or intentional human exposure have not been feasible, provided the results of those animal studies establish that the drug is reasonably likely to produce clinical benefit and certain other conditions are met.

FibroGen has initiated discussions with MCART at the University of Maryland regarding evaluation of FG-3019 in their established model of whole thorax lung irradiation (WTLI) in non-human primates. If efficacy can be demonstrated in non-human primates comparable to that achieved in the radiation inducted fibrosis in mice, it could enable limited FDA approval of FG-3019 as a medical countermeasure. Such an approval could potentially lead to procurement of FG-3019 for national health security.

Other Potential Indications for FG-3019

We believe that FG-3019 has potential to be a treatment for cancers and a broad array of fibrotic disorders, including:

- Cancers—melanoma, breast cancer, and squamous cell lung carcinoma for which there is an estimated U.S. prevalence of over 80,000 patients.

- Lung—scleroderma lung disease
- Liver—NASH, graft rejection
- Kidney—diabetic nephropathy, focal segmental glomerular sclerosis
- Cardiovascular system—congestive heart failure, pulmonary arterial hypertension

Investigational New Drug and Clinical Trial Applications

FG-3019 is being studied in the United States for the treatment of IPF under an IND that we submitted to the FDA in August 2003. FG-3019 is also being studied in the United States for the treatment of locally advanced or metastatic pancreatic cancer under an IND that we submitted to the FDA in September 2004. We have not submitted an IND for liver fibrosis as the Phase 2 clinical studies are being conducted in Hong Kong and Thailand. We submitted the CTA for FG-3019 in liver fibrosis in Thailand in September 2012 and two clinical trial certificates (CTA equivalent) for FG-3019 in liver fibrosis in Hong Kong in May of 2010 and March of 2013. We have not submitted an IND for Duchenne muscular dystrophy as it is still in the preclinical phase of development.

Commercialization Strategy for FG-3019

Our goal, if FG-3019 is successful, is to be a leader in the development and commercialization of novel approaches for inhibiting deep organ fibrosis and treating some forms of cancer. To date, we have retained exclusive worldwide rights for FG-3019. We plan to retain commercial rights to FG-3019 in North America and will also continue to evaluate the opportunities to establish co-development partnerships for FG-3019 as well as commercialization collaborations for territories outside of North America.

COLLABORATIONS

Our 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 United States and EU 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. The aggregate amount of such consideration received through June 30, 2014 totals $462.6 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 a calculation based on net sales of roxadustat in the low 20% range.

In addition, Astellas has separately invested $80.5 million in the preferred stock of FibroGen, Inc. to date.

AstraZeneca

We also have two agreements with AstraZeneca for the development and commercialization of roxadustat for anemia, one for China, or the China agreement, and one for the United States and all other countries not previously licensed to Astellas (the RoW), or the U.S. / RoW agreement. Under these agreements we provided AstraZeneca the right to develop and commercialize roxadustat for anemia in these territories.

We will share responsibility with AstraZeneca for clinical development activities required for United States regulatory approval of roxadustat. AstraZeneca will be responsible for all of our development costs incurred under the agreed development plan for roxadustat in the United States and EU, to the extent those costs are not covered by Astellas, after an initial 50% development cost sharing period in which our funding obligations are limited to a total of $116.5 million. Thereafter, AstraZeneca will be solely responsible for additional development costs for all such costs. In China, our subsidiary FibroGen China 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, which we expect to receive in various amounts through 2015, and including a $62 million time based development milestone which became non-contingent as of July 30, 2014. 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 June 30, 2014 totals $220.2 million.

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 may, subject to certain conditions, purchase $20 million of our common stock at the initial public offering price in a concurrent sale with this offering, or pay us $20 million at the time of this offering, and in any event no later than December 15, 2015. AstraZeneca has elected to enter into an agreement to purchase shares of our common stock with an aggregate purchase price of $20 million in a separate private placement concurrent with the completion of this offering at a price per share equal to the initial public offering price. The sale of these shares will not be registered under the Securities Act. The closing of this offering is not conditioned upon the closing of such concurrent private placement, and if the offering is not completed by December 1, 2015, then AstraZeneca remains obligated to pay us $20 million no later than December 15, 2015. In connection with the purchase of our shares of common stock in the concurrent private placement AstraZeneca has also entered into a standstill agreement which provides that for five years following the date of the final prospectus for this offering, neither AstraZeneca nor its representatives will, directly or indirectly, among other things, acquire any additional securities or assets of ours, solicit proxies for our securities, participate in a business combination involving us, or seek to influence our management or policies, except with the prior consent of our board of directors and in certain other specified circumstances involving a change of control of our company. In addition, AstraZeneca has agreed to vote its shares in favor of nominees to our board of directors, increases in the authorized capital stock of the company and amendments to our equity plans approved by the board of directors, in each case as recommended by a majority of our board of directors. AstraZeneca has also agreed, subject to specified exceptions, not to sell shares purchased by it in the concurrent private placement for the two-year period following such purchase and to limitations on the volume of its sales of such shares thereafter. In addition, AstraZeneca has entered into a 180-day lock-up agreement in favor of the underwriters in this offering.

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 United States commercialization of roxadustat, with FibroGen undertaking specified promotional activities in the ESRD segment in the United States. 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, the commercial collaboration is structured as a 50/50 profit share. AstraZeneca will conduct commercialization activities in China as well as serve as the master distributor for roxadustat and will fund roxadustat launch costs in China until FibroGen China 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 the regulatory filings and approvals for roxadustat in the affected territories, grant us licenses and conduct certain transition activities.

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 liver fibrosis. 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 liver fibrosis, 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.

If either of our lead product candidates is 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

If roxadustat is approved for the treatment of anemia in patients with CKD, competing drugs are expected to include ESAs such as epoetin alfa (EPOGEN® marketed by Amgen Inc. in the United States, Procrit® marketed by Johnson & Johnson, Inc. in the United States, and Eprex® also marketed by Johnson & Johnson in other markets and Espo® marketed by Kyowa Hakko Kirin, or KHK, in Japan and China), darbepoetin (Aranesp® marketed by Amgen in the United States and Europe, and by KHK in Hong Kong; NESP® marketed by KHK in Japan, Korea, Singapore, Taiwan, Thailand), as well as Mircera® (marketed by Hoffmann-La Roche, or Roche, in Europe and approved in the United States) and NeoRecormon®/Epogin® (marketed by Roche in China and Japan). ESAs have been the standard of care in the treatment of anemia in CKD for over 20 years, serving a significant majority of dialysis patients as well as those non-dialysis patients receiving anemia therapy under nephrology care. Physicians and patients may be reluctant to switch to roxadustat from products with which they have become familiar.

We, and our collaboration partners, will also likely face competition from potential new anemia therapies currently in clinical development. For example, while roxadustat is currently the only HIF-PH inhibitor in Phase 3 development, Akebia Pharmaceuticals, Inc., Bayer Corporation and GlaxoSmithKline plc are all in Phase 2 development of HIF-PH inhibitor product candidates for anemia indications. We may face competition for patient recruitment and enrollment for clinical trials and potentially in commercial sales. In addition, Acceleron Pharma Inc., in partnership with Celgene Corporation, is in Phase 2 development of protein therapeutic candidates to treat anemia and associated complications in patients with b-thalassemia and MDS, and recently received orphan drug status for sotatercept. Noxxon Pharma AG is developing an anti-hepcidin Spiegelmer® (NOX-H94) a mirror image of a natural oligonucleotide, is in Phase 2 development in cancer for the treatment of anemia associated with chronic disease.

The introduction of biosimilars for ESAs into the U.S. market may also increase the competition for roxadustat. A biosimilar product is a follow-on version of an existing, branded biologic product. Under current laws, an application for a biosimilar product should not be approved by the FDA until 12 years after the existing, patent-protected product was approved under a BLA. The patents for epoetin alfa (EPOGEN) expired in 2004 in the EU, and in the United States the remaining patents will expire by 2015. Several biosimilar versions of currently marketed ESAs are available for sale in the EU and many other markets, and several biosimilar versions of epoetin alfa are currently under development, including in the United States. In China, biosimilars of epoetin alfa are offered by Chinese pharmaceutical companies such as EPIAO marketed by 3SBio Inc. and Xue Da Sheng marketed by Hayao Biological.

Two of the largest operators of dialysis clinics in the United States, DaVita Healthcare Partners Inc., or DaVita, and Fresenius Medical Care AG & Co. KGaA, or Fresenius, collectively represent more than 60% of the dialysis market in the United States, and have entered into long-term supply agreements with Amgen that began in January 2012 for 7 years and 3 years, respectively. DaVita is committed to purchase over 90% of its anemia drug needs under an exclusive arrangement. The Fresenius arrangement is non-exclusive. Successful penetration in this market would require a significant agreement with at least either Fresenius or DaVita, on favorable terms and on a timely basis. The currently marketed ESA products are also supported by large pharmaceutical companies with greater experience and expertise in commercialization in the anemia market, including securing reimbursement, government contracts and relationships with key opinion leaders. We expect that significant resources will be required from us and our collaboration partners, AstraZeneca and Astellas, to overcome the challenges of bringing a new product into an established market with concentrated buyers.

FG-3019

We are currently in Phase 2 development of FG-3019 to treat IPF, pancreatic cancer and liver fibrosis. 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 FG-3019. For example, both InterMune and Boehringer Ingelheim Pharma GmbH & Co. KG, who are seeking approval for product candidates for the treatment of IPF in the United States, 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 to treat IPF, FG-3019 would compete with pirfenidone, which is approved for marketing in Europe, Canada and Japan. As of October 2014, InterMune has obtained approval in the United States for pirfenidone for the treatment of IPF and Boehringer Ingelheim has obtained approval in the United States for nintedanib for the treatment of IPF. Nintedanib has also been submitted for accelerated approval in the EU. We believe that if FG-3019 can be shown to safely stabilize or reverse lung fibrosis, and thus stabilize or improve lung function, 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 FG-3019 from a product they are already familiar with. We will also likely face competition from potential new IPF therapies.

FG-3019 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 Phase 2 development for IPF include Gilead Sciences, Inc.’s simtuzumab, Celgene Corporation’s CC-4047 and CC-930, Janssen Biotech, Inc. and Johnson & Johnson Inc.’s CNTO-888, Sanofi’s GC-1008, Novartis’ QAX-576 and Biogen Idec’s STX-100.

Pancreatic Cancer

We are developing FG-3019 to be used in combination with Abraxane® (nab-paclitaxel) and gemcitabine in pancreatic cancer. Celgene’s Abraxane was launched in the United States and Europe in 2013 and 2014, respectively, and was the first drug approved in this disease in nearly a decade. Merrimack Pharmaceuticals, Inc. is currently conducting a pivotal Phase 3 clinical trial of MM-398 for the treatment of patients with metastatic pancreatic cancer who have previously failed treatment with gemcitabine. In addition, treatments for cancer are often used in combination instead of as monotherapy; thus, we also face competition for FG-3019 from other agents seeking approval in conjunction with gemcitabine and Abraxane. Examples include: Threshold Pharmaceuticals, Inc. in partnership with Merck KGaA, is in Phase 3 clinical trials of its compound TH-302 in combination with gemcitabine and in Phase 1 clinical trials for TH-302 in combination with gemcitabine and Abraxane, for the treatment of pancreatic cancer; Gilead Sciences, Inc. is in Phase 2 clinical trials of its anti-fibrotic drug candidate, simtuzumab, in combination with gemcitabine for the treatment of pancreatic cancer; and Halozyme Therapeutics, Inc. is in Phase 2 clinical trials to treat pancreatic cancer with its compound PEGPH20 in combination with gemcitabine and Abraxane.

There are a number of other product candidates in clinical trials for pancreatic cancer, many of which are in combination with existing chemotherapies, as both first-line and second-line therapy for metastatic pancreatic cancer. We will not only face a large number of product candidates competing for patient recruitment and enrollment for our clinical trials, but we could also face a substantial number of competitors if FG-3019 is approved for the treatment of pancreatic cancer.

Liver Fibrosis

If approved to treat HBV and HCV associated liver fibrosis, FG-3019 would compete with advances in HBV and HCV antiviral therapy, which may significantly decrease the potential market for FG-3019 in liver fibrosis. HBV and HCV therapies include: Gilead’s sofosbuvir (Sovaldi®), entecavir (Baraclude®), adefovir (Hepsera®), lamivudine (Epivir®), simeprevir (Olysio®), tenofovir (Viread®), telbivudine (Tyzeka®), boceprevir, telaprevir and interferon alpha-2a and PEGylated interferon alpha-2a (Pegasys®). Nonetheless, a significant proportion of hepatitis patients have pre-cirrhotic or cirrhotic liver fibrosis and treatments that address the fibrotic process itself could provide benefit for patients with approaching liver failure. Potential antifibrotic competitors in the area of liver fibrosis include Gilead's simtuzumab and Intercept Pharmaceuticals, Inc.'s obeticholic acid (OCA).

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 for territories outside of China. 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 are discussing the timing of entry 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 plans for roxadustat, FG-3019 and FG-5200.

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. Our third party manufacturers of roxadustat Phase 3 study material include Shanghai SynTheAll Pharmaceutical Co., Ltd. and STA Pharmaceutical Hong Kong Limited and their respective affiliates, or collectively WuXi STA, and Catalent Pharma Solutions, or Catalent. WuXi STA is located in China and currently supplies our API, and intermediate needs for those materials used in our Phase 3 clinical trials. WuXi STA has passed inspections by several regulatory agencies, including the FDA and CFDA, and is cGMP compliant. Catalent is located in the United States and supplies our Phase 3 tablet materials and provides tablet development services. 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 current Good Manufacturing Practices, or cGMP, regulations 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 more than a metric ton of roxadustat drug substance. We are in discussions with multiple parties, including WuXi STA and other potential suppliers regarding longer term commercial supply arrangements.

In China, we plan to use the clinical material from WuXi STA and will conduct bioequivalence tests before NDA product manufactured at the FibroGen China manufacturing facility in China. We plan to use API and drug product from our FibroGen China manufacturing facility upon commercialization. Until our FibroGen China manufacturing facility is qualified and licensed for the China market, we have no internal manufacturing capabilities and will continue to rely on external contract manufacturers. Even when our manufacturing facility is available to manufacture in and for China, we may use contract manufacturers to supplement commercial supply for China. We do not expect to manufacture from our China facility for use outside of China.

Irix Letter Agreement

In July 2002, we and IRIX Pharmaceuticals, Inc., a third party manufacturer, entered into a Letter of Agreement for IRIX Pharmaceuticals Single Source Manufacturing Agreement, or 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 GMP 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.

FG-3019

To date, FG-3019 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 FG-3019. Our contract manufacturer is only obligated to supply the amounts of FG-3019 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.

FG-5200

The manufacture of FG-5200 requires three distinct steps under cGMP and involves three parties in three locations. Our proprietary recombinant human collagen is produced under contract by a third party in Finland. After quality assurance release, the material is then shipped to our vendor for conversion to a freeze-dried form suitable for production of the FG-5200 medical device. We are currently designing a fabrication plant within the FibroGen China manufacturing facility where the freeze dried collagen will be shipped for the production of FG-5200, first for preclinical and clinical testing using a small scale, pilot process and then potentially as an automated process for commercial use.

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 United States 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 United States, 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 United States and other countries. The steps required before a drug or biologic may be approved for marketing in the United States generally include:

- Preclinical laboratory tests and animal tests conducted under Good Laboratory Practices.
- The submission to the FDA of an Investigational New Drug application, or IND application 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 Biologic License Application, or 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, or 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 risk evaluation and mitigation strategy, or 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, or BPCA, 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, or a 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, or 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, or 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, or 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 US 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, or 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 payers 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, or 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 payer. 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 payers. Third-party payers 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 payers 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 payers. These third-party payers 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 payers' drug formularies, or lists of medications for which third-party payers 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 payers 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 payer 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 payer 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 payer-by-payer basis, obtaining acceptable coverage and reimbursement from one payer does not guarantee that we will obtain similar acceptable coverage or reimbursement from another payer. If we are unable to obtain coverage of, and adequate reimbursement and payment levels for, our product candidates from third-party payers, 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 EU 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 EU 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 United States 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 US 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, or the 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 payers. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers 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 payers.

Moreover, the recently enacted federal Drug Supply Chain Security Act, 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 United States 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, payer 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 CFDA, including its provincial and local branches. As a developer, manufacturer and supplier of drugs, we are subject to regulation and oversight by the CFDA 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 registered and approved by the CFDA before it can be manufactured and marketed for sale. To obtain CFDA approval, the applicant must conduct clinical trials, which must be approved by the CFDA and are subject to the CFDA’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 United States. In addition, the CFDA 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 a national and provincial levels of the CFDA, 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 New Drug Application, 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.

Class 1 refers to a new drug which has never been marketed in any country. Domestic Class 1.1 refers to a chemical drug within Class 1. FibroGen China as a domestic entity will be submitting a domestic New Drug Application under the Domestic Class 1.1 designation which is the anticipated route by which we expect roxadustat to be considered.

In order to obtain market authorization, FibroGen China must submit to the CFDA an NDA package that contains information similar to what is necessary for a U.S. NDA, including preclinical data, clinical data, technical data on active pharmaceutical ingredient and drug product and related stability data. The stability data must be generated from a three-batch registration campaign that is conducted at our Beijing facility, from which samples will be tested by the CFDA.

If the NDA package is acceptable, FibroGen China will be granted a New Drug License confirming the drug as suitable for marketing. In addition, FibroGen China will be granted a Manufacturing License which lists the Drug Approval Code as well as the name and address of the Manufacturing License holder. Manufacturing further requires a Pharmaceutical Production Permit, or PPP, as well as GMP certification. We recently received a PPP, certifying that our manufacturing facility and manufacturing process in that facility are suitable for the manufacture of a drug for clinical or commercial purposes. A PPP requires demonstration that the facility has: (i) legally qualified pharmaceutical and engineering professionals and necessary technical workers; (ii) the premises, facilities and hygienic environment required for drug manufacturing; (iii) institutions, personnel, instruments and equipment necessary to conduct quality control and testing for drugs to be produced; and (iv) rules and regulations to ensure the quality of drugs. The PPP is required prior to conducting the registration campaign for stability and other data for the NDA.

After NDA approval, FibroGen China will be required to conduct a three-batch validation campaign, one of which will be observed onsite by the CFDA. At the successful completion of the validation campaign and associated inspection, FibroGen China will be granted a GMP certification for the commercial production of roxadustat at our Beijing manufacturing facility. Only after the issuance of the GMP license can roxadustat be manufactured and sold commercially to the China market.

Drug Price Controls

The administration of price control of pharmaceutical products is vested in the national and provincial price administration authorities. Depending on the categories of pharmaceutical products in question, the prices of pharmaceutical products listed in the Medical Insurance Catalogs, drugs with patents and other drugs whose production or trading may constitute monopolies are subject to the control of the National Development and Reform Commission of China, or the NDRC, and the relevant provincial or local price administration authorities. With respect to pharmaceutical products manufactured in China, the national price administration authority from time to time publishes price control lists setting out the names of pharmaceutical products and their respective price ceilings. The provincial price administration authorities also publish price control lists in respect of the pharmaceutical products which are manufactured within their respective areas. The main purpose of the price control policy is to set an upper limit to the prices of pharmaceutical products to prevent excessive increases in the prices of such products. Price controls on medicines are determined based on profit margins that the relevant authority deems acceptable, the type and quality of the medicine, its production costs, the prices of substitutes and the manufacturer’s compliance with applicable GMP standards. Drug companies may apply for an increase in the retail price of their drug to the relevant national or provincial authority if their product has superior effectiveness or other advantages.

Tendering Process for Hospital Purchases of Medicines

Provincial and municipal government agencies such as provincial or municipal health departments also operate a mandatory tender process for purchases by hospitals of a medicine included in provincial medicine catalogs. These government agencies organize tenders in their province or city and typically invite manufacturers of provincial catalog medicines that are on the hospitals' formularies and are in demand by these hospitals to participate in the tender process. A government-approved committee consisting of physicians, experts and officials is delegated by these government agencies the power to review bids and select one or more medicines for the treatment of a particular medical condition. The selection is based on a number of factors, including bid price, quality and a manufacturer's reputation and service. The bidding price of a wining medicine will become the price required for purchases of that medicine by all hospitals in that province or city. This price, however, is effective only until the next tender, where the manufacturer of the winning medicine must submit a new bid. Increasingly, large hospitals are forming purchasing networks in order to increase their purchasing power. In addition, hospitals of certain provinces have begun to implement collective tender processes through online bidding, which is expected to increase the transparency and competitiveness of the tendering system and allow greater access to new entrants.

Device Regulation

In China, medical devices are classified into three different categories, Class I, Class II and Class III, depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. Classification of a medical device is important because the class to which a medical device is assigned determines, among other things, whether a manufacturer needs to obtain a production permit and whether clinical trials are required. Classification of a medical device also determines the types of registration required and the level of regulatory authority involved in effecting the product registration. FibroGen China has submitted a device classification application to the CFDA to designate FG-5200 corneal implants as a Domestic Class III medical device. Class III devices also require product registration and are regulated by the CFDA under the strictest regulatory control.

Before a Class III medical device can be manufactured for commercial distribution, a manufacturer must effect medical device registration by proving the safety and effectiveness of the medical device to the satisfaction of respective levels of the food and drug administration and clinical trials are required for registration of Class III medical devices. In order to conduct a clinical trial on a Class III medical device, the CFDA requires manufacturers to apply for and obtain in advance a favorable inspection result for the device from an inspection center jointly recognized by the CFDA and the State Administration of Quality Supervision, Inspection and Quarantine. The application for clinical trials involving a Class III medical device with high risk must be approved by the CFDA before the manufacturer may begin clinical trials. A registration application for a Class III medical device must provide required pre-clinical and clinical trial data and information about the medical device and its components regarding, among other things, device design, manufacturing and labeling. The CFDA must provide the application data to the technical evaluation institute for an evaluation opinion within three working days after its acceptance of the application package and decide, within twenty business days after its receipt of the evaluation opinion, whether the application for registration is approved. However, the time for conducting any detection, expert review and hearing process, if necessary, will not be counted in the abovementioned time limit. If the CFDA requires supplemental information, the approval process may take much longer. The registration is valid for five years and application is required for renewal upon expiration of the existing registration certificate. Once a device is approved, a manufacturer must possess a production permit from the provincial level food and drug administration before manufacturing Class III medical devices.

Foreign Regulation Outside of China

We are planning on seeking approval for roxadustat, and potentially for our other product candidates, in Europe, Japan and China as well as other countries. In order to market any product outside of the United States, 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 United States 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, a sponsor must submit a clinical trial application, or 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 EU, 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 United States 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 5 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 United States 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 new chemical entity (NCE) never previously approved by FDA either alone or in combination with another active moiety. No application or abbreviated new drug application (ANDA) directed to the same NCE may be submitted during the 5-year exclusivity period, except that such applications may be submitted after 4 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, or 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

FG-3019 has received orphan drug designation in IPF in the United States. 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 United States, or if it affects more than 200,000 individuals in the United States there is no reasonable expectation that the cost of developing and making a drug product available in the United States 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.

Orphan designation status in the EU has similar but not identical benefits in that jurisdiction.

Products receiving orphan designation in the EU 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 EU 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 EU also provides opportunities for additional market exclusivity. For example, in the EU, 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 EU 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 new chemical entity. 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 1.1, and the CFDA determines that it is appropriate to protect public health with respect to the safety and efficacy of the approved drug, the CFDA may elect to monitor such drug for up to five years. During this post-marketing observation period, the CFDA 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 new chemical entity 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 United States 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 United States, Europe, China and other territories that provide periods of non-patent-based exclusivity for qualifying drug products. *See "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 patent estate, on a worldwide basis, encompasses over 200 granted patents and 150 pending patent applications, including over 90 granted patents and 100 pending patent applications relating to roxadustat (FG-4592) and FG-3019. Our currently granted patents with respect to composition-of-matter for roxadustat and FG-3019 are expected to expire in 2024 or 2025. 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 additional protection for product candidates. Currently granted patents are expected to expire between 2022 and 2025, and pending patent applications, if granted, could extend patent protection to between 2033 and 2034.

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 United States 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 (FG-4592) Patent Portfolio

Our roxadustat patent portfolio includes three granted U.S. patents and one pending U.S. patent application offering protection for roxadustat including composition-of-matter, pharmaceutical compositions, and 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. A corresponding regional patent application has been granted in Europe and validated in multiple European Patent Convention member states. Additional corresponding patents and patent applications provide broad international protection in multiple territories worldwide. Exclusive of any patent term extension, these granted foreign patents and pending patent applications, if granted, would extend patent protection to 2024.

Under the Hatch-Waxman Act, we believe that, if roxadustat is approved, we will be eligible for the full five year patent term extension for a granted U.S. patent relating to roxadustat, which extension would expire in 2029 or 2030, depending on the patent extended. *See "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 for and formulations of roxadustat, crystalline forms and polymorphs of roxadustat, and methods for use of roxadustat to treat anemia or associated conditions, or to improve clinical parameters relating to anemia. Exclusive of any patent term extension, these granted patents are due to expire in 2024 to 2027, and pending patent applications, if granted, could extend patent protection to 2032 to 2034. For example, the crystalline forms patent application has been allowed by the U.S. Patent and Trademark Office and is expected to issue with patent term to 2033, without extension.

Roxadustat China Patent Portfolio

Our Chinese patent portfolio relating to roxadustat includes three granted Chinese patents covering medicaments containing roxadustat for treating conditions including anemia of chronic disease, iron deficiency, and ischemic disorders. These granted patents are due to expire in 2022 through 2024. Our roxadustat patent portfolio in China also includes 15 pending Chinese patent applications relating to composition-of-matter, pharmaceutical compositions containing roxadustat, manufacturing processes for roxadustat, polymorphs and crystalline forms of roxadustat, and various other aspects relating to the treatment of anemia or improvement of anemia-related parameters using roxadustat, which pending applications, if granted, could be expected to expire between 2022 and 2033.

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 CFDA-imposed new drug monitoring period. *See "Government Regulation—Regulatory Exclusivity for Approved Products—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. This portfolio currently contains over 45 granted patents and 65 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 extensive 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 erythropoietin in anemic CKD patients.
- 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, IL-1, and interleukin 6, 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 transferrin saturation, or TSAT%.
- To overcome iron deficiency through effects on iron regulatory factors such as ferroportin and hepcidin.
- To provide coordinated erythropoiesis resulting in increased reticulocyte hemoglobin content, or CHr, and increased mean corpuscular volume, or MCV.
- 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	PROJECTED EXPIRATION
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.

In March 2013, we obtained the grant of European Patent No. 1463823 (the ‘823 patent), which claims, among other things, the use of a heterocyclic carboxamide compound selected from the group consisting of pyridine carboxamides, quinoline carboxamides, isoquinoline carboxamides, cinnoline carboxamides and beta-carboline carboxamides that inhibits HIF-PH enzyme activity in the manufacture of a medicament for increasing EPO in the prevention, pretreatment, or treatment of anemia. The granted claims of the ‘823 patent encompass the use of roxadustat for the treatment of anemia. On December 5, 2013, Akebia Therapeutics, Inc. filed an opposition to the ‘823 patent with the European Patent Office. An opposition is a mechanism providing for a third-party challenge to a granted European patent. While we believe the ‘823 patent will be upheld in its entirety, the ultimate outcome of the opposition remains uncertain, and ultimate resolution of the proceeding may take two to four years or longer. However, narrowing or even revocation of the ‘823 patent would not affect our exclusivity for roxadustat or our freedom-to-operate with respect to use of roxadustat for the treatment of anemia. Akebia and other third parties may initiate additional or similar proceedings with the European Patent Office or other similar foreign jurisdictions.

FG-3019 Patent Portfolio

Our FG-3019 patent portfolio includes two granted U.S. patents and one pending U.S. patent application providing composition-of-matter protection for FG-3019 and related antibodies, and methods of using FG-3019 or related antibodies in the treatment of fibroproliferative disorders, including IPF, liver fibrosis, and pancreatic cancer, which cases are owned by us or are exclusively licensed by us from Medarex, Inc. (now Bristol-Myers Squibb Co.). Exclusive of any patent term extension, the U.S. patents relating to composition-of-matter of FG-3019 are due to expire in 2024 or 2025. A corresponding regional patent application has been granted in Europe and validated in multiple European Patent Convention member states. Additional corresponding patents and patent applications provide broad international protection in multiple territories worldwide. Exclusive of any patent term extension, these foreign patents, and any patents that may grant from the pending foreign patent applications, are due to expire in 2024.

Under the Hatch-Waxman Act, we believe that, if FG-3019 is approved, we will be eligible for a full five year patent term extension for one U.S. patent relating to FG-3019. In addition, we believe that FG-3019, if approved under a BLA, should qualify for a 12-year period of exclusivity currently permitted by the BPCIA. See *“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 FG-3019 to treat IPF, liver fibrosis, pancreatic cancer and other disorders. Exclusive of any patent term extension, these granted patents are due to expire in 2022 to 2025, and pending patent applications, if granted, could extend patent protection to between 2031 and 2033.

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, or 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 (HIF-alpha), 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, or 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 include U.S. and foreign patents that relate to biologically active fragments of connective tissue growth factor (CTGF), and corresponding nucleic acids, proteins, and antibodies, and are due to expire in 2019, exclusive of any patent term extension that may be available. The licensed patents relate to FG-3019 and related products.

Under the University agreement, we are obligated to pay for all ongoing patent prosecution expenses for the licensed patents. We are 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 $50,000 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, or 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 or HuMAb-Mouse technology during a specified research period, or 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 FG-3019 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, for FG-3019 to date. At our election, the remaining milestone payments may be paid in common stock of FibroGen, Inc., preferred 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 same foregoing royalties or a high double-digit percentage 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 June 30, 2014, we had 317 full-time employees, 118 of whom held Ph.D. or M.D. degrees, 244 of whom were engaged in research and development and 73 of whom were engaged in 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 China 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. In addition, we have a leased facility located in South San Francisco, California, which was used as our corporate headquarters prior to moving to our current facility in 2008. The South San Francisco facility is approximately 106,000 square feet and is fully subleased. We also lease approximately 67,000 square feet of office and manufacturing space in Beijing, China. Our lease in China expires in 2021. 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.

MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information with respect to our executive officers and directors as of September 30, 2014:

Name	Age	Position
Thomas B. Neff	60	Chairman, Founder, Chief Executive Officer, Director
Pat Cotroneo	50	Vice President, Finance, and Chief Financial Officer
Frank H. Valone, M.D.	65	Chief Medical Officer
K. Peony Yu, M.D.	52	Vice President, Clinical Development
Thomas F. Kearns (2)(3)	77	Director
Kalevi Kurkijärvi, Ph.D. (1)	62	Director
Miguel Madero (3)	65	Director
Rory B. Riggs (1) (3)	61	Director
Roberto Pedro Rosenkranz, Ph.D., M.B.A. (2)(3)	64	Director
Jorma Routti, Ph.D. (2)	75	Director
James A. Schoeneck (1)(2)	57	Director
Julian N. Stern (1)(2)	89	Director
Toshinari Tamura, Ph.D. (3)	70	Director

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(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

Thomas B. Neff founded FibroGen, Inc. and has served as our Chairman and Chief Executive Officer and as a member of our Board of Directors since 1993. He serves as a Director of FibroGen China Anemia Holdings, Ltd and serves as General Manager of FibroGen (China) Medical Technology Development Co., Ltd. Mr. Neff received a B.A. from Claremont McKenna College with concentrations in Molecular Biology and Government. Subsequently he studied Economics and Finance at the University of the Chicago Graduate School of Business, and was a Fellow of the Thomas J Watson Foundation. He was employed as an investment banker first at Paine Webber Incorporated (1983-1988) and then at Lazard Freres & Co. through 1992. In 1991, he was among 40 selected as future financial industry leaders in a poll of 600 financial leaders by Institutional Investor. Mr. Neff was founder of Pharmaceutical Partners I and Pharmaceutical Partners II, the pioneer entities investing in drug royalties and predecessors to what is now Royalty Pharma. He left the group in 1998 to concentrate on FibroGen but remained as Managing General Partner of PP1 and PPII until all assets were distributed to partners through 2009. He was also founder and General Partner of Three Arch Bay Health Science Fund, a private investment fund focused on emerging biomedical companies, from 1993 to completion in 2011. He received an honorary doctor of medical sciences from Oulu University, Oulu, Finland in 2009. He has been a director of Kolltan Pharmaceuticals, a spin-out from Yale University, since 2009. Mr. Neff is a named inventor on over 100 of our patents and patent applications. The Board believes that Mr. Neff, who has extensive experience and tenure as our founder and Chief Executive Officer, brings historic knowledge, extensive insights into the strategic value of our technologies and continuity to our board of directors. In addition, the Board believes that his financial, corporate structuring and transactional expertise and experience in the life sciences sector provide him with financial, operational, scientific, intellectual property, risk management and industry expertise that is important to our Board.

Pat Cotroneo has served as our Chief Financial Officer since 2008. Mr. Cotroneo joined us in 2000 as Controller, was promoted to Vice President of Finance, and subsequently promoted to Chief Financial Officer in 2008. Prior to joining us, Mr. Cotroneo was at SyStemix, Inc. where he assumed Controller responsibilities for both SyStemix and Genetic Therapy, Inc. (Novartis subsidiaries) from 1993 to 2000. Prior to SyStemix, he was employed by Deloitte & Touche from 1987 to 1993 in various positions. Mr. Cotroneo received a B.S. with honors from the University of San Francisco and was selected a Louise M. Davies scholar.

Frank H. Valone, M.D., has served as our Chief Medical Officer since December 2008. Dr. Valone has more than 14 years of biotechnology industry experience in the leadership of clinical and preclinical development, medical and regulatory affairs and quality assurance and control. He served as Senior Vice President of Medical Affairs of Bayhill Therapeutics Inc., a biopharmaceutical company, from November 2003 to November 2008. He was responsible for clinical, regulatory, quality and nonclinical toxicology/safety aspects related to the development of Bayhill's investigational therapies. Dr. Valone served as Executive Vice President of Clinical Development and Regulatory Affairs of Titan Pharmaceuticals Inc., a biopharmaceutical company, from March 2002 to October 2003. He was responsible for the clinical development of three antibody vaccines, as well as several small molecule and cell therapy development programs for CNS diseases and cancer. From 1994 to 2002, Dr. Valone was the Chief Medical Officer and Senior Vice President of Clinical and Regulatory Affairs of Dendreon Corporation, a biotechnology company. From 1991 to 1996, he served in various positions of The Dartmouth-Hitchcock Medical Center as Adjunct Professor of Medicine and Norris Cotton Cancer Center including Professor of Medicine. From 1982 to 1991, Dr. Valone held various positions at The University of California, San Francisco, including Associate and Chief of Hematology and Oncology at the San Francisco VA Medical Center. From 1995 to 2001, he was Clinical Associate Professor, Department of Medicine, Stanford University. Dr. Valone received a B.A. from Hamilton College and an M.D. from Harvard Medical School. His Post-Doctoral training was at the Brigham and Womens Hospital in Internal Medicine/Allergy and Rheumatology and at Dana-Farber Cancer Institute in Medical Oncology in 1980.

K. Peony Yu, M.D, has served as our Vice President of Clinical Development since December 2008. Dr. Yu brings to us expertise in design and execution of all phases of clinical development programs, including clinical and regulatory strategy, interactions with regulatory authorities in the United States and EU, as well as experience with successful leadership of clinical teams. Prior to joining us, Dr. Yu was Vice President of Clinical Research at Anesiva, Inc., where she was responsible for management of clinical research, statistics/data management, clinical operations, and medical affairs/medical information for all clinical programs, including the late-stage clinical development and approval of Zingo, a drug-device combination for pain management. Prior to Anesiva, Dr. Yu was Director, Clinical Development, at ALZA Corporation (a subsidiary of Johnson & Johnson) where she was Global Clinical Lead for IONSYS, a drug-device combination for post-operative pain, and led a successful New Drug Application resubmission with the U.S. Food & Drug Administration and multiple interactions with European regulatory authorities resulting in marketing approval in 25 European countries. Prior to ALZA, Dr. Yu held previous posts at Pain Therapeutics, Inc., and at Elan Pharmaceuticals. Dr. Yu received a B.S. in Chemical Engineering and an M.D. both from the University of California, Davis, followed by residency training at Stanford Medical School.

Non-Employee Directors

Thomas F. Kearns Jr. has served on our board of directors since November 1996. Mr. Kearns is a retired Partner of The Bear Stearns Companies Inc., an investment banking firm, where he was an investment banker in the healthcare area from 1974 until 1987. Prior to his career at Bear Stearns, Mr. Kearns worked for Merrill Lynch, an investment banking firm, from January 1959 until August 1969. Mr. Kearns is Chairman of the National Advisory Board of Carolina Performing Arts at the University of North Carolina. In 2013, he joined the board of directors of Franklin Street Partners. Mr. Kearns was a Trustee of the University of North Carolina Foundation and Endowment Fund for 16 years and served on the board of directors of Biomet Inc. from January 1980 until May 2005. He received his B.A. in History from the University of North Carolina. We believe that Mr. Kearns is qualified to serve on our board of directors due to his financial expertise stemming from a career in investment banking with a focus on the healthcare industry.

Kalevi Kurkijärvi, Ph.D. has served on our board of directors since November 1996. He has also served on the board of directors of our subsidiary, FibroGen Europe Oy, since November 1997. Dr. Kurkijärvi has been the Chairman and Founding Partner of Innomedica Oy, a business development company specialized in licensing, distributor search and strategic planning for companies in the pharmaceutical or medtech industry, since March 2010, and from August 1997 to February 2010 he acted as Director having financial matters as his main responsibility. He was also the Founding Partner and former Chief Executive Officer of Bio Fund Management

Ltd, a Finnish-Danish venture capital company, from 1997 until 2010. He has also been Chairman and Chief Executive Officer of his family’s import-export trading company, Biketex Ltd, since October 1993. Dr. Kurkijärvi has over twenty years experience in international life science business and over ten years in corporate finance. He currently serves on the boards of directors of Innomedica Oy (chair), Biketex Ltd (chair) and Hytest Oy (chair). He previously served on the boards of directors at other biotechnology companies such as of Paratek Pharmaceuticals Inc., Ark Therapeutics Plc, BioTie Therapies Plc (chair), Stick Tech Oy (chair), Hormos Medical Oy (chair), Map Medical Oy (chair), Bio Orbit Oy (chair) and Juvantia Pharma Oy, among others. Prior to founding Bio Fund, Dr. Kurkijärvi worked as Executive Director of the venture capital group at the Finnish National Fund of Research and Development (SITRA). He has also served as Executive Vice President at Wallac Oy, and as President and Chief Executive Officer of Pharmacia Diagnostics Production Oy. Dr. Kurkijärvi received a Ph.D. in Biochemistry and Molecular Biology from the University of Turku in 1992, where he also worked for several years in research and teaching. We believe Dr. Kurkijärvi is qualified to serve on our board of directors because of his scientific and technical background, international business and management experience, and expertise in the life sciences and biotechnology industries as evidenced by the various leadership roles and positions he has held in such industries.

Miguel Madero has served on our board of directors since January 1995. Mr. Madero is the Managing Director at Fomento y Direccion, an investment bank located in Mexico City that he co-founded in 1985. Mr. Madero currently serves on the boards of directors of Provo International, Financiera Convergencia, S.A. de C.V, and MEB Global, S.A. de C.V. and Grupo REMABLO, S.A. DE C.V. He earned a B.A. in Industrial Engineering from the Universidad Iberoamericana in Mexico City and an M.B.A. from the University of Texas at Austin. We believe that Mr. Madero is qualified to serve on our board of directors due to his financial expertise and management experience.

Rory B. Riggs has served on our board of directors since October 1993. Since April 2010, Mr. Riggs has served as founder and Chief Executive Officer of Syntax Analytics, LLC, a development stage venture focused on creating a new information technology platform for large-scale portfolio management. Since June 2006, Mr. Riggs has also served as Managing Member of New Ventures, a venture fund focused on biotechnology and healthcare. Mr. Riggs has been the Managing Member of Balfour LLC, an investment management company focused on biotechnology and healthcare, since January 2001. Mr. Riggs served as the President of Biomatrix, Inc., a biomedical company, from 1996 until 2000. In addition, he was the Chief Financial Officer of Biomatrix from 1996 to 1998. He serves on the boards of directors of Royalty Pharma (Chair), Cibus Global Ltd., Intra-Cellular Therapies, Inc., eReceivables, LLC (Chair), and GeneNews, Ltd. From 1991 to 1995, he was Chief Executive Officer of RF&P Corporation, an investment company owned by the Virginia Retirement System. He was also Managing Director of PaineWebber and Company, a stock brokerage and asset management firm, in the mergers and acquisitions field. Mr. Riggs holds a B.A. from Middlebury College, Vermont and an M.B.A. from Columbia University. We believe that Mr. Riggs is qualified to serve on our board of directors due to his industry experience, management experience and public financial expertise.

Roberto Pedro Rosenkranz, Ph.D., MBA, has served on our board of directors since April 2010. Dr. Rosenkranz was Chairman and Chief Executive Officer of ROXRO Pharma, Inc., a pharmaceutical company, from October 1999 to December 2010. He is also currently executive chairman of Altos Therapeutics LLC, a pharmaceutical company, and has been serving in that capacity since 2012. Dr. Rosenkranz is also on the board of directors of Pherin Pharmaceuticals, Inc., a pharmaceutical company, and the Ronald and Ann Williams Charitable Foundation. Prior to assuming his leadership role at ROXRO, Dr. Rosenkranz was President and Chief Operating Officer of Scios, Inc., a biopharmaceutical company, from 1996 to 1997. From 1995 to 1996, he occupied multiple research, development and marketing positions at Roche Laboratories, a pharmaceutical company. From 1982 to 1996, Dr. Rosenkranz occupied multiple research, development and marketing positions at Syntex Laboratories, Inc., a pharmaceutical company. Dr. Rosenkranz previously sat on the boards of Medcenter Solutions do Brasil SA and Gemini Genomics Limited (also referred to as Gemini Genomics Plc). Dr. Rosenkranz received a B.A. in psychology from Stanford University, a Ph.D. in pharmacology and toxicology from the University of California, Davis, and an M.B.A from Santa Clara University. We believe that Dr. Rosenkranz is qualified to serve on our board of directors because of his scientific and technical background, as well as his experience in various leadership and management roles in the pharmaceutical industry.

Jorma Routti, Ph.D. has served on our board of directors since March 1994. He is also the Chairman of the board of directors of our subsidiary, FibroGen Europe Oy, and has served in that capacity since 2001. Since 2001, Dr. Routti has served as Executive Chairman of CIM Creative Industries Management Ltd., a venture capital firm located in Helsinki, Finland, where he works with investments and research in intellectual property oriented companies as well as with Knowledge Economy developments in several countries. Dr. Routti has served from 1995 to 2000 as Director General of Research of the European Commission, the executive body of the European Union. From 1985 to 1995, Dr. Routti served as President of SITRA, the Finnish Innovation Fund. Dr. Routti served as Dean and Professor at the Helsinki University of Technology from 1972 to 1985 and as a Scientist at CERN in Geneva from 1967 to 1972 and at the University of California, Berkeley. He has served on the board of directors (including as chairman) of several major corporations, high technology companies and international research establishments. Honors received by Dr. Routti include Fulbright and Eisenhower Exchange Fellowships and decorations in Finland and France. He has received a Ph.D. from the University of California, Berkeley in Physics, as well as a MSc in Technical Physics and a DrTechn h.c. in Technology from the Helsinki University of Technology. Dr. Routti was awarded with an honorary doctorate in philosophy from the University of Jyvaskyla, Finland. We believe that Dr. Routti is qualified to serve on our board of directors because of his scientific and technical background, vast experience with research and development, and leadership roles he has assumed serving on the boards of technology and research organizations.

James A. Schoeneck has served on our board of directors since April 2010. He joined Depomed, Inc., a pharmaceutical company, as President and Chief Executive Officer in April 2011 and has served as a director of Depomed, Inc. since December 2007. From September 2005 until he joined Depomed, Inc., Mr. Schoeneck was Chief Executive Officer of BrainCells Inc., a privately-held biopharmaceutical company. Prior to joining BrainCells Inc., he served as Chief Executive Officer of ActivX BioSciences, a development stage biotechnology company. Mr. Schoeneck's pharmaceutical experience also includes three years as President and Chief Executive Officer of Prometheus Laboratories Inc., a pharmaceutical and diagnostics company. Prior to joining Prometheus, Mr. Schoeneck spent three years as vice president and General Manager, Immunology, at Centocor, Inc. (now Janssen Biotech, Inc.), a biotechnology company, where he led the development of Centocor's commercial capabilities. His group launched Remicade®, which has become one of the world's largest pharmaceutical products. Earlier in his career, he spent 13 years at Rhone-Poulenc Rorer, Inc. (now Sanofi), a pharmaceutical company, serving in various sales and marketing positions of increasing responsibility. Mr. Schoeneck holds a B.S. degree in education from Jacksonville State University. We believe that Mr. Schoeneck is qualified to serve on our board of directors because of his extensive management experience in biotechnology.

Julian N. Stern has served as our corporate Secretary since 1993 and has served on our board of directors since November 1996. He is of counsel to the law firm of Goodwin Procter LLP, which he joined in 2008. Prior to joining Goodwin Procter in 2008, Mr. Stern was a partner at and counsel to the law firm of Heller Ehrman White & McAuliffe LLP. For forty six years, Mr. Stern has worked with healthcare-related and technology-related companies with a focus on corporate, financing and intellectual property law. Mr. Stern was the incorporator of ALZA Corporation, a developer and manufacturer of drug delivery based products, and served on its board of directors and as its corporate secretary until it was acquired by Johnson & Johnson in 2001. He also incorporated Affymax, N.V., a drug discovery company, and served as its secretary and director from inception until its acquisition by Glaxo P.L.C. in 1995. Mr. Stern incorporated Cetus Corporation, a biotechnology company, and served as its corporate secretary and as director until its acquisition by Chiron in 1991. Mr. Stern was a director and corporate secretary of DepoMed, Inc., a specialty pharmaceutical company from 2005 to 2013, and also serves as chairman and director of Pherin Pharmaceuticals, Inc., a privately held drug development company. He served as founder, corporate secretary and director of ROXRO Pharma, Inc., a drug development company, from 2001 until its sale in 2011 to Luitpold, a subsidiary of Dai Ichi. Mr. Stern is also Chairman and President of the Ronald and Ann Williams Charitable Foundation and a trustee of the Peter and Vernice Gasser Charitable Foundation. Mr. Stern received a B.S. from New York University in accounting and economics, and an LL.B. from Yale Law School. We believe Mr. Stern is qualified to serve on our board of directors due to his expertise in advising clients on corporate, securities, finance and technology law matters, as well as experience serving in leadership roles at various healthcare and technology companies.

Toshinari Tamura, Ph.D. has served on our board of directors since September 2008. He previously worked at Yamanouchi Pharmaceutical Co., Ltd., starting in 1972, and ultimately became Executive Corporate Officer and Representative Director. Following the merger to form Astellas Pharma, Inc., he was named Executive Vice President and Chief Science Officer of Astellas Pharma, Inc. and served in those roles and on the board of directors of Astellas from April 2005 until June 2008. Dr. Tamura was in charge of research and development of our PHI anemia program in 2004 and has remained familiar with the science of the program since that time. Dr. Tamura served as director of the board of KinoPharma, Inc., a drug development company, from September 2009 to March 2010. Dr. Tamura served as director of the board of IMMD Inc., a drug development company, from October 2010 to November 2012. Dr. Tamura is currently advisor to Shin Nippon Biomedical Laboratories, Ltd., a drug development company (from September 2008), Innovation Network Corporation of Japan, a government-sponsored private equity firm (from February 2010), and Japan Science and Technology Agency, a government sponsored organization promoting science and technology (from September 2012). Dr. Tamura holds a Ph.D. and Master degree in organic chemistry from the University of Tokyo, Graduate School of Pharmaceutical Sciences. Dr. Tamura also holds a Bachelor degree from Chiba University, Department of Pharmaceutical Sciences in pharmaceutical science. We believe that Dr. Tamura is qualified to serve on our board of directors because of his extensive management experience in the biotechnology and pharmaceutical industries in Japan, as well as his technical background in organic chemistry and pharmaceutical sciences.

Board Composition

Our business and affairs are managed under the direction of our board of directors, which currently consists of ten members. The members of our board of directors were elected in compliance with the provisions of our certificate of incorporation, as amended.

Our board of directors will consist of ten members upon completion of this offering. In accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- The Class I directors will be Thomas B. Neff, Miguel Madero and James A. Schoeneck, and their terms will expire at the annual meeting of stockholders to be held in 2015;
- The Class II directors will be Rory B Riggs, Roberto Pedro Rosenkranz and Jorma Routti, and their terms will expire at the annual meeting of stockholders to be held in 2016; and
- The Class III directors will be Thomas F. Kearns, Jr., Kalevi Kurkijärvi, Julian N. Stern and Toshinari Tamura, and their terms will expire at the annual meeting of stockholders to be held in 2017.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director Independence

Under the listing requirements and rules of The NASDAQ Stock Market, independent directors must comprise a majority of our board of directors as a listed company within a specified period of the completion of this offering. In addition, the rules of The NASDAQ Stock Market require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and corporate governance committees must be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Under the rules of The NASDAQ Stock Market, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

In order to be considered to be independent for purposes of Rule 10A-3 of the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries.

Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that Thomas F. Kearns Jr., Kalevi Kurkijarvi, Miguel Madero, Rory. B. Riggs, Roberto Pedro Rosenkranz, Jorma Routti, James A. Schoeneck, Julian N. Stern and Toshinari Tamura, representing a majority of our directors, do not have any relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is “independent” as that term is defined under the applicable rules and regulations of the SEC and the listing requirements of The NASDAQ Stock Market. Our board of directors also determined that Messrs. Riggs, Schoeneck and Stern and Dr. Kurkijärvi, who comprise our audit committee, Messrs. Kearns, Schoeneck and Stern and Drs. Rosenkranz and Routti, who comprise our compensation committee and Messrs. Kearns, Madero and Riggs and Drs. Rosenkranz and Tamura, who comprise our nominating and corporate governance committee, satisfy the independence standards for those committees established by applicable rules and regulations of the SEC and the listing requirements of The NASDAQ Stock Market. In making this determination, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors.

Audit Committee

Upon the closing of this offering, our audit committee will consist of Messrs. Riggs, Schoeneck and Stern and Dr. Kurkijärvi. Our board of directors has determined that Messrs. Riggs, Schoeneck and Stern and Dr. Kurkijärvi are independent under The NASDAQ Stock Market listing standards and Rule 10A-3(b)(1) of the Exchange Act. Upon the closing of this offering, the chair of our audit committee will be Mr. Riggs, whom our board of directors has determined is an “audit committee financial expert” within the meaning of the SEC regulations. Our board of directors has also determined that each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, the board of directors has examined each audit committee member’s scope of experience and the nature of their employment in the corporate finance sector. The functions of this committee include:

- selecting a qualified firm to serve as the independent registered public accounting firm to audit our financial statements and approving fees payable to such firm;
- helping to ensure the independence and performance of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;

- reviewing our policies on risk assessment and risk management;
- reviewing related party transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality-control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving (or, as permitted, pre-approving) all audit and all permissible non-audit services, other than de minimis non-audit services, to be performed by the independent registered public accounting firm.

Compensation Committee

Upon the closing of this offering, our compensation committee will consist of Messrs. Kearns, Schoeneck and Stern and Drs. Rosenkranz and Routti. Our board of directors has determined that Messrs. Kearns, Schoeneck and Stern and Drs. Rosenkranz and Routti are independent under The NASDAQ Stock Market listing standards, each is a “non-employee director” as defined in Rule 16b-3 promulgated under the Exchange Act and each is an “outside director” as that term is defined in Section 162(m) of the Internal Revenue Code of 1986, as amended, or Section 162(m). Upon the closing of this offering, the chair of our compensation committee will be Mr. Schoeneck. The functions of this committee include:

- reviewing and approving, or recommending that our board of directors approve, the compensation of our executive officers;
- reviewing and recommending to our board of directors the compensation of our directors;
- reviewing and approving, or recommending that our board of directors approve, the terms of compensatory arrangements with our executive officers;
- administering our stock and equity incentive plans;
- selecting independent compensation consultants, approving fees payable to them, and assessing conflict of interest of compensation consultants;
- reviewing and approving, or recommending that our board of directors approve, incentive compensation and equity plans; and
- reviewing and establishing general policies relating to compensation and benefits of our employees and reviewing our overall compensation strategy.

Nominating and Corporate Governance Committee

Upon the closing of this offering, our nominating and corporate governance committee will consist of Messrs. Kearns, Madero and Riggs and Drs. Rosenkranz and Tamura. Our board of directors has determined that Messrs. Kearns, Madero and Riggs and Drs. Rosenkranz and Tamura are independent under the current rules and regulations of the SEC and The NASDAQ Stock Market. Upon the closing of this offering, the chair of our nominating and corporate governance committee will be Mr. Kearns. The functions of this committee include:

- identifying, evaluating and selecting, or recommending that our board of directors approve, nominees for election to our board of directors and its committees;
- evaluating the performance of our board of directors and of individual directors;
- considering and making recommendations to our board of directors regarding the composition of our board of directors and its committees;
- reviewing developments in corporate governance practices;
- evaluating the adequacy of our corporate governance practices and reporting;

- reviewing management succession plans;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing an annual evaluation of the board of directors' performance.

Code of Business Conduct and Ethics

We will adopt a Code of Business Conduct and Ethics that applies to all of our employees, officers, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions and agents and representatives, including directors and consultants. The full text of our Code of Business Conduct and Ethics will be posted on our website at www.FibroGen.com. We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics, or waivers of such provisions applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and our directors, on our website identified above.

Compensation Committee Interlocks and Insider Participation

During 2013, our compensation committee consisted of Messrs. Kearns, Madero and Stern and Drs. Rosenkranz and Routti. None of the members of the compensation committee is currently or has been at any time one of our employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Non-Employee Director Compensation

Cash Compensation

No cash compensation was paid to our non-employee directors in 2013. Although we do not have a written policy, we generally reimburse our directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

Equity Incentive Compensation

The following table sets forth information regarding non-cash compensation earned by or paid to our non-employee directors during 2013:

Name (2)	Option Awards (1)	Total
Thomas F. Kearns	$175,950	$175,950
Kalevi Kurkijärvi.	117,300	117,300
Miguel Madero	117,300	117,300
Rory B. Riggs	117,300	117,300
Roberto Pedro Rosenkranz	175,950	175,950
Jorma Routti	117,300	117,300
James A. Schoeneck	175,950	175,950
Julian N. Stern	175,950	175,950
Toshinari Tamura	117,300	117,300

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(1) The amounts reported do not reflect the amounts actually received by our non-employee directors. Instead, these amounts reflect the aggregate grant date fair market value of each stock option granted to our non-employee directors during the fiscal year ended December 31, 2013, as computed in accordance with FASB ASC 718. Assumptions used in the calculation of these amounts are included in Note 9 to our financial statements included in this prospectus.

(2) The table below lists the aggregate number of shares and additional information with respect to outstanding option awards held by each of our non-employee directors as of December 31, 2013.

The following table lists the aggregate number of shares with respect to the outstanding option awards held by each of our non-employee directors as of December 31, 2013:

Name	Number of shares subject to outstanding options as of December 31, 2013
Thomas F. Kearns	292,500
Kalevi Kurkijärvi	285,000
Miguel Madero	195,000
Rory B. Riggs	257,000
Roberto Pedro Rosenkranz	62,500
Jorma Routti	225,000
James A. Schoeneck	150,000
Julien N. Stern	292,500
Toshinari Tamura	195,000

Future Director Compensation

Our board of directors has adopted a director compensation policy for non-employee directors which provides for cash and equity compensation. The policy will become effective upon the date on which this offering becomes effective. Pursuant to the director compensation policy, non-employee directors will be paid annual cash compensation of $35,000. In addition, non-employee directors will be paid $10,000 annually for serving on the audit committee ($20,000 annually for the chairman), $7,500 annually for serving on the compensation committee ($15,000 annually for the chairman), and $5,000 annually for serving on the nominating and governance committee ($10,000 annually for the chairman). Non-employee directors will be reimbursed for their reasonable out-of-pocket expenses to cover attendance at and participation in meetings of our board of directors.

Our non-employee directors will be granted initial and/or annual option grants under our 2014 Equity Incentive Plan (or the 2014 Plan). Newly appointed or newly elected directors will be granted an option to purchase 30,000 shares of our common stock. The initial option grant will vest in equal quarterly installments over three years from the date of grant, subject to the non-employee director's continuous service on each applicable vesting date. On the date of each annual meeting of our shareholders, each individual who is elected or appointed as a non-employee director and each other non-employee director who continues to serve as a non-employee director immediately after such annual meeting of our shareholders will be granted an option to purchase 30,000 shares of our common stock; *provided*, that if the individual is elected or appointed to the board at a time other than at our annual meeting of shareholders, the number of shares of our common stock subject to such annual grant will be pro-rated based on the number of days between the date of such director's election or appointment and the first anniversary of the most recent annual shareholder meeting to occur prior to such director's election or appointment to our board. The annual option grant will vest in equal quarterly installments over two years following the vesting commencement date, subject to the non-employee director's continuous service on each applicable vesting date. All options granted under our director compensation policy will be granted with an exercise price equal to the fair market value of our common stock on the grant date. The vesting of all options will cease upon a non-employee director's resignation from the board or other cessation of service, unless our board determines otherwise. All unvested options will vest in full immediately prior to a change in control (as defined in the 2014 Plan), subject to the non-employee director's continuous service as of the day prior to the closing of such change in control.

EXECUTIVE COMPENSATION

Our named executive officers, or NEOs, for 2013, which consist of our principal executive officer and the next two most highly compensated executive officers, are:

- Thomas B. Neff, Chief Executive Officer;
- Frank H. Valone, Chief Medical Officer; and
- K. Peony Yu, Vice President, Clinical Development.

2013 Summary Compensation Table

The following table sets forth all of the compensation awarded to, earned by or paid to our NEOs during 2013.

Name and principal position	Year	Salary ($)	Bonus ($)(1)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)(2)	All Other Compensation ($)(3)	Total ($)
Thomas B. Neff *Chief Executive Officer*	2013	709,139	600,000	—	482,750	8,994	1,800,883
Frank H. Valone *Chief Medical Officer*	2013	424,360	50,000	—	192,816	—	667,176
K. Peony Yu *Vice President, Clinical Development*	2013	394,057	173,850	—	180,275	—	748,182

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(1) Amount represents an one-time discretionary cash bonus earned in 2013.

(2) Amount represents each NEO’s annual performance-based cash bonuses earned for 2013 performance.

(3) Amount represents annual health club membership fees and an associated tax gross-up in respect of such fees.

Outstanding Equity Awards at December 31, 2013

The following table provides information regarding outstanding equity awards held by each of our NEOs as of December 31, 2013.

	Option Awards				
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable(1)	Option Exercise Price ($)	Option Expiration Date
Thomas B. Neff	3/1/2007(1)	775,000	—	1.61	3/1/2017
	3/1/2007(2)	775,000	—	1.61	8/20/2017
	3/1/2008(3)	1,000,000	—	0.94	3/12/2018
	3/1/2009(3)	1,250,000	—	1.44	3/11/2019
	3/1/2010(4)	742,500	247,500	1.16	6/9/2020
	3/1/2011(4)	495,000	405,000	1.40	6/7/2021
	3/1/2012(4)	196,875	253,125	2.38	6/27/2022
Frank H. Valone	12/1/2008(3)	140,000	—	0.94	12/3/2018
	3/1/2009(4)	47,500	2,500	1.57	8/11/2019
	3/1/2010(4)	75,000	25,000	1.16	6/9/2020
	3/1/2011(4)	55,000	45,000	1.40	6/7/2021
	3/1/2012(4)	14,871	27,625	2.38	6/27/2022
K. Peony Yu	3/1/2010(4)	75,000	25,000	1.16	6/9/2020
	12/3/2008(3)	175,000	—	1.16	6/24/2020
	3/1/2011(4)	55,000	45,000	1.40	6/7/2021
	3/1/2012(4)	15,750	29,250	2.38	6/27/2022

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(1) All shares subject to the option were vested on the vesting commencement date.

(2) All shares subject to the option vest on the third anniversary of the vesting commencement date.

(3) Twenty-five percent of the shares subject to the option vests on the first anniversary of the vesting commencement date, and the remainder vests in equal amounts quarterly thereafter for the following three years.

(4) Twenty percent of the shares subject to each option vests on the first anniversary of the vesting commencement date and 80% of the shares subject to each option vests in 16 substantially equal quarterly installments thereafter over for the following four years.

Offer Letter Agreements

Frank H. Valone

We entered into an offer letter agreement with Dr. Valone, our Chief Medical Officer, in November 2008. The offer letter has no specific term and constitutes an at-will employment arrangement. Dr. Valone's annual base salary as of December 31, 2013 was $428,480. In connection with his employment, Dr. Valone was granted an initial option to purchase 200,000 shares of our common stock, pursuant to the terms of our Amended and Restated 2005 Stock Plan (described below). Dr. Valone has exercised part of the option to purchase 60,000 shares of our common stock and the remainder of the option is fully vested and exercisable.

K. Peony Yu

We entered into an offer letter agreement with Dr. Yu, our Vice President, Clinical Development, in November 2008. The offer letter has no specific term and constitutes an at-will employment arrangement. Dr. Yu's annual base salary as of December 31, 2013 was $400,610. In connection with her employment, Dr. Yu was granted an initial option to purchase 175,000 shares of our common stock, pursuant to the terms of our Amended and Restated 2005 Stock Plan. The option is fully vested and exercisable.

Potential Payments and Acceleration of Equity upon Termination or in Connection with a Change in Control

The section below describes the payments and benefits that we would have made to our NEOs in connection with certain terminations of employment or certain corporate transactions like a change in control, if such events had occurred on December 31, 2013.

The form of option agreement under our Amended and Restated 2005 Stock Plan, or the 2005 Plan, provides that in the event an option holder is terminated by us without cause (as defined below) following a change in control (as defined below) or if the option holder incurs a constructive termination (as defined below) within 12 months following a change in control, any outstanding unvested options will accelerate in full as of the date of any such termination. Accordingly, if any of our named executive officers incurred a qualifying termination of employment following a change in control on December 31, 2013, all outstanding unvested options granted to them under our 2005 Plan would accelerate in full as of December 31, 2013, and such options would remain exercisable for the applicable post-termination exercise period set forth in their option grant documents.

For purposes of the standard form of option agreement under the 2005 Plan, "cause" generally means (1) a commission of a felony related to us or our business or any crime involving fraud or moral turpitude; (2) the attempted commission of, or participation in, a fraud against us; (3) the unauthorized use or disclosure of our confidential information or trade secrets; or (4) the participant's willful failure to substantially perform his or her duties and responsibilities owed to us. For purposes of the standard form of option agreement under the 2005 Plan, "constructive termination" generally means (1) a substantial reduction in the participant's duties or responsibilities in effect immediately prior to the effective time of a change in control; (2) a material reduction in a participant's annual base salary as in effect on the closing date of the change in control or as increased thereafter; (3) any failure by us to continue in effect any benefit plan or program in which the participant was participating immediately prior to the effective time of a change in control or the taking of any action by us that would adversely affect a participant's participation in or reduce benefits under any such plans or programs (provided, that a constructive termination will not be deemed to have occurred if we provide for the participation in benefit plans and programs that, taken as a whole, are comparable to those that were provided immediately prior to the change in control); (4) a relocation of the participant's business office to a location more than 50 miles from the location at which the participant performed his or her duties as of the effective time of the change in control; or (5) a material breach by us of any provision of any material agreement between the participant and us concerning the terms and conditions of the participant's employment.

On October 21, 2014, our compensation committee approved a form of change in control severance agreement, or the Change in Control Severance Agreement, which has been filed as an exhibit to the registration statement of which this prospectus is a part. It is expected that each of our executive officers, including each of our named executive officers, will enter into a Change in Control Severance Agreement on or about the date on which this offering becomes effective.

Under the terms of the Change in Control Severance Agreement, if an executive's employment is terminated by the Company without cause and other than due to death or disability or the executive resigns for good reason, in either case, in connection with or within eighteen (18) months following the effective date of a change in control (as defined in the Change in Control Severance Agreement), subject to the executive's timely execution (and non-revocation) of a release of claims within sixty (60) days following the date of such termination, the executive will be entitled to the following severance benefits: (1) cash severance equal to either twelve (12), eighteen (18) or twenty-four (24) months of the executive's base salary then in effect (with the applicable multiplier, that is, twelve, eighteen or twenty-four, varying depending on the executive), payable in a either a lump sum or over the twelve (12), eighteen (18) or twenty-four (24) month period, as applicable, following the date of termination (with the applicable multiplier varying depending on the executive), with such payment to be made (or to commence, as applicable) within five (5) days following the date on which the release becomes effective; (2) subject to the executive's timely election of continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or another state law equivalent (COBRA), payment by the Company of COBRA premiums for the executive and his or her eligible dependents for a period of up to eighteen (18) months following the date of the executive's termination; and (3) all outstanding stock options held by the executive will become fully vested and exercisable as of immediately prior to the date of executive's termination of employment. With respect to the cash severance benefits payable to our named executive officers under the Change in Control Severance Agreements, the applicable severance multiplier is 24 for Thomas Neff, and 18 for each of Frank Valone and K. Peony Yu, respectively, and the cash severance will be paid in installments over the applicable 24 month or 18 month severance period for each of our named executive officers. Notwithstanding the foregoing, to the extent that an 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 the Change in Control Severance Agreement, the executive will be entitled to receive the greater of the severance benefits provided under such plan or policy or the severance benefits provided under the Change in Control Severance Agreement.

In addition, to the extent that any payment or benefit that an executive would receive under the Change in Control Agreement or otherwise would constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code and such payments or benefits would be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code, then such payments or benefits will either be (1) provided to the executive in full, or (2) reduced to such lesser amount that would result in no portion of such payments or benefits being subject to the excise tax, whichever amount after taking into account all applicable taxes, including the excise tax, would result in the executive's receipt, on an after-tax basis, of the greatest amount of such payments or benefits.

For purposes of the Change in Control Severance Agreement, "cause" for termination of an executive's employment will exist if an executive is terminated for any of the following reasons: (1) the executive's willful failure substantially to perform his or her duties and responsibilities to the Company or a deliberate violation of a Company policy; (2) the 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; (3) unauthorized use or disclosure by the 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 (4) the executive's willful breach of any of his or her obligations under any written agreement or covenant with the Company.

For purposes of the Change in Control Severance Agreement, "good reason" generally means the existence of any of the following conditions without the executive's written consent: (1) a material reduction in job duties or responsibilities inconsistent with the executive's position with the Company (provided, that any such reduction or change after a change in control will not constitute good reason if the executive retains reasonably comparable duties and responsibilities with respect to the Company's business within the successor entity following a change in control); (2) a reduction of the executive's then current base salary; (3) the relocation of the executive's principal place of employment to a place that increases the executive's one-way commute by more than forty (40) miles as compared to the executive's principal place of employment prior to such relocation; (4) any material breach by the Company of the Change in Control Severance Agreement or any other written agreement between the Company and the executive; or (5) the failure by any successor to the Company to assume the Change in Control Severance Agreement and any obligations thereunder. In order to resign for good reason, the executive must give 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 decision to take any action set forth above, the Company must fail to cure such condition within thirty (30) days after receipt of the executive's written notice and the executive must terminate his or her employment within thirty (30) days following the expiration of the cure period.

Equity Incentive Plans

The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus is a part.

2014 Equity Incentive Plan

Our board of directors adopted, and we expect that our stockholders will approve, our 2014 Equity Incentive Plan, or 2014 Plan, prior to this offering. The 2014 Plan will become effective on the date of the underwriting agreement between us and the underwriters for this offering, or the IPO Date. The 2014 Plan will be the successor to our Amended and Restated 2005 Stock Plan, or the 2005 Plan, which is described below. Once the 2014 Plan becomes effective, no further grants will be made under the 2005 Plan.

Stock Awards. The 2014 Plan provides for the grant of incentive stock options, or ISOs, to our employees and for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, performance-based cash awards and other stock awards to our employees, directors and consultants.

Authorized Shares. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2014 Plan after the IPO Date will be 19,008,777 (which shares are as of September 9, 2014 and are currently reserved for future grant under our 2005 Plan and will cease to be reserved under our 2005 Plan immediately prior to the time our 2014 Plan becomes effective) plus any of the 32,432,460 shares subject to outstanding stock options or other stock awards that would have otherwise returned to our 2005 Plan (such as upon the expiration or termination of a stock option under such plan prior to its exercise). Additionally, the number of shares of our common stock reserved for issuance under our 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2016 and ending on and including January 1, 2024, by 4.0% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under our 2014 Plan is 60,000,000.

Shares issued under our 2014 Plan include authorized but unissued or reacquired shares of our common stock. Shares subject to stock awards granted under our 2014 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, do not reduce the number of shares available for issuance under our 2014 Plan. Additionally, shares issued pursuant to stock awards under our 2014 Plan that we repurchase or that are forfeited, as well as shares used to pay the exercise price of a stock award or to satisfy the tax withholding obligations related to a stock award, become available for future grant under our 2014 Plan.

Plan Administration. Our board of directors, or a duly authorized committee of our board of directors, will administer our 2014 Plan. Our board of directors may also delegate to one or more of our officers the authority to (i) designate employees (other than officers) to receive specified stock awards, and (ii) determine the number of shares of our common stock to be subject to such stock awards. Subject to the terms of our 2014 Plan, the board of directors has the authority to determine the terms of awards, including recipients, the exercise, purchase or strike price of stock awards, if any, the number of shares subject to each stock award, the fair market value of a share of our common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, and the form of consideration, if any, payable upon exercise or settlement of the award and the terms of the award agreements. The board of directors has the power to modify outstanding awards under our 2014 Plan.

Section 162(m) Limits. At such time as is necessary for compliance with Section 162(m) of the Internal Revenue Code, no participant may be granted stock awards covering more than 2,000,000 shares of our common stock (subject to adjustment to reflect any split of our common stock) under our 2014 Plan during any calendar year pursuant to stock options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise price or strike price of at least 100% of the fair market value of our common stock on the date of grant. Additionally, no participant may be granted in a calendar year a performance stock award covering more than 2,000,000 shares of our common stock (subject to adjustment to reflect any split of our common stock) or a performance cash award having a maximum value in excess of $2,000,000 under our 2014 Plan. These limitations are intended to give us the flexibility to grant compensation to covered employees that may qualify for the “qualified performance-based compensation” exception to the $1,000,000 annual limitation on the income tax deductibility imposed by Section 162(m) of the Internal Revenue Code.

Performance Awards. Our 2014 Plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the $1,000,000 limitation on the income tax deductibility imposed by Section 162(m) of the Internal Revenue Code. Our compensation committee may structure awards so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. However, we retain the discretion to grant awards under the 2014 Plan that may not qualify for full deductibility under Section 162(m) of the Internal Revenue Code.

Our compensation committee may establish performance goals by selecting from one or more performance criteria set forth in the 2014 Plan:

- earnings (including earnings per share and net earnings);
- earnings before interest, taxes and depreciation;
- earnings before interest, taxes, depreciation and amortization;
- earnings before interest, taxes, depreciation, amortization and legal settlements;
- earnings before interest, taxes, depreciation, amortization, legal settlements and other income (expense);

- earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense) and stock-based compensation;
- earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation and changes in deferred revenue;
- total stockholder return;
- return on equity or average stockholder’s equity;
- return on assets, investment, or capital employed;
- stock price;
- margin (including gross margin);
- income (before or after taxes);
- operating income;
- operating income after taxes;
- pre-tax profit;
- operating cash flow;
- sales or revenue targets;
- increases in revenue or product revenue;
- expenses and cost reduction goals;
- improvement in or attainment of working capital levels;
- economic value added (or an equivalent metric);
- market share
- cash flow;
- cash flow per share;
- share price performance;
- debt reduction;
- implementation or completion of projects or processes;
- employee retention;
- stockholders’ equity;
- capital expenditures;
- debt levels;
- operating profit or net operating profit;
- workforce diversity;
- growth of net income or operating income;
- billings;
- bookings;
- initiation of phases of clinical trials and/or studies by specified dates;
- patient enrollment rates;
- budget management;

- regulatory body approval with respect to products, studies and/or trials;
- commercial launch of products; and
- to the extent that an Award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by the Board.

The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or relevant indices.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2014 Plan; (2) the class and maximum number of shares by which the share reserve may increase automatically each year; (3) the class and maximum number of shares that may be issued upon the exercise of incentive stock options; (4) the class and maximum number of shares subject to stock awards that can be granted in a calendar year (as established under our 2014 Plan pursuant to Section 162(m) of the Internal Revenue Code); and (5) the class and number of shares and exercise price, strike price, or purchase, price, if applicable, of all outstanding stock awards.

Corporate Transactions. Our 2014 Plan provides that in the event of certain specified significant corporate transactions, as defined under our 2014 Plan, unless otherwise provided in an individual agreement between us and the award holders, each outstanding award will be treated as our plan administrator determines. The plan administrator may (1) arrange for the assumption, continuation or substitution of a stock award by a successor corporation; (2) arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation; (3) accelerate the vesting (and exercisability, if applicable), in whole or in part, of the stock award and provide for its termination, if not exercised, as applicable, prior to the transaction; (4) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us; or (5) cancel or arrange for the cancellation of the stock award, to the extent not vested or not exercised prior to the transaction, in exchange for a cash payment, if any, determined by the board; or (6) cancel or arrange for the cancellation of the stock award, to the extent not vested or not exercised prior to the transaction, in exchange for a payment (in such form as determined by the board), equal to the excess, if any, of the value of the property the participant would have received upon exercise of the award immediately prior to the transaction, over any exercise price payable in connection with such exercise. The plan administrator is not obligated to treat all stock awards or portions of stock awards, even those that are of the same type, in the same manner.

Change in Control. A stock award may be subject to additional acceleration of vesting and exercisability upon or after a change in control, as defined in the 2014 Plan, as may be provided in the stock award agreement for such stock award or in any other written agreement between us and a participant, but in the absence of such a provision, no such acceleration will occur.

Plan Amendment or Termination. Subject to the terms of the 2014 Plan, our board of directors has the authority to amend, suspend, or terminate our 2014 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2014 Plan.

Our board of directors approved a standard form of option grant notice and agreement and a form of option grant notice and agreement providing for change in control acceleration benefits, or the change in control form of option grant notice and agreement, to be used in connection with the grant of options under the 2014 Plan. In addition, our compensation committee of the board of directors approved a standard form of restricted stock unit grant notice and agreement to be used in connection with the grant of restricted stock units under the 2014 Plan. Each of the foregoing forms of award agreements has been filed as an exhibit to the registration statement of which this prospectus is a part.

Under our change in control form of option grant notice and agreement, in the event of a change in control (as defined in the 2014 Plan), (1) if at the time of the change in control, a participant's outstanding option is assumed, continued or otherwise substituted in the change in control transaction and the participant's employment is involuntarily terminated by the Company or its successor corporation without cause or due to a constructive termination within twelve (12) months following the closing of such change in control transaction, the vesting and exercisability of the unvested portion of the participant's option will accelerate in full on the date of such termination, and/or (2) if a participant's outstanding option is not assumed, continued or otherwise substituted in the change in control transaction, the unvested portion of the participant's option will vest and become exercisable as of immediately prior to the closing of the change in control transaction.

For purposes of the change in control form of option grant notice and agreement, "constructive termination" generally means a participant's termination of employment, without the participant's written consent, of any of the following events: (1) a substantial reduction in the participant's duties or responsibilities (and not simply a change in title or reporting relationships) in effect immediately prior to the effective date of a change in control; (2) a material reduction in the participant's annual base salary, as in effect on the effective date of the change in control or as increased thereafter; (3) the failure by the Company (or its successor) to continue in effect any benefit plan or program, including incentive plans or plans with respect to the receipt of securities of the Company, in which the participant was participating immediately prior to the effective date of the change in control, or the Benefit Plans, or the taking of any action by the Company (or its successor) that would adversely affect the participant's participation in or would reduce the participant's benefits under the Benefit Plans or that would deprive the participant of any fringe benefit that the participant enjoyed immediately prior to the effective date of the change in control, except that a constructive termination will not be deemed to have occurred if the Company (or its successor) provides for the participant's participation in benefit plans and programs that, taken as a whole, are comparable to the Benefit Plans; (4) a relocation of the participant's business office location more than fifty (50) miles from the location at which the participant performed his or her duties as of the effective date of the change in control; or (5) a material breach by the Company (or its successor) of any provision of any material agreement between the participant and the Company concerning the terms and conditions of the participant's employment.

Amended and Restated 2005 Stock Plan

Our 2005 Plan, was adopted by our board of directors on February 17, 2005 and approved by our stockholders in September 2005 and was last amended by our board of directors on March 20, 2014 and approved by our stockholders on July 8, 2014. The 2005 Plan amended and restated our Amended and Restated 1999 Stock Plan (described below). The 2005 Plan will terminate on the IPO Date. However, any outstanding awards granted under the 2005 Plan will remain outstanding, subject to the terms of the 2005 Plan and applicable award agreements thereunder, until such awards are exercised (if applicable) or otherwise terminate or expire by their terms.

Awards. The 2005 Plan provides for the discretionary grant of incentive stock options, nonstatutory stock options, stock purchase awards, stock bonus awards, stock appreciation rights, stock unit awards and other stock awards to our eligible employees, non-employee directors and consultants.

Authorized Shares. Subject to the provisions of the 2005 Plan relating to any capitalization adjustments to reflect any split or change to our common stock, the maximum number of shares of our common stock that may be issued under the 2005 Plan is 65,717,152 shares. Subject to any capitalization adjustments to reflect any split or change to our common stock, the maximum number of shares of common stock that may be issued upon the exercise of incentive stock options under our 2005 Plan is 65,717,152 shares.

Plan Administration. Our board of directors or a duly authorized committee of our board of directors administers the 2005 Plan and the awards granted under the 2005 Plan. Subject to the terms of the 2005 Plan, our board of directors (or its delegate) has the authority to determine and amend the terms of stock awards, including recipients, the number of shares subject to stock awards, the vesting schedule applicable to stock awards, the form of consideration, if any, payable upon exercise or settlement of any stock award, the exercise or strike price of stock awards, if applicable, and any accelerated vesting and exercisability provisions. Our board of directors may, with the consent of any adversely affected optionholder, reduce the exercise price of any outstanding option under the 2005 Plan, cancel any outstanding option and grant a new award in substitution therefor, or take any other action that is treated as a repricing under generally accepted accounting principles.

Capitalization Adjustments. In the event that any change is made in, or other events occur with respect to, our common stock subject to the 2005 Plan or any stock award, such as certain mergers, consolidations, reorganizations, recapitalizations, stock dividends, stock splits, or other similar transactions, appropriate adjustments will be made to the classes and maximum number of shares subject to the 2005 Plan, any limits on the number of shares that may be granted to any person under the 2005 Plan, and the number of shares subject to, and the price per share, if applicable, of any outstanding stock awards.

Corporate Transactions. The 2005 Plan generally provides that unless otherwise provided in a written agreement between us or any of our affiliates and a participant, in the event of certain corporate transactions, outstanding stock awards may be assumed, continued or substituted for similar stock awards by the surviving or acquiring corporation (or its parent) and any reacquisition or repurchase rights held by us may be assigned to the successor company (or its parent). If outstanding stock awards are not so assumed, continued or substituted by the surviving or acquiring corporation (or its parent), then, contingent upon the closing of the corporate transaction, the vesting and exercisability of any outstanding stock awards held by participants who are providing continuous service at the effective time of the corporate transaction or whose continuous service with us has not terminated more than 3 months prior to the effective time of the corporate transaction, or recent participants, will be accelerated to a date prior to the effective time of the corporate transaction (except if an employee is terminated for cause (as defined in the employee’s stock award agreement)) and, at or prior to the effective time of the corporate transaction, such stock awards will terminate if not exercised (if applicable) and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse. If outstanding stock awards are not assumed, continued or substituted by the surviving or acquiring corporation (or its parent), any outstanding stock awards held by participants who are not recent participants (other than a stock award consisting of vested and outstanding shares of common stock not subject to our right of repurchase) will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction; however, any reacquisition or repurchase rights held by us with respect to such stock awards may continue to be exercised. In addition, if a stock award will terminate if not exercised prior to the effective time of a corporate transaction, our board of directors may provide that such stock awards will be canceled in exchange for a payment, in such form as may be determined by our board of directors, equal to the excess, if any, of the value of the property the holder of such stock award would have received upon exercise of the stock award over any exercise price payable by such holder.

Change in Control. If provided in a stock award agreement, stock awards may be subject to additional acceleration of vesting and exercisability upon or after a change in control (as defined in the 2005 Plan). The standard form of option agreement under the 2005 Plan provides that all outstanding options held by a participant will accelerate in full if the participant is terminated without cause (as defined below) following a change in control. The standard form of option agreement under the 2005 Plan also provides that any outstanding options held by a participant will accelerate in full if the participant incurs a constructive termination (as defined below) within 12 months following a change in control. For purposes of the standard form of option agreement under the 2005 Plan, “cause” generally means (1) a commission of a felony related to us or our business or any crime involving fraud or moral turpitude; (2) the attempted commission of, or participation in, a fraud against us; (3) the unauthorized use or disclosure of our confidential information or trade secrets; or (4) the participant’s willful failure to substantially perform his or her duties and responsibilities owed to us. For purposes of the standard form of option agreement under the 2005 Plan, “constructive termination” generally means (1) a substantial reduction in the participant’s duties or responsibilities in effect immediately prior to the effective time of a change in control; (2) a material reduction in a participant’s annual base salary as in effect on the closing date of the change in control or as increased thereafter; (3) any failure by us to continue in effect any benefit plan or program in which the participant was participating immediately prior to the effective time of a change in control or the taking of any action by us that would adversely affect a participant's participation in or reduce benefits under any such plans or programs (provided, that a constructive termination will not be deemed to have occurred if we provide for the participation in benefit plans and programs that, taken as a whole, are comparable to those that were provided immediately prior to the change in control); (4) a relocation of the participant's business office to a location more than 50 miles from the location at which the participant performed his or her duties as of the effective time of the change in control; or (5) a material breach by us of any provision of any material agreement between the participant and us concerning the terms and conditions of the participant's employment.

Plan Amendment or Termination. Subject to the terms of the 2005 Plan, our board of directors generally has the authority to amend, suspend or terminate the 2005 Plan at any time; *provided*, that no such action will impair the existing rights of any outstanding stock awards without the affected participant's written consent. As described above, the 2005 Plan will be terminated upon the IPO Date and no new stock awards will be granted under the 2005 Plan on or after such date.

Amended and Restated 1999 Stock Plan

Our Amended and Restated 1999 Stock Plan, or the 1999 Plan, was adopted by our board of directors on February 12, 1999 and approved by our stockholders in January 2000. The 1999 Plan was last amended on November 15, 2002. The 1999 Plan terminated on the date the 2005 Plan became effective. No new awards may be granted under the 1999 Plan; however, any outstanding awards granted under the 1999 Plan remain outstanding and subject to the terms of the 1999 Plan and award agreements thereunder, except that in the event of a corporate transaction, the provisions of the 2005 Plan (as described above) governing the treatment of awards in the event of a corporate transaction will govern all outstanding awards under the 1999 Plan.

The 1999 Plan provided for the discretionary grant of incentive stock options, nonstatutory options, and stock awards to our eligible employees, directors and consultants. The number of shares of our common stock subject to outstanding awards under the 1999 Plan is 47,773 shares.

Our board of directors or a duly authorized committee of our board of directors administers the 1999 Plan and the awards granted under the 1999 Plan. In the event of certain corporate transactions, the treatment of outstanding awards under the 1999 Plan will be governed by the corporate transaction provisions set forth in the 2005 Plan, and summarized above.

Subject to the terms of the 1999 Plan, our board of directors generally may amend the terms of awards granted under the 1999 Plan at any time, except that no amendment may adversely affect outstanding stock awards without the written consent of the affected participants.

2014 Employee Stock Purchase Plan

Our board of directors adopted, and we expect that our stockholders will approve, our 2014 Employee Stock Purchase Plan, or the ESPP, prior to this offering. The ESPP will become effective upon the IPO Date. The ESPP is intended to qualify as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code.

Authorized Shares. The maximum aggregate number of shares of our common stock that may be issued under our ESPP is 4,000,000 shares. Additionally, the number of shares of our common stock reserved for issuance under our ESPP will increase automatically each year, beginning on January 1, 2016 and continuing through and including January 1, 2024, by the lesser of (i) 1.0% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year; and (ii) 3,000,000 shares of common stock. Our board of directors may act prior to the first day of any calendar year to provide that there will be no January 1 increase or that the increase will be for a lesser number of shares than would otherwise occur. Shares subject to purchase rights granted under our ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under our ESPP.

Administration. Our board of directors will administer our ESPP. Our board of directors may delegate authority to administer our ESPP to our compensation committee. Our ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings (as defined by the board of directors in each offering) for the purchase of our common stock under the ESPP. Common stock will be purchased for the accounts of employees participating in the ESPP at a price per share not less than the lower of (a) 85% of the fair market value of a share of our common stock on the first date of an offering; and (b) 85% of the fair market value of a share of our common stock on the date of purchase. For the initial offering, which we expect will commence upon the execution and delivery of the underwriting agreement relating to this offering, the fair market value on the first day of the initial offering will be the price at which shares are first sold to the public.

Limitations. Our employees, including executive officers, may have to satisfy one or more of the following service requirements before participating in our ESPP, as determined by the administrator: (i) customary employment for more than 20 hours per week and more than five months per calendar year, or (ii) continuous employment for a minimum period of time, not to exceed two years. An employee may not be granted rights to purchase stock under our ESPP if such employee (a) immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of our common stock, or (b) holds rights to purchase stock under our ESPP that would accrue at a rate that exceeds $25,000 worth of our stock for each calendar year that the rights remain outstanding.

Changes in Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to (1) the number of shares reserved under the ESPP, (2) the maximum number of shares by which the share reserve may increase automatically each year, (3) the number of shares and purchase price of all outstanding purchase rights, and (4) the number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. In the event of a specified corporate transaction, such as a merger or sale of all or substantially all of our assets, a successor corporation may assume, continue or substitute each outstanding purchase right. If the successor corporation does not assume, continue or substitute for the outstanding purchase rights, the offering in progress will be shortened and the participants' accumulated contributions will be used to purchase shares within 10 business days prior to the effective date of the corporate transaction.

Amendments; Termination. Our board of directors has the authority to amend, suspend or terminate our ESPP, at any time and for any reason; provided, that except in certain circumstances such amendment or termination may not materially impair outstanding purchase rights without the holder's consent. Our ESPP will remain in effect until terminated by the administrator in accordance with the terms of the ESPP.

401(k) Plan

We maintain a tax-qualified retirement plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may defer eligible compensation subject to applicable annual Internal Revenue Code limits. The 401(k) plan permits participants to make both pre-tax and certain after-tax (Roth) deferral contributions. These contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participant's directions. Employees are immediately and fully vested in their contributions. Commencing in 2014, active contributing participants in the 401(k) plan are eligible to receive employer matching contributions of up to 2%, 4% or 6% of salary, depending upon a participant's number of years of service. Employer matching contributions are subject to applicable annual Internal Revenue Code limits and are fully vested when made. The 401(k) plan is intended to be qualified under Section 401(a) of the Internal Revenue Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Internal Revenue Code.

Pension Benefits

We do not maintain any pension benefit plans.

Nonqualified Deferred Compensation

We do not maintain any nonqualified deferred compensation plans.

Limitations on Liability and Indemnification Matters

Upon the completion of this offering, our amended and restated certificate of incorporation will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit. Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws will provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law. Our amended and restated bylaws will also provide that, upon satisfaction of certain conditions, we shall advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by our board of directors. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought and we are not aware of any threatened litigation that may result in claims for indemnification.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy. Prior to 180 days after the date of this offering (subject to early termination), the sale of any shares under such plan would be subject to the lock-up agreement that the director or officer has entered into with the underwriters.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the director and executive compensation arrangements discussed above in "Management" and "Executive Compensation" and the registration rights described below in "Description of Capital Stock—Stockholder Registration Rights," below we describe transactions since January 1, 2011, to which we have been or will be a participant, in which the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or holders of more than 5% of any class of our voting stock, or any member of the immediate family of, or person sharing the household with, any of these individuals, had or will have a direct or indirect material interest.

Sale of Series A Preference Shares by FibroGen China Anemia Holdings, Ltd.

In July and December 2012 and February 2013, pursuant to a Share Purchase Agreement, our subsidiary, FibroGen China Anemia Holdings, Ltd., sold an aggregate of 6,758,000 Series A Preference Shares at a purchase price of $1.00 per share. The following table summarizes purchases of such shares by our directors, executive officers or holders of more than 5% of any class of our voting stock:

Stockholder	Series A Preference Shares	Aggregate purchase price
Stern Family Trust (1)	500,000	$ 500,000.00
Grama Ventures LLC (2)	450,000	$ 450,000.00

(1) Julian N. Stern is one of our directors and a trustee of Stern Family Trust.
(2) Roberto Pedro Rosenkranz, Ph.D., M.B.A. is one of our directors and President of Grama Ventures LLC.

On February 16, 2012, our Chief Executive Officer and Chairman of the Board, Thomas B. Neff, repaid a June 2002 stockholder note that we issued in connection with our previous policy of allowing officers to exercise options to purchase our common stock using a promissory note. The note related to the exercise of Mr. Neff's outstanding stock options prior to 2002 and was repaid in accordance with its terms.

Investor Rights Agreements

We have entered into investor rights agreements with certain of our investors in connection with certain of our preferred stock financings. We have also entered into investor rights agreements with certain of our warrant holders. These investors and warrant holders are entitled to rights with respect to the registration of their shares following the completion of this offering. For a more detailed description of these registration rights, see the section of the prospectus captioned "Description of Capital Stock—Stockholder Registration Rights."

Astellas Collaboration

Astellas is an equity investor in FibroGen, Inc. and considered a related party. During the years ended December 31, 2012 and 2013 and the six months ended June 30, 2013 and 2014, we recorded revenue related to collaboration agreements with Astellas of $65.1 million, $25.7 million, $18.5 million and $8.1 million, respectively. During the years ended December 31, 2012 and 2013 and the six months ended June 30, 2013 and 2014, we recorded expense related to collaboration agreements with Astellas of $0.3 million, $4.0 million, $0.8 million and $4.5 million, respectively. For a more detailed description of our collaboration agreements with Astellas, see "Business—Collaborations."

Employment Offer Letters

We have entered into offer letter agreements with our executive officers. For more information regarding these agreements, see the section of the prospectus captioned "Executive Compensation—Offer Letter Agreements."

Indemnification Agreements

Our amended and restated certificate of incorporation, which will be effective upon the completion of this offering, will contain provisions limiting the liability of directors, and our amended and restated bylaws will provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by our board of directors. In addition, we have entered into an indemnification agreement with each of our directors and our executive officers. For more information regarding these agreements, see the section of the prospectus captioned “Executive Compensation—Limitations on Liability and Indemnification Matters.”

Policy on Future Related Party Transactions

All future transactions between us and our officers, directors, principal stockholders and their affiliates will be approved by the audit committee, or a similar committee consisting of entirely independent directors, according to the terms of our Code of Business Conduct.

We believe that we have executed all the transactions described above on terms no less favorable to us than we could have obtained from unaffiliated third parties. It is our intention to ensure that all future transactions between us and our officers, directors and principal stockholders and their affiliates, are approved by the audit committee, or a similar committee consisting of entirely independent directors, according to the terms of our Code of Business Conduct, and are on terms no less favorable to us than those that we could obtain from unaffiliated third parties.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of June 30, 2014, as adjusted to reflect the shares of common stock to be issued and sold in the offering and the concurrent private placement assuming no exercise of the underwriters' option to purchase additional shares from us in the offering, for:

- each of our named executive officers;
- each of our directors;
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power. Shares of common stock issuable under options or warrants that are exercisable within 60 days after June 30, 2014 are deemed beneficially owned and such shares are used in computing the percentage ownership of the person holding the options or warrants, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person. The information contained in the following table is not necessarily indicative of beneficial ownership for any other purpose, and the inclusion of any shares in the table does not constitute an admission of beneficial ownership of those shares.

Unless otherwise indicated below, to our knowledge, all persons named in the table have sole voting and dispositive power with respect to their shares of common stock, except to the extent authority is shared by spouses under community property laws.

Our calculation of the percentage of beneficial ownership prior to this offering and the concurrent private placement is based on 118,514,511 shares of our common stock (including preferred stock on an as-converted basis) outstanding as of June 30, 2014. We have based our calculation of beneficial ownership after this offering and the concurrent private placement on   shares of our common stock outstanding immediately after the closing of this offering and the concurrent private placement (assuming no exercise of the underwriters' option to purchase additional shares of common stock in the offering).

Unless otherwise indicated below, the address of each beneficial owner listed in the table below is c/o FibroGen, Inc., 409 Illinois Street, San Francisco, CA 94158.

		Percentage of Shares Beneficially Owned	
Name of Beneficial Owner	**Number of Shares Beneficially Owned**	**Before the Offering and the Concurrent Private Placement**	**After the Offering and the Concurrent Private Placement**
5% Stockholders:			
Thomas B. Neff (1)	15,755,025	12.7%	%
Astellas Pharma Inc. 2-5-1 Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411 Japan	12,420,921	10.5%	%
Directors and Named Executive Officers:			
Thomas B. Neff (1)	15,755,025	12.7%	%
K. Peony Yu (2)	432,750	*	%
Frank H. Valone (3)	512,875	*	%
Thomas F. Kearns Jr. (4)	1,031,345	*	%
Kalevi Kurkijärvi, Ph.D. (5)	395,000	*	%
Miguel Madero (6)	1,163,920	1.0%	%
Rory B. Riggs (7)	1,325,500	1.1%	%
Roberto Pedro Rosenkranz, Ph.D., M.B.A. (8)	150,100	*	%
Jorma Routti, Ph.D. (9)	395,000	*	%
James A. Schoeneck (2)	150,000	*	%
Julian N. Stern (10)	680,612	*	%
Toshinari Tamura (2)	195,000	*	%
All executive officers and directors as a group (13 persons) (11)	22,953,045	18.0%	%

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* Represents beneficial ownership of less than one percent (1%) of the outstanding common stock.

(1) Consists of (a) 9,587,906 shares held by Thomas B. Neff, (b) 362,677 shares held by the Thomas B. Neff Family Partnership, (c) 50,000 shares held by Mr. Neff's spouse and (d) 150,442 shares held by BioGrowth Partners LP. Also includes 5,604,000 shares issuable pursuant to stock options exercisable within 60 days of June 30, 2014.

(2) Represents shares issuable pursuant to stock options exercisable within 60 days of June 30, 2014.

(3) Includes 452,875 shares issuable pursuant to stock options exercisable within 60 days of June 30, 2014.

(4) Consists of (a) 463,845 shares held by Thomas F. Kearns, Jr., and 275,000 shares held by the Kearns Trust, of which Mr. Kearns is a trustee and has sole voting and dispositive power. Also includes 292,500 shares issuable pursuant to stock options exercisable within 60 days of June 30, 2014.

(5) Includes 285,000 shares issuable pursuant to stock options exercisable within 60 days of June 30, 2014.

(6) Includes an aggregate of 917,420 shares held in accounts for family members for which Mr. Madero maintains power of attorney to manage and control. Also includes 195,000 shares issuable pursuant to stock options exercisable within 60 days of June 30, 2014.

(7) Consists of (a) 1,275,500 shares held by Rory B. Riggs and (b) 50,000 shares held jointly by Rory B. Riggs and Robin Rhys.

(8) Includes (a) 87,500 shares held by Roberto Pedro Rosenkranz and (b) 100 shares held by Mr. Rosenkranz's spouse as custodian for Mr. Rosenkranz's daughter. Also includes 62,500 shares issuable pursuant to stock options exercisable within 60 days of June 30, 2014.

(9) Includes 225,000 shares issuable pursuant to stock options exercisable within 60 days of June 30, 2014.

(10) Consists of (a) 357,672 shares held by Julian N. Stern and an aggregate of 30,440 held in various trusts for which Mr. Stern's spouse, Dorothy Stern, is the sole trustee and has sole voting and investment control. Also includes 292,500 shares issuable pursuant to stock options exercisable within 60 days of June 30, 2014.

(11) Consists of (a) 14,100,002 shares held by the directors and executive officers as of June 30, 2014 and (b) 8,853,043 shares issuable to our directors and officers pursuant to stock options exercisable within 60 days of June 30, 2014.

DESCRIPTION OF CAPITAL STOCK

The description below summarizes the material terms of our capital stock and provisions of our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon completion of the offering.

General

Upon the completion of this offering, our authorized capital stock will consist of shares, all with a par value of $0.01 per share, of which:

- shares are designated as common stock; and
- shares are designated as preferred stock.

The following information reflects the filing of our amended and restated certificate of incorporation and the conversion of all outstanding shares of our convertible preferred stock into shares of common stock upon the completion of this offering.

As of June 30, 2014, there were outstanding:

- 33,714,272 shares of common stock held by 553 stockholders, with no shares of common stock issued pursuant to early exercise of stock options or restricted stock issuances that are subject to repurchase; and
- 32,584,115 shares of common stock, of which 26,552 were cancelled upon shareholder approval (which approval was obtained in July 2014), issuable upon exercise of outstanding options.

Our shares of common stock are not redeemable and, following the completion of this offering, will not have preemptive rights.

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

As of June 30, 2014, there were 84,800,239 shares of our preferred stock outstanding, which will be converted into 84,800,239 shares of common stock immediately prior to the completion of this offering.

Upon the completion of this offering, our board of directors may, without further action by our stockholders, fix the rights, preferences, privileges and restrictions of up to an aggregate of   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. Upon the completion of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Options

As of June 30, 2014, under both our 1999 and 2005 Plans, options to purchase an aggregate of 32,584,115 shares of common stock, of which 26,552 were cancelled upon shareholder approval, which approval was obtained in July 2014, having a weighted-average exercise price of $2.23 per share were outstanding and 18,942,169 additional shares of common stock were available for future grant. For additional information regarding the terms of these plans, see the section of this prospectus captioned “Executive Compensation—Equity Incentive Plans.”

Warrants

As of June 30, 2014, we had outstanding warrants to acquire 432,790 shares of common stock having a weighted-average exercise price of $3.03 per share. Certain of these warrants are exercisable until the earlier of (1) the date one year after the effectiveness of this offering or (2) the effective date of our merger with or into, our consolidation with, or our sale of all or substantially all of our assets to another entity such that our stockholders do not retain the majority of the voting capital of the resulting entity. Certain of these warrants are exercisable until the earlier of (1) the fifth anniversary of the effective date of this registration statement or (2) the effective date of our merger with or into, our consolidation with, or our sale of all or substantially all of our assets to another entity such that our stockholders do not retain the majority of the voting capital of the resulting entity.

Stockholder Registration Rights

Under our investor rights agreements, after the completion of this offering, certain holders of our common stock, including certain holders of 5% of our capital stock and entities affiliated with certain of our directors, will be entitled to certain rights with respect to registration of such shares under the Securities Act, in each case described below. These shares are referred to as registrable securities. Registration pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Registration Rights—Early Rights Agreements

Certain registration rights are provided for under the terms of our Investor Rights Agreement dated as of December 1995, entered into with certain of our investors in connection with our Series B Preferred Stock financing, our Investor Rights Agreement dated as of February 20, 1998, entered into with certain of our investors in connection with our Series C Preferred Stock financing and our Investor Rights Agreements dated as of June 3, 1999 and February 8, 2000, entered into with certain of our warrant holders, collectively our Early

Rights Agreements. We will pay the registration expenses, other than underwriting fees, discounts or commissions and any out-of-pocket expenses of the selling holders, of the shares registered pursuant to the piggyback registration described below.

Piggyback Registration Rights

If we propose to register for offer and sale any of our securities under the Securities Act in another offering, either for our own account or for the account of other security holders, the holders of the registrable securities subject to our Early Rights Agreements will be entitled to certain “piggyback” registration rights allowing them to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, including a registration statement on Form S-3 (other than with respect to this registration statement or a registration statement on Forms S-4 or S-8), the holders of these shares are entitled to notice of the registration and have the right, subject to certain limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration.

Registration Rights—2000 and 2004 Rights Agreements

Certain provisions relating to registration rights described below are provided for under the terms of our Investor Rights Agreement dated as of May 12, 2000, as amended in December 2004 and September 2005, or our 2000 Rights Agreement, entered into in connection with our Series E Preferred Stock financing and our Investor Rights Agreement dated as of December 22, 2004, as amended in September 2005, or our 2004 Rights Agreement, entered into in connection with our Series F Preferred Stock financing. Under the terms of these agreements, these registration rights are not exercisable five years after the effective date of our initial public offering, or, with respect to any particular holder, at such earlier time that all registrable shares held by such holder (and any affiliate of the holder with whom such holder must aggregate sales under Rule 144 of the Securities Act) can be sold under Rule 144 of the Securities Act. We would pay the registration expenses, other than underwriting discounts and commissions and the fees and disbursements of counsel for the selling holders, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Demand Registration Rights

Our 2000 and 2004 Rights Agreements contain provisions that would entitle holders of registrable securities to certain demand registration rights. At any time 180 days following the effective date of this registration statement, the holders of at least 50% of these securities may request that we register all or a portion of their shares, subject to certain specified exceptions. If the holders requesting registration intend to distribute their shares by means of an underwriting, the underwriters of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares. We would not be required to effect more than two demand registrations pursuant to each of our 2000 Rights Agreement and our 2004 Rights Agreement, not including any registration in which more than 50% of the registrable securities that holders request to be registered are excluded from such registration due to marketing limitations. Depending on certain conditions, we may defer such registration for up to 90 days once in any 12-month period.

Piggyback Registration Rights

Our 2000 and 2004 Rights Agreements contain provisions that would entitle holders of our registrable securities to include their shares of registrable securities in this offering, subject to certain marketing and other limitations. If we propose to register for offer and sale any of our securities under the Securities Act in another offering, either for our own account or for the account of other security holders, the holders of these shares would be entitled to certain “piggyback” registration rights allowing them to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, including a registration statement on Form S-3 as discussed below (other than with respect to a registration relating solely to the sale of securities to participants in our stock plans, a registration on any form (including Forms S-4 or S-8) that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the registrable shares, a registration statement related to a corporate reorganization or other transaction under Rule 145 of the Securities Act, or a registration statement related to stock issued upon conversion of debt securities), the holders of these shares would be entitled to notice of the registration and have the right, subject to certain limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration.

Form S-3 Registration Rights

Our 2000 and 2004 Rights Agreements contain provisions that would entitle the holders of the registrable securities subject to will be entitled to certain Form S-3 registration rights. Any holder of these shares would make a request that we register for offer and sale their shares on Form S-3 if we are qualified to file a registration statement on Form S-3, subject to certain specified exceptions. Such request for registration on Form S-3 must cover securities the aggregate offering price of which, before payment of the underwriting discounts and commissions, equals or exceeds $2,000,000. We would not be required to effect more than two registrations on Form S-3 pursuant to each of our 2000 Rights Agreement and our 2004 Rights Agreement, and no more than one such registration under each agreement within any 6-month period. Depending on certain conditions, we may defer such registration for up to 90 days once in any 12-month period.

Anti-Takeover Effects of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Our amended and restated certificate of incorporation and amended and restated bylaws to be in effect upon the completion of this offering contain certain provisions that could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions and certain provisions of Delaware law, which are summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate more favorable terms with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (1) by persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 $^2/_3$% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 may discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws to be in Effect upon the Completion of this Offering

Our amended and restated certificate of incorporation to be in effect upon the completion of this offering will provide for our board of directors to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation and our amended and restated bylaws to be effective upon the completion of this offering will also provide that directors may be removed by the stockholders only for cause upon the vote of 66 ⅔% of all then-outstanding shares of capital stock entitled to vote generally at an election of directors. Furthermore, the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum.

Our amended and restated certificate of incorporation and amended and restated bylaws will also provide that all stockholder actions must be effected at a duly called meeting of stockholders and will eliminate the right of stockholders to act by written consent without a meeting. Our bylaws will also provide that only our chairman of the board, chief executive officer or the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders.

Our amended and restated bylaws will also provide that stockholders seeking to present proposals before a meeting of stockholders to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and will specify requirements as to the form and content of a stockholder’s notice. Our amended and restated certificate of incorporation and amended and restated bylaws will provide that the stockholders cannot amend many of the provisions described above except by a vote of 66 2/3% or more of our outstanding common stock.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

Listing

We intend to list our common stock on the NASDAQ Global Select Market under the symbol “FGEN”.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Wells Fargo Bank, National Association. The transfer agent’s address is 1110 Centre Pointe Curve, Suite 101, Mendota Heights, Minnesota 55120-4101.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market existed for our capital stock. Future sales of shares of our common stock in the public market after this offering, and the availability of shares for future sale, could adversely affect the market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nonetheless, sales of substantial amounts of our common stock, or the perception that these sales could occur, could adversely affect prevailing market prices for our common stock and could impair our future ability to raise equity capital.

Based on the number of shares outstanding on June 30, 2014, upon completion of this offering and the concurrent private placement,   shares of common stock will be outstanding, assuming the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock and the exchange of FibroGen Europe shares for shares of our common stock immediately prior to the completion of this offering and the concurrent private placement, the exercise of warrants to purchase   shares of our common stock and no exercise of the underwriters' option to purchase additional shares of common stock, no exercises of options outstanding as of June 30, 2014. All of the shares sold in this offering, plus any shares sold upon exercise of the underwriters' option to purchase additional shares from us in the offering, will be freely tradable without restrictions or further registration under the Securities Act, except for any shares sold to our "affiliates," as that term is defined under Rule 144 under the Securities Act.

The remaining shares of common stock will be deemed "restricted securities" as defined in Rule 144 under the Securities Act. These restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, which rules are summarized below.

Subject to the lock-up agreements described below and the provisions of Rule 144 and 701 under the Securities Act, these restricted securities will be available for sale in the public market as follows:

Date	Approximate Number of Shares
On the date of this prospectus	
Between 90 and 180 days after the date of this prospectus	
At various times beginning 181 days after the date of this prospectus	

In addition, of the 32,584,115 shares of our common stock, of which 26,552 shares were cancelled upon shareholder approval, which approval was obtained in July 2014, that were subject to stock options outstanding as of June 30, 2014, options to purchase 24,767,556 shares of common stock were vested as of June 30, 2014 and will be eligible for sale 180 days following the effective date of this offering, as described in "Underwriting."

Rule 144

In general, under Rule 144, as currently in effect, a person who has beneficially owned restricted shares of our common stock for at least six months, including the holding period of any prior owner other than our affiliates, would be entitled to sell their securities provided that (1) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale, (2) we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale, and (3) we are current in our Exchange Act reporting at the time of sale. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell those shares without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, persons who have beneficially owned restricted shares of our common stock for at least six months, but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after the completion of this offering and the concurrent private placement based on the number of common shares outstanding as of , 2014; and
- the average weekly trading volume of our common stock on during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Such sales by affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Rule 701

In general, under Rule 701 a person who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been one of our affiliates during the immediately preceding 90 days may sell these shares in reliance upon Rule 144, but without being required to comply with the holding period or public information requirements of Rule 144. Rule 701 also permits affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701. As of , shares of our outstanding common stock had been issued in reliance on Rule 701 as a result of exercises of stock options and issuance of restricted stock. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Form S-8 Registration Statements

As soon as practicable after the completion of this offering, we intend to file with the SEC one or more registration statements on Form S-8 under the Securities Act to register the offer and sale of shares of our common stock that are issuable pursuant to our 1999 Plan, 2005 Plan and 2014 Plan. These registration statements will become effective immediately upon filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below and Rule 144 limitations applicable to affiliates.

Lock-Up Agreements

We and all of our directors and officers, as well as the other holders of substantially all shares of our common stock outstanding immediately prior to the completion of this offering, have agreed with the underwriters that, for a period of 180 days following the date of this prospectus, subject to certain exceptions, we and they will not, directly or indirectly, offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale, or otherwise dispose of or hedge any of our shares of common stock, any options or warrants to purchase any shares of our common stock, or any securities convertible into, or exchangeable for or that represent the right to receive shares of our common stock. Goldman, Sachs & Co., Citigroup Global Markets Inc. and Leerink Partners LLC may, in their sole discretion, at any time without prior notice, release all or any portion of the shares from the restrictions in any such agreement.

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain security holders, including the investor rights agreement and our standard form of option agreement under our 2005 Plan, that contain market stand-off provisions imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus. We have also entered into agreements with certain security holders, including our standard form of option agreement under our 1999 Plan, that contain market stand-off provisions imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 90 days following the date of this prospectus.

Registration Rights

Upon the completion of this offering and assuming no exercise of the underwriters' option to purchase additional shares, the holders of   shares of our common stock, or their transferees, will be entitled to certain rights with respect to the registration of the offer and sale of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See the section of this prospectus captioned "Description of Capital Stock—Stockholder Registration Rights" for additional information.

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following is a discussion of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. All prospective non-U.S. holders of our common stock should consult their own tax advisors with respect to the U.S. federal income tax consequences of the purchase, ownership and disposition of our common stock, as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local and non-U.S. tax consequences and any U.S. federal non-income tax consequences. In general, a non-U.S. holder means a beneficial owner of our common stock (other than a partnership or an entity or arrangement treated as a partnership for U.S. federal income tax purposes) that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or an entity treated as a corporation for U.S. federal income tax purposes, created or organized in the United States or under the laws of the United States or of any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if (1) a U.S. court can exercise primary supervision over the trust’s administration and one or more U.S. persons have the authority to control all of the trust’s substantial decisions or (2) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing U.S. Treasury Regulations promulgated thereunder, published administrative rulings and judicial decisions, all as in effect as of the date of this prospectus. These laws are subject to change and to differing interpretation, possibly with retroactive effect. Any change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus.

This discussion is limited to non-U.S. holders that hold shares of our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, for investment). This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder’s individual circumstances, nor does it address any aspects of U.S. estate or gift tax, or any state, local or non-U.S. taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as holders that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below), corporations that accumulate earnings to avoid U.S. federal income tax, tax-exempt organizations, banks, financial institutions, insurance companies, brokers, dealers or traders in securities, commodities or currencies, tax-qualified retirement plans, holders subject to the alternative minimum tax or Medicare contribution tax, holders who hold or receive our common stock pursuant to the exercise of employee stock options or otherwise as compensation, holders holding our common stock as part of a hedge, straddle or other risk reduction strategy, conversion transaction or other integrated investment, holders deemed to sell our common stock under the constructive sale provisions of the Code, controlled foreign corporations, passive foreign investment companies, and U.S. expatriates and certain former citizens or long-term residents of the United States.

In addition, this discussion does not address the tax treatment of partnerships (or entities or arrangements that are treated as partnerships for U.S. federal income tax purposes) or persons that hold their common stock through such partnerships or such entities or arrangements. If a partnership, including any entity or arrangement treated as a partnership for U.S. federal income tax purposes, holds shares of our common stock, the U.S. federal income tax treatment of a partner in such partnership will generally depend upon the status of the partner, the activities of the partnership and certain determinations made at the partner level. Such partners and partnerships should consult their own tax advisors regarding the tax consequences of the purchase, ownership and disposition of our common stock.

There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein, and we have not obtained, nor do we intend to obtain, a ruling with respect to the U.S. federal income tax consequences with respect to the matters discussed below.

Distributions on Our Common Stock

Distributions, if any, on our common stock generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder’s investment, up to such holder’s adjusted tax basis in the common stock. Any remaining excess will be treated as capital gain from the sale or exchange of such common stock, subject to the tax treatment described below in “Gain on Sale, Exchange or Other Disposition of Our Common Stock.”

Subject to the discussion below regarding backup withholding and foreign accounts, dividends paid to a non-U.S. holder will generally be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty generally will be required to provide a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E (or successor form) and satisfy relevant certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. To claim the exemption, the non-U.S. holder must furnish to us or our paying agent a valid IRS Form W-8ECI (or applicable successor form), certifying that the dividends are effectively connected with the non-U.S. holder’s conduct of a trade or business within the United States. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code), unless a specific treaty exemption applies. Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional “branch profits tax” at a 30% rate or such lower rate as may be specified by an applicable income tax treaty.

Gain on Sale, Exchange or Other Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, in general, a non-U.S. holder will not be subject to any U.S. federal income tax on any gain realized upon such holder’s sale, exchange or other disposition of shares of our common stock unless:

- the gain is effectively connected with a U.S. trade or business of the non-U.S. holder and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed base maintained in the United States by such non-U.S. holder, in which case the non-U.S. holder generally will be taxed at the graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in “Distributions on Our Common Stock” may also apply;

- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition, which may be offset by U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States) provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- our common stock constitutes a U.S. real property interest because we are, or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation." Even if we are or become a U.S. real property holding corporation, provided that our common stock is regularly traded on an established securities market, our common stock will be treated as a U.S. real property interest only with respect to a non-U.S. holder that holds more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. In such case, such non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code). Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the dividends on our common stock paid to such holder and the tax withheld, if any, with respect to such dividends. Non-U.S. holders will have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. U.S. backup withholding generally will not apply to a Non-U.S. holder who provides a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E or otherwise establishes an exemption. Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them. Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder may be allowed as a credit against the non-U.S. holder's U.S. federal income tax liability, if any, and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Foreign Accounts

The Code generally imposes a U.S. federal withholding tax of 30% on dividends and the gross proceeds of a disposition of our common stock paid to a "foreign financial institution" (as specifically defined for this purpose), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which may include certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing these withholding and reporting requirements may be subject to different rules. This U.S. federal withholding tax of 30% also applies to dividends and the gross proceeds of a disposition of our common stock paid to a non-financial foreign entity, unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding substantial direct and indirect U.S. owners of the entity. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules. The withholding provisions described above will generally apply to dividends on our common stock, and will also generally apply with respect to gross proceeds of a sale or other disposition of our common stock on or after January 1, 2017. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. Non-U.S. holders are encouraged to consult with their own tax advisors regarding the possible implications of the legislation on their investment in our common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman, Sachs & Co., Citigroup Global Markets Inc. and Leerink Partners LLC are the representatives of the underwriters.

Underwriters	Number of Shares
Goldman, Sachs & Co.	
Citigroup Global Markets Inc.	
Leerink Partners LLC	
RBC Capital Markets, LLC	
Stifel, Nicolaus & Company, Incorporated	
William Blair & Company, L.L.C.	
Total	

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

Paid by Us	No Exercise	Full Exercise
Per Share	$	$
Total	$	$

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $ per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our officers, directors, and holders of substantially all of our common stock have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date that is 180 days after the date of this prospectus, except with the prior written consent of Goldman, Sachs & Co., Citigroup Global Markets Inc. and Leerink Partners LLC. This agreement does not apply to any existing employee benefit plans. The foregoing restrictions do not apply to equity issuances by us in connection with any licensing, commercialization, joint venture, technology transfer or development collaboration agreement and commercial credit, equipment financing or commercial property lease transactions of up to 5% of the total number of shares of common stock issued and outstanding immediately following the consummation of this offering (provided that in each case the recipient agrees not to sell, dispose of, transfer or hedge the equity they receive for the balance of the lock-up period). See "Shares Eligible for Future Sale" for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for the shares. The initial public offering price has been negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We intend to list our common stock on the NASDAQ Global Select Market under the symbol “FGEN”.

In connection with the offering, the underwriters may purchase and sell shares of common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional shares for which the underwriters’ option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. “Naked” short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our common stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of our common stock. As a result, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the NASDAQ Global Select Market, in the over-the-counter market or otherwise.

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State), each underwriter has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) it has not made and will not make an offer of shares to the public in that Relevant Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of shares to the public in that Relevant Member State at any time:

(a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;

(b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the relevant underwriter or underwriters nominated by the Issuer for any such offer; or

(c) in any other circumstances which do not require the publication by the Issuer of a prospectus pursuant to Article 3(2) of the Prospectus Directive;

provided that no such offer of shares shall require the Issuer or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer of shares to the public” in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression Prospectus Directive means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression 2010 PD Amending Directive means Directive 2010/73/EU.

Each underwriter has represented and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act, or the FSMA) received by it in connection with the issue or sale of the shares in circumstances in which Section 21(1) of the FSMA does not apply to the Issuer; and

(b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

The shares may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), or (ii) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 by a relevant person which is: (a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries’ rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the shares under Section 275 except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) by operation of law.

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and each underwriter has agreed that it will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

The underwriters do not expect sales to discretionary accounts to exceed five percent of the total number of shares offered.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately $. We have also agreed to reimburse the underwriters for certain FINRA-related expenses incurred by them in connection with the offering in an amount not to exceed $30,000 as set forth in the underwriting agreement.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Goldman, Sachs & Co., certain of its affiliates and certain investment funds managed by them collectively beneficially owned preferred stock convertible into an aggregate of   shares of our common stock.

CONCURRENT PRIVATE PLACEMENT

AstraZeneca, one of our collaboration partners, has agreed to purchase from us concurrently with the closing of this offering in a private placement shares of our common stock with an aggregate purchase price of $20 million at a price per share equal to the initial public offering price.

VALIDITY OF COMMON STOCK

The validity of the shares of common stock offered hereby will be passed upon for us by Cooley LLP, Palo Alto, California and for the underwriters by Sullivan & Cromwell LLP, Palo Alto, California.

EXPERTS

The consolidated financial statements as of December 31, 2012 and 2013 and for the years then ended included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of such firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered under this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits. For further information about us and our common stock, you should refer to the registration statement and the exhibits and schedules filed with the registration statement. With respect to the statements contained in this prospectus regarding the contents of any agreement or any other document, in each instance, the statement is qualified in all respects by the complete text of the agreement or document, a copy of which has been filed as an exhibit to the registration statement.

Upon completion of this offering, we will be required to file annual, quarterly and current reports, proxy statements and other information with the SEC pursuant to the Exchange Act. You may read and copy this information at the SEC at its public reference facilities located at 100 F Street N.E., Room 1580, Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains periodic reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that site is www.sec.gov.

We intend to furnish our stockholders with annual reports containing audited financial statements and to file with the SEC quarterly reports containing unaudited interim financial data for the first three quarters of each fiscal year. We also maintain a website on the Internet at www.FibroGen.com. However, the information contained in or accessible through our website is not part of this prospectus or the registration statement of which this prospectus forms a part, and investors should not rely on such information in making a decision to purchase our common stock in this offering.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

FibroGen, Inc.

Report of Independent Registered Public Accounting Firm

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of comprehensive income (loss), of redeemable convertible preferred stock and equity (deficit) and of cash flows present fairly, in all material respects, the financial position of FibroGen, Inc. and its subsidiaries (the “Company”) at December 31, 2013 and 2012, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California
June 11, 2014

FibroGen, Inc.

Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31,		June 30,	Pro forma Equity June 30,
	2012	2013	2014 (unaudited)	2014 (See Note 2) (unaudited)
Assets				
Current assets:				
Cash and cash equivalents	$ 38,872	$ 76,332	$ 182,662	
Short-term investments	1,017	46,477	19,427	
Accounts receivable ($8,784, $6,012 and $7,262 from related party)	8,784	17,495	16,166	
Prepaid expenses and other current assets	4,130	3,339	2,375	
Total current assets	52,803	143,643	220,630	
Restricted cash	7,254	7,254	7,254	
Long-term investments	81,613	15,356	7,732	
Property and equipment, net	123,664	129,898	133,337	
Other assets	254	801	3,704	
Total assets	$ 265,588	$ 296,952	$ 372,657	
Liabilities, redeemable convertible preferred stock and total equity (deficit)				
Current liabilities:				
Accounts payable	$ 3,107	$ 1,066	$ 1,256	
Accrued liabilities ($1,121, $2,765 and $4,455 to related party)	16,480	29,559	36,938	
Deferred revenue	2,393	5,741	9,826	
Current portion of capital lease obligation	329	—	—	
Cease-use liability	966	710	524	
Current portion of lease financing obligations	403	403	403	
Total current liabilities	23,678	37,479	48,947	
Long-term portion of lease financing obligations	92,499	96,406	96,511	
Product development obligations (Note 6)	17,152	18,257	18,291	
Deferred rent	5,809	5,503	5,321	
Deferred revenue, net of current	3,371	30,908	63,110	
Cease-use liability, net of current	895	184	—	
Other long-term liabilities	—	612	612	
Total liabilities	143,404	189,349	232,792	
Commitments and Contingencies (Note 8)				
Series E and F redeemable convertible preferred stock (“Senior Preferred Stock”); par value of $0.01, 38,340,182 shares authorized, 38,340,182 shares issued and outstanding at December 31, 2012 and 2013, and June 30, 2014 (unaudited), and no shares authorized, issued or outstanding pro forma at June 30, 2014 (unaudited) (liquidation value: $173,690 at June 30, 2014)	168,436	168,436	168,436	—
Stockholders’ equity (deficit):				
Series A, B, C, D, G-1 and royalty acquisition convertible preferred stock (“Junior Preferred Stock”); par value of $0.01, 86,659,818 shares authorized, 46,460,057 shares issued and outstanding at December 31, 2012 and 2013, and June 30, 2014 (unaudited), and no shares authorized, issued or outstanding pro forma at June 30, 2014 (unaudited) (liquidation value: $138,060 at June 30, 2014)	136,313	136,313	136,313	—
Common stock; par value of $0.01, 225,000,000 shares authorized, 32,918,008, 33,003,325, and 33,714,272 shares issued and outstanding at December 31, 2012 and 2013, and June 30, 2014 (unaudited), respectively, and 118,514,511 shares outstanding pro forma at June 30, 2014 (unaudited)	329	330	337	1,185
Additional paid-in capital	37,409	40,936	43,225	347,126
Accumulated other comprehensive loss	(167)	(3,508)	(4,133)	(4,133)
Accumulated deficit	(247,836)	(262,779)	(232,188)	(232,188)
Total stockholders’ equity (deficit)	(73,952)	(88,708)	(56,446)	111,990
Non-controlling interests	27,700	27,875	27,875	27,875
Total equity (deficit)	(46,252)	(60,833)	(28,571)	139,865
Total liabilities, redeemable convertible preferred stock and equity (deficit)	$ 265,588	$ 296,952	$ 372,657	

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

FibroGen, Inc.

Consolidated Statements of Operations
(in thousands, except per share data)

	Years ended December 31, 2012	Years ended December 31, 2013	Six Months ended June 30, 2013 (unaudited)	Six Months ended June 30, 2014 (unaudited)
Revenue:				
License and milestone revenue (includes $62,845, $22,326, $16,895 and $6,460 from related party)	$ 62,845	$ 94,961	$ 16,895	$ 97,148
Collaboration services and other revenue (includes $2,275, $3,335, $1,628 and $1,617 from related party)	3,088	7,209	1,637	10,686
Total revenue	65,933	102,170	18,532	107,834
Operating expenses:				
Research and development	74,222	85,710	33,092	58,919
General and administrative	18,934	24,409	9,610	13,948
Total operating expenses	93,156	110,119	42,702	72,867
Income (loss) from operations	(27,223)	(7,949)	(24,170)	34,967
Interest and other, net:				
Interest expense	(10,026)	(10,702)	(5,307)	(5,451)
Interest income	4,397	3,552	1,840	1,080
Other income (expense), net	181	156	164	(5)
Total interest and other, net	(5,448)	(6,994)	(3,303)	(4,376)
Income (loss) before income taxes	(32,671)	(14,943)	(27,473)	30,591
Benefit from income taxes	100	—	—	—
Net income (loss)	$ (32,571)	$ (14,943)	$(27,473)	$ 30,591
Net income (loss) per share basic	$ (0.99)	$ (0.45)	$ (0.83)	$ 0.30
Net income (loss) per share diluted	$ (0.99)	$ (0.45)	$ (0.83)	$ 0.18
Weighted-average number of common shares used in net income (loss) per share—basic	32,820	32,964	32,938	33,198
Weighted-average number of common shares used in net income (loss) per share—diluted	32,820	32,964	32,938	53,970
Pro forma net income (loss) per share—basic (unaudited)		$ (0.13)		$ 0.26
Pro forma net income (loss) per share—diluted (unaudited)		$ (0.13)		$ 0.22
Pro forma weighted-average number of common shares used in net income (loss) per share—basic (unaudited)		117,764		117,998
Pro forma weighted-average number of common shares used in net income (loss) per share—diluted (unaudited)		117,764		140,164

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

FibroGen, Inc.

Consolidated Statements of Comprehensive Income (Loss)
(in thousands)

	Years ended December 31,		Six Months ended June 30,	
	2012	2013	2013	2014
			(unaudited)	
Net income (loss)	$ (32,571)	$ (14,943)	$(27,473)	$30,591
Other comprehensive income (loss):				
Foreign currency translation adjustments	(400)	(665)	284	195
Available-for-sale investments:				
Unrealized gain (loss) on investments, net of tax effect	643	(1,936)	(1,261)	(820)
Reclassification adjustments for realized gain included in net income, net of tax effect	(96)	(740)	(292)	—
Net change in unrealized gain (loss) on available-for-sale investments	547	(2,676)	(1,553)	(820)
Other comprehensive income (loss), net of taxes	147	(3,341)	(1,269)	(625)
Comprehensive income (loss)	$ (32,424)	$ (18,284)	$(28,742)	$29,966

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

FibroGen, Inc.

Consolidated Statements of Redeemable Convertible Preferred Stock and Equity (Deficit)

(in thousands, except share and per share data)

	Senior Preferred Stock		Junior Preferred Stock		Common Stock		Additional Paid-in Capital	Stockholder's Note Receivable (Related Party)	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Non-Controlling Interests	Total
	Shares	Amount	Shares	Amount	Shares	Amount						
Balance at December 31, 2011	38,340,182	$168,436	46,460,057	$136,313	32,793,508	$ 328	$ 32,699	$ (789)	$ (314)	$ (215,265)	$ 21,118	$(25,910)
Net loss	—	—	—	—	—	—	—	—	—	(32,571)	—	(32,571)
Change in unrealized loss on investments	—	—	—	—	—	—	—	—	547	—	—	547
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	(400)	—	—	(400)
Issuance of Series A Preferred to non-controlling interest	—	—	—	—	—	—	—	—	—	—	6,582	6,582
Stock options exercised	—	—	—	—	124,500	1	149	—	—	—	—	150
Repayment of stockholder's note	—	—	—	—	—	—	—	789	—	—	—	789
Stock-based compensation	—	—	—	—	—	—	4,561	—	—	—	—	4,561
Balance at December 31, 2012	38,340,182	168,436	46,460,057	136,313	32,918,008	329	37,409	—	(167)	(247,836)	27,700	(46,252)
Net loss	—	—	—	—	—	—	—	—	—	(14,943)	—	(14,943)
Change in unrealized loss on investments	—	—	—	—	—	—	—	—	(2,676)	—	—	(2,676)
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	(665)	—	—	(665)
Issuance of Series A Preferred to non-controlling interest	—	—	—	—	—	—	—	—	—	—	175	175
Stock options exercised	—	—	—	—	85,317	1	83	—	—	—	—	84
Stock-based compensation	—	—	—	—	—	—	3,444	—	—	—	—	3,444
Balance at December 31, 2013	38,340,182	168,436	46,460,057	136,313	33,003,325	330	40,936	—	(3,508)	(262,779)	27,875	(60,833)
Net income (*)	—	—	—	—	—	—	—	—	—	30,591	—	30,591
Change in unrealized loss on investments (*)	—	—	—	—	—	—	—	—	(820)	—	—	(820)
Foreign currency translation adjustments (*)	—	—	—	—	—	—	—	—	195	—	—	195
Stock options exercised (*)	—	—	—	—	710,947	7	824	—	—	—	—	831
Stock-based compensation (*)	—	—	—	—	—	—	1,465	—	—	—	—	1,465
Balance at June 30, 2014 (*)	38,340,182	$168,436	46,460,057	$136,313	33,714,272	$ 337	$ 43,225	$ —	$ (4,133)	$ (232,188)	$ 27,875	$(28,571)

(*) Unaudited

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,		Six Months ended June 30,	
	2012	2013	2013	2014
			(unaudited)	
Operating activities				
Net income (loss)	$(32,571)	$(14,943)	$(27,473)	$ 30,591
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:				
Depreciation and amortization	5,598	5,084	2,631	1,843
Amortization (accretion) of premium (discount) of investments	909	841	420	307
Gain on sale of investments, net	(365)	(301)	(237)	—
Gain on disposal of property and equipment	(2)	(1)	(2)	—
Stock-based compensation	4,561	3,444	1,755	1,465
Changes in operating assets and liabilities:				
Accounts receivable ($14,147, $2,772, $(3,364) and $(1,250) from related party)	14,147	(8,711)	3,364	1,329
Prepaid expenses and other current assets	450	791	444	964
Other assets	410	(547)	(242)	(694)
Accounts payable	770	(2,041)	(2,234)	190
Accrued liabilities and deferred rent ($14, $1,644, $670 and $1,690 from related party)	1,478	11,307	(2,661)	4,828
Deferred revenue	(973)	30,885	(1,126)	36,287
Cease-use liability	(1,008)	(967)	(470)	(371)
Lease financing liability	627	690	392	306
Other long-term liabilities	364	387	184	193
Net cash provided by (used in) operating activities	(5,605)	25,918	(25,255)	77,238
Investing activities				
Purchases of property and equipment	(744)	(6,806)	(1,886)	(3,952)
Proceeds from sale of property and equipment	2	2	2	—
Purchases of investments	(2,160)	—	—	—
Proceeds from sales of investments	10,055	16,582	—	—
Proceeds from maturities of investments	11,999	1,000	7,610	33,546
Net cash provided by investing activities	19,152	10,778	5,726	29,594
Financing activities				
Borrowings under credit facility	17,300	11,500	—	—
Repayments under credit facility	(17,300)	(11,500)	—	—
Repayments of capital lease obligations	(311)	(329)	(162)	—
Repayments of lease liability	(403)	(403)	(201)	(201)
Proceeds from lease financing liability	—	553	—	—
Repayment of stockholder’s note receivable (related party)	789	—	—	—
Proceeds from convertible promissory note	—	600	600	—
Proceeds from non-controlling interest	6,582	175	175	—
Proceeds from issuance of Common Stock upon exercise of stock options	150	84	47	831
Payment of equity issuance costs	—	—	—	(1,167)
Net cash provided by (used in) financing activities	6,807	680	459	(537)
Effect of exchange rate changes on cash and cash equivalents	(66)	84	13	35
Net increase (decrease) in cash and cash equivalents	20,288	37,460	(19,057)	106,330
Cash and cash equivalents at beginning of period	18,584	38,872	38,872	76,332
Cash and cash equivalents at end of period	$ 38,872	$ 76,332	$ 19,815	$182,662
Supplemental cash flow information:				
Interest payments	$ 506	$ 433	$ 233	$ 194
Purchases of property and equipment in accounts payable and accrued liabilities	$ 210	$ 1,655	$ 150	$ 2,988
Assets acquired under facility lease	$ —	$ 3,067	$ 3,067	$ —
Deferred offering costs recorded in accounts payable and accrued liabilities	$ —	$ —	$ —	$ 1,044

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

Note 1–The Company

FibroGen, Inc. ("FibroGen" or the "Company") is a research-based biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics to treat serious unmet medical needs. The Company's focus in the areas of fibrosis and hypoxia-inducible factor ("HIF") biology have generated multiple programs targeting various therapeutic areas. The Company's most advanced product candidate, roxadustat, or FG-4592, is an oral small molecule inhibitor of HIF prolyl hydroxylases ("HIF-PHs"), in Phase 3 clinical development for the treatment of anemia in chronic kidney disease ("CKD"). FG-3019 is the Company's monoclonal antibody in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer and liver fibrosis. The Company has taken a global approach with respect to the development and future commercialization of its product candidates, and this includes development and commercialization in the People's Republic of China, or China.

Note 2–Summary of Significant Accounting Policies

Basis of Presentation and Liquidity

The consolidated financial statements include the accounts of the Company, its wholly owned subsidiaries and its majority-owned subsidiaries, FibroGen Europe Oy ("FibroGen Europe") and FibroGen China Anemia Holdings, Ltd. (FibroGen China). All inter-company transactions and balances have been eliminated in consolidation.

Based upon the current status of, and plans for, its product development, the Company believes that its existing cash and cash equivalents and its short term and long term investments, in addition to expected milestone payments related to certain collaboration agreements, will be adequate to satisfy the Company's capital needs through at least the next twelve months. However, the process of developing and commercializing products requires significant research and development, preclinical testing and clinical trials, manufacturing arrangements as well as regulatory approvals. These costs, together with the Company's general and administrative expenses, are expected to result in operating losses until the commercialization of the Company's products or partner collaborations generate sufficient revenue to cover expenses. To achieve sustained profitability, the Company, alone or with others, must successfully develop its product candidates, obtain required regulatory approvals and successfully manufacture and market its products.

Foreign Currency Translation

The reporting currency of the Company and its subsidiaries is the United States dollar. The functional currency of FibroGen Europe is the Euro. The assets and liabilities of FibroGen Europe are translated to United States dollars at exchange rates in effect at the balance sheet date. All income statement accounts are translated at monthly average exchange rates. Resulting foreign currency translation adjustments are recorded directly in accumulated other comprehensive income (loss) as a separate component of stockholders' equity (deficit).

The functional currency of FibroGen, Inc. and all other subsidiaries is the United States 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 other income (expense), 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 accounting principles generally accepted in the United States of America ("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. Actual results could differ from those estimates.

Unaudited interim consolidated financial information

The accompanying interim consolidated balance sheet as of June 30, 2014, the interim consolidated statements of operations, comprehensive income (loss), and cash flows for the six months ended June 30, 2013 and 2014, the interim consolidated statements of redeemable convertible preferred stock and equity (deficit) for the six months ended June 30, 2014, and the related footnote disclosures, are unaudited. These unaudited interim consolidated financial statements have been prepared in accordance with U.S. GAAP on the same basis as the audited consolidated financial statements and, in the opinion of management, reflect all adjustments, consisting of only normal recurring adjustments, considered necessary to state fairly the Company's financial position as of June 30, 2014 and the results of operations and cash flows for the six months ended June 30, 2013 and 2014. The results of operations for the six months ended June 30, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014 or any other interim periods, or any future year or period.

Unaudited Pro Forma Consolidated Balance Sheet Data

Immediately prior to the completion of the initial public offering contemplated by the Company, all of the outstanding shares of Senior preferred stock and Junior preferred stock will automatically convert into shares of Common Stock, assuming the Company raises at least $50.0 million. The June 30, 2014 unaudited pro forma consolidated balance sheet data has been prepared assuming the conversion of all the Senior preferred stock and Junior preferred stock outstanding into 84,800,239 shares of Common Stock, but excludes the assumed conversion of preferred stock held by investors of FibroGen Europe into 2,397,505 shares of FibroGen, Inc. common stock as the conversions are subject to withdrawal until certain triggering events occur related to the Company's initial public offering.

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. A portion of cash on hand is invested in a diversified portfolio of investment grade corporate bonds issued by U.S. corporations as rated investment grade corporate bonds. Any remaining cash is deposited with major financial institutions in the United States, 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:

	As of December 31,		As of June 30,
	2012	2013	2014 (unaudited)
Astellas Pharma Inc. "Astellas"—Related party	100%	34%	45%
AstraZeneca AB "AstraZeneca"	— %	66%	55%

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 Cash

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 include money market accounts, various deposit accounts, and money market funds. Restricted cash includes an irrevocable standby letter of credit as security deposit for a long-term property lease with the Company's landlord. Restricted cash as of each of December 31, 2012 and 2013, and June 30, 2014 (unaudited) totaled $7.3 million.

Investments

The Company classifies its investments as available-for-sale. Those investments with maturities less than 12 months are considered short-term investments. Those investments with maturities greater than 12 months are considered long-term investments. 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 that are deemed temporary in nature are recorded in accumulated other comprehensive income (loss) as a separate component of stockholders' equity (deficit).

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.

Deferred Offering Costs

Deferred offering costs consisted primarily of direct incremental costs related to the Company's proposed initial public offering of its common stock. Approximately $2.2 million (unaudited) of deferred offering costs are included in other assets on the Company's consolidated balance sheet as of June 30, 2014. Upon completion of the initial public offering contemplated herein, these amounts will be offset against the proceeds of the offering. If the offering is terminated, the deferred offering costs will be expensed.

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 due to their short maturities.

Property and Equipment

Property and equipment (except for costs of construction of certain long-lived assets–See Note 8) are recorded at cost and depreciated over their estimated useful lives using the straight-line method. Computer equipment, laboratory equipment, 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.

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

Substantially all of the Company's revenues to date have been generated from its collaboration agreements.

The Company's collaboration agreements include multiple deliverables, and the Company therefore follows the guidance in Accounting Standards Codification Topic 605-25, "Revenue Recognition–Multiple-Element Arrangements," or ASC Topic 605-25 ("ASC 605-25"). ASC 605-25:

- provides guidance on how deliverables in an arrangement should be separated and how the arrangement consideration should be allocated to the separate units of accounting;

- requires an entity to determine the selling price of a separate deliverable using a hierarchy of (i) vendor-specific objective evidence, or VSOE, (ii) third-party evidence, or TPE, or (iii) best estimate of selling price, or BESP; and
- requires the allocation of the arrangement consideration, at the inception of the arrangement, to the separate units of accounting based on relative selling price.

The Company evaluates all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. Based on this evaluation, the deliverables are separated into units of accounting. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. Significant judgment may be required in determining whether a deliverable provides stand-alone value, determining the amount of arrangement consideration that is fixed or determinable, and estimating the stand-alone selling price of each unit of accounting.

To date, the Company has determined that the selling price for the deliverables within its collaboration agreements should be determined using BESP, as neither VSOE nor TPE is available. The process for determining BESP involves significant judgment on the Company’s part 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.

For each unit of accounting identified within an arrangement, the Company determines the period over which the deliverables are provided and the performance obligation is satisfied. Service revenue is recognized using a proportional performance method. Direct labor hours or full time equivalents are typically used as the measurement of performance. Revenue may be recognized using a straight line method when performance is expected to occur roughly consistently over a period of time.

Payments or reimbursements resulting from the Company’s research and development efforts for those arrangements where such efforts are considered as deliverables are recognized as the services are performed and are presented on a gross basis. To the extent payments are required to be made to the collaboration partners pursuant to research and development efforts, those costs are charged to research and development using the guidance pursuant to ASC 605-250, Customer Payments and Incentives, which states that cash consideration given by a vendor to a customer is presumed to be a reduction of the selling prices unless the vendor receives an identifiable benefit in exchange for the consideration that is sufficiently separable from the recipient’s purchase of the vendor’s products, and the vendor can reasonably estimate the fair value of the benefit.

Each of the Company’s collaboration agreements includes milestones for which the Company follows ASC Topic 605-28, Revenue Recognition—Milestone Method (“ASC 605-28”). ASC 605-28 establishes the milestone method as an acceptable method of revenue recognition for certain contingent event-based payments under research and development arrangements. Under the milestone method, a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event (i) that can only be achieved based in whole or in part on either the Company’s performance or on the occurrence of a specific outcome resulting from the Company’s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the Company. Determining whether a milestone is substantive is a matter of judgment and that assessment must be made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the milestone is (i) commensurate with either the Company’s performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the Company’s performance to achieve the milestone, (ii) relates solely to past performance and (iii) is reasonable relative to all deliverables and payment terms in the arrangement. Payments for achieving milestones which are not considered substantive are treated as additional arrangement consideration and are allocated following the relative selling price method previously described.

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.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses for executive, operational, finance, legal and human resource functions. Other general and administrative expenses include facility-related costs and professional service fees, other outside services, 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 accompanying Consolidated Statements of Operations. The Company has not incurred any interest or penalties related to unrecognized tax benefits in any of the periods presented.

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 the years ended December 31, 2012 and 2013, and for the six months ended June 30, 2013 and 2014 (unaudited).

The Company measures and recognizes compensation expense for all stock options 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.

Recent Accounting Pronouncements

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected not to avail itself of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as public companies that are not emerging growth companies.

In April 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-08, *Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity*." The ASU amendment changes the requirements for reporting discontinued operations in Subtopic 205-20. The amendment is effective on a prospective basis for financial statements issued for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2014. Early adoption is permitted for disposals that have not been reported in financial statements previously issued. The Company will apply the provisions of this ASU to any future transactions after the effective date which qualify for reporting discontinued operations.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which supersedes the revenue recognition requirements in ASC 605, *Revenue Recognition*. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The ASU's effective date will be the first quarter of fiscal year 2017 (for a public entity) or the first quarter of 2018 (for a non-public entity, but with earlier adoption permitted) using one of two retrospective application methods. The Company has not determined the potential effects of this ASU on its consolidated financial statements.

In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income* (ASU 2013-02). This newly issued accounting standard update requires an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. This ASU is effective for reporting periods beginning after December 15, 2012. The Company adopted this guidance in the first quarter of 2013 and the adoption of this guidance did not have an impact on its consolidated financial statements.

In July 2013, the FASB issued ASU No. 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a Consensus of the FASB Emerging Issues Task Force*) (ASU 2013-02). This newly issued accounting standard update requires a liability related to an unrecognized tax benefit to be presented as a reduction of a deferred tax asset for a net operating loss carryforward, a similar tax loss or a tax credit carryforward if such settlement is required or expected in the event the uncertain tax position is disallowed. The Company adopted this guidance in the first quarter of 2014 and the adoption of this guidance did not have an impact on its consolidated financial statements.

Note 3—Collaboration Agreements

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). The Japan Agreement also provides for additional development and regulatory approval milestone payments up to $117.5 million, a commercial sales related milestone of $15.0 million and additional consideration based on net sales (as defined) in the low 20% range after commercial launch.

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. Under the Europe Agreement, Astellas committed to fund fifty percent 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.

AstraZeneca Agreements

US/Rest of World Agreement

Effective July 30, 2013, the Company entered into a collaboration agreement with AstraZeneca AB ("AstraZeneca") for the development and commercialization of roxadustat for the treatment of anemia in the United States and all other countries in the world, other than China, not previously licensed under the Astellas Europe and Astellas Japan Agreements ("US/RoW Agreement"). It also excludes China, which is covered by a separate agreement with AstraZeneca described below. Under the terms of the agreement, AstraZeneca has agreed to pay upfront, non-contingent and time-based payments totaling $374.0 million, which the Company expects to receive in various amounts through June 2016, of which $82.0 million was received as of December 31, 2013 and were determined to be fixed and determinable upon the execution of the collaboration agreement. Out of the remaining payments of $292.0 million which are contractually due, $230.0 million have extended payment terms and, accordingly, are not considered to be fixed or determinable upon the execution of the agreement. As such, for these remaining payments, the amount of revenue recognized is limited to the amount of cash consideration received; additionally, for each of the amounts received, the amount of revenue recognized will be determined on the basis of applying the relative selling price method to each of the units of accounting underlying the agreement as further described below. Further, $62.0 million of the remaining payment is contingent upon the occurrence of a specified event and accordingly is also not considered fixed or determinable. In addition, the US/RoW Agreement also provides for development and regulatory approval based milestone payments of up to $550.0 million, which include potential future indications which the companies choose to pursue, and commercial related milestone payments of up to $325.0 million.

Under the US/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. Any additional development costs incurred by FibroGen during the development period in excess of the $233.0 million (aggregated spend) will be 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.

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, of which $16.2 million was received as of December 31, 2013 and were determined to be fixed and determinable upon the execution of the collaboration agreement. The remainder of the upfront payments of $12.0 million had extended payment terms and, accordingly, are not considered to be fixed or determinable upon the execution of the agreement. This payment of $12.0 million (unaudited) was received as of March 31, 2014. In addition, the China Agreement provides for AstraZeneca to pay regulatory approval and other approval related milestones of up to $161.0 million. The China Agreement also provides for sales related milestone payments of up to $167.5 million and contingent payments of $20.0 million related to possible future compounds. 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, which was ongoing at June 30, 2014), to be shared equally during the development.

Accounting for the Astellas Agreements

For each of the Astellas agreements, the Company has evaluated the deliverables within the respective arrangements and has separated them into various units of accounting.

Deliverables that did not provide standalone value have been combined with other deliverables to form a unit of accounting that collectively has standalone value, with revenue being recognized on the combined unit of accounting, rather than the individual deliverables. There are no right of return provisions for the delivered items in the Astellas agreements.

For the Astellas agreements, the Company allocated arrangement consideration to various units of accounting based on BESP of each deliverable within each unit of accounting using the relative selling price method as the Company did not have VSOE or TPE of selling price for such deliverables. Arrangement consideration includes non-contingent upfront payments of $360.1 million and co-development payments of $96.0 million (for Europe Agreement) that are deemed to be fixed and determinable.

For the technology license under the Japan Agreement and Europe Agreement, BESP 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. BESP also considered certain future royalty payments associated with commercial performance of the Company's compounds, transfer prices and expected gross margins.

The units of accounting that were analyzed, along with their general timing of delivery or performance of service and general timing of revenue recognition, are as follows:

- 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 terms, or when the agreements were signed, and any contingencies had been removed. In both cases, the Company concluded at the time of the agreement that its collaboration partner, Astellas, would have the knowledge and capabilities to exploit the licenses without the Company's further involvement. However, the Japan Agreement with Astellas has contractual limitations that might affect Astellas' ability to exploit the license and therefore, potentially, the conclusion as to whether the license provides stand-alone value. 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 did not have stand-alone value, the Company considered the intent of the parties and the substantive reasons that led to that feature of the agreement.
- 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 Company and Astellas could have structured the arrangement with a transfer of manufacturing rights and compensated the Company through a royalty or other feature without significantly diminishing the prospects of the drug product. Therefore, the Company has determined that the license in Japan provides stand-alone value to the customer despite the lack of manufacturing rights.
- 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 deliverables are generally delivered throughout the term of the agreements and are recognized as revenue as the services are provided.
- Co-development services (Europe Agreement). This deliverable relates to co-development services that were reasonably expected to be performed by the Company at the time the collaboration agreement was signed. Revenue is recognized as reimbursements for such co-development services are earned. The period related to this deliverable represented the Company's determination of the non-contingent

performance period, which was estimated to be 36 months for the Europe Agreement from the signing of the agreement. There was no provision for co-development services in the Japan agreement.

- Manufacturing of clinical supplies of products. This deliverable 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. Revenue is recognized based on the estimated proportion of the development services performed during the development period. These estimates are made at the beginning of each accounting period and will likely change throughout the course of the terms of both agreements. As new information related to these estimates becomes available, the Company may adjust the timing of revenue recognition related to this unit of accounting.
- Manufacturing commercial supplies of products. This deliverable is satisfied and revenue is recognized as supplies are shipped for commercial use during the commercialization period. As this deliverable is considered a contingent deliverable, it is outside the scope of the initial allocation of upfront and other consideration.
- Committee service. This deliverable is satisfied and revenue is recognized throughout the course of the various agreements as meetings are attended.

Any consideration received for each agreement after the initial proceeds on the agreement signing date were also (and will be also) allocated to the various units of accounting above per agreement using the relative selling price method under ASC 605-25-30-2 and 30-5.

Under the Europe Agreement, the Company is also eligible to receive from Astellas an aggregate of approximately $425.0 million in potential milestone payments, comprised of (i) up to $90.0 million in substantive milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $335.0 million in substantive milestone payments upon achievement of specified regulatory milestone events, including up to $25.0 million in milestone payments in connection with receipt of marketing approval in Russia. Clinical milestone payments of $40.0 million and $50.0 million were received in 2010 and 2012, respectively. The Company evaluated the criteria under ASC 605-28 (as disclosed in Note 2) and concluded that each of those milestones were substantive.

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 substantive milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $95.0 million in substantive 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. A clinical milestone payment of $12.5 million was received in 2013. The Company evaluated the criteria under ASC 605-28 (as disclosed in Note 2) and concluded that the aforementioned milestone was substantive.

Accounting for the AstraZeneca Agreements

The Company has considered the criteria in AICPA TIS Section 5100.39 in evaluating whether the US/RoW and China Agreements should be accounted for as a single arrangement and concluded that the agreements should be accounted for as a single arrangement as the presumption under the guidance is that two or more agreements executed with a single customer at or around the same time should be presumed to be a single arrangement. Accordingly, upfront and other non-contingent arrangement consideration received and to be received has been and will be pooled together and allocated to each of the units of accounting in both the US/RoW and China Agreements based on their relative fair values.

The Company has evaluated the deliverables within the arrangement and has separated them into various units of accounting.

Deliverables that did not provide stand-alone value have been combined with other deliverables to form a unit of accounting that collectively has stand-alone value, with revenue being recognized on the combined unit of accounting, rather than the individual deliverables. There are no right of return provisions for the delivered items in the agreements.

For the technology license under the AstraZeneca US/RoW Agreement, BESP 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 IRR 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%.

US/RoW Agreement:

The units of accounting that were analyzed, along with their general timing of delivery or performance of service and general timing of revenue recognition, are as follows:

- License to the Company's technology existing at the effective date of the agreements. For the US/RoW agreement, the license was delivered at the beginning of the agreement terms as all contingencies had been removed. The Company concluded that AstraZeneca has the knowledge and capabilities to exploit the US/RoW license without the Company's further involvement.
- Co-development services. This deliverable relates to co-development services which were reasonably expected to be performed by the Company at the time the Agreement was signed. Revenue is recognized as reimbursements for such co-development services are earned. The period related to this deliverable represented the Company's determination of the non-contingent performance period, which was estimated to be 65 months from the signing of the US/RoW agreement.
- Manufacturing of clinical supplies of products. This deliverable 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. Revenue is recognized based on the estimated proportion of the development services performed during the development period. These estimates are made at the beginning of each accounting period and will likely change throughout the course of the agreements. As new information related to these estimates becomes available, the Company may adjust the timing of revenue recognition related to this unit of accounting.
- Manufacturing commercial supplies of products. This deliverable is satisfied and revenue is recognized as supplies are shipped for commercial use during the commercialization period. As this deliverable is considered a contingent deliverable, it is outside the scope of the initial allocation of upfront and other consideration.
- Committee service. This deliverable is satisfied and revenue is recognized throughout the course of the various agreements as meetings are attended.

Under the US/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 substantive milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $325.0 million in substantive milestone payments upon achievement of specified regulatory milestone events, (iii) up to $160.0 million in non-substantive deferred approval milestone, which would be paid if certain competitors do not launch an HIF compound in the U.S. on or before January 1, 2023 and (iv) up to approximately $325.0 million in milestone payments upon the achievement of specified commercial sales events.

China Agreement:

The units of accounting that were analyzed, along with their general timing of delivery or performance of service and general timing of revenue recognition, 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 as all contingencies had been removed. However, the China Agreement with AstraZeneca has contractual limitations that might affect AstraZeneca's ability to exploit the license and therefore, potentially, the conclusion as to whether the license provides stand-alone value. 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 did not have stand-alone value, the Company considered the intent of the parties and the substantive reasons that led to that feature of the agreement.

  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. Because the retention of manufacturing rights by the Company was a significant factor in the collaboration strategy, rather than simply a mechanism to properly compensate FibroGen, management concluded that the license and development services do not have stand-alone value apart from the manufacturing rights. Accordingly, all the deliverables identified, including co-development services, under the China Agreement have been treated as a single unit of account and all revenue allocable to this unit of account is deferred until delivery of commercial drug product has begun. Upon commencement of delivery of commercial drug product, revenue would be recognized in a pattern consistent with estimated deliveries of the commercial drug product.

Under the China Agreement, the Company is also eligible to receive from AstraZeneca an aggregate of approximately $328.5 million in potential milestone payments, comprised of (i) up to $15.0 million in substantive milestone payments upon achievement of specified clinical and development milestone events, (ii) up to $146.0 million in substantive milestone payments upon achievement of specified regulatory milestone events, and (iii) up to approximately $167.5 million in milestone payments upon the achievement of specified commercial sales events.

As the Company is accounting for both the US/RoW and China Agreements as one arrangement, any consideration received after the initial proceeds on the agreement signing date were also (and will be also) allocated to the various units of accounting above using the relative selling price method under ASC 605-25-30-2 and 30-5.

Summary of revenue recognized under the collaboration agreements

The table below summarizes the accounting treatment for the various deliverables pursuant to each agreement. License amounts identified below are included in the "License and milestone revenue" line item in the consolidated statements of operations. All other elements identified below are included in the "Collaboration services and other revenue" line item in the consolidated statements of operations. Amounts recognized as revenue are shown below (in thousands):

		Cumulative Through December 31,	Years ended December 31,		Six Months Ended June 30,	
Agreement	**Deliverable**	**2011**	**2012**	**2013**	**2013**	**2014**
					(unaudited)	
Japan	License	$ 39,002	$1,136	$ 566	$ 329	$ 230
	Milestones	—	—	12,500	12,500	—
	Total license and milestone revenue	$ 39,002	$1,136	$13,066	$12,829	$ 230
	Collaboration services revenue*	$ 780	$ 229	$ 433	$ 218	$ 176

As of June 30, 2014, the total arrangement consideration has been allocated to each of the following deliverables, along with any associated deferred revenue as follows (in thousands):

	Cumulative Revenue Through June 30, 2014 (unaudited)	Deferred Revenue	Total Consideration
License	$ 40,934	$ —	$ 40,934
When and if available compounds	9	31	40
Manufacturing—clinical supplies	1,599	308	1,907
Committee services	11	5	16
Total	$ 42,553	$ 344	$ 42,897

* When and if available compounds, manufacturing—clinical supplies and committee services have each been identified as separate units of accounting with standalone value and amounts allocable to these elements have been recognized and classified within the Collaboration services revenue line item within the consolidated statements of operations.

Agreement	Deliverable	Cumulative Through December 31, 2011	Years ended December 31, 2012	Years ended December 31, 2013	Six Months Ended June 30, 2013 (unaudited)	Six Months Ended June 30, 2014 (unaudited)
Europe	License	$ 348,735	$ 11,709	$ 9,260	$ 4,066	$ 6,230
	Milestones	40,000	50,000	—	—	—
	Total license and milestone revenue	$ 388,735	$ 61,709	$ 9,260	$ 4,066	$ 6,230
	Collaboration services revenue*	$ 31,553	$ 2,046	$ 2,902	$ 1,410	$ 1,441

As of June 30, 2014, the total arrangement consideration has been allocated to each of the following deliverables, along with any associated deferred revenue as follows (in thousands):

	Cumulative Revenue Through June 30, 2014 (unaudited)	Deferred Revenue	Total Consideration
License	$ 375,934	$ —	$ 375,934
When and if available compounds	263	453	716
Manufacturing—clinical supplies	7,338	1,666	9,004
Development services – in progress	30,120	—	30,120
Committee services	220	40	260
Total	$ 413,875	$ 2,159	$ 416,034

* When and if available compounds, manufacturing—clinical supplies, development services – in progress at the time of signing of the agreement, and committee services have each been identified as a separate unit of accounting with standalone value and amounts allocable to these units have been recognized in revenue as services are performed and classified within the Collaboration services revenue line item within the consolidated statements of operations.

Agreement	Deliverable	Year Ended December 31, 2013	Six Months Ended June 30, 2014 (unaudited)
US/RoW	License	$ 72,635	$ 90,688
& China	Milestones	—	—
	Total license and milestone revenue	$ 72,635	$ 90,688
	Collaboration services revenue*	$ 3,843	$ 9,025
	China single unit of accounting**	$ —	$ —

As of June 30, 2014, the total arrangement consideration has been allocated to each of the following deliverables, along with any associated deferred revenue as follows (in thousands):

	Cumulative Revenue Through June 30, 2014 (unaudited)	Deferred Revenue	Total Consideration
License	$ 163,322	$ —	$ 163,322
Co-development, information sharing & committee services	12,823	36,832	49,655
Manufacturing—clinical supplies	46	124	170
China-single unit of accounting	—	33,477	33,477
Total	$ 176,191	$70,433	$ 246,624

* Co-development, information sharing, and committee services have been combined into a single unit of accounting because the requirements to share information and serve on committees are useful only in combination with the development services, and because all three items are delivered over the same period while manufacturing—clinical supplies has been identified as a separate unit of accounting with standalone value and amounts allocable to this unit of accounting have been recognized and classified within the Collaboration services revenue line item within the consolidated statements of operations.

** All revenues attributable to the China unit of accounting are deferred until all deliverables are met. The China license and collaboration services elements have been combined into a single unit of accounting and consideration allocable to this unit is being deferred due to FibroGen's retention of manufacturing rights and lack of standalone value.

Other Revenues

Other revenues consist of royalty payments received, which are recorded on a monthly basis as they are reported to and collagen feasibility sales. Other revenues were $0.8 million and immaterial for the years ended December 31, 2012 and 2013, respectively. Other revenues were immaterial for the six months ended June 30, 2013 and 2014 (unaudited), respectively.

Deferred Revenue

Deferred revenue represents amounts billed to our 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 deliverables. 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 deliverables. The long term portion of deferred revenue also 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, which is not expected to occur within the next year.

Note 4—Fair Value Measurements

In accordance with the authoritative guidance on fair value measurements and disclosures under GAAP, the Company presents the fair values 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 US 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 following table sets forth the fair value of the Company's financial assets that were measured on a recurring basis (in thousands):

	December 31, 2012			
	Level 1	Level 2	Level 3	Total
Certificates of deposit	$ —	$ 296	$ —	$ 296
Corporate bonds	—	82,446	—	82,446
Equity investments	184	—	—	184
Sub total	184	82,742	—	82,926
Money market funds	18,571	—	—	18,571
Total	$18,755	$82,742	$ —	$101,497

	December 31, 2013			
	Level 1	Level 2	Level 3	Total
Corporate bonds	$ —	$61,624	$ —	$ 61,624
Equity investments	209	—	—	209
Sub-total	209	61,624	—	61,833
Money market funds	48,857	—	—	48,857
Total	$49,066	$61,624	$ —	$110,690

	June 30, 2014			
	Level 1	Level 2	Level 3	Total
	(unaudited)			
Corporate bonds	$ —	$26,950	$ —	$ 26,950
Equity investments	209	—	—	209
Sub-total	209	26,950	—	27,159
Money market funds	139,286	—	—	139,286
Total	$139,495	$26,950	$ —	$166,445

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.

The following table sets forth the fair value of the Company's financial liabilities that are carried at historical cost (in thousands):

	December 31, 2012			
	Level 1	Level 2	Level 3	Total
Cease-use liability	$ —	$ —	$ 1,861	$ 1,861
Lease financing obligations	—	—	92,902	92,902
Total	$ —	$ —	$94,763	$94,763

	December 31, 2013			
	Level 1	Level 2	Level 3	Total
Cease-use liability	$ —	$ —	$ 894	$ 894
Lease financing obligations	—	—	96,809	96,809
Total	$ —	$ —	$97,703	$97,703

	June 30, 2014			
	Level 1	Level 2	Level 3	Total
	(unaudited)			
Cease-use liability	$ —	$ —	$ 524	$ 524
Lease financing obligations	—	—	96,914	96,914
Total	$ —	$ —	$97,438	$97,438

The fair value of the Company's financial liabilities were each derived by using an income approach which required Level 3 inputs such as discounted estimated future cash flows. Refer to Note 5 for further information regarding the calculation of the cease-use liability and Note 8 for further information regarding the calculation of the lease financing liability.

There were no transfers of assets or liabilities between levels for the years ended December 31, 2012 and 2013, or the six months ended June 30, 2014 (unaudited).

Note 5—Balance Sheet Components

Cash and Cash Equivalents

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

	December 31, 2012	December 31, 2013	June 30, 2014 (unaudited)
Cash	$20,005	$27,475	$ 43,376
Money market funds	18,571	48,857	139,286
Certificates of deposit	296	—	—
Cash and cash equivalents	$38,872	$76,332	$ 182,662

Accounts Receivable

Accounts receivable consisted of the following (in thousands):

	December 31, 2012	December 31, 2013	June 30, 2014 (unaudited)
Astellas—Related party	$8,784	$ 6,012	$ 7,262
AstraZeneca	—	11,483	8,904
Accounts receivable	$8,784	$17,495	$ 16,166

Property and Equipment

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

	December 31, 2012	December 31, 2013	June 30, 2014 (unaudited)
Laboratory equipment	$ 12,097	$ 12,346	$ 12,480
Computer equipment	4,294	4,490	4,767
Furniture and fixtures	4,791	4,824	5,078
Leasehold improvements	83,793	83,801	83,839
Building shell (see Note 8)	50,812	53,879	53,879
Construction in progress	889	8,613	13,107
	156,676	167,953	173,150
Less accumulated depreciation and amortization	(33,012)	(38,055)	(39,813)
Property and equipment, net	$123,664	$129,898	$ 133,337

Depreciation and amortization expense for the years ended December 31, 2012 and 2013, and the six months ended June 30, 2013 and 2014 was $5.6 million, $5.1 million, $2.6 million (unaudited) and $1.8 million (unaudited), respectively.

Investments

All investments are classified as available-for-sale. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's available-for-sale investments by major investments type are summarized in the tables below (in thousands):

	December 31, 2012			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Investments				
Corporate bonds	$ 78,291	$ 4,175	$ (20)	$ 82,446
Equity investments	125	62	(3)	184
Total investments	$ 78,416	$ 4,237	$ (23)	$ 82,630

	December 31, 2013			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Investments				
Corporate bonds	$ 60,169	$ 1,455	$ —	$ 61,624
Equity investments	125	87	(3)	209
Total investments	$ 60,294	$ 1,542	$ (3)	$ 61,833

	June 30, 2014			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
	(unaudited)			
Investments				
Corporate bonds	$ 26,316	$ 634	$ —	$ 26,950
Equity investments	124	85	—	209
Total investments	$ 26,440	$ 719	$ —	$ 27,159

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

	December 31, 2013	June 30, 2014
		(unaudited)
Within one year	$ 46,477	$ 19,427
After one year through three years	15,147	7,523
Total debt investments	61,624	26,950
Equity investments	209	209
Total investments	$ 61,833	$ 27,159

Available-for-sale investments are reported at fair value and as such, their associated unrealized gains and losses are reported as a separate component of stockholders' equity (deficit) as accumulated other comprehensive income (loss).

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	As of December 31,		As of June 30,
	2012	2013	2014 (unaudited)
Preclinical and clinical trial accruals	$ 7,719	$13,117	$ 21,237
Payroll and related accruals	5,381	11,924	7,561
Construction-in-progress obligations	210	1,385	2,343
Professional services	1,521	1,278	2,501
Deferred rent, current portion	293	342	358
Taxes	186	59	21
Other	1,170	1,454	2,917
Total accrued liabilities	$16,480	$29,559	$ 36,938

Cease-Use Liability

In April 2009, in conjunction with the move of the Company's headquarters to a new facility, the Company completed the exit from one of the two formerly occupied buildings. This facility closure was accounted for in accordance with accounting guidance related to costs associated with exit or disposal activities. Based upon this guidance, the Company recorded a cease-use liability equal to the net present value of the future minimum lease payments, net of expected future sublease payments, through the end of the remaining lease term. Any adjustments to the cease-use liability, due to factors such as expected future sublease payments, will be recorded in general and administrative expenses in the period those adjustments occur. A rollforward of the cease-use liability is shown below (in thousands):

	Years Ended December 31,		Six Months Ended June 30,
	2012	2013	2014 (unaudited)
Beginning liability balance	$2,868	$1,861	$ 894
Payments made	(885)	(967)	(370)
Adjustments to estimates (1)	(122)	—	—
Ending liability balance	$1,861	$ 894	$ 524

(1) This adjustment related to the change in estimate for future sublease income.

Note 6—Product Development Obligations

The 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 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, 2013 and June 30, 2014, the Company had $13.0 million of principal outstanding, and $5.3 million and $5.4 million (unaudited) of interest accrued, respectively, which have been included in the product development obligations line item 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.

Note 7—Credit Facility and Convertible Note Payable

In September 2012, the Company entered into a credit agreement (the “Credit Facility”) with a lender for a revolving line of credit of up to $50.0 million. The Credit Facility is collateralized by the short and long-term investments of the Company held by the lender. Under the terms of the Credit Facility, the balance outstanding cannot exceed $50.0 million. The Company drew down amounts on the Credit Facility during both the years ended December 31, 2012 and 2013 (which were also repaid in those periods). Interest expense of less than $0.1 million was recognized for both years ended December 31, 2012 and 2013, and the six months ended June 30, 2013 and 2014 at a rate of 1% above daily three month LIBOR. The Credit Facility terminated in September 2013.

In January 2013, FibroGen China entered into a $0.6 million convertible promissory note. The note bears simple interest at a rate of two percent (2.00%) per annum, accrued on an annual basis in arrears. The outstanding principal balance and unpaid accrued interest on the note is due and payable upon the earlier of (a) the effectiveness of the initial public offering of FibroGen China or (b) the eight year anniversary of the date of the note. The total outstanding principal balance and unpaid accrued interest on the note will be converted into Series A Preferred Stock of FibroGen China at the option of the lender or by the Company at its discretion.

Note 8—Commitments and Contingencies

Operating Leases

Future minimum lease payments under all non-cancelable operating lease obligations as of December 31, 2013 are as follows (in thousands):

Year Ending	Operating Leases
2014	$ 3,917
2015	501
2016	45
2017	9
Total minimum payments	$ 4,472

Capital Leases

The Company does not have any capital lease obligations beyond December 31, 2012.

Facility Lease Financing Obligations

FibroGen, Inc.

In September 2006, the Company entered into a long-term property lease with Shorenstein Properties LLC (“Alexandria” or “landlord”) providing the Company with 234,249 square feet of space for an initial term of 15 years. Upon signing, a stand-by letter of credit was established in the amount of $7.3 million which has been included in restricted cash. The agreement included an expansion option to occupy part of an adjacent building within 31 months of the lease commencement date of November 20, 2008. In June 2012, the Company gave notice to its landlord that it would not exercise this expansion option, which resulted in a $5.0 million payment liability to the landlord which is being financed over the remaining lease term of its lease.

In connection with this lease, the Company was responsible for approximately 60% of the construction costs for the tenant improvements. The Company is deemed, for accounting purposes only, to be the accounting owner of the entire project including the building shell, even though it is not the legal owner. The balance of the tenant improvements were paid by Alexandria in the form of a tenant improvement allowance of $140.50 per square foot of rentable space, or $32.5 million.

In connection with the Company's accounting for this transaction, the Company capitalized Alexandria's costs of constructing the building shell which totaled $50.8 million, and recognized a corresponding lease financing obligation. The Company also recognized, as an additional lease financing obligation, the reimbursements totaling $32.5 million from landlord for tenant improvements since these reimbursements are also deemed to be a financing obligation.

A portion of the monthly lease payment will be allocated to land rent and recorded as an operating lease expense and the non-interest portion of the amortized lease payments to the landlord related to rent of the building will be applied to the lease financing liability.

FibroGen China

In February 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 leased space is 4,820 square meters over an eight (8) year term starting February 1, 2013.

In connection with this lease, the Company was responsible for approximately 100% of the construction costs for the tenant improvements. The Company is deemed, for accounting purposes only, to be the accounting owner of the entire project, including the building shell, even though it is not the legal owner.

In connection with the Company's accounting for this transaction, the Company capitalized BDA Management Committee's costs of constructing the building shell which totaled $3.1 million, and recognized a corresponding lease financing obligation. The Company also recognized, as an additional lease financing obligation, the reimbursements totaling $0.5 million from BYBP for a rent subsidy since this reimbursement is also deemed to be a financing obligation.

A portion of the monthly lease payment will be allocated to land rent and recorded as an operating lease expense and the non-interest portion of the amortized lease payments to the landlord related to rent of the building will be applied to the lease financing liability.

Future minimum lease payments under the Company's facility lease financing obligations as of December 31, 2013 are as follows (in thousands):

Year Ending	Lease Financing Obligation
2014	$ 13,286
2015	13,535
2016	13,741
2017	14,080
2018	14,303
Thereafter	70,641
Total minimum payments	$ 139,586

Apart from the property leases with Alexandria and BDA Management Committee, rent expense for leased facilities under operating lease commitments, was $2.9 million, $3.0 million, $1.5 million and $1.5 million for the years ended December 31, 2012 and 2013, and for the six months ended June 30, 2013 and 2014 (unaudited), respectively. The Company received sublease income of $4.3 million, $4.5 million, $2.2 million and $2.4 million for the years ended December 31, 2012 and 2013, and for the six months ended June 30, 2013 and 2014 (unaudited), respectively.

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.

Note 9—Redeemable Convertible Preferred Stock and Equity (Deficit)

Convertible Preferred Stock ("Preferred Stock")

As of December 31, 2012 and 2013, the Company had authorized 125,000,000 shares of Preferred Stock. All shares of Preferred Stock have a par value of $0.01 per share.

The Series A Preferred Stock ("Series A"), Series B Preferred Stock ("Series B"), Series C Preferred Stock ("Series C"), Series D Preferred Stock ("Series D"), Royalty Acquisition Preferred Stock ("Royalty Acquisition") and Series G-1 Preferred Stock ("Series G-1") are collectively referred to as the "Junior Preferred Stock".

The Series E Redeemable Convertible Preferred Stock ("Series E") and Series F Redeemable Convertible Preferred Stock ("Series F") are collectively referred to as the "Senior Preferred Stock".

The Preferred Stock authorized, issued and outstanding at December 31, 2012 and 2013, and as of June 30, 2014 (unaudited) are as follows (in thousands):

	Authorized Shares	Shares Issued and Outstanding	Carrying Value	Liquidation Preference
Senior Preferred Stock:				
Series E	12,621	12,621	$ 56,071	$ 56,669
Series F	25,719	25,719	112,365	117,021
Total Senior Preferred Stock	38,340	38,340	$168,436	$ 173,690
Junior Preferred Stock:				
Series A	7,383	7,383	$ 7,009	$ 7,383
Series B	14,037	14,037	18,046	18,248
Series C	3,535	3,535	7,005	7,070
Series D	7,098	7,098	37,934	39,040
Royalty Acquisition	7,074	7,074	11,319	11,319
Series G-1	9,200	7,333	55,000	55,000
Unassigned	38,333	—	—	—
Total Junior Preferred Stock	86,660	46,460	136,313	138,060
Total Preferred Stock	125,000	84,800	$304,749	$ 311,750

For presentation purposes, on the face of the consolidated balance sheets, 38,333,333 of the authorized shares (noted above as Unassigned) have been included in the authorized shares amounts disclosed for Junior Preferred Stock, even though such amounts can be designated for issuance of both Senior Preferred Stock and Junior Preferred Stock.

Senior Preferred Stock

The holders of the Company's Senior Preferred Stock have the following rights, preferences and privileges:

Liquidation—In the event of liquidation, dissolution, merger (where a change of control occurs), sales of all or substantially all of the assets of the Company, or winding up of the Company, either voluntary or involuntary, the holders of Senior Preferred Stock are entitled to be paid an amount equal to the product of the number of shares held by a holder of shares of Senior Preferred Stock and the original issue price of $4.49 and $4.55 per share for Series E and Series F, respectively (subject to equitable adjustment for any stock dividend, combination, split, reclassification, recapitalization or other similar event involving the Senior Preferred Stock) plus all declared and unpaid dividends thereon (collectively, the "Liquidation Amount") before any distribution may be made with respect to the Junior Preferred Stock or the Common Stock.

Conversion—Each share of Senior Preferred Stock is convertible at the option of the holder thereof into the number of fully paid and non-assessable shares of Common Stock 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. For the Senior Preferred Stock, the conversion price is equal to the original issuance price such that the conversion ratio to Common Stock is 1:1 as of all periods presented. The Senior Preferred Stock will automatically convert to Common Stock (i) at any time upon the affirmative election of the holders at least fifty percent of the outstanding shares of such series voting as a single class, or (ii) upon the closing of an underwritten public offering pursuant to an effective registration statement if (x) the per share price is at least one hundred and twenty five percent of the original issue price (as adjusted for stock splits, etc.), (y) the gross cash proceeds to the Company are, for the Series E, at least $40.0 million, and for the Series F, at least $50.0 million, and (z) the Common Stock is listed on a specified national securities exchange.

The issuance price of each series of Senior Preferred Stock exceeded the fair value of Common Stock on the date of issuance and there have been no subsequent adjustments to the conversion prices in the periods presented. Accordingly, no beneficial conversion amounts, measured as the intrinsic value of the conversion feature as of the issuance date, have resulted from issuances of senior preferred stock.

Voting—The holders of Senior Preferred Stock are entitled to vote together with the Common Stock on all matters submitted for a vote of the stockholders. The holder of each share of Senior Preferred Stock has the number of votes equal to the number of shares of Common Stock into which it is convertible. In addition, the holders of Senior Preferred Stock have special series voting rights ("protective provisions") which provide that the Company may not, without the approval of the holders of at least a majority of the outstanding shares of each series of the Senior Preferred Stock, each voting as a separate class, take any of the following actions:

- authorize or issue, or increase or decrease the authorized number of, (other than by redemption or conversion) any shares of Common Stock or Preferred Stock or shares of any new class or series of stock or any other securities convertible into the Company's equity securities ranking (i) on a parity with or senior to the Senior Preferred Stock in liquidation preference, voting or dividends or (ii) senior to the Senior Preferred Stock in rights of redemption;
- redeem or repurchase any capital stock or pay dividends or other distributions with respect to the Company's capital stock (except for acquisitions of Common Stock by the Company pursuant to agreements which permit the Company to repurchase such shares upon termination of services to the Company or in exercise of the Company's right of first refusal upon a proposed transfer);

- take any action or agreement by the Company or its stockholders regarding a reorganization in which the consideration paid or proposed to be paid to the holders of capital stock of the Company implies a price or value per share of the respective series of Senior Preferred Stock less than the Liquidation Amount of such series of Senior Preferred Stock;
- take any action or knowingly fail to take any action that would result in or effectuate the liquidation, dissolution or winding up of the Company; or
- effectuate any amendment, alteration, or repeal of any provision of the certificate of incorporation or bylaws of the Company that alters or changes the voting powers, preferences, or other special rights or privileges, qualifications, limitations, or restrictions of the Senior Preferred Stock.

Dividends—The holders of shares of Senior Preferred Stock are entitled to receive non-cumulative cash dividends at a rate of 8% of the original issue price, per annum, when and if declared by the board of directors, in preference to holders of Junior Preferred Stock and the Common Stock. Subsequent to the payment of the 8% cash dividend, the Senior Preferred Stock holders do not participate to the same extent as, on the same basis as, or at the same rate as and contemporaneously with the Common Stock.

Contingent Redemption—In the event of a reorganization of the Company, the holders of Senior Preferred Stock may be entitled to cash or stock distributions, which may differ from the form of consideration given to the Junior Preferred Stock and Common Stock holders. As a result, the Company has classified the Senior Preferred Stock outside of permanent equity in the accompanying consolidated balance sheets.

Junior Preferred Stock

The holders of the Company's Junior Preferred Stock have the following rights, preferences and privileges:

Liquidation—In the event of liquidation, dissolution, or winding up of the Company, either voluntary or involuntary, (i) the holders of Junior Preferred Stock (other than Royalty Acquisition) are entitled to be paid an amount equal to the product of the number of shares held by a holder of shares of Junior Preferred Stock (other than Royalty Acquisition) and the original issue price of $1.00, $1.30, $2.00, $5.50 and $7.50 per share for Series A, Series B, Series C, Series D and Series G-1, respectively (subject to equitable adjustment for any stock dividend, combination, split, reclassification, recapitalization) plus all declared and unpaid dividends thereon after any distribution has been made with respect to the Senior Preferred Stock and before any distribution may be made with respect to the Royalty Acquisition and Common Stock, and (ii) the holders of Royalty Acquisition are entitled to be paid an amount equal to the product of the number of shares held by a holder of shares of Royalty Acquisition and the original issue price of $1.60 per share for Royalty Acquisition (subject to equitable adjustment for any stock dividend, combination, split, reclassification, recapitalization) plus all declared and unpaid dividends thereon after any distribution has been made with respect to the Senior Preferred Stock and Junior Preferred Stock (other than Royalty Acquisition) and before any distribution may be made with respect to the Common Stock.

Conversion—Each share of Junior Preferred Stock is convertible at the option of the holder thereof into the number of fully paid and non-assessable shares of Common Stock 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. For the Junior Preferred Stock, the conversion price is equal to the original issuance price such that the conversion ratio to Common Stock is 1:1 as of all periods presented. In general, the Junior Preferred Stock will automatically convert to Common Stock upon an initial public offering ("IPO") of Common Stock if (x) the IPO offering price is at (i) $2.00 per share for the Series A, Series B and Royalty Acquisition, and (ii) $2.75 per share for the Series C, and (y) the gross cash proceeds to the Company are at least $10.0 million. However, the Series D and Series G-1 do not have the minimum per share price requirement.

The issuance price of each series of Junior Preferred Stock exceeded the fair value of Common Stock on the date of issuance and there have been no subsequent adjustments to the conversion prices in the periods presented. Accordingly, no beneficial conversion amounts, measured as the intrinsic value of the conversion feature as of the issuance date, have resulted from issuances of Junior Preferred Stock.

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

Dividends—There is no prescribed dividend rate for the Junior Preferred Stock, and thus, after payment of the 8% noncumulative cash dividend to the Senior Preferred Stock, the holders of Junior Preferred Stock are entitled to receive cash dividends when and if declared by the Board of Directors of the Company, to the same extent as, on the same basis as, and at the same rate as and contemporaneously with the holders of Common Stock.

Subsidiary Stock and Non-Controlling Interests

FibroGen Europe

FibroGen Europe currently has a total of 42,619,022 shares of Preferred Stock outstanding, of which there are 1,700,845 shares of Series A Preferred Stock, 1,875,000 shares of Series B Preferred Stock, 1,599,503 shares of Series C Preferred Stock, 1,520,141 shares of Series D Preferred Stock, 459,565 shares of Series E Preferred Stock, 5,714,332 shares of Series F Preferred Stock, 9,927,500 shares of Series G Preferred Stock and 19,822,136 shares of Series H Preferred Stock.

The holders of Series A Preferred Stock have the right to exchange their shares of Series A Preferred Stock for shares of Common Stock of FibroGen, Inc. (“FibroGen”) pursuant to a specific exchange ratio provided in the exchange option agreements upon certain triggering events, including but not limited to, (i) the initial public offering of FibroGen’s Common Stock, (ii) sale of all of FibroGen Europe’s business or a transfer of all of FibroGen’s recombinant collagen production technology (except to an affiliate of FibroGen or FibroGen Europe), or (iii) sale of substantially all of FibroGen’s assets or a merger or consolidation of FibroGen with an unrelated third party after which the stockholder of FibroGen immediately before such transaction do not possess at least fifty percent of the voting power of the surviving corporation immediately after the transaction as the result of their holdings of FibroGen stock.

The holders of Series B Preferred Stock have the right to exchange their shares of Series B Preferred Stock for shares of FibroGen’s Common Stock pursuant to a specific exchange ratio provided in their exchange option agreements upon certain triggering events, including but not limited to, (i) the initial public offering of FibroGen’s Common Stock, (ii) sale of all of FibroGen Europe’s business or a transfer of all of FibroGen’s recombinant collagen and gelatin production technology (except to an affiliate of FibroGen or FibroGen Europe), or (iii) sale of substantially all of FibroGen’s business operation or assets or a transfer of all of FibroGen’s recombinant collagen and gelatin production technology (except to an affiliate) or a merger or consolidation of FibroGen with an unrelated third party after which the stockholder of FibroGen immediately before such transaction do not possess at least fifty percent of the voting power of the surviving corporation immediately after the transaction as the result of their holdings of FibroGen stock.

The holders of Series D Preferred Stock and Series E Preferred Stock have the right to exchange their shares of Series D Preferred Stock and Series E Preferred Stock for shares of FibroGen’s Common Stock pursuant to a specific exchange ratio provided in their exchange option agreements upon certain triggering events, which include, but are not limited to, (i) the initial public offering of FibroGen’s Common Stock, and (ii) sale of all of FibroGen’s assets or a merger or consolidation of FibroGen with an unrelated third party after which the stockholder of FibroGen immediately before such transaction do not possess at least fifty percent of the voting power of the surviving corporation immediately after the transaction as the result of their holdings of FibroGen stock, or (iii) the sale by FibroGen of all or substantially all of its shares of capital stock of FibroGen Europe.

The holders of FibroGen Europe's shares of Preferred Stock ("Preferred Shares") also 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 EU 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 licence 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

During the years ended December 31, 2012 and 2013 FibroGen China, issued a total of 6,758,000 Series A Preference Shares. 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, 2012 and 2013, and as of June 30, 2014. 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.

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 reserved for future issuance relate to FibroGen Europe preferred stock, FibroGen China Preferred stock, warrants, and stock options as follows (in thousands):

	As of December 31, 2013	**As of June 30, 2014 (unaudited)**
Common Stock	33,003	33,714
Convertible Preferred Stock:		
Series A Preferred Stock	7,383	7,383
Series B Preferred Stock	14,037	14,037
Royalty Acquisition	7,074	7,074
Series C Preferred Stock	3,535	3,535
Series D Preferred Stock	7,098	7,098
Series E Preferred Stock	12,621	12,621
Series F Preferred Stock	25,719	25,719
Series G-1 Preferred Stock	7,333	7,333
Stock Options Outstanding	27,710	26,923
Common Stock Warrants	433	433
FibroGen Europe Shares	2,398	2,398
Stock Options Available for Grant	1	77
Total Shares of Common Stock Reserved	148,345	148,345

Stock Plans

Under the 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 date of grant.

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, 2013, and June 30, 2014, no shares of Common Stock were subject to repurchase by the Company.

Stock option transactions, including forfeited options granted under the 2005 Stock Plan as well as prior plans, are summarized below:

	Options Available for Grant	**Number of Options Outstanding**	**Weighted-Average Exercise Price**
Balance at December 31, 2011	506,424	21,914,072	$ 1.19
Granted	(5,457,166)	5,457,166	1.87
Authorized	5,500,000	—	
Exercised	—	(124,500)	1.21
Forfeited	448,236	(448,236)	1.66
Balance at December 31, 2012	997,494	26,798,502	$ 1.32
Granted	(1,402,525)	1,402,525	4.53
Exercised	—	(85,317)	0.99
Expired	51,319	(51,319)	1.12
Forfeited	354,324	(354,324)	2.71
Balance at December 31, 2013	612	27,710,067	$ 1.47
Exercised (unaudited)	—	(710,947)	1.17
Expired (unaudited)	21,437	(21,437)	0.80
Forfeited (unaudited)	55,250	(55,250)	3.29
Balance at June 30, 2014 (unaudited)	77,299	26,922,433	$ 1.48
Vested and expected to vest, December 31, 2013		27,447,415	$ 1.45
Vested and expected to vest, June 30, 2014 (unaudited)		26,780,493	$ 1.47

The table above excludes 5,661,682 options granted during the six months ended June 30, 2014 that are subject to shareholder approval (which had not yet been received as of June 30, 2014). In July 2014, the Company obtained the required shareholder approval, and accordingly, for accounting purposes, the grant date was established at this time. Stock-based compensation expense for these option grants will be accounted for beginning with the quarter ended September 30, 2014.

Stock options outstanding and exercisable as of December 31, 2013 are as follows:

	Options Outstanding			Options Vested		
Exercise Price	Number of Options	Weighted-Average Remaining Contractual Life *(In years)*	Aggregate Intrinsic Value (in thousands)	Number of Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value (in thousands)
$0.80	936,119	1.85	$ 4,400	936,119	$ 0.80	$ 4,400
0.94	3,501,239	4.34	15,966	3,501,239	0.94	15,966
1.16	11,905,888	6.49	51,672	11,276,858	1.16	48,942
1.40	3,710,304	7.44	15,212	2,457,992	1.40	10,078
1.44	1,430,000	5.19	5,806	1,430,000	1.44	5,806
1.57	660,369	5.94	2,595	634,682	1.57	2,494
1.61	1,927,411	3.38	7,498	1,927,411	1.61	7,498
2.00	60,000	2.73	210	60,000	2.00	210
2.38	2,120,812	8.49	6,617	989,325	2.38	3,087
3.07	160,400	8.70	390	50,126	3.07	122
3.91	814,375	9.03	1,295	290,731	3.91	462
5.49	445,650	9.75	5	—	5.49	—
5.50	37,500	9.93	—	—	5.50	—
$1.47	27,710,067	6.18	$111,666	23,554,483	$ 1.29	$ 99,065

The Company has computed the aggregate intrinsic value amounts disclosed in the above table based upon the difference between the original exercise price of the options and the Company's estimate of the deemed fair value of the Company's Common Stock at December 31, 2013. The total intrinsic value of options exercised for the years ended December 31, 2012 and 2013, and for the six months ended June 30, 2014 was approximately $0.2 million, $0.3 million and $3.3 million (unaudited), respectively.

Stock-Based Compensation

Stock-based compensation related to options granted is allocated to research and development and general and administrative expense for the periods ended December 31 and June 30 was as follows (in thousands):

	Years Ended December 31,		Six Months Ended June 30, (unaudited)	
	2012	2013	2013	2014
Research and development	$ 2,277	$ 1,925	$ 953	$ 883
General and administrative	2,284	1,519	802	582
Total stock-based compensation expense	$ 4,561	$ 3,444	$ 1,755	$ 1,465

The Company, in making its determinations of the fair value of its Common Stock, considered a variety of quantitative and qualitative factors, including (i) the fair market value of the stock of comparable publicly-traded companies, (ii) net present value of the Company's projected earnings, (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.

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. The estimated weighted-average fair value of the employee stock options granted during the years ended December 31, 2012 and 2013 was $1.56 per share and $2.48 per share, respectively.

The fair value of employee stock options 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.

Expected Volatility. Since the Company is a private entity to date with no historical data regarding the volatility of its Common Stock, the expected volatility is 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 weighted-average assumptions used to estimate the fair value of stock options using the Black-Scholes option valuation model were as follows:

	Years Ended December 31,	
	2012	**2013**
Expected term (in years)	4.5	4.1
Expected volatility	78.1%	71.6%
Risk-free interest rate	0.7%	0.8%
Expected dividend yield	0.0%	0.0%

As of December 31, 2013 and June 30, 2014 there was $5.2 million and $4.0 million (unaudited), respectively 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 2.1 years and 1.8 years (unaudited), respectively.

Warrants

The following warrants to purchase shares of Common Stock were issued in connection with certain facility and equipment lease financing arrangements and are outstanding at December 31, 2012 and 2013 and June 30, 2014 (unaudited):

Year of Issuance	Number of shares	Exercise Price per share	Reason for Issuance	Expiration date
1995	67,200	$ 1.25	Issued in connection with equipment lease	One year after initial public offering or upon merger or sale of the Company’s assets, whichever occurs first
1996	184,000	$ 1.75	Issued in connection with lease agreement	Five years after initial public offering or upon merger or sale of the Company’s assets, whichever occurs first
1997	43,140	$ 1.75	Issued in connection with equipment lease	One year after initial public offering or upon merger or sale of the Company’s assets, whichever occurs first
2000	138,450	$ 6.00	Issued in connection with lease agreement	Five years after initial public offering or upon merger or sale of the Company’s assets, whichever occurs first

Note 10—Net Income (Loss) Per Share

The Company applies the two-class method to calculate basic and diluted net income (loss) per share of Common Stock. The Junior Preferred Stock are participating securities due to their dividend rights and the Senior Preferred Stock has stated dividend rates. The two-class method is an earnings allocation method under which earnings per share is calculated for Common Stock considering a participating security’s rights to undistributed earnings as if all such earnings had been distributed during the period. The Company’s participating securities are not included in the computation of net income (loss) per share in periods of net loss because the preferred stockholders have no contractual obligation to participate in losses.

The following table presents the calculation of basic and diluted net loss per share (in thousands, except per share data):

	Years Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
			(unaudited)	
Net income (loss)	$(32,571)	$(14,943)	$(27,473)	$ 30,591
Less: Undistributed earnings allocated to preferred stockholders	—	—	—	(20,738)
Net income (loss) attributable to common stockholders	(32,571)	(14,943)	(27,473)	9,853
Weighted-average shares used to compute basic net income (loss) per share	32,820	32,964	32,938	33,198
Weighted-average shares used to compute diluted net income (loss) per share	32,820	32,964	32,938	53,970
Basic net income (loss) per share	$ (0.99)	$ (0.45)	$ (0.83)	$ 0.30
Diluted net income (loss) per share	$ (0.99)	$ (0.45)	$ (0.83)	$ 0.18

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

	Years Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
			(unaudited)	
Senior Preferred Stock	38,340	38,340	46,460	46,460
Junior Preferred Stock	46,460	46,460	38,340	38,340
Employee stock options	26,799	27,710	27,406	—
Warrants	433	433	433	—
FibroGen Europe Preferred stock	2,398	2,398	2,398	—
	114,430	115,341	115,037	84,800

Unaudited Pro Forma Net Income (Loss) per Share

Pro forma basic and diluted net income (loss) per share were computed to give effect to the automatic conversion of all of the Senior and Junior Preferred Stock using the as-if converted method into common shares as of the beginning of the first period presented or the original date of issuance, if later. Pro forma diluted net income (loss) per share includes the dilutive effect of employee stock options and warrants using the treasury stock method, as well as the effect of the conversion of preferred stock held by investors of FibroGen Europe into a maximum total of 2,397,505 shares of FibroGen, Inc. common stock.

The following table presents the calculation of basic and diluted pro forma net loss per share (in thousands, except per share data):

	Year Ended December 31, 2013	Six Months Ended June 30, 2014
Net income (loss)	$ (14,943)	$ 30,591
Basic shares:		
Weighted-average shares used to compute basic net income (loss) per share	32,964	33,198
Pro forma adjustment to reflect assumed conversion of Senior and Junior Preferred Stock to occur upon consummation of the Company’s initial public offering	84,800	84,800
Weighted-average shares used to compute basic pro forma net income (loss) per share	117,764	117,998
Effect of potentially dilutive securities:		
Employee stock options	—	19,558
Common stock warrants	—	210
FibroGen Europe shares	—	2,398
Weighted-average shares used to compute diluted pro forma net income (loss) per share	117,764	140,164
Pro forma net income (loss) per share:		
Basic	$ (0.13)	$ 0.26
Diluted	$ (0.13)	$ 0.22

Note 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 20% of their pretax salary during 2013, but not more than statutory limits. The Company may elect to match employee contributions; no such matching contributions were made for the years ended December 31, 2012 and 2013, or the six months ended June 30, 2013. Matching contributions of $1.2 million were made during the six months ended June 30, 2014.

Note 12—Income Taxes

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

	Years ended December 31,	
	2012	2013
Domestic	$(20,399)	$ (3,107)
Foreign	(12,272)	(11,836)
Loss before provision for income taxes	$(32,671)	$(14,943)

The benefit from income taxes consists of the following at December 31 (in thousands):

	Years ended December 31,	
	2012	2013
Current:		
Federal	$ —	$ —
State	(2)	—
Foreign	—	—
Total current	(2)	—
Deferred:		
Federal	96	—
State	6	—
Foreign	—	—
Total deferred	102	—
Total benefit from income taxes	$ 100	$ —

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

	Years ended December 31,	
	2012	2013
Tax at statutory federal rate	34.0 %	34.0 %
State tax	0.0 %	0.0 %
Stock compensation expense	(2.9)%	(5.7)%
Deferred tax expense (benefit) on unrealized gain (loss) on investments	0.3 %	— %
Net operating losses not benefitted	(17.8)%	(1.6)%
Foreign net operating losses not benefitted	(12.8)%	(26.9)%
Other	(0.5)%	0.2 %
Total	0.3 %	— %

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

	As of December 31,	
	2012	2013
Federal and state net operating loss carryforwards	$ 45,237	$ 43,526
Foreign net operating loss carryforwards	4,777	3,603
Tax credit carryforwards	17,609	20,369
Deferred revenue	1,719	1,179
Reserves and accruals	6,406	8,460
Other	1,140	973
Subtotal	76,888	78,110
Less: Valuation allowance	(73,997)	(74,196)
Net deferred tax assets	2,891	3,914
Deferred tax liabilities:		
Fixed assets	(4,412)	(4,440)
Unrealized gain on investments	1,521	526
Net deferred tax liabilities	(2,891)	(3,914)
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 $4.1 million and $0.2 million for the years ended December 31, 2012 and 2013, respectively. Due to uncertainty surrounding the realization of the favorable tax attributes in the future returns, the Company has established a valuation allowance against its otherwise recognizable net deferred tax assets.

At December 31, 2013, the Company had net operating loss carryforwards available to offset future taxable income of approximately $115.4 million and $171.7 million for federal and state tax purposes, respectively. These carryforwards will begin to expire in 2024 for federal and 2014 for state purposes, if not utilized before these dates. The Company also had foreign net operating loss carryforwards of approximately $17.3 million which expire between 2014 and 2023 if not utilized.

At December 31, 2013, the Company had approximately $18.4 million of federal and $14.0 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 2018 and the California research credits have no expiration dates.

The Company tracks a portion of its deferred tax assets attributable to stock option benefits in a separate memorandum account. Therefore, these amounts are not included in the Company's gross or net deferred tax assets. The benefit of these stock options will not be recorded in equity unless it reduces taxes payable. As of December 31, 2013, the portion of the federal and state net operating losses related to stock option benefits was approximately $1.3 million.

Utilization of net operating losses and tax credit carryforwards may be limited by the "ownership change" rules, as defined in Section 382 of the Internal Revenue Code (any such limitation, a "Section 382 limitation"). Similar rules may apply under state tax laws. The Company has performed an analysis to determine whether an "ownership change" occurred from inception to December 31, 2013. Based on this analysis, management determined that the Company did experience historical ownership changes of greater than 50% during this period. Therefore, the utilization of a portion of the Company's net operating losses and credit carryforwards is currently limited. However, these Section 382 limitations are not expected to result in a permanent loss of the net operating losses and credit carryforwards. As such, a reduction of the Company's gross deferred tax asset for its net operating loss and tax credit carryforwards is not necessary prior to considering the valuation allowance. In the event the Company experiences any subsequent changes in ownership, the amount of net operating losses and research and development credit carryforwards useable in any taxable year could be limited and may expire unutilized.

Uncertain Tax Positions

The Company had unrecognized tax benefits of approximately $13.5 million as of December 31, 2013. These unrecognized tax benefits, if recognized, would not affect the effective tax rate. There are no interest or penalties accrued as of December 31, 2012 or 2013.

A reconciliation of the beginning and ending amounts of unrecognized income tax benefits during the years ended December 31, 2012 and 2013 is as follows (in thousands):

	Federal and State
Balance as of January 1, 2012	$ 12,685
Increase (decrease) due to prior positions	(216)
Increase (decrease) due to current year position	76
Balance as of December 31, 2012	12,545
Increase (decrease) due to prior positions	294
Increase (decrease) due to current year position	680
Balance as of December 31, 2013	$ 13,519

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 2007 to 2013. The Company is not currently under audit in any tax jurisdiction.

Note 13—Related Party Transactions

On February 16, 2012, the Company’s Chief Executive Officer and Chairman of the Board, Thomas B. Neff, repaid a June 2002 stockholder note that was issued by the Company in connection with its previous policy of allowing officers of the Company to exercise stock options to purchase Company Common Stock using a promissory note. The note related to the exercise of Mr. Neff’s outstanding stock options prior to 2002 and was repaid in accordance with its terms.

Astellas is an equity investor in the Company and considered a related party. During the years ended December 31, 2012 and 2013 and the six months ended June 30, 2013 and 2014, the Company recorded revenue related to collaboration agreements with Astellas of $65.1 million, $25.7 million, $18.5 million (unaudited) and $8.1 million (unaudited), respectively. During the years ended December 31, 2012 and 2013 and the six months ended June 30, 2013 and 2014, the Company recorded expense related to collaboration agreements with Astellas of $0.3 million, $4.0 million, $0.8 million (unaudited) and $4.5 million (unaudited), respectively.

As of December 31, 2012 and 2013 and as of June 30, 2014, accounts receivable from Astellas were $8.8 million, $6.0 million and $7.2 million (unaudited), respectively, and amounts due to Astellas were

$1.1 million, $2.8 million and $4.5 million (unaudited), as of the same periods. The amounts due are included in Accrued liabilities on the consolidated balance sheets.

On July 11, 2012, Julian N. Stern (trustee of Stern Family Trust) and Roberto Pedro Rosenkranz (President of Grama Ventures LLC), who are also members of the Company's board of directors, purchased 500,000 shares and 350,000 shares, respectively, of FibroGen China Series A Preference Shares at a purchase price of $1.00 per share. In addition, on December 28, 2012, Grama Ventures purchased an additional 100,000 shares of FibroGen China Series A Preference Shares at a purchase price of $1.00 per share.

Note 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, milestone and collaboration services 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,		Six Months Ended June 30,	
	2012	2013	2013	2014
			(unaudited)	
Europe	$ —	$ 76,478	$ —	$ 99,713
Japan—Related party	65,120	25,661	18,523	8,078
All Other	813	31	9	43
Total revenue	$ 65,933	$ 102,170	$ 18,532	$ 107,834

Geographic Long-Lived Assets

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

	December 31,		June 30,
	2012	2013	2014
			(unaudited)
United States	$123,422	$118,336	$ 117,283
China	242	11,562	16,054
Total Property and equipment	$123,664	$129,898	$ 133,337

Customer Concentration

The following collaboration partners accounted for more than 10% of the Company's total revenue or accounts receivable:

	As of or for the year ended December 31,			
	Percentage of Revenue		Percentage of Accounts Receivable	
	2012	2013	2012	2013
Astellas—Related party	99%	25%	100%	34%
AstraZeneca	— %	75%	— %	66%

	Percentage of Revenue Six Months Ended June 30,		Percentage of Accounts Receivable June 30,
	2013	2014	2014
		(unaudited)	
Astellas—Related party	100%	8%	45%
AstraZeneca	— %	92%	55%

Note 15—Subsequent Events

The Company has evaluated subsequent events that occurred after December 31, 2013 through June 11, 2014, the date that the audited consolidated financial statements were issued.

Note 16—Subsequent Events (unaudited)

The Company has evaluated subsequent events that occurred after June 30, 2014 through September 3, 2014, the date that the unaudited interim consolidated financial statements were issued.

On October 20, 2014, the Company's board of directors approved a 2.5-for-1 reverse split of its common stock. The reverse stock split will become effective prior to the effectiveness of the Company public offering of its securities. Upon the effectiveness of the reverse stock split, (i) every 2.5 shares of outstanding common stock will be combined into one share of common stock, (ii) the number of shares of common stock for which each outstanding option or warrant to purchase common stock is exercisable will be proportionately decreased on a 2.5-for-1 basis, (iii) the exercise price of each outstanding option or warrant to purchase common stock will be proportionately increased on a 2.5-for-1 basis, (iv) the exchange ratio for each share of outstanding FibroGen Europe share of stock which is exchangeable into the Company's common stock will be proportionately reduced on a 2.5-for-1 basis, and (v) the conversion ratio for each share of outstanding preferred stock which is convertible into the Company's common stock will be proportionately reduced on a 2.5-for-1 basis.

On October 20, 2014, the Company entered into an agreement with AstraZeneca under which AstraZeneca has agreed to purchase shares of the Company's common stock with an aggregate purchase price of $20 million in a separate private placement concurrent with the completion of the Company's public offering at a price per share equal to the initial public offering price. The closing of the Company's public offering is not conditioned upon the closing of such concurrent private placement, and if the offering is not completed by December 1, 2015, then AstraZeneca remains obligated to pay the Company $20 million in cash no later than December 15, 2015.

Shares

Common Stock

FIBROGEN

Goldman, Sachs & Co.

Citigroup

Leerink Partners

RBC Capital Markets

Stifel

William Blair

Through and including , 2014 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth all expenses, other than the underwriting discounts and commissions, payable by us in connection with the sale of the common stock being registered. All the amounts shown are estimates except the SEC registration fee, the FINRA filing fee and the NASDAQ Global Select Market listing fee.

	Amount to be Paid
SEC registration fee	$ 16,100
FINRA filing fee	*
NASDAQ listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Blue Sky fees and expenses	*
Miscellaneous fees and expenses	*
Total	$

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* To be provided by Amendment.

Item 14. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers under certain circumstances and subject to certain limitations. The terms of Section 145 of the Delaware General Corporation Law are sufficiently broad to permit such indemnification under certain circumstances for liabilities, including reimbursement for expenses incurred, arising under the Securities Act of 1933, as amended, or the Securities Act.

Our amended and restated certificate of incorporation that will be in effect upon the completion of this offering provides for indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the Delaware General Corporation Law, and our amended and restated bylaws that will be in effect upon the completion of this offering provide for indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the Delaware General Corporation Law.

We have entered into indemnification agreements with our directors and officers whereby we have agreed to indemnify our directors and officers to the fullest extent permitted by law, including indemnification against expenses and liabilities incurred in legal proceedings to which the director or officer was, or is threatened to be made, a party by reason of the fact that such director or officer is or was a director, officer, employee or agent of FibroGen, provided that such director or officer acted in good faith and in a manner that the director or officer reasonably believed to be in, or not opposed to, the best interest of FibroGen. At present, there is no pending litigation or proceeding involving a director or officer of FibroGen regarding which indemnification is sought, nor is the registrant aware of any threatened litigation that may result in claims for indemnification.

We maintain insurance policies that indemnify our directors and officers against various liabilities arising under the Securities Act and the Exchange Act of 1934, as amended, that might be incurred by any director or officer in his capacity as such.

The underwriters are obligated, under certain circumstances, pursuant to the underwriting agreement to be filed as Exhibit 1.1 hereto, to indemnify us, our officers and directors against liabilities under the Securities Act.

Item 15. Recent Sales of Unregistered Securities

Since January 1, 2011, we have made the following sales of unregistered securities:

(1) We granted stock options under our 2005 Plan to purchase an aggregate of 13,902,573 shares of our common stock having exercise prices ranging from $1.16 to $5.83 per share to our employees, directors and consultants.

(2) We have issued and sold to our employees an aggregate of 1,406,977 shares of our common stock upon the exercise of options under our 2005 Plan at exercise prices ranging from $0.80 to $5.83 per share, for an aggregate amount of approximately $1,779,246.

(3) We have granted stock appreciation rights for an aggregate of 45,000 shares of our common stock under our 2005 Plan to our employees, directors and consultants.

(4) We have issued and sold to our employees an aggregate of 125,845 shares of our common stock upon the exercise of options under our 1999 Plan at exercise prices ranging from $0.55 to $0.80 per share, for an aggregate amount of approximately $92,051.

The offers, sales and issuances of the securities described in paragraphs (1), (2), (3) and (4) were exempt from registration under either (a) Section 4(a)(2) of the Securities Act in that the transactions were by an issuer not involving any public offerings or under (b) compensatory benefit plans and contracts relating to compensation as provided under Rule 701 promulgated under the Securities Act.

Item 16. Exhibits and Financial Statement Schedule

(a) Exhibits.

The following exhibits are included herein or incorporated herein by reference:

Exhibit Number	Description of Document
1.1*	Form of Underwriting Agreement.
3.1**	Certificate of Incorporation of the Registrant, as amended and as presently in effect.
3.2**	Bylaws of the Registrant, as amended and as presently in effect.
3.3**	Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect upon completion of this offering.
3.4**	Form of Amended and Restated Bylaws of the Registrant, to be in effect upon completion of this offering.
4.1*	Form of Common Stock Certificate
4.2**	Investor Rights Agreement by and among the Registrant and certain of its stockholders, dated as of December 1995.
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4.4**	Investor Rights Agreement by and among the Registrant and certain of its stockholders, dated as of May 12, 2000, as amended in December 2004 and September 2005.
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4.10**	Warrant to Purchase 4,000 Shares of Common Stock issued to Laurence S. Shushan and Magdalena Shushan, Trustees of The Laurence and Magdalena Shushan Family Trust, dated as of June 3, 1999.
4.11**	Warrant to Purchase 180,000 Shares of Common Stock issued to Slough Estates USA, Inc., dated as of June 3, 1999.
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Exhibit Number	Description of Document
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10.28(x)†**	Amendment No. 8 to the Process Development and Clinical Supply Agreement by and between the Registrant and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of July 10, 2012.
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21.1	Subsidiaries of the Registrant.
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23.2*	Consent of Cooley LLP (included in Exhibit 5.1).
24.1**	Power of Attorney (included in signature pages).

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* To be filed by Amendment.
** Previously filed.
† Confidential Treatment Requested.
\+ Indicates a management contract or compensatory plan.

(b) Financial Statement Schedules.

See index to Consolidated Financial Statements on page F-1. All other schedules have been omitted because they are not required or are not applicable.

Item 17. Undertakings

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post- effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Francisco, State of California on the 24th day of October, 2014.

FIBROGEN, INC.

By: /S/ THOMAS B. NEFF
Name: Thomas B. Neff
Title: Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
/S/ THOMAS B. NEFF **Thomas B. Neff**	Chief Executive Officer and Chairman of the Board *(Principal Executive Officer)*	October 24, 2014
/S/ PAT COTRONEO **Pat Cotroneo**	Vice President, Finance, and Chief Financial Officer *(Principal Financial and Accounting Officer)*	October 24, 2014
* **Thomas F. Kearns Jr.**	Director	October 24, 2014
* **Kalevi Kurkijärvi, Ph.D.**	Director	October 24, 2014
* **Miguel Madero**	Director	October 24, 2014
* **Rory B. Riggs**	Director	October 24, 2014
* **Roberto Pedro Rosenkranz, Ph.D. M.B.A**	Director	October 24, 2014
* **Jorma Routti, Ph.D.**	Director	October 24, 2014
* **James A. Schoeneck**	Director	October 24, 2014
* **Julian N. Stern**	Director	October 24, 2014

Signature	Title	Date
* **Toshinari Tamura, Ph.D.**	Director	October 24, 2014

* Pursuant to Power of Attorney

By: /S/ THOMAS B. NEFF
Thomas B. Neff
Attorney-in-Fact

EXHIBIT INDEX

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1.1*	Form of Underwriting Agreement.
3.1**	Certificate of Incorporation of the Registrant, as amended and as presently in effect.
3.2**	Bylaws of the Registrant, as amended and as presently in effect.
3.3**	Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect upon completion of this offering.
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* To be filed by Amendment.
** Previously Filed.
† Confidential Treatment Requested.
\+ Indicates a management contract or compensatory plan.

Exhibit 4.17

EXECUTION VERSION

COMMON STOCK PURCHASE AGREEMENT

THIS COMMON STOCK PURCHASE AGREEMENT (this "***Agreement***") is dated as of October 20, 2014, by and among FibroGen, Inc., a Delaware corporation (the "***Company***"), and AstraZeneca AB, a company incorporated in Sweden (the "***Purchaser***").

RECITALS

A. The Company and the Purchaser are executing and delivering this Agreement in reliance upon the exemption from securities registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended (the "***Securities Act***"), and Rule 506 of Regulation D ("***Regulation D***") as promulgated by the United States Securities and Exchange Commission (the "***Commission***") under the Securities Act.

B. The Purchaser wishes to purchase, and the Company wishes to sell, upon the terms and conditions stated in this Agreement, such number of shares of the common stock (the "***Common Stock***") of the Company as specified herein.

C. Contemporaneously with the execution and delivery of this Agreement, the Purchaser shall execute and deliver to the Company a Standstill Agreement, substantially in the form attached hereto as **Exhibit A** (the "***Standstill Agreement***").

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and the Purchasers hereby agree as follows:

ARTICLE 1

DEFINITIONS

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms shall have the meanings indicated in this Section 1.1:

"Affiliate" shall have the meaning set forth in Rule 12b-2 of the regulations promulgated under the Securities Exchange Act of 1934, as amended.

"***Agreement***" shall have the meaning ascribed to such term in the Preamble.

"***Closing***" means the closing of the purchase by the Purchaser and sale by the Company of the Shares to the Purchaser pursuant to this Agreement on the Closing Date as provided in Section 2 hereof, which shall be contingent on and concurrent with the closing of the sale and issuance of shares of Common Stock by the Company pursuant to the Underwriting Agreement.

"***Closing Date***" shall be the First Time of Delivery (as defined in the Underwriting Agreement).

“***Common Stock***” has the meaning set forth in the Recitals, and also includes any securities into which the Common Stock may hereafter be reclassified or changed.

“***Company Counsel***” means Cooley LLP.

“***Company Deliverables***” has the meaning set forth in Section 2.2(a).

“***Company’s Knowledge***” means the actual knowledge of the executive officers (as defined in Rule 405 under the Securities Act) of the Company, after due inquiry.

“***IPO***” means the proposed underwritten initial public offering of shares of the Company’s Common Stock pursuant to the Registration Statement.

“***Lien***” means any lien, charge, claim, encumbrance, security interest, right of first refusal, preemptive right or other restrictions of any kind.

“***Material Adverse Effect***” means a material adverse effect on (a) the results of operations, assets, liabilities, business, or financial condition of the Company, taken as a whole, or (b) the ability of the Company to perform its obligations under the Transaction Documents, except that any of the following, either alone or in combination, shall not be deemed a Material Adverse Effect: (i) effects caused by changes or circumstances affecting general market conditions in the U.S. economy or which are generally applicable to the industry in which the Company operates, (ii) effects resulting from or relating to the announcement or disclosure of the sale of the Shares or other transactions contemplated by this Agreement, or (iii) effects caused by any event, occurrence or condition resulting from or relating to the taking of any action in accordance with this Agreement.

“***Material Contract***” means any contract of the Company that has been filed or was required to have been filed as an exhibit to the Registration Statement pursuant to Item 601(b)(4) or Item 601(b)(10) of Regulation S-K.

“***Person***” means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

“***Purchase Price***” means the per share initial public offering price in the IPO (prior to any underwriting discounts and commissions).

“***Purchaser Deliverables***” has the meaning set forth in Section 2.2(b).

“***Registration Statement***” means the registration statement on Form S-1 (File No.333-199069), including a prospectus filed pursuant to Rule 424 under the Securities Act and any free writing prospectuses, relating to the underwritten public offering of shares of the Company’s Common Stock.

“***Restriction Period***” means the period commencing on the Closing Date and continuing until the date that is two years from such date.

“***Securities Act***” means the Securities Act of 1933, as amended.

“***Shares***” means such number of shares of Common Stock equal to the quotient resulting from dividing (i) the Subscription Amount by (ii) the Purchase Price.

“***Standstill Agreement***” has the meaning set forth in the Recitals.

“***Subscription Amount***” means $20,000,000, which shall be the aggregate amount to be paid for the Shares purchased hereunder.

“***Transaction Documents***” means this Agreement, any schedules and exhibits attached hereto, the Standstill Agreement and any other documents or agreements executed in connection with the transactions contemplated hereunder.

“***Underwriting Agreement***” means that certain Underwriting Agreement expected to be entered into by and among the Company and the several underwriters of the Company’s Common Stock in connection with the IPO (together, the “***Underwriters***”), relating to the underwritten public offering of shares of the Company’s Common Stock as described in the Registration Statement.

“***Voting Securities***” shall mean at any time shares of any class of capital stock of the Company which are then entitled to vote generally in the election of directors.

ARTICLE 2

PURCHASE AND SALE

2.1 Closing.

(a) Amount. Subject to the terms and conditions set forth in this Agreement, at the Closing, the Company shall issue and sell the Shares to the Purchaser, and the Purchaser shall purchase the Shares from the Company.

(b) Closing. The Closing of the purchase and sale of the Shares shall be contingent on and shall take place concurrently with the closing of the IPO at the offices of Company Counsel, 3175 Hanover Street, Palo Alto, California on the Closing Date or at such other locations or remotely by facsimile transmission or other electronic means as the parties may mutually agree.

(c) Form of Payment. On the Closing Date, the Purchaser shall wire its Subscription Amount, in United States dollars and in immediately available funds, by wire transfer to the Company’s account, as set forth in instructions previously provided to the Purchaser.

2.2 Closing Deliveries.

(a) On the Closing, the Company shall issue, deliver or cause to be delivered to the Purchaser the following (the “***Company Deliverables***”):

(i) the Shares registered in the name of the Purchaser.

(b) On or prior to the Closing, the Purchaser shall deliver or cause to be delivered to the Company the following (the “***Purchaser Deliverables***”):

(i) its Subscription Amount, in United States dollars and in immediately available funds, by wire transfer to the Company’s account as previously provided to the Purchaser; and

(ii) the Standstill Agreement, duly executed by the Purchaser.

ARTICLE 3

REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. The Company hereby represents and warrants as of the date hereof and the Closing Date (except for the representations and warranties that speak as of a specific date, which shall be made as of such date), to the Purchaser that, except as set forth in the schedules delivered herewith or disclosed in the Registration Statement:

(a) Organization and Qualification. The Company is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its respective incorporation, with the requisite corporate power and authority to own or lease and use its properties and assets and to carry on its business as currently conducted. The Company is not in violation of any of the provisions of its Certificate of Incorporation or Bylaws. The Company is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, would not have a Material Adverse Effect.

(b) Authorization; Enforcement; Validity. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by each of the Transaction Documents to which it is a party and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of each of the Transaction Documents to which the Company is a party and the consummation by it of the transactions contemplated hereby and thereby (including, but not limited to, the sale and delivery of the Shares) have been duly authorized by all necessary corporate action on the part of the Company, and no further corporate action is required by the Company, its Board of Directors or its stockholders in connection therewith. Each of the Transaction Documents to which it is a party has been (or upon delivery will have been) duly executed by the Company and is, or when delivered in accordance with the terms hereof, will constitute the legal, valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium, liquidation or similar laws relating to, or affecting generally the enforcement of, creditors' rights and remedies or by other equitable principles of general application. Except as disclosed in the Registration Statement, there are no stockholder agreements, voting agreements, or other similar arrangements with respect to the Company's capital stock to which the Company is a party or, to the Company's Knowledge, between or among any of the Company's stockholders.

(c) No Conflicts. The execution, delivery and performance by the Company of the Transaction Documents to which it is a party and the consummation by the Company of the transactions contemplated hereby or thereby (including, without limitation, the issuance of the Shares) do not and will not (i) conflict with or violate any provisions of the Company's Certificate of Incorporation or Bylaws or otherwise result in a violation of the organizational documents of the Company, (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any Material Contract, or (iii) result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company is subject, or by which any property or asset of the Company is bound or affected, except in the case of clause (iii) such as would not, individually or in the aggregate, be reasonably expected to have a Material Adverse Effect.

(d) Issuance of the Securities. The Shares have been duly authorized and, when issued and paid for in accordance with the terms of the Transaction Documents, will be duly and validly issued, fully paid and nonassessable and free and clear of all Liens, other than restrictions on transfer provided for in the Transaction Documents or imposed by applicable securities laws, and shall not be subject to preemptive or similar rights. Assuming the accuracy of the representations and warranties of the Purchaser in this Agreement, the Shares will be issued in compliance with all applicable federal and state securities laws.

(e) Private Placement. Assuming the accuracy of the Purchaser's representations and warranties set forth in Section 3.2 of this Agreement, no registration under the Securities Act is required for the offer and sale of the Shares by the Company to the Purchaser under the Transaction Documents.

(f) Brokers and Finders. No Person will have, as a result of the transactions contemplated by this Agreement, any valid right, interest or claim against or upon the Company or any Purchaser for any commission, fee or other compensation pursuant to any agreement, arrangement or understanding entered into by or on behalf of the Company.

3.2 Representations and Warranties of the Purchaser. The Purchaser hereby represents and warrants as of the date hereof and as of the Closing Date to the Company as follows:

(a) Organization; Authority. The Purchaser is an entity duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization with the requisite corporate or partnership power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents to which it is a party and otherwise to carry out its obligations hereunder and thereunder. The execution, delivery and performance by the Purchaser of the transactions contemplated by this Agreement have been duly authorized by all necessary corporate or, if the Purchaser is not a corporation, such partnership, limited liability company or other applicable like action, on the part of the Purchaser. Each of this Agreement and the Standstill Agreement has been (or upon delivery will have been) duly executed by the Purchaser, and when delivered by the Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of the Purchaser, enforceable against it in accordance with its terms, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium, liquidation or similar laws relating to, or affecting generally the enforcement of, creditors' rights and remedies or by other equitable principles of general application.

(b) No Conflicts. To Purchaser's knowledge, the execution, delivery and performance by the Purchaser of this Agreement and the Standstill Agreement and the consummation by the Purchaser of the transactions contemplated hereby and thereby will not (i) result in a violation of the organizational documents of the Purchaser, (ii) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, indenture or instrument to which the Purchaser is a party, or (iii) result in a violation of any law, rule, regulation, order, judgment or decree (including federal and state securities laws) applicable to the Purchaser, except in the case of clauses (ii) and (iii) above, for such conflicts, defaults, rights or violations which would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the ability of the Purchaser to perform its obligations hereunder.

(c) Restricted Securities. The Purchaser understands that the Shares are being issued in a transaction that was not, and will not be, registered under the Securities Act by reason of a specific exemption from the registration provisions of the Securities Act which depends upon, among other things, the bona fide nature of the investment intent and the accuracy of the Purchaser's representations as expressed herein. The Purchaser understands that the Shares are "restricted securities" under applicable U.S. federal and state securities laws and that, pursuant to these laws, the Purchaser must hold the Shares indefinitely unless they are registered with the Commission and qualified by state authorities, or an exemption from such registration and qualification requirements is available. The Purchaser acknowledges that the Company has no obligation to register or qualify the Shares for resale. The Purchaser further acknowledges that if an exemption from registration or qualification is available, it may be conditioned on various requirements including, but not limited to, the time and manner of sale, the holding period for the Shares, and on requirements relating to the Company which are outside of the Purchaser's control, and which the Company is under no obligation and may not be able to satisfy.

(d) Accredited Investor. The Purchaser is an accredited investor as defined in Rule 501(a) of Regulation D promulgated under the Securities Act. The Purchaser's principal executive offices are in the jurisdiction set forth immediately below the Purchaser's name on the applicable signature page attached hereto.

(e) Experience of the Purchaser. The Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Shares, and has so evaluated the merits and risks of such investment. The Purchaser is able to bear the economic risk of an investment in the Shares and is able to afford a complete loss of such investment.

(f) Access to Information. The Purchaser acknowledges that it has received all the information it considers necessary or appropriate for deciding whether to purchase the Shares and has been afforded (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the terms and conditions of the offering of the Shares and the merits and risks of investing in the Shares; (ii) access to information about the Company and its respective financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (iii) the opportunity to obtain such additional information that the Company possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment. Neither such inquiries nor any other investigation conducted by or on behalf of the Purchaser or its representatives or counsel shall modify, amend or affect the Purchaser’s right to rely on the truth, accuracy and completeness of the Registration Statement and the Company’s representations and warranties contained in the Transaction Documents.

(g) Brokers and Finders. No Person will have, as a result of the transactions contemplated by this Agreement, any valid right, interest or claim against or upon the Company or any Purchaser for any commission, fee or other compensation pursuant to any agreement, arrangement or understanding entered into by or on behalf of the Purchaser.

(h) Reliance on Exemptions. The Purchaser understands that the Shares being offered and sold to it in reliance on specific exemptions from the registration requirements of United States federal and state securities laws and that the Company is relying in part upon the truth and accuracy of, and the Purchaser’s compliance with, the representations, warranties, agreements, acknowledgements and understandings of the Purchaser set forth herein in order to determine the availability of such exemptions and the eligibility of the Purchaser to acquire the Shares.

ARTICLE 4

PURCHASER COVENANTS

4.1 Trading Restrictions.

(a) Restriction Period No Sell. The Purchaser agrees that during the Restriction Period, except as my be permitted under the Standstill Agreement or as otherwise specified herein, neither the Purchaser nor any of its Affiliates shall offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of in any manner, either directly or indirectly (“Sale” or “Sell”), any Shares or any Voting Securities of the Company permitted to be acquired by the Purchaser and its Affiliates pursuant hereto or pursuant to the Standstill Agreement or any securities of the Company issued as a dividend or distribution on, or involving a recapitalization or reorganization with respect to, such Shares or such Voting Securities (collectively, “Covenant Shares”), other than as specified herein or in the Standstill Agreement. The Company shall use commercially reasonable efforts to permit the Shares to be eligible for clearance and settlement through the facilities of The Depository Trust Company immediately following the termination of the Restricted Period.

(b) Post-Restriction Period Selling Restrictions. After the Restriction Period, neither the Purchaser nor its Affiliates shall Sell a number of Covenant Shares in any three-month period that collectively exceeds 25% of the aggregate Covenant Shares held by the Purchaser and its Affiliates as of the end of the Restriction Period.

(c) Invalid Transfers. Any sale, assignment or other transfer of Covenant Shares by the Purchaser or any of its Affiliates, as applicable, contrary to the provisions of this Article 6 shall be null and void, and the transferee shall not be recognized by the Company as the holder or owner of the Covenant Shares sold, assigned, or transferred for any purpose (including, without limitation, voting or dividend rights), unless and until the Purchaser or such Affiliate, as applicable, has satisfied the requirements of this Article 6 with respect to such sale. The Purchaser shall provide the Company with written evidence that such requirements have been met or waived, prior to it or its Affiliates consummating any sale, assignment or other transfer of securities, and no Covenant Shares shall be transferred on the books of the Company until such written evidence has been received by the Company from the Purchaser.

(d) Performance by Affiliates. The Purchaser shall remain responsible for and guarantee its Affiliates’ performance in connection with this Agreement, and shall cause each such Affiliate to comply fully with the provisions of this Agreement in connection with such performance. The Purchaser hereby expressly waives any requirement that the Company exhaust any right, power or remedy, or proceed directly against such an Affiliate, for any obligation or performance hereunder, prior to proceeding directly against the Purchaser.

(e) Exceptions. The restrictions set forth in this Agreement shall not apply to (1) any transfers to any stockholder, partner or member of, or owner of a similar equity interest in, Purchaser, as the case may be, if, in any such case, such transfer is not for value, or (2) any transfer made by Purchaser (a) in connection with the sale or other bona fide transfer in a single transaction or series of related transactions of all or substantially all of Purchaser’s capital stock or other similar equity interests, as the case may be, or all or substantially all of Purchaser’s assets, in any such case not undertaken for the purpose of avoiding the restrictions imposed by this agreement or (b) to another corporation, partnership, limited liability company or other business entity so long as the transferee is an affiliate (as defined below) of the undersigned and such transfer is not for value; provided, however, that it shall be a condition to the transfer that in the case of any transfer described in clause (1) above, if Purchaser is required to file a report under Section 16(a) of the Securities Exchange Act of 1934, as amended, reporting a reduction in beneficial ownership of shares of Common Stock or Beneficially Owned Shares or any securities convertible into or exercisable or exchangeable for Common Stock or Beneficially Owned Shares during the Restriction Period, the undersigned shall include a statement in such report to the effect that, (A) in the case of any transfer pursuant to clause (2) above, such transfer is being made to a stockholder, partner or member of, or owner of a similar equity interest in, the undersigned and is not a transfer for value, or (B) in the case of any transfer pursuant to clause (2) above, such transfer is being made either (a) in connection with the sale or other bona fide transfer in a single transaction of all or substantially all of the undersigned's capital stock, partnership interests, membership interests or other similar equity interests, as the case may be, or all or substantially all of the undersigned's assets or (b) to another corporation, partnership, limited liability company or other business entity that is an affiliate of the undersigned and such transfer is not for value.

4.2 Legends. The Purchaser understands that the Shares may bear one or all of substantially the following legends:

"THE SHARES REPRESENTED BY THIS CERTIFICATE WERE ISSUED IN A TRANSACTION THAT WAS NOT REGISTERED UNDER THE SECURITIES ACT OF 1933, AND HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SUCH SALE OR DISTRIBUTION MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL IN A FORM REASONABLY SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933."

"THESE SHARES ARE SUBJECT TO AN AGREEMENT (THE "LOCK-UP AGREEMENT") BY THE REGISTERED HOLDER HEREOF NOT TO SELL SUCH SHARES FOR A PERIOD OF TWO YEARS FOLLOWING   , THE DATE OF THE FINAL PROSPECTUS RELATING TO THE PUBLIC OFFERING OF COMMON STOCK OF THE COMPANY PURSUANT TO A REGISTRATION STATEMENT FILED BY THE COMPANY WITH THE SECURITIES AND EXCHANGE COMMISSION, AND TO RESTRICTIONS ON TRANSFER THEREAFTER."

"THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO CERTAIN RESTRICTIONS ON TRANSFER AS SET FORTH IN THE COMMON STOCK PURCHASE AGREEMENT BETWEEN THE ISSUER AND THE ORIGINAL HOLDER OF THESE SHARES, A COPY OF WHICH MAY BE OBTAINED AT THE PRINCIPAL OFFICE OF THE ISSUER. SUCH TRANSFER RESTRICTIONS ARE BINDING ON TRANSFEREES OF THESE SHARES."

(a) Any legend required by the Blue Sky laws of any state to the extent such laws are applicable to the Shares represented by the certificate so legended.

ARTICLE 5

CONDITIONS PRECEDENT TO CLOSING

5.1 Conditions Precedent to the Obligations of the Purchaser to Purchase Shares at the Closing. The obligation of the Purchaser to acquire Shares at the Closing is subject to the fulfillment to the Purchaser's satisfaction, on or prior to the Closing Date, of each of the following conditions, any of which may be waived by the Purchaser (as to itself only):

(a) Representations and Warranties. The representations and warranties of the Company contained herein shall be true and correct in all material respects (except for those representations and warranties which are qualified as to materiality, in which case such representations and warranties shall be true and correct in all respects) as of the date of this Agreement and as of the Closing Date, as though made on and as of the Closing Date, except for such representations and warranties that speak as of a specific date.

(b) IPO Shares. The Underwriters shall have purchased, concurrent with the purchase of the Shares by the Purchaser hereunder, the Firm Shares (as defined in the Underwriting Agreement) at the same purchase price (less any underwriting discounts or commissions) per share payable by the Purchaser hereunder.

(c) No Injunction. No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction that prohibits the consummation of any of the transactions contemplated by the Transaction Documents.

(d) Company Deliverables. The Company shall have delivered the Company Deliverables in accordance with Section 2.2(a).

5.2 Conditions Precedent to the Obligations of the Company to sell Shares at the Closing. The Company's obligation to sell and issue the Shares to the Purchaser at the Closing is subject to the fulfillment to the satisfaction of the Company on or prior to the Closing Date of the following conditions, any of which may be waived by the Company:

(a) Representations and Warranties. The representations and warranties made by the Purchaser in Section 3.2 hereof shall be true and correct in all material respects as of the date of this Agreement, and as of the Closing Date as though made on and as of the Closing Date, except for representations and warranties that speak as of a specific date.

(b) IPO Shares. The Underwriters shall have purchased, concurrent with the purchase of the Shares by the Purchaser hereunder, the Firm Shares (as defined in the Underwriting Agreement) at the same purchase price (less any underwriting discounts or commissions) per share payable by the Purchaser hereunder.

(c) No Injunction. No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction that prohibits the consummation of any of the transactions contemplated by the Transaction Documents.

(d) Purchaser Deliverables. The Purchaser shall have delivered its Purchaser Deliverables in accordance with Section 2.2(b).

(e) Lock-Up Agreement. The Purchaser shall have executed and delivered to the Underwriters a lock-up agreement in substantially the form delivered to the Underwriters pursuant to the Underwriting Agreement, and such Lock-Up Agreement shall be in full force and effect.

ARTICLE 6

MISCELLANEOUS

6.1 Termination. This Agreement shall automatically terminate upon the earliest to occur of (i) the written consent of each of the Company and the Purchaser, (ii) the withdrawal by the Company of the Registration Statement, or (iii) following the execution of the Underwriting Agreement, the termination of such Underwriting Agreement in accordance with its terms.

6.2 Fees and Expenses. Each party shall pay its own fees and expenses incurred in connection with the negotiation, preparation, execution, delivery and performance of this Agreement.

6.3 Entire Agreement. The Transaction Documents, together with any exhibits and schedules thereto, contain the entire understanding of the parties with respect to the subject matter hereof and supersede all prior agreements, understandings, discussions and representations, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules. At or after the Closing, and without further consideration, the Company and the Purchaser will execute and deliver to the other such further documents as may be reasonably requested in order to give practical effect to the intention of the parties under the Transaction Documents.

6.4 Notices. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly given if mailed or transmitted and confirmed by any standard form of telecommunication. The address for such notices and communications shall be as follows:

If to the Company:

FibroGen, Inc.
409 Illinois Street
San Francisco, CA 94158
Facsimile No.:
Attention: Michael Lowenstein, Vice President,
Legal Affairs

With a copy to:

Cooley LLP
3175 Hanover Street
Palo Alto, California 94304
Facsimile No.: (650) 849-7400
Attention: Glen Y. Sato and Michael E. Tenta

If to the Purchaser:	AstraZeneca AB Pepparredsleden 1, 431 83 Mölndal Gothenburg Sweden Attention: Chief Financial Officer
With a copy to:	AstraZeneca UK Limited Alderley Park Macclesfield Cheshire SK10 4TF Attention: Liam McIlveen, Deputy General Counsel

or such other address as may be designated in writing hereafter, in the same manner, by such Person.

6.5 Amendments; Waivers; No Additional Consideration. No amendment or waiver of any provision of this Agreement, nor any consent or approval to any departure therefrom, shall in any event be effective unless the same shall be in writing and signed by the parties hereto.

6.6 Construction. The headings herein are included for convenience of reference only and are not intended to be part of, or to affect the meaning or interpretation of, this Agreement.

6.7 Successors and Assigns. The provisions of this Agreement shall inure to the benefit of and be binding upon the parties and their successors and permitted assigns. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person.

6.8 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of California, without regard to the principles of conflicts of law thereof.

6.9 Survival. The representations and warranties contained herein shall survive the Closing and the delivery of the Shares for a period of one (1) year from the Closing Date. The agreements and covenants contained herein shall survive for the applicable statute of limitations.

6.10 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party, it being understood that both parties need not sign the same counterpart.

6.11 Severability. If any provision of this Agreement is held to be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Agreement shall not in any way be affected or impaired thereby and the parties will attempt to agree upon a valid and enforceable provision that is a reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Agreement.

6.12 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, each of the Purchaser and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations described in the foregoing sentence and hereby agree to waive in any action for specific performance of any such obligation (other than in connection with any action for a temporary restraining order) the defense that a remedy at law would be adequate.

[SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, the parties hereto have caused this Common Stock Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

COMPANY:

FIBROGEN, INC.

By: /s/ Thomas B. Neff
Name: Tom Neff
Title: CEO

IN WITNESS WHEREOF, the parties hereto have caused this Common Stock Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

PURCHASER:

ASTRAZENECA AB

By: /s/ Yvonne Bertlin
Name: Yvonne Bertlin
Title: Director, CFO

EXHIBIT A

STANDSTILL AGREEMENT

October 20, 2014

FibroGen, Inc.
409 Illinois Street
San Francisco, CA 94158

Ladies and Gentlemen:

Pursuant to that certain Stock Purchase Agreement, dated on or about October 20, 2014, between AstraZeneca AB (“AZ”) and FibroGen, Inc. (the “Company”), AZ has agreed to be legally bound to the terms set forth below.

1. Standstill. During the five year period commencing on the date of the final prospectus used in connection with the Company’s initial public offering (the “Standstill Period”), neither AZ nor any of AZ’s Representatives will, in any manner, directly or indirectly:

(a) make, effect, initiate, cause or participate in (i) any acquisition of Beneficial Ownership of any securities of the Company, (ii) any acquisition of any assets of the Company, (iii) any tender offer, exchange offer, merger, business combination, recapitalization, restructuring, liquidation, dissolution or extraordinary transaction involving the Company, or involving any securities or assets of the Company, or (iv) any “solicitation” of “proxies” (as those terms are used in the proxy rules of the Securities and Exchange Commission) or consents with respect to any securities of the Company;

(b) form, join or participate in a “group” (as described in the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (the “Exchange Act”)) with respect to the Beneficial Ownership of any securities of the Company;

(c) act, alone or in concert with others, to seek to control or influence the management, Board of Directors or policies of the Company;

(d) take any action that might require the Company to make a public announcement regarding any of the types of matters set forth in clause “(a)” of this sentence;

(e) agree or offer to take, or encourage or propose (publicly or otherwise) the taking of, any action referred to in clause “(a)”, “(b)”, “(c)” or “(d)” of this sentence;

(f) assist, induce or encourage any other Person to take any action of the type referred to in clause “(a)”, “(b)”, “(c)”, “(d)” or “(e)” of this sentence;

(g) enter into any discussions, negotiations, arrangement or agreement with any other Person relating to any of the foregoing; or

(h) request or propose that the Company or any of the Company’s Representatives amend, waive or consider the amendment or waiver of any provision set forth herein.

2. Exceptions; Suspensions.

(a) Notwithstanding the restrictions of Section 1, nothing in this Agreement shall prohibit AZ or any of its Affiliates from making a confidential proposal to the Board of Directors of the Company for a transaction involving a Change of Control, and/or (ii) owning and/or acquiring the legal and/or beneficial interest in up to 4.99% of the outstanding shares of the Company; provided, that, for purposes of calculating such 4.99%, there shall not be taken into account any passive investments in the Company held by a pension plan or other employee benefit plan or trust for employees of AZ or its Affiliates.

(b) Subject to Sections 2(c) and 2(b), the restrictions of Section 1 shall be suspended upon the following (each, a “Release Event”) (i) the Company (X) entering into a definitive agreement with a third party to effect a Change of Control transaction, or (Y) publicly announcing the Company’s or its Board of Directors’ approval or recommendation of, or intent to enter into, any Change of Control transaction; or (ii) any person (A) becoming the beneficial owner (within the meaning of Section 13(d)(1) of the Exchange Act) of 35% or more of the Company’s outstanding equity securities, (B) commencing a tender or exchange offer that, if consummated, would make such person (or any of its Affiliates) the beneficial owner (within the meaning of Section 13(d)(1) of the Exchange Act) of more than 50% of the Company’s equity securities, or any rights or options to acquire such ownership, including from a third party, except if such third party tender or exchange offer is withdrawn or terminated within ten (10) business days after its commencement, or the Company or its Board of Directors rejects such third party offer or recommends that the stockholders of the Company do not tender or exchange their securities within ten (10) business days after its commencement, or (C) entering into an agreement or commencing a proxy solicitation in which the person or group would, if successful, elect, or acquire the ability to elect, a majority of the Board of Directors of the Company.

(c) If the restrictions of Section 1 are suspended pursuant to Section 2(b), such restrictions shall be reinstated immediately upon the following (each, a “Reinstatement Event”) (i) in the case of the Company (X) entering into a definitive agreement with a third party to effect a Change of Control transaction, or (Y) publicly announcing the Company’s or its Board of Directors’ approval or recommendation of, or intent to enter into, any Change of Control transaction, by the announcement by the Company that such definitive agreement has been terminated or such approval or recommendation has been withdrawn; or (ii) in the case of any person (A) becoming the beneficial owner (within the meaning of Section 13(d)(1) of the Exchange Act) of 35% or more of the Company’s outstanding equity securities, by the public disclosure of the disposition by such person of such beneficial ownership to less than 35% (B) commencing a tender or exchange offer that, if consummated, would make such person (or any of its Affiliates) the beneficial owner (within the meaning of Section 13(d)(1) of the Exchange Act) of more than 50% of the Company's equity securities, or any rights or options to acquire such ownership, including from a third party, by the withdrawal or termination of such third party tender or exchange offer, or by the rejection by the Company or its Board of Directors of such third party offer or recommendation by the Company or its Board of Directors that the stockholders of the Company do not tender or exchange their securities, or (C) entering into an agreement or commencing a proxy solicitation in which the person or group would, if successful, elect, or acquire the ability to elect, a majority of the Board of Directors of the Company, by the termination of such agreement or suspension of such solicitation.

(d) At the time of the Reinstatement Event, AZ shall sell or distribute, and the Company shall use reasonable efforts to assist AZ in selling or distributing, any shares it acquired during the time period between the Release Event and the Reinstatement Event in an orderly fashion over a period of six (6) months such that it shall own at the end of such six (6) month period the same number and type of shares and other securities of the Company as it owned immediately prior to the Release Event.

3. Voting Obligations; Affiliate Lock-Up. During the Standstill Period, AZ shall:

(a) take such action as may be required so that all shares of any securities of the Company for which it has Beneficial Ownership are voted for or cast in favor of: (i) nominees to the Board of Directors of the Company in accordance with the recommendations of a majority of the Board of Directors of the Company, (ii) increases in the authorized capital stock of the Company and amendments to stock option plans and employee stock purchase plans, in each case approved by the Company's Board of Directors, and (iii) Change of Control transactions which have been approved by the Company's Board of Directors;

(b) not exercise any dissenter's rights, if any, that it may have under applicable law in connection with any merger, consolidation or other reorganization which is approved by the Company's Board of Directors;

(c) enter into a standard affiliate lock-up agreement if requested by the Company provided, however, that all directors and officers of the Company enter into such agreements;

(d) except as set forth in paragraphs (a) and (b) above, nothing in this Agreement shall preclude AZ from voting shares of any securities of the Company for which it has Beneficial Ownership in such manner as AZ determines, in its sole discretion, on any matter presented to the holders of securities of the Company for a vote, consent or other approval.

(e) So long as a AZ has Beneficial Ownership of voting securities of the Company, AZ, as the holder of such securities, shall be present, in person or by proxy, at all meetings of stockholders of the Company so that all shares of any securities of the Company held by AZ may be counted for purposes of determining the presence of a quorum at such meetings

4. No Waiver. No failure or delay by the Company or any of its Representatives in exercising any right, power or privilege under this letter agreement will operate as a waiver thereof, and no single or partial exercise of any such right, power or privilege will preclude any other or future exercise thereof or the exercise of any other right, power or privilege under this letter agreement. No provision of this letter agreement can be waived except by means of a written instrument that is validly executed on behalf of the Company and that refers specifically to the particular provision or provisions being waived.

5. Successors and Assigns; Applicable Law; Jurisdiction and Venue. This letter agreement will be binding upon AZ and its Representatives and their respective heirs, successors and assigns, and will inure to the benefit of the Company and its Representatives and their respective heirs, successors and assigns. This letter agreement will be governed by and construed in accordance with the laws of the State of California (without giving effect to principles of conflicts of laws). AZ and its Representatives: (a) irrevocably and unconditionally consent and submit to the jurisdiction of the state and federal courts located in the State of California for purposes of any action, suit or proceeding arising out of or relating to this letter agreement; (b) agree that service of any process, summons, notice or document by U.S. registered mail to the address set forth at the end of this letter agreement shall be effective service of process for any action, suit or proceeding brought against AZ or any of AZ's Representatives; (c) irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding arising out of or relating to this letter agreement in any state or federal court located in the State of California; and (d) irrevocably and unconditionally waive the right to plead or claim, and irrevocably and unconditionally agree not to plead or claim, that any action, suit or proceeding arising out of or relating to this letter agreement that is brought in any state or federal court located in the State of California has been brought in an inconvenient forum.

6. Miscellaneous.

(a) For purposes of this letter agreement, a party's "Representatives" will be deemed to include each Person that is or becomes (i) a subsidiary, officer, director or other Affiliate of such party, or (ii) an employee, partner, attorney, advisor, accountant, agent or representative of such party or of any of such party's subsidiaries or other Affiliates. The term "Affiliate" shall have the meaning set forth in Rule 12b-2 of the regulations promulgated under the Exchange Act.

(b) The term "Person," as used in this letter agreement, will be broadly interpreted to include any individual and any corporation, partnership, entity, group, tribunal or governmental authority.

(c) The term "Beneficial Ownership" shall have the meaning ascribed to it by Rule 13d-3 or any successor rule or regulation promulgated under the Exchange Act.

(d) The term “Change of Control” as used in this letter agreement will mean (a) a merger or consolidation of the Company with or into any other entity or person, or any other corporate reorganization, business combination, tender or exchange offer, purchase of a majority of the Company’s assets or businesses, or similar transactions involving the Company, in which the holders of the Company’s outstanding voting securities immediately prior to such transaction own, immediately after such transaction, securities representing less than 50% of the voting power of the entity surviving such transaction or the surviving entity’s parent, but excluding any such transaction effected exclusively to change the domicile of the Company, or (b) the acquisition by any person (within the meaning of Section 13(d)(3) or Section 14(d)(2) of the Exchange Act in a single transaction or series of related transactions, of Beneficial Ownership of securities representing 50% or more of the combined voting power of the then-outstanding securities of the Company, excluding in any case securities of the Company purchased from the Company in a transaction the principal purpose of which is to raise capital for the Company.

(e) The bold-faced captions appearing in this letter agreement have been included only for convenience and shall not affect or be taken into account in the interpretation of this letter agreement.

(f) The invalidity or unenforceability of any provision of this letter agreement shall not affect the validity or enforceability of any other provision of this letter agreement.

(g) This letter agreement constitutes the entire agreement between AZ and the Company regarding the subject matter hereof and supersedes any prior agreement between AZ and the Company regarding the subject matter hereof; *provided, however*, that any confidentiality agreement between AZ and the Company shall continue in full force and effect.

Very truly yours,

AstraZeneca AB

By: /s/ Yvonne Bertlin
Title: Director, CFO
Address: Södertälje
SE-151 85
Sweden

Exhibit 10.4

FIBROGEN, INC.

2014 EQUITY INCENTIVE PLAN

ADOPTED BY THE BOARD OF DIRECTORS: SEPTEMBER 09, 2014
APPROVED BY THE STOCKHOLDERS: SEPTEMBER 30, 2014
IPO DATE/EFFECTIVE DATE: [ ], 2014

1. GENERAL.

(a) Successor to and Continuation of Prior Plan.

(i) The Plan is the successor to and continuation of the FibroGen Amended and Restated 2005 Stock Plan, as amended (the "***Prior Plan***"). From and after 12:01 a.m. Pacific time on the Effective Date, no additional stock awards will be granted under the Prior Plan. All stock awards granted under the Prior Plan remain subject to the terms of the Prior Plan. All Awards granted on or after 12:01 a.m. Pacific Time on the Effective Date will be granted under the Plan.

(ii) Any shares that would otherwise remain available for future grants under the Prior Plan as of 12:01 a.m. Pacific Time on the Effective Date ceased to be available under the Prior Plan at such time. Instead, that number of shares of Common Stock equal to the number of shares of Common Stock of the Company then available for future grants under the Prior Plan (the "***Prior Plan's Available Reserve***") was added to the Share Reserve (as further described in Section 3(a) below) and became immediately available for grants and issuance pursuant to Stock Awards under the Plan, up to the maximum number set forth in Section 3(a) below.

(iii) From and after 12:01 a.m. Pacific time on the Effective Date, a number of shares of Common Stock equal to the total number of shares of Common Stock subject, at such time, to outstanding stock options granted under the Prior Plan that: (A) expire or terminate for any reason prior to exercise or settlement; (B) are forfeited or reacquired because of the failure to meet a contingency or condition required to vest such shares or are repurchased at the original issuance price; or (C) are otherwise reacquired or withheld (or not issued) to satisfy a tax withholding obligation in connection with an award (the "***Returning Shares***") will immediately be added to the Share Reserve (as further described in Section 3(a) below) as and when such shares become Returning Shares (up to the maximum number set forth in Section 3(a)), and become available for issuance pursuant to Stock Awards granted hereunder.

(b) Eligible Award Recipients. Employees, Directors and Consultants are eligible to receive Awards.

(c) Available Awards. The Plan provides for the grant of the following Awards: (i) Incentive Stock Options, (ii) Nonstatutory Stock Options, (iii) Stock Appreciation Rights (iv) Restricted Stock Awards, (v) Restricted Stock Unit Awards, (vi) Performance Stock Awards, (vii) Performance Cash Awards, and (viii) Other Stock Awards.

(d) Purpose. The Plan, through the granting of Awards, is intended to help the Company secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate, and provide a means by which the eligible recipients may benefit from increases in value of the Common Stock.

2. ADMINISTRATION.

(a) Administration by Board. The Board will administer the Plan. The Board may delegate administration of the Plan to a Committee or Committees, as provided in Section 2(c).

(b) Powers of Board. The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine: (A) who will be granted Awards; (B) when and how each Award will be granted; (C) what type of Award will be granted; (D) the provisions of each Award (which need not be identical), including when a person will be permitted to exercise or otherwise receive cash or Common Stock under the Award; (E) the number of shares of Common Stock subject to, or the cash value of, an Award; and (F) the Fair Market Value applicable to a Stock Award.

(ii) To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for administration of the Plan and Awards. The Board, in the exercise of these powers, may correct any defect, omission or inconsistency in the Plan or in any Award Agreement or in the written terms of a Performance Cash Award, in a manner and to the extent it will deem necessary or expedient to make the Plan or Award fully effective.

(iii) To settle all controversies regarding the Plan and Awards granted under it.

(iv) To accelerate, in whole or in part, the time at which an Award may be exercised or vest (or at which cash or shares of Common Stock may be issued).

(v) To suspend or terminate the Plan at any time. Except as otherwise provided in the Plan or an Award Agreement, suspension or termination of the Plan will not materially impair a Participant’s rights under his or her then-outstanding Award without his or her written consent, except as provided in subsection (viii) below.

(vi) To amend the Plan in any respect the Board deems necessary or advisable, including, without limitation, by adopting amendments relating to Incentive Stock Options and certain nonqualified deferred compensation under Section 409A of the Code and/or to bring the Plan or Awards granted under the Plan into compliance therewith, subject to the limitations, if any, of applicable law. If required by applicable law or listing requirements, and except as provided in Section 9(a) relating to Capitalization Adjustments, the Company will seek stockholder approval of any amendment of the Plan that (A) materially increases the number of shares of Common Stock available for issuance under the Plan, (B) materially expands the class of individuals eligible to receive Awards under the Plan, (C) materially increases the benefits accruing to Participants under the Plan, (D) materially extends the term of the Plan, or (E) materially expands the types of Awards available for issuance under the Plan. Except as otherwise provided in the Plan or an Award Agreement, no amendment of the Plan will materially impair that Participant's rights under an outstanding Award without his or her written consent.

(vii) To submit any amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of (A) Section 162(m) of the Code regarding the exclusion of performance-based compensation from the limit on corporate deductibility of compensation paid to Covered Employees, (B) Section 422 of the Code regarding "incentive stock options" or (C) Rule 16b-3.

(viii) To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more outstanding Awards. Except with respect to amendments that disqualify or impair the status of an Incentive Stock Option or as otherwise provided in the Plan or an Award Agreement, no amendment of an outstanding Award will materially impair that Participant's rights under his or her outstanding Award without his or her written consent. To be clear, unless prohibited by applicable law, the Board may amend the terms of an Award without the affected Participant's consent if necessary (A) to maintain the qualified status of the Award as an Incentive Stock Option, (B) to clarify the manner of exemption from, or to bring the Award into compliance with, Section 409A of the Code, or (C) to comply with other applicable laws or listing requirements.

(ix) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Awards.

(x) To adopt such procedures and sub-plans as are necessary or appropriate to permit or facilitate participation in the Plan by Employees, Directors or Consultants who are foreign nationals or employed outside the United States or allow Awards to qualify for special tax treatment in a foreign jurisdiction; *provided*, that Board approval will not be necessary for immaterial modifications to the Plan or any Award Agreement that are required for compliance with the laws of the relevant foreign jurisdiction.

(c) Delegation to Committee.

(i) General. The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee, as applicable). Any delegation of administrative powers will be reflected in resolutions, not inconsistent with the provisions of the Plan, adopted from time to time by the Board or Committee (as applicable). The Committee may, at any time, abolish the subcommittee and/or revest in the Committee any powers delegated to the subcommittee. The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revest in the Board some or all of the powers previously delegated.

(ii) Section 162(m) and Rule 16b-3 Compliance. The Committee may consist solely of two or more Outside Directors, in accordance with Section 162(m) of the Code, or solely of two or more Non-Employee Directors, in accordance with Rule 16b-3.

(d) Delegation to an Officer. The Board may delegate to one or more Officers the authority to do one or both of the following (i) designate Employees who are not Officers to be recipients of Options and SARs (and, to the extent permitted by applicable law, other Stock Awards) and, to the extent permitted by applicable law, the terms of such rights and options, and (ii) determine the number of shares of Common Stock to be subject to such Stock Awards granted to such Employees; *provided, however*, that the Board resolutions regarding such delegation will specify the total number of shares of Common Stock that may be subject to the Stock Awards granted by such Officer and that such Officer may not grant a Stock Award to himself or herself. Any such Stock Awards will be granted on the form of Stock Award Agreement most recently approved for use by the Committee or the Board, unless otherwise provided in the resolutions approving the delegation authority. The Board may not delegate authority to an Officer who is acting solely in the capacity of an Officer (and not also as a Director) to determine the Fair Market Value (as defined below).

(e) Effect of Board's Decision. All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

3. SHARES SUBJECT TO THE PLAN.

(a) Share Reserve.

(i) Subject to Section 9(a) relating to Capitalization Adjustments and the “evergreen” provision in Section 3(a)(ii), the aggregate number of shares of Common Stock that may be issued pursuant to Stock Awards from and after the Effective Date (the “***Share Reserve***”) will not exceed the Prior Plan's Available Reserve, which was 19,008,777 shares as of September 09, 2014, as increased from time to time by any Returning Shares in an amount not to exceed 32,432,460 shares.

(ii) In addition, the Share Reserve will automatically increase on January 1st of each year, for the period commencing on (and including) January 1, 2016 and ending on (and including) January 1, 2024, in an amount equal to 4.0% of the total number of shares of Capital Stock outstanding on December 31st of the preceding calendar year. Notwithstanding the foregoing, the Board may act prior to January 1st of a given year to provide that there will be no January 1st increase in the Share Reserve for such year or that the increase in the Share Reserve for such year will be a lesser number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence.

(iii) For clarity, the Share Reserve is a limitation on the number of shares of Common Stock that may be issued under the Plan. As a single share may be subject to grant more than once (e.g., if a share subject to a Stock Award is forfeited, it may be made subject to grant again as provided in Section 3(b) below), the Share Reserve is not a limit on the number of Stock Awards that can be granted.

(iv) Shares may be issued in connection with a merger or acquisition as permitted by NASDAQ Listing Rule 5635(c) or, if applicable, NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

(b) Reversion of Shares to the Share Reserve. If a Stock Award or any portion of a Stock Award (i) expires or otherwise terminates without all of the shares covered by such Stock Award having been issued or (ii) is settled in cash (*i.e.*, the Participant receives cash rather than stock), such expiration, termination or settlement will not reduce (or otherwise offset) the number of shares of Common Stock that may be available for issuance under the Plan. If any shares of Common Stock issued pursuant to a Stock Award are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares that are forfeited or repurchased will revert to and again become available for issuance under the Plan. Any shares reacquired by the Company in satisfaction of tax withholding obligations on a Stock Award or as consideration for the exercise or purchase price of a Stock Award will again become available for issuance under the Plan.

(c) Incentive Stock Option Limit. Subject to the provisions of Section 9(a) relating to Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options will be 60,000,000 shares of Common Stock.

(d) Section 162(m) Limitations. Subject to the provisions of Section 9(a) relating to Capitalization Adjustments, at such time as the Company may be subject to the applicable provisions of Section 162(m) of the Code: (i) a maximum of 2,000,000 shares of Common Stock subject to Options, SARs and Other Stock Awards whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the Fair Market Value on the date the Stock Award is granted may be granted to any one Participant during any one calendar year, (ii) a maximum of 2,000,000 shares of Common Stock subject to Performance Stock Awards may be granted to any one Participant during any one calendar year (whether the grant, vesting or exercise is contingent upon the attainment during the Performance Period of the Performance Goals) and (iii) a maximum of $2,000,000 may be granted as a Performance Cash Award to any one Participant during any one calendar year. If a Performance Stock Award is in the form of an Option, it will count only against the Performance Stock Award limit. If a Performance Stock Award could (but is not required to) be paid out in cash, it will count only against the Performance Stock Award limit.

(e) Source of Shares. The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

4. ELIGIBILITY.

(a) Eligibility for Specific Stock Awards. Incentive Stock Options may be granted only to employees of the Company or a "parent corporation" or "subsidiary corporation" thereof (as such terms are defined in Sections 424(e) and 424(f) of the Code). Stock Awards other than Incentive Stock Options may be granted to Employees, Directors and Consultants; *provided, however*, that Stock Awards may not be granted to Employees, Directors and Consultants who are providing Continuous Service only to any "parent" of the Company, as such term is defined in Rule 405 of the Securities Act, unless (i) the stock underlying such Stock Awards is treated as "service recipient stock" under Section 409A of the Code (for example, because the Stock Awards are granted pursuant to a corporate transaction such as a spin off transaction), (ii) the Company, in consultation with its legal counsel, has determined that such Stock Awards are otherwise exempt from Section 409A of the Code, or (iii) the Company, in consultation with its legal counsel, has determined that such Stock Awards comply with the distribution requirements of Section 409A of the Code.

(b) Ten Percent Stockholders. A Ten Percent Stockholder will not be granted an Incentive Stock Option unless the exercise price of such Option is at least 110% of the Fair Market Value on the date of grant and the Option is not exercisable after the expiration of five years from the date of grant.

5. PROVISIONS RELATING TO OPTIONS AND STOCK APPRECIATION RIGHTS.

Each Option or SAR will be in such form and will contain such terms and conditions as the Board deems appropriate. All Options will be separately designated Incentive Stock Options or Nonstatutory Stock Options at the time of grant, and, if certificates are issued, a separate certificate or certificates will be issued for shares of Common Stock purchased on exercise of each type of Option. If an Option is not specifically designated as an Incentive Stock Option, or if an Option is designated as an Incentive Stock Option but some portion or all of the Option fails to qualify as an Incentive Stock Option under the applicable rules, then the Option (or portion thereof) will be a Nonstatutory Stock Option. The provisions of separate Options or SARs need not be identical; *provided, however*, that each Award Agreement will conform to (through incorporation of provisions hereof by reference in the applicable Award Agreement or otherwise) the substance of each of the following provisions:

(a) Term. Subject to the provisions of Section 4(b) regarding Ten Percent Stockholders, no Option or SAR will be exercisable after the expiration of ten years from the date of its grant or such shorter period specified in the Award Agreement.

(b) Exercise Price. Subject to the provisions of Section 4(b) regarding Ten Percent Stockholders, the exercise or strike price of each Option or SAR will be not less than 100% of the Fair Market Value of the Common Stock subject to the Option or SAR on the date the Award is granted. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise or strike price lower than 100% of the Fair Market Value of the Common Stock subject to the Award if such Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Corporate Transaction and in a manner consistent with the provisions of Section 409A of the Code and, if applicable, Section 424(a) of the Code. Each SAR will be denominated in shares of Common Stock equivalents.

(c) Purchase Price for Options. The purchase price of Common Stock acquired pursuant to the exercise of an Option may be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment set forth below. The Board will have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to use a particular method of payment. The permitted methods of payment are as follows:

(i) by cash, check, bank draft or money order payable to the Company;

(ii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;

(iv) if an Option is a Nonstatutory Stock Option, by a “net exercise” arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; *provided*, *however*, that the Company will accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued. Shares of Common Stock will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are reduced to pay the exercise price pursuant to the “net exercise,” (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

(v) in any other form of legal consideration that may be acceptable to the Board and specified in the applicable Award Agreement.

(d) Exercise and Payment of a SAR. To exercise any outstanding SAR, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Right Agreement evidencing such SAR. The appreciation distribution payable on the exercise of a SAR will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the SAR) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under such SAR, and with respect to which the Participant is exercising the SAR on such date, over (B) the aggregate strike price of the number of Common Stock equivalents with respect to which the Participant is exercising the SAR on such date. The appreciation distribution may be paid in Common Stock, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Award Agreement evidencing such SAR.

(e) Transferability of Options and SARs. The Board may, in its sole discretion, impose such limitations on the transferability of Options and SARs as the Board will determine. In the absence of such a determination by the Board to the contrary, the following restrictions on the transferability of Options and SARs will apply:

(i) Restrictions on Transfer. An Option or SAR will not be transferable except by will or by the laws of descent and distribution (or pursuant to subsections (ii) and (iii) below), and will be exercisable during the lifetime of the Participant only by the Participant. The Board may permit transfer of the Option or SAR in a manner that is not prohibited by applicable tax and securities laws. Except as explicitly provided in the Plan, neither an Option nor a SAR may be transferred for consideration.

(ii) Domestic Relations Orders. Subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to the terms of a domestic relations order or official marital settlement agreement or other divorce or separation instrument as permitted by Treasury Regulations Section 1.421-1(b)(2). If an Option is an Incentive Stock Option, such Option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

(iii) Beneficiary Designation. Subject to the approval of the Board or a duly authorized Officer, a Participant may, by delivering written notice to the Company, in a form approved by the Company (or the designated broker), designate a third party who, on the death of the Participant, will thereafter be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, the executor or administrator of the Participant’s estate will be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. However, the Company may prohibit designation of a beneficiary at any time, including due to any conclusion by the Company that such designation would be inconsistent with the provisions of applicable laws.

(f) Vesting Generally. The total number of shares of Common Stock subject to an Option or SAR may vest and therefore become exercisable in periodic installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of Performance Goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the minimum number of shares of Common Stock as to which an Option or SAR may be exercised.

(g) Termination of Continuous Service. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant’s Continuous Service terminates (other than for Cause and other than upon the Participant’s death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Award as of the date of termination of Continuous Service) within the period of time ending on the earlier of (i) the date which occurs three months following the termination of the Participant’s Continuous Service (or such longer or shorter period specified in the applicable Award Agreement) and (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR will terminate.

(h) Extension of Termination Date. Except as otherwise provided in the applicable Award Agreement, if the exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause and other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option or SAR will terminate on the earlier of (i) the expiration of a total period of three months (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of such registration requirements, and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Agreement. In addition, unless otherwise provided in a Participant's Award Agreement, if the sale of any Common Stock received upon exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause) would violate the Company's insider trading policy, then the Option or SAR will terminate on the earlier of (i) the expiration of a period of days or months (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the sale of the Common Stock received upon exercise of the Option or SAR would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Agreement.

(i) Disability of Participant. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date which occurs 12 months following such termination of Continuous Service (or such longer or shorter period specified in the Award Agreement), and (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR (as applicable) will terminate.

(j) Death of Participant. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the period (if any) specified in the Award Agreement for exercisability after the termination of the Participant's Continuous Service for a reason other than death, then the Option or SAR may be exercised (to the extent the Participant was entitled to exercise such Option or SAR as of the date of death) by the Participant's estate, by a person who acquired the right to exercise the Option or SAR by bequest or inheritance or by a person designated to exercise the Option or SAR upon the Participant's death, but only within the period ending on the earlier of (i) the date which occurs 18 months following the date of death (or such longer or shorter period specified in the Award Agreement), and (ii) the expiration of the term of such Option or SAR as set forth in the Award Agreement. If, after the Participant's death, the Option or SAR is not exercised within the applicable time frame, the Option or SAR will terminate.

(k) Termination for Cause. Except as explicitly provided otherwise in a Participant's Award Agreement or other individual written agreement between the Company or any Affiliate and the Participant, if a Participant's Continuous Service is terminated for Cause, the Option or SAR will terminate immediately upon the date on which the event giving rise to the termination for Cause first occurred, and the Participant will be prohibited from exercising his or her Option or SAR from and after the date on which the event giving rise to the termination for Cause first occurred (or, if required by law, the date of termination of Continuous Service). If a Participant's Continuous Service is suspended pending an investigation of the existence of Cause, all of the Participant's rights under the Option or SAR will also be suspended during the investigation period.

(l) Non-Exempt Employees. If an Option or SAR is granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, the Option or SAR will not be first exercisable for any shares of Common Stock until at least six (6) months following the date of grant of the Option or SAR (although the Award may vest prior to such date). Consistent with the provisions of the Worker Economic Opportunity Act, (i) if such non-exempt Employee dies or suffers a Disability, (ii) upon a Corporate Transaction in which such Option or SAR is not assumed, continued, or substituted, (iii) upon a Change in Control, or (iv) upon the Participant's retirement (as such term may be defined in the Participant's Award Agreement in another agreement between the Participant and the Company, or, if no such definition, in accordance with the Company's then current employment policies and guidelines), the vested portion of any Options and SARs may be exercised earlier than six (6) months following the date of grant. The foregoing provision is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay. To the extent permitted and/or required for compliance with the Worker Economic Opportunity Act to ensure that any income derived by a non-exempt employee in connection with the exercise, vesting or issuance of any shares under any other Stock Award will be exempt from the employee's regular rate of pay, the provisions of this Section 5(l) will apply to all Stock Awards and are hereby incorporated by reference into such Stock Award Agreements.

6. PROVISIONS OF STOCK AWARDS OTHER THAN OPTIONS AND SARS.

(a) Restricted Stock Awards. Each Restricted Stock Award Agreement will be in such form and will contain such terms and conditions as the Board will deem appropriate. To the extent consistent with the Company's bylaws, at the Board's election, shares of Common Stock may be (x) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse; or (y) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Award Agreements need not be identical. Each Restricted Stock Award Agreement will conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of legal consideration (including future services) that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. Shares of Common Stock awarded under the Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.

(iii) Termination of Participant's Continuous Service. If a Participant's Continuous Service terminates, the Company may receive through a forfeiture condition or a repurchase right any or all of the shares of Common Stock held by the Participant that have not vested as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Agreement.

(iv) Transferability. Rights to acquire shares of Common Stock under the Restricted Stock Award Agreement will be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Agreement, as the Board will determine in its sole discretion, so long as Common Stock awarded under the Restricted Stock Award Agreement remains subject to the terms of the Restricted Stock Award Agreement.

(v) Dividends. A Restricted Stock Award Agreement may provide that any dividends paid on Restricted Stock will be subject to the same vesting and forfeiture restrictions as apply to the shares subject to the Restricted Stock Award to which they relate.

(b) Restricted Stock Unit Awards. Each Restricted Stock Unit Award Agreement will be in such form and will contain such terms and conditions as the Board will deem appropriate. The terms and conditions of Restricted Stock Unit Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Agreements need not be identical. Each Restricted Stock Unit Award Agreement will conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) Payment. A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Agreement.

(iv) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) Dividend Equivalents. Dividend equivalents may be credited in respect of shares of Common Stock covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Restricted Stock Unit Award Agreement. At the sole discretion of the Board, such dividend equivalents may be converted into additional shares of Common Stock covered by the Restricted Stock Unit Award in such manner as determined by the Board. Any additional shares covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying Restricted Stock Unit Award Agreement to which they relate.

(vi) Termination of Participant's Continuous Service. Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

(c) Performance Awards.

(i) Performance Stock Awards. A Performance Stock Award is a Stock Award (covering a number of shares not in excess of that set forth in Section 3(d) above) that is payable or that may be granted, may vest or may be exercised, contingent upon the attainment during a Performance Period of certain Performance Goals. A Performance Stock Award may, but need not, require the completion of a specified period of Continuous Service. The length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained will be conclusively determined by the Committee (or, if not required for compliance with Section 162(m) of the Code, the Board), in its sole discretion. In addition, to the extent permitted by applicable law and the applicable Award Agreement, the Board may determine that cash may be used in payment of Performance Stock Awards.

(ii) Performance Cash Awards. A Performance Cash Award is a cash award (for a dollar value not in excess of that set forth in Section 3(d) above) that is payable contingent upon the attainment during a Performance Period of certain Performance Goals. A Performance Cash Award may also require the completion of a specified period of Continuous Service. At the time of grant of a Performance Cash Award, the length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained will be conclusively determined by the Committee (or, if not required for compliance with Section 162(m) of the Code, the Board), in its sole discretion. The Board may specify the form of payment of Performance Cash Awards, which may be cash or other property, or may provide for a Participant to have the option for his or her Performance Cash Award, or such portion thereof as the Board may specify, to be paid in whole or in part in cash or other property.

(iii) **Section 162(m) Compliance**. Unless otherwise permitted in compliance with the requirements of Section 162(m) of the Code with respect to an Award intended to qualify as “performance-based compensation” thereunder, the Committee will establish the Performance Goals applicable to, and the formula for calculating the amount payable under, the Award no later than the earlier of (a) the date 90 days after the commencement of the applicable Performance Period, and (b) the date on which 25% of the Performance Period has elapsed, and in any event at a time when the achievement of the applicable Performance Goals remains substantially uncertain. Prior to the payment of any compensation under an Award intended to qualify as “performance-based compensation” under Section 162(m) of the Code, the Committee will certify the extent to which any Performance Goals and any other material terms under such Award have been satisfied (other than in cases where such relate solely to the increase in the value of the Common Stock). Notwithstanding satisfaction of any completion of any Performance Goals, the number of shares of Common Stock, Options, cash or other benefits granted, issued, retainable and/or vested under an Award on account of satisfaction of such Performance Goals may be reduced by the Committee on the basis of such further considerations as the Committee, in its sole discretion, will determine.

(d) **Other Stock Awards**. Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof, may be granted either alone or in addition to Stock Awards provided for under Section 5 and the preceding provisions of this Section 6. Subject to the provisions of the Plan, the Board will have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards.

7. COVENANTS OF THE COMPANY.

(a) **Availability of Shares.** The Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy then-outstanding Awards.

(b) **Securities Law Compliance.** The Company will seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; *provided*, *however*, that this undertaking will not require the Company to register under the Securities Act the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained. A Participant will not be eligible for the grant of an Award or the subsequent issuance of cash or Common Stock pursuant to the Award if such grant or issuance would be in violation of any applicable securities law.

(c) No Obligation to Notify or Minimize Taxes. The Company will have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company will have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of an Award to the holder of such Award.

8. MISCELLANEOUS.

(a) Use of Proceeds from Sales of Common Stock. Proceeds from the sale of shares of Common Stock pursuant to Awards will constitute general funds of the Company.

(b) Corporate Action Constituting Grant of Awards. Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (e.g., Board consents, resolutions or minutes) documenting the corporate action constituting the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Agreement or related grant documents as a result of a clerical error in the papering of the Award Agreement or related grant documents, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Agreement or related grant documents.

(c) Stockholder Rights. No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to an Award unless and until (i) such Participant has satisfied all requirements for exercise of, or the issuance of shares of Common Stock under, the Award pursuant to its terms, and (ii) the issuance of the Common Stock subject to such Award has been entered into the books and records of the Company.

(d) No Employment or Other Service Rights. Nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or will affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without Cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

(e) Change in Time Commitment. In the event a Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence) after the date of grant of any Award to the Participant, the

Board has the right in its sole discretion to (x) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Award that is scheduled to vest or become payable after the date of such change in time commitment, and (y) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Award that is so reduced or extended.

(f) Incentive Stock Option Limitations. To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and any Affiliates) exceeds $100,000 (or such other limit established in the Code) or otherwise does not comply with the rules governing Incentive Stock Options, the Options or portions thereof that exceed such limit (according to the order in which they were granted) or otherwise do not comply with the rules will be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

(g) Investment Assurances. The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Award, (i) to give written assurances satisfactory to the Company as to the Participant’s knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Award for the Participant’s own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, will be inoperative if (A) the issuance of the shares upon the exercise or acquisition of Common Stock under the Award has been registered under a then currently effective registration statement under the Securities Act, or (B) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

(h) Withholding Obligations. Unless prohibited by the terms of an Award Agreement, the Company may, in its sole discretion, satisfy any federal, state or local tax withholding obligation relating to an Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Award; *provided*, *however*, that no shares of Common Stock are withheld with a value exceeding the minimum amount of tax required to be withheld by law (or such lesser amount as may be necessary to avoid classification of the Stock Award as a liability for financial accounting purposes); (iii) withholding cash from an Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant, including proceeds from the sale of shares of Common Stock issued pursuant to a Stock Award; or (v) by such other method as may be set forth in the Award Agreement.

(i) Electronic Delivery. Any reference herein to a “written” agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto) or posted on the Company’s intranet (or other shared electronic medium controlled by the Company to which the Participant has access).

(j) Deferrals. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code (to the extent applicable to a Participant). Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company. The Board is authorized to make deferrals of Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant’s termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

(k) Compliance with Section 409A. Unless otherwise expressly provided for in an Award Agreement, the Plan and Award Agreements will be interpreted to the greatest extent possible in a manner that makes the Plan and the Awards granted hereunder exempt from Section 409A of the Code, and, to the extent not so exempt, in compliance with Section 409A of the Code. If the Board determines that any Award granted hereunder is not exempt from and is therefore subject to Section 409A of the Code, the Award Agreement evidencing such Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award Agreement is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Award Agreement. Notwithstanding anything to the contrary in this Plan (and unless the Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding an Award that constitutes “deferred compensation” under Section 409A of the Code is a “specified employee” for purposes of Section 409A of the Code, no distribution or payment of any amount that is due because of a “separation from service” (as defined in Section 409A of the Code without regard to alternative definitions thereunder) will be issued or paid before the date that is six (6) months following the date of such Participant’s “separation from service” or, if earlier, the date of the Participant’s death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six (6) month period elapses, with the balance paid thereafter on the original schedule.

(l) Clawback/Recovery. All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company’s securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of an event constituting Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for “good reason” or “constructive termination” (or similar term) under any agreement with the Company or an Affiliate.

9. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; OTHER CORPORATE EVENTS.

(a) Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a), (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 3(c), (iii) the class(es) and maximum number of securities that may be awarded to any person pursuant to Sections 3(d), and (iv) the class(es) and number of securities and price per share of stock subject to outstanding Stock Awards. The Board will make such adjustments, and its determination will be final, binding and conclusive.

(b) Dissolution or Liquidation. Except as otherwise provided in the Stock Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company’s right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company’s repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service; *provided*, *however*, that the Board may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

(c) Corporate Transaction. The following provisions will apply to Stock Awards in the event of a Corporate Transaction unless otherwise provided in the instrument evidencing the Stock Award or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board at the time of grant of a Stock Award. In the event of a Corporate Transaction, then, notwithstanding any other provision of the Plan, the Board will take one or more of the following actions with respect to Stock Awards, contingent upon the closing or completion of the Corporate Transaction:

(i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation’s parent company) to assume or continue the Stock Award or to substitute a similar stock award for the Stock Award (including, but not limited to, an award to acquire the same consideration paid to the stockholders of the Company pursuant to the Corporate Transaction);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to the Stock Award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

(iii) accelerate the vesting, in whole or in part, of the Stock Award (and, if applicable, the time at which the Stock Award may be exercised) to a date prior to the effective time of such Corporate Transaction as the Board determines (or, if the Board does not determine such a date, to the date that is five (5) days prior to the effective date of the Corporate Transaction), with such Stock Award terminating if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction;

(iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to the Stock Award;

(v) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for such cash consideration, if any, as the Board, in its sole discretion, may consider appropriate; and

(vi) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for a payment, in such form as may be determined by the Board, equal to the excess, if any, of (A) the value of the property the Participant would have received upon the exercise of the Stock Award immediately prior to the effective time of the Corporate Transaction, over (B) any exercise price payable by such holder in connection with such exercise.

(vii) The Board need not take the same action or actions with respect to all Stock Awards or portions thereof or with respect to all Participants. The Board may take different actions with respect to the vested and unvested portions of a Stock Award.

(d) **Change in Control.** A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Agreement for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration will occur.

10. TERMINATION OR SUSPENSION OF THE PLAN.

(a) The Board may suspend or terminate the Plan at any time. No Incentive Stock Options may be granted after the tenth anniversary of the earlier of (i) the date the Plan is adopted by the Board (the "***Adoption Date***"), and (ii) the date the Plan is approved by the stockholders of the Company. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

11. EXISTENCE OF THE PLAN; TIMING OF FIRST GRANT OR EXERCISE.

The Plan will come into existence on the Adoption Date; *provided, however*, that no Award may be granted prior to the IPO Date (that is, the Effective Date). In addition, no Stock Award will be exercised (or, in the case of a Restricted Stock Award, Restricted Stock Unit Award, Performance Stock Award, or Other Stock Award, will be granted) and no Performance

Cash Award will be settled unless and until the Plan has been approved by the stockholders of the Company, which approval will be within 12 months after the Adoption Date.

12. CHOICE OF LAW.

The law of the State of Delaware will govern all questions concerning the construction, validity and interpretation of this Plan, without regard to that state's conflict of laws rules.

13. DEFINITIONS. As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

(a) "***Affiliate***" means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405 of the Securities Act. The Board will have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(b) "***Award***" means a Stock Award or a Performance Cash Award.

(c) "***Award Agreement***" means a written agreement between the Company and a Participant evidencing the terms and conditions of an Award.

(d) "***Board***" means the Board of Directors of the Company.

(e) "***Capitalization Adjustment***" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Stock Award after the Adoption Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large non-recurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(f) ***"Capital Stock"*** means each and every class of common stock of the Company, regardless of the number of votes per share.

(g) "***Cause***" will have the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any one or more of the following events: (i) the Participant's commission of any felony or any crime involving fraud, dishonesty or moral turpitude; (ii) the Participant's attempted commission of or participation in a fraud or act of dishonesty against the Company that results in (or might have reasonably resulted in) material harm to the business of the Company; (iii) the Participant's intentional, material violation of any contract or agreement between the Participant and the Company or any statutory duty that the Participant owes to the Company; or (iv) the Participant's unauthorized use or disclosure of the Company's confidential information or trade secrets; or (v) the Participant's conduct that constitutes gross insubordination, incompetence or habitual neglect of duties and that results in (or might have reasonably resulted in) material harm to the business of the Company. The determination that a termination of the Participant's Continuous Service is either for Cause or without Cause will be made by the Company, in its sole discretion. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company or the Participant for any other purpose.

(h) "***Change in Control***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company; (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities; or (C) solely because the level of Ownership held by any Exchange Act Person (the "***Subject Person***") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(iv) individuals who, on the date the Plan is adopted by the Board, are members of the Board (the "***Incumbent Board***") cease for any reason to constitute at least a majority of the members of the Board; *provided*, *however*, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Plan, be considered as a member of the Incumbent Board.

For purposes of determining voting power under the term Change in Control, voting power shall be calculated by assuming the conversion of all equity securities convertible (immediately or at some future time) into shares entitled to vote, but not assuming the exercise of any warrant or right to subscribe to or purchase those shares. In addition, (A) the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, (B) the term Change in Control will not include a change in the voting power of any one or more stockholders as a result of the conversion of any class of the Company's securities into another class of the Company's securities having a different number of votes per share pursuant to the conversion provisions set forth in the Company's Amended and Restated Certificate of Incorporation, and (C) the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant will supersede the foregoing definition with respect to Awards subject to such agreement; *provided*, *however*, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition will apply. If required for compliance with Section 409A of the Code, in no event will a Change in Control be deemed to have occurred if such transaction is not also a "change in the ownership or effective control of" the Company or "a change in the ownership of a substantial portion of the assets of" the Company as determined under Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder). The Board may, in its sole discretion and without a Participant's consent, amend the definition of "Change in Control" to conform to the definition of "Change in Control" under Section 409A of the Code, and the regulations thereunder.

(i) "***Code***" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(j) "***Committee***" means a committee of one or more Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

(k) "***Common Stock***" means, as of the IPO Date, the common stock of the Company, having one vote per share.

(l) "***Company***" means FibroGen, Inc., a Delaware corporation.

(m) "***Consultant***" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a "Consultant" for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form

S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company's securities to such person.

(n) "***Continuous Service***" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, will not terminate a Participant's Continuous Service; *provided*, *however*, that if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board, in its sole discretion, such Participant's Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting in an Award only to such extent as may be provided in the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law. In addition, to the extent required for exemption from or compliance with Section 409A of the Code, the determination of whether there has been a termination of Continuous Service will be made, and such term will be construed, in a manner that is consistent with the definition of "separation from service" as defined under Treasury Regulation Section 1.409A-1(h) (without regard to any alternative definition thereunder).

(o) "***Corporate Transaction***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) the consummation of a sale or other disposition of all or substantially all, as determined by the Board, in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) the consummation of a sale or other disposition of at least 90% of the outstanding securities of the Company;

(iii) the consummation of a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) the consummation of a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

To the extent required for compliance with Section 409A of the Code, in no event will an event be deemed a Corporate Transaction if such transaction is not also a "change in the ownership or effective control of" the Company or "a change in the ownership of a substantial portion of the assets of" the Company as determined under Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder).

(p) "***Covered Employee***" will have the meaning provided in Section 162(m)(3) of the Code.

(q) "***Director***" means a member of the Board.

(r) "***Disability***" means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than 12 months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(s) "***Effective Date***" means the IPO Date.

(t) "***Employee***" means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan.

(u) "***Entity***" means a corporation, partnership, limited liability company or other entity.

(v) "***Exchange Act***" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(w) "***Exchange Act Person***" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities.

(x) "***Fair Market Value***" means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock will be, unless otherwise determined by the Board, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

(ii) Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

(y) "***Incentive Stock Option***" means an option granted pursuant to Section 5 of the Plan that is intended to be, and qualifies as, an "incentive stock option" within the meaning of Section 422 of the Code.

(z) "***IPO Date***" means the date of the underwriting agreement between the Company and the underwriter(s) managing the initial public offering of the Common Stock, pursuant to which the Common Stock is priced for the initial public offering.

(aa) "***Non-Employee Director***" means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("***Regulation S-K***")), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3.

(bb) "***Nonstatutory Stock Option***" means any option granted pursuant to Section 5 of the Plan that does not qualify as an Incentive Stock Option.

(cc) "***Officer***" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

(dd) "***Option***" means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(ee) "***Option Agreement***" means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option grant. Each Option Agreement will be subject to the terms and conditions of the Plan.

(ff) "***Optionholder***" means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(gg) "***Other Stock Award***" means an award based in whole or in part by reference to the Common Stock which is granted pursuant to the terms and conditions of Section 6(d).

(hh) "***Other Stock Award Agreement***" means a written agreement between the Company and a holder of an Other Stock Award evidencing the terms and conditions of an Other Stock Award grant. Each Other Stock Award Agreement will be subject to the terms and conditions of the Plan.

(ii) "***Outside Director***" means a Director who either (i) is not a current employee of the Company or an "affiliated corporation" (within the meaning of Treasury Regulations promulgated under Section 162(m) of the Code), is not a former employee of the Company or an "affiliated corporation" who receives compensation for prior services (other than benefits under a tax-qualified retirement plan) during the taxable year, has not been an officer of the Company or an "affiliated corporation," and does not receive remuneration from the Company or an "affiliated corporation," either directly or indirectly, in any capacity other than as a Director, or (ii) is otherwise considered an "outside director" for purposes of Section 162(m) of the Code.

(jj) "***Own,***" "***Owned,***" "***Owner,***" "***Ownership***" A person or Entity will be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(kk) "***Parent***" means any corporation (other than the Company) in an unbroken chain of corporations ending with the Company, if each of the corporations other than the Company owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain. A corporation that attains the status of a Parent on a date after the adoption of the Plan shall be considered a Parent commencing as of such date.

(ll) "***Participant***" means a person to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.

(mm) "***Performance Cash Award***" means an award of cash granted pursuant to the terms and conditions of Section 6(c)(ii).

(nn) "***Performance Criteria***" means the one or more criteria that the Committee (which to the extent that an Award is intended to comply with Section 162(m) of the Code shall consist solely of two or more Outside Directors in accordance with Section 162(m) of the Code) will select for purposes of establishing the Performance Goals for a Performance Period. The Performance Criteria that will be used to establish such Performance Goals may be based on any one of, or combination of, the following as determined by the Committee (which to the extent that an Award is intended to comply with Section 162(m) of the Code shall consist solely of two or more Outside Directors in accordance with Section 162(m) of the Code): (i) earnings (including earnings per share and net earnings); (ii) earnings before interest, taxes and depreciation; (iii) earnings before interest, taxes, depreciation and amortization; (iv) earnings before interest, taxes, depreciation, amortization and legal settlements; (v) earnings before interest, taxes, depreciation, amortization, legal settlements and other income (expense); (vi) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense) and stock-based compensation; (vii) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation and changes in deferred revenue; (viii) total stockholder return; (ix) return on equity or average stockholder's equity; (x) return on assets, investment, or capital employed; (xi) stock price; (xii) margin (including gross margin); (xiii) income (before or after taxes); (xiv) operating income; (xv) operating income after taxes; (xvi) pre-tax profit; (xvii) operating cash flow; (xviii) sales or revenue targets; (xix) increases in revenue or product revenue; (xx) expenses and cost reduction goals; (xxi) improvement in or attainment of working capital levels; (xxii) economic value added (or an equivalent metric); (xxiii) market share; (xxiv) cash flow; (xxv) cash flow per share; (xxvi) share price performance; (xxvii) debt reduction; (xxviii) implementation or completion of projects or processes; (xxix) employee retention; (xxx) stockholders' equity; (xxxi) capital expenditures; (xxxii) debt levels; (xxxiii) operating profit or net operating profit; (xxxiv) workforce diversity; (xxxv) growth of net income or operating income; (xxxvi) billings; (xxxvii) bookings; (xxxviii) initiation or completion of phases of clinical trials and/or studies by specified dates; (xxxix) patient enrollment rates, (xxxx) budget management; (xxxxi) regulatory body approval with respect to products, studies and/or trials; (xxxxii) commercial launch of products; and (xxxxiii) to the extent that an Award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by the Board.

(oo) "***Performance Goals***" means, for a Performance Period, the one or more goals established by the Board for the Performance Period based upon the Performance Criteria. Performance Goals may be based on a Company-wide basis, with respect to one or more business units, divisions, Affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the Board (i) in the Award Agreement at the time the Award is granted or (ii) in such other document setting forth the Performance Goals at the time the Performance Goals are established, the Board will appropriately make adjustments in the method of calculating the attainment of Performance Goals for a Performance Period as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of any "extraordinary items" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by the Company achieved performance objectives at targeted levels during the balance of a Performance Period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of common stock of the Company by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under the Company's bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to expensed under generally accepted accounting principles; (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; (12) to exclude the effect of any other unusual, non-recurring gain or loss or other extraordinary item; (13) to exclude the effects of the timing of acceptance for review and/or approval of submissions to the Food and Drug Administration or any other regulatory body and (14) to exclude the effects of entering into or achieving milestones involved in licensing joint ventures. In addition, the Board retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of Performance Goals and to define the manner of calculating the Performance Criteria it selects to use for such Performance Period. Partial achievement of the specified criteria may result in the payment or vesting corresponding to the degree of achievement as specified in the Stock Award Agreement or the written terms of a Performance Cash Award.

(pp) “***Performance Period***” means the period of time selected by the Board over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant’s right to and the payment of a Stock Award or a Performance Cash Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of the Board.

(qq) “***Performance Stock Award***” means a Stock Award granted under the terms and conditions of Section 6(c)(i).

(rr) “***Plan***” means this FibroGen, Inc. 2014 Equity Incentive Plan.

(ss) “***Restricted Stock Award***” means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(a).

(tt) “***Restricted Stock Award Agreement***” means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. Each Restricted Stock Award Agreement will be subject to the terms and conditions of the Plan.

(uu) “***Restricted Stock Unit Award***” means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(b).

(vv) “***Restricted Stock Unit Award Agreement***” means a written agreement between the Company and a holder of a Restricted Stock Unit Award evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Agreement will be subject to the terms and conditions of the Plan.

(ww) “***Rule 16b-3***” means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(xx) “***Securities Act***” means the Securities Act of 1933, as amended.

(yy) “***Stock Appreciation Right***” or “***SAR***” means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 5.

(zz) “***Stock Appreciation Right Agreement***” means a written agreement between the Company and a holder of a Stock Appreciation Right evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Agreement will be subject to the terms and conditions of the Plan.

(aaa) “***Stock Award***” means any right to receive Common Stock granted under the Plan, including an Incentive Stock Option, a Nonstatutory Stock Option, a Restricted Stock Award, a

Restricted Stock Unit Award, a Stock Appreciation Right, a Performance Stock Award or any Other Stock Award.

(bbb) “***Stock Award Agreement***” means a written agreement between the Company and a Participant evidencing the terms and conditions of a Stock Award grant. Each Stock Award Agreement will be subject to the terms and conditions of the Plan.

(ccc) “***Subsidiary***” means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

(ddd) “***Ten Percent Stockholder***” means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than ten percent of the total combined voting power of all classes of stock of the Company or any Affiliate.

Standard Form

FIBROGEN, INC.
STOCK OPTION GRANT NOTICE
(2014 EQUITY INCENTIVE PLAN)

FibroGen, Inc. (the "***Company***"), pursuant to its 2014 Equity Incentive Plan (the "***Plan***"), hereby grants to Optionholder an option to purchase the number of shares of the Company's Common Stock set forth below. This option is subject to all of the terms and conditions as set forth in this notice, in the Option Agreement, the Plan and the Notice of Exercise, all of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein but defined in the Plan or the Option Agreement will have the same definitions as in the Plan or the Option Agreement. If there is any conflict between the terms in this notice and the Plan, the terms of the Plan will control.

Optionholder: ______________________________
Date of Grant: ______________________________
Vesting Commencement Date: ______________________________
Number of Shares Subject to Option: ______________________________
Exercise Price (Per Share): ______________________________
Total Exercise Price: ______________________________
Expiration Date: ______________________________

Type of Grant: ☐ Incentive Stock Option[1] ☐ Nonstatutory Stock Option

Exercise Schedule: ☐ Same as Vesting Schedule ☐ Early Exercise Permitted

Vesting Schedule: [One-fourth **(**1/4th) of the shares vest one year after the Vesting Commencement Date; the balance of the shares vest in a series of twelve (12) successive substantially equal quarterly installments measured from the first anniversary of the Vesting Commencement Date, subject to Optionholder's Continuous Service as of each such vesting date.]

Payment: By one or a combination of the following items (described in the Option Agreement):

☒ By cash, check, bank draft or money order payable to the Company
☒ Pursuant to a Regulation T Program if the shares are publicly traded
☒ By delivery of already-owned shares if the shares are publicly traded
☐ If and only to the extent this option is a Nonstatutory Stock Option, and subject to the Company's consent at the time of exercise, by a "net exercise" arrangement

Additional Terms/Acknowledgements: Optionholder acknowledges receipt of, and understands and agrees to, this Stock Option Grant Notice, the Option Agreement and the Plan. Optionholder acknowledges and agrees that this Stock Option Grant Notice and the Option Agreement may not be modified, amended or revised except as provided in the Plan. Optionholder further acknowledges that as of the Date of Grant, this Stock Option Grant Notice, the Option Agreement, and the Plan set forth the entire understanding between Optionholder and the Company regarding this option award and supersede all prior oral and written agreements, promises and/or representations on that subject with the exception of (i) options previously granted and delivered to Optionholder, (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law and (iii) any written employment or severance arrangement that would provide for vesting acceleration of this option upon the terms and conditions set forth therein.

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[1] If this is an Incentive Stock Option, it (plus other outstanding Incentive Stock Options) cannot be first *exercisable* for more than $100,000 in value (measured by exercise price) in any calendar year. Any excess over $100,000 is a Nonstatutory Stock Option.

By accepting this option, Optionholder consents to receive such documents by electronic delivery and to participate in the Plan through an online or electronic system established and maintained by the Company or another third party designated by the Company.

FIBROGEN, INC.		**OPTIONHOLDER:**	
By:	______________________ Signature		______________________ Signature
Title:	______________________	Date:	______________________
Date:	______________________		

ATTACHMENTS: Option Agreement, 2014 Equity Incentive Plan and Notice of Exercise

ATTACHMENT I

OPTION AGREEMENT

FIBROGEN, INC.
2014 EQUITY INCENTIVE PLAN

OPTION AGREEMENT
(INCENTIVE STOCK OPTION OR NONSTATUTORY STOCK OPTION)

Pursuant to your Stock Option Grant Notice (“***Grant Notice***”) and this Option Agreement, FibroGen, Inc. (the “***Company***”) has granted you an option under its 2014 Equity Incentive Plan (the “***Plan***”) to purchase the number of shares of the Company’s Common Stock indicated in your Grant Notice at the exercise price indicated in your Grant Notice. The option is granted to you effective as of the date of grant set forth in the Grant Notice (the “***Date of Grant***”). If there is any conflict between the terms in this Option Agreement and the Plan, the terms of the Plan will control. Capitalized terms not explicitly defined in this Option Agreement or in the Grant Notice but defined in the Plan will have the same definitions as in the Plan.

The details of your option, in addition to those set forth in the Grant Notice and the Plan, are as follows:

1. VESTING. Subject to the provisions contained herein, your option will vest as provided in your Grant Notice. Vesting will cease upon the termination of your Continuous Service.

2. NUMBER OF SHARES AND EXERCISE PRICE. The number of shares of Common Stock subject to your option and your exercise price per share in your Grant Notice will be adjusted for Capitalization Adjustments.

3. EXERCISE RESTRICTION FOR NON-EXEMPT EMPLOYEES. If you are an Employee eligible for overtime compensation under the Fair Labor Standards Act of 1938, as amended (that is, a “***Non-Exempt Employee***”), and except as otherwise provided in the Plan, you may not exercise your option until you have completed at least six (6) months of Continuous Service measured from the Date of Grant, even if you have already been an employee for more than six (6) months. Consistent with the provisions of the Worker Economic Opportunity Act, you may exercise your option as to any vested portion prior to such six (6) month anniversary in the case of (i) your death or disability, (ii) a Corporate Transaction in which your option is not assumed, continued or substituted, (iii) a Change in Control or (iv) your termination of Continuous Service on your “retirement” (as defined in the Company’s benefit plans).

4. EXERCISE PRIOR TO VESTING (“EARLY EXERCISE”). If permitted in your Grant Notice (*i.e.*, the “Exercise Schedule” indicates “Early Exercise Permitted”) and subject to the provisions of your option, you may elect at any time that is both (i) during the period of your Continuous Service and (ii) during the term of your option, to exercise all or part of your option, including the unvested portion of your option; *provided, however,* that:

(a) a partial exercise of your option will be deemed to cover first vested shares of Common Stock and then the earliest vesting installment of unvested shares of Common Stock;

(b) any shares of Common Stock so purchased from installments that have not vested as of the date of exercise will be subject to the purchase option in favor of the Company as described in the Company's form of Early Exercise Stock Purchase Agreement;

(c) you will enter into the Company's form of Early Exercise Stock Purchase Agreement with a vesting schedule that will result in the same vesting as if no early exercise had occurred; and

(d) if your option is an Incentive Stock Option, then, to the extent that the aggregate Fair Market Value (determined at the Date of Grant) of the shares of Common Stock with respect to which your option plus all other Incentive Stock Options you hold are exercisable for the first time by you during any calendar year (under all plans of the Company and its Affiliates) exceeds one hundred thousand dollars ($100,000), your option(s) or portions thereof that exceed such limit (according to the order in which they were granted) will be treated as Nonstatutory Stock Options.

5. METHOD OF PAYMENT. You must pay the full amount of the exercise price for the shares you wish to exercise. You may pay the exercise price in cash or by check, bank draft or money order payable to the Company or in any other manner permitted by your Grant Notice, which may include one or more of the following:

(a) Provided that at the time of exercise the Common Stock is publicly traded, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds. This manner of payment is also known as a "broker-assisted exercise", "same day sale", or "sell to cover".

(b) Provided that at the time of exercise the Common Stock is publicly traded, by delivery to the Company (either by actual delivery or attestation) of already-owned shares of Common Stock that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. "Delivery" for these purposes, in the sole discretion of the Company at the time you exercise your option, will include delivery to the Company of your attestation of ownership of such shares of Common Stock in a form approved by the Company. You may not exercise your option by delivery to the Company of Common Stock if doing so would violate the provisions of any law, regulation or agreement restricting the redemption of the Company's stock.

(c) If this option is a Nonstatutory Stock Option, subject to the consent of the Company at the time of exercise, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issued upon exercise of your option by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price. You must pay any remaining balance of the aggregate exercise price not satisfied by the "net exercise" in cash or other permitted form of payment. Shares of Common Stock will no longer be outstanding under your option and will not be exercisable thereafter if those shares (i) are used to pay the exercise price pursuant to the "net exercise," (ii) are delivered to you as a result of such exercise, and (iii) are withheld to satisfy your tax withholding obligations.

6. WHOLE SHARES. You may exercise your option only for whole shares of Common Stock.

7. SECURITIES LAW COMPLIANCE. In no event may you exercise your option unless the shares of Common Stock issuable upon exercise are then registered under the Securities Act or, if not registered, the Company has determined that your exercise and the issuance of the shares would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with all other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations (including any restrictions on exercise required for compliance with Treas. Reg. 1.401(k)-1(d)(3), if applicable).

8. TERM. You may not exercise your option before the Date of Grant or after the expiration of the option's term. The term of your option expires, subject to the provisions of Section 5(h) of the Plan, upon the earliest of the following:

(a) immediately upon the date on which the event giving rise to your termination of Continuous Service for Cause occurs (or, if required by law, the date of termination of Continuous Service for Cause);

(b) three (3) months after the termination of your Continuous Service for any reason other than Cause, your Disability or your death (except as otherwise provided in Section 8(d) below); *provided*, *however*, that if during any part of such three (3) month period your option is not exercisable solely because of the condition set forth in the section above relating to "Securities Law Compliance," your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service; *provided further*, if during any part of such three (3) month period, the sale of any Common Stock received upon exercise of your option would violate the Company's insider trading policy, then your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service during which the sale of the Common Stock received upon exercise of your option would not be in violation of the Company's insider trading policy. Notwithstanding the foregoing, if (i) you are a Non-Exempt Employee, (ii) your Continuous Service terminates within six (6) months after the Date of Grant, and (iii) you have vested in a portion of your option at the time of your termination of Continuous Service, your option will not expire until the earlier of (x) the later of (A) the date that is seven (7) months after the Date of Grant, and (B) the date that is three (3) months after the termination of your Continuous Service, and (y) the Expiration Date;

(c) twelve (12) months after the termination of your Continuous Service due to your Disability (except as otherwise provided in Section 8(d)) below;

(d) eighteen (18) months after your death if you die either during your Continuous Service or within three (3) months after your Continuous Service terminates for any reason other than Cause or Disability;

(e) the Expiration Date indicated in your Grant Notice; or

(f) the day before the tenth (10th) anniversary of the Date of Grant.

If your option is an Incentive Stock Option, note that to obtain the federal income tax advantages associated with an Incentive Stock Option, the Code requires that at all times beginning on the Date of Grant and ending on the day three (3) months before the date of your option's exercise, you must be an employee of the Company or an Affiliate, except in the event of your death or Disability. The Company has provided for extended exercisability of your option under certain circumstances for your benefit but cannot guarantee that your option will necessarily be treated as an Incentive Stock Option if you continue to provide services to the Company or an Affiliate as a Consultant or Director after your employment terminates or if you otherwise exercise your option more than three (3) months after the date your employment with the Company or an Affiliate terminates.

9. EXERCISE.

(a) You may exercise the vested portion of your option (and the unvested portion of your option if your Grant Notice so permits) during its term by (i) delivering a Notice of Exercise (in a form designated by the Company) or completing such other documents and/or procedures designated by the Company for exercise and (ii) paying the exercise price and any applicable withholding taxes to the Company's Secretary, stock plan administrator, or such other person as the Company may designate, together with such additional documents as the Company may then require.

(b) By exercising your option you agree that, as a condition to any exercise of your option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any tax withholding obligation of the Company arising by reason of (i) the exercise of your option, (ii) the lapse of any substantial risk of forfeiture to which the shares of Common Stock are subject at the time of exercise, or (iii) the disposition of shares of Common Stock acquired upon such exercise.

(c) If your option is an Incentive Stock Option, by exercising your option you agree that you will notify the Company in writing within fifteen (15) days after the date of any disposition of any of the shares of the Common Stock issued upon exercise of your option that occurs within two (2) years after the Date of Grant or within one (1) year after such shares of Common Stock are transferred upon exercise of your option.

10. TRANSFERABILITY. Except as otherwise provided in this Section 10, your option is not transferable, except by will or by the laws of descent and distribution, and is exercisable during your life only by you.

(a) Certain Trusts. Upon receiving written permission from the Board or its duly authorized designee, you may transfer your option to a trust if you are considered to be the sole beneficial owner (determined under Section 671 of the Code and applicable state law) while the option is held in the trust. You and the trustee must enter into transfer and other agreements required by the Company.

(b) Domestic Relations Orders. Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your option pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by Treasury Regulation 1.421-1(b)(2) that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this option with the Company prior to finalizing the domestic relations order or marital settlement agreement to help ensure the required information is contained within the domestic relations order or marital settlement agreement. If this option is an Incentive Stock Option, this option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

(c) Beneficiary Designation. Upon receiving written permission from the Board or its duly authorized designee, you may, by delivering written notice to the Company, in a form approved by the Company and any broker designated by the Company to handle option exercises, designate a third party who, on your death, will thereafter be entitled to exercise this option and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, your executor or administrator of your estate will be entitled to exercise this option and receive, on behalf of your estate, the Common Stock or other consideration resulting from such exercise.

11. OPTION NOT A SERVICE CONTRACT. Your option is not an employment or service contract, and nothing in your option will be deemed to create in any way whatsoever any obligation on your part to continue in the employ of the Company or an Affiliate, or of the Company or an Affiliate to continue your employment. In addition, nothing in your option will obligate the Company or an Affiliate, their respective stockholders, boards of directors, officers or employees to continue any relationship that you might have as a Director or Consultant for the Company or an Affiliate.

12. WITHHOLDING OBLIGATIONS.

(a) At the time you exercise your option, in whole or in part, and at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for (including by means of a "same day sale" pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board to the extent permitted by the Company), any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise of your option.

(b) If this option is a Nonstatutory Stock Option, then upon your request and subject to approval by the Company, and compliance with any applicable legal conditions or restrictions, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon the exercise of your option a number of whole shares of Common Stock having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the minimum amount of tax required to be withheld by law (or such lower amount as may be necessary to avoid classification of your option as a liability for financial accounting purposes). If the date of determination of any tax withholding obligation is deferred to a date later than the date of exercise of your option, share withholding pursuant to the preceding sentence shall not be permitted unless you make a proper and timely election under Section 83(b) of the Code, covering the aggregate number of shares of Common Stock acquired upon such exercise with respect to which such determination is otherwise deferred, to accelerate the determination of such tax withholding obligation to the date of exercise of your option. Notwithstanding the filing of such election, shares of Common Stock shall be withheld solely from fully vested shares of Common Stock determined as of the date of exercise of your option that are otherwise issuable to you upon such exercise. Any adverse consequences to you arising in connection with such share withholding procedure shall be your sole responsibility.

(c) You may not exercise your option unless the tax withholding obligations of the Company and/or any Affiliate are satisfied. Accordingly, you may not be able to exercise your option when desired even though your option is vested, and the Company will have no obligation to issue a certificate for such shares of Common Stock or release such shares of Common Stock from any escrow provided for herein, if applicable, unless such obligations are satisfied.

13. TAX CONSEQUENCES. You hereby agree that the Company does not have a duty to design or administer the Plan or its other compensation programs in a manner that minimizes your tax liabilities. You will not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from your option or your other compensation. In particular, you acknowledge that this option is exempt from Section 409A of the Code only if the exercise price per share specified in the Grant Notice is at least equal to the “fair market value” per share of the Common Stock on the Date of Grant and there is no other impermissible deferral of compensation associated with the option.

14. NOTICES. Any notices provided for in your option or the Plan will be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this option by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this option, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

15. GOVERNING PLAN DOCUMENT. Your option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. If there is any conflict between the provisions of your option and those of the Plan, the provisions of the Plan will control. In addition, your option (and any compensation paid or shares issued under your option) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

16. OTHER DOCUMENTS. You hereby acknowledge receipt of and the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company's policy permitting certain individuals to sell shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

17. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS. The value of this option will not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

18. VOTING RIGHTS. You will not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this option until such shares are issued to you. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this option, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

19. SEVERABILITY. If all or any part of this Option Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Option Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Option Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

20. MISCELLANEOUS.

(a) The rights and obligations of the Company under your option will be transferable to any one or more persons or entities, and all covenants and agreements hereunder will inure to the benefit of, and be enforceable by the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your option.

(c) You acknowledge and agree that you have reviewed your option in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your option, and fully understand all provisions of your option.

(d) This Option Agreement will be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Option Agreement will be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

* * *

This Option Agreement will be deemed to be signed by you upon the signing by you of the Grant Notice to which it is attached.

ATTACHMENT II

2014 EQUITY INCENTIVE PLAN

ATTACHMENT III

NOTICE OF EXERCISE

NOTICE OF EXERCISE

FibroGen, Inc.
Attention: [Stock Plan Administrator]
409 Illinois St.
San Francisco, CA 94158

Date of Exercise:

This constitutes notice to FibroGen, Inc. (the “***Company***”) under my stock option that I elect to purchase the below number of shares of Common Stock of the Company (the “***Shares***”) for the price set forth below.

Type of option (check one):	Incentive ☐	Nonstatutory ☐
Stock option dated:		
Number of Shares as to which option is exercised:		
Certificates to be issued in name of:		
Total exercise price:	$	$
Cash payment delivered herewith:	$	$
Value of Shares delivered herewith:	$	$
Value of Shares pursuant to net exercise:	$	$
Regulation T Program (cashless exercise):	$	$

By this exercise, I agree (i) to provide such additional documents as you may require pursuant to the terms of the FibroGen, Inc. 2014 Equity Incentive Plan, (ii) to provide for the payment by me to you (in the manner designated by you) of your withholding obligation, if any, relating to the exercise of this option, and (iii) if this exercise relates to an Incentive Stock Option, to notify you in writing within fifteen (15) days after the date of any disposition of any of the Shares issued upon exercise of this option that occurs within two (2) years after the date of grant of this option or within one (1) year after such Shares are issued upon exercise of this option.

[Signature Follows]

Very truly yours,

Signature

Print Name

Change in Control Acceleration

FIBROGEN, INC.
STOCK OPTION GRANT NOTICE
(2014 EQUITY INCENTIVE PLAN)

FibroGen, Inc. (the “***Company***”), pursuant to its 2014 Equity Incentive Plan (the “***Plan***”), hereby grants to Optionholder an option to purchase the number of shares of the Company’s Common Stock set forth below. This option is subject to all of the terms and conditions as set forth in this notice, in the Option Agreement, the Plan and the Notice of Exercise, all of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein but defined in the Plan or the Option Agreement will have the same definitions as in the Plan or the Option Agreement. If there is any conflict between the terms in this notice and the Plan, the terms of the Plan will control.

Optionholder: ______________________________
Date of Grant: ______________________________
Vesting Commencement Date: ______________________________
Number of Shares Subject to Option: ______________________________
Exercise Price (Per Share): ______________________________
Total Exercise Price: ______________________________
Expiration Date: ______________________________

Type of Grant: ☐ Incentive Stock Option[1] ☐ Nonstatutory Stock Option

Exercise Schedule: ☐ Same as Vesting Schedule ☐ Early Exercise Permitted

Vesting Schedule: [Subject to Section 9 of the Option Agreement, one-fourth **(**1/4th) of the shares vest one year after the Vesting Commencement Date; the balance of the shares vest in a series of twelve (12) successive substantially equal quarterly installments measured from the first anniversary of the Vesting Commencement Date, subject to Optionholder’s Continuous Service as of each such vesting date.]

Payment: By one or a combination of the following items (described in the Option Agreement):

☒ By cash, check, bank draft or money order payable to the Company
☒ Pursuant to a Regulation T Program if the shares are publicly traded
☒ By delivery of already-owned shares if the shares are publicly traded
☐ If and only to the extent this option is a Nonstatutory Stock Option, and subject to the Company’s consent at the time of exercise, by a “net exercise” arrangement

Additional Terms/Acknowledgements: Optionholder acknowledges receipt of, and understands and agrees to, this Stock Option Grant Notice, the Option Agreement and the Plan. Optionholder acknowledges and agrees that this Stock Option Grant Notice and the Option Agreement may not be modified, amended or revised except as provided in the Plan. Optionholder further acknowledges that as of the Date of Grant, this Stock Option Grant Notice, the Option Agreement, and the Plan set forth the entire understanding between Optionholder and the Company regarding this option award and supersede all prior oral and written agreements, promises and/or representations on that subject with the exception of (i) options previously granted and delivered to Optionholder, (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law and (iii) any written employment or severance arrangement that would provide for vesting acceleration of this option upon the terms and conditions set forth therein.

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[1] If this is an Incentive Stock Option, it (plus other outstanding Incentive Stock Options) cannot be first *exercisable* for more than $100,000 in value (measured by exercise price) in any calendar year. Any excess over $100,000 is a Nonstatutory Stock Option.

By accepting this option, Optionholder consents to receive such documents by electronic delivery and to participate in the Plan through an online or electronic system established and maintained by the Company or another third party designated by the Company.

FIBROGEN, INC.	**OPTIONHOLDER:**
By: ____________________ Signature	____________________ Signature
Title: ____________________	Date: ____________________
Date: ____________________	

ATTACHMENTS: Option Agreement, 2014 Equity Incentive Plan and Notice of Exercise

ATTACHMENT I

OPTION AGREEMENT

FIBROGEN, INC.
2014 EQUITY INCENTIVE PLAN

OPTION AGREEMENT
(INCENTIVE STOCK OPTION OR NONSTATUTORY STOCK OPTION)

Pursuant to your Stock Option Grant Notice (“***Grant Notice***”) and this Option Agreement, FibroGen, Inc. (the “***Company***”) has granted you an option under its 2014 Equity Incentive Plan (the “***Plan***”) to purchase the number of shares of the Company’s Common Stock indicated in your Grant Notice at the exercise price indicated in your Grant Notice. The option is granted to you effective as of the date of grant set forth in the Grant Notice (the “***Date of Grant***”). If there is any conflict between the terms in this Option Agreement and the Plan, the terms of the Plan will control. Capitalized terms not explicitly defined in this Option Agreement or in the Grant Notice but defined in the Plan will have the same definitions as in the Plan.

The details of your option, in addition to those set forth in the Grant Notice and the Plan, are as follows:

1. VESTING. Subject to the provisions contained herein, your option will vest as provided in your Grant Notice. Vesting will cease upon the termination of your Continuous Service.

2. NUMBER OF SHARES AND EXERCISE PRICE. The number of shares of Common Stock subject to your option and your exercise price per share in your Grant Notice will be adjusted for Capitalization Adjustments.

3. EXERCISE RESTRICTION FOR NON-EXEMPT EMPLOYEES. If you are an Employee eligible for overtime compensation under the Fair Labor Standards Act of 1938, as amended (that is, a “***Non-Exempt Employee***”), and except as otherwise provided in the Plan, you may not exercise your option until you have completed at least six (6) months of Continuous Service measured from the Date of Grant, even if you have already been an employee for more than six (6) months. Consistent with the provisions of the Worker Economic Opportunity Act, you may exercise your option as to any vested portion prior to such six (6) month anniversary in the case of (i) your death or disability, (ii) a Corporate Transaction in which your option is not assumed, continued or substituted, (iii) a Change in Control or (iv) your termination of Continuous Service on your “retirement” (as defined in the Company’s benefit plans).

4. EXERCISE PRIOR TO VESTING (“EARLY EXERCISE”). If permitted in your Grant Notice (*i.e.*, the “Exercise Schedule” indicates “Early Exercise Permitted”) and subject to the provisions of your option, you may elect at any time that is both (i) during the period of your Continuous Service and (ii) during the term of your option, to exercise all or part of your option, including the unvested portion of your option; *provided*, *however*, that:

(a) a partial exercise of your option will be deemed to cover first vested shares of Common Stock and then the earliest vesting installment of unvested shares of Common Stock;

(b) any shares of Common Stock so purchased from installments that have not vested as of the date of exercise will be subject to the purchase option in favor of the Company as described in the Company's form of Early Exercise Stock Purchase Agreement;

(c) you will enter into the Company's form of Early Exercise Stock Purchase Agreement with a vesting schedule that will result in the same vesting as if no early exercise had occurred; and

(d) if your option is an Incentive Stock Option, then, to the extent that the aggregate Fair Market Value (determined at the Date of Grant) of the shares of Common Stock with respect to which your option plus all other Incentive Stock Options you hold are exercisable for the first time by you during any calendar year (under all plans of the Company and its Affiliates) exceeds one hundred thousand dollars ($100,000), your option(s) or portions thereof that exceed such limit (according to the order in which they were granted) will be treated as Nonstatutory Stock Options.

5. METHOD OF PAYMENT. You must pay the full amount of the exercise price for the shares you wish to exercise. You may pay the exercise price in cash or by check, bank draft or money order payable to the Company or in any other manner permitted by your Grant Notice, which may include one or more of the following:

(a) Provided that at the time of exercise the Common Stock is publicly traded, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds. This manner of payment is also known as a "broker-assisted exercise", "same day sale", or "sell to cover".

(b) Provided that at the time of exercise the Common Stock is publicly traded, by delivery to the Company (either by actual delivery or attestation) of already-owned shares of Common Stock that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. "Delivery" for these purposes, in the sole discretion of the Company at the time you exercise your option, will include delivery to the Company of your attestation of ownership of such shares of Common Stock in a form approved by the Company. You may not exercise your option by delivery to the Company of Common Stock if doing so would violate the provisions of any law, regulation or agreement restricting the redemption of the Company's stock.

(c) If this option is a Nonstatutory Stock Option, subject to the consent of the Company at the time of exercise, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issued upon exercise of your option by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price. You must pay any remaining balance of the aggregate exercise price not satisfied by the “net exercise” in cash or other permitted form of payment. Shares of Common Stock will no longer be outstanding under your option and will not be exercisable thereafter if those shares (i) are used to pay the exercise price pursuant to the “net exercise,” (ii) are delivered to you as a result of such exercise, and (iii) are withheld to satisfy your tax withholding obligations.

6. WHOLE SHARES. You may exercise your option only for whole shares of Common Stock.

7. SECURITIES LAW COMPLIANCE. In no event may you exercise your option unless the shares of Common Stock issuable upon exercise are then registered under the Securities Act or, if not registered, the Company has determined that your exercise and the issuance of the shares would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with all other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations (including any restrictions on exercise required for compliance with Treas. Reg. 1.401(k)-1(d)(3), if applicable).

8. TERM. You may not exercise your option before the Date of Grant or after the expiration of the option’s term. The term of your option expires, subject to the provisions of Section 5(h) of the Plan, upon the earliest of the following:

(a) immediately upon the date on which the event giving rise to your termination of Continuous Service for Cause occurs (or, if required by law, the date of termination of Continuous Service for Cause);

(b) three (3) months after the termination of your Continuous Service for any reason other than Cause, your Disability or your death (except as otherwise provided in Section 8(d) below); *provided*, *however*, that if during any part of such three (3) month period your option is not exercisable solely because of the condition set forth in the section above relating to “Securities Law Compliance,” your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service; *provided further*, if during any part of such three (3) month period, the sale of any Common Stock received upon exercise of your option would violate the Company’s insider trading policy, then your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service during which the sale of the Common Stock received upon exercise of your option would not be in violation of the Company’s insider trading policy. Notwithstanding the foregoing, if (i) you are a Non-Exempt Employee, (ii) your Continuous Service terminates within six (6) months after the Date of Grant, and (iii) you have vested in a portion of your option at the time of your termination of Continuous Service, your option will not expire until the earlier of (x) the later of (A) the date that is seven (7) months after the Date of Grant, and (B) the date that is three (3) months after the termination of your Continuous Service, and (y) the Expiration Date;

(c) twelve (12) months after the termination of your Continuous Service due to your Disability (except as otherwise provided in Section 8(d)) below;

(d) eighteen (18) months after your death if you die either during your Continuous Service or within three (3) months after your Continuous Service terminates for any reason other than Cause or Disability;

(e) the Expiration Date indicated in your Grant Notice; or

(f) the day before the tenth (10th) anniversary of the Date of Grant.

If your option is an Incentive Stock Option, note that to obtain the federal income tax advantages associated with an Incentive Stock Option, the Code requires that at all times beginning on the Date of Grant and ending on the day three (3) months before the date of your option's exercise, you must be an employee of the Company or an Affiliate, except in the event of your death or Disability. The Company has provided for extended exercisability of your option under certain circumstances for your benefit but cannot guarantee that your option will necessarily be treated as an Incentive Stock Option if you continue to provide services to the Company or an Affiliate as a Consultant or Director after your employment terminates or if you otherwise exercise your option more than three (3) months after the date your employment with the Company or an Affiliate terminates.

9. VESTING UPON A CHANGE IN CONTROL.

(a) In the event of a Change in Control (as defined in the Plan, except as set forth in Section 9(c) below), if your option is assumed, continued or otherwise substituted in the Change in Control, and your employment is involuntarily terminated by the Company or its successor corporation without Cause (and other than due to your death or disability) within twelve (12) months following the consummation of the Change in Control, or if you terminate your employment due to a Constructive Termination (as defined below) within twelve (12) months following the consummation of the Change in Control, the vesting and exercisability of the unvested portion of your option will accelerate in full on the date of your termination. Notwithstanding the foregoing, in the event of a Change in Control, if your option is not assumed, continued or otherwise substituted in the Change in Control transaction, the unvested portion of your option will vest and become exercisable as of immediately prior to the consummation of the Change in Control.

(b) For purposes of this Agreement, "***Constructive Termination***" means your termination of employment following the occurrence, without your written consent, of any one of the following events:

(i) a substantial reduction in your duties or responsibilities (and not simply a change in title or reporting relationships) in effect immediately prior to the effective date of the Change in Control; *provided*, *however*, that it shall not be a "Constructive Termination" if the Company is retained as a separate legal entity or business unit following the effective date of the Change in Control and you hold the same position in such legal entity or business unit as you held before the effective date of the Change in Control;

(ii) a material reduction by the Company (or its successor corporation) in your annual base salary, as in effect on the effective date of the Change in Control or as increased thereafter;

(iii) any failure by the Company (or its successor corporation) to continue in effect any benefit plan or program, including incentive plans or plans with respect to the receipt of securities of the Company, in which you were participating immediately prior to the effective date of the Change in Control (hereinafter referred to as "***Benefit Plans***"), or the taking of any action by the Company (or its successor corporation) that would adversely affect your participation in or reduce your benefits under the Benefit Plans or deprive you of any fringe benefit that you enjoyed immediately prior to the effective date of the Change in Control; *provided*, *however*, that a Constructive Termination shall not be deemed to have occurred if the Company (or its successor corporation) provides for your participation in benefit plans and programs that, taken as a whole, are comparable to the Benefit Plans;

(iv) a relocation of your business office location more than fifty (50) miles from the location at which you performed your duties as of the effective date of the Change in Control, except for required travel by you on the Company's (or its successor corporation's) business to an extent substantially consistent with your business travel obligations prior to the effective date of the Change in Control; or

(v) a material breach by the Company (or its successor corporation) of any provision of any material agreement between you and the Company concerning the terms and conditions of your employment.

(c) For purposes of this Agreement, notwithstanding anything to the contrary contained in the Plan, the term "Change in Control" shall be defined as in the Plan, except that the term shall not include the implementation of anti-takeover measures, including, without limitation, a recapitalization or reorganization of the Company's capital structure, whether by merger, amendment of the Company's certificate of incorporation or certificate(s) of designations, or otherwise, solely for the purposes of the implementation of a dual class stock structure, in which one class of securities has greater voting power on matters involving a change of control and other related issues, irrespective of (i) whether such anti-takeover measure includes a voting agreement or a proxy with respect to the Company's shares; or (ii) whether such recapitalization, reorganization or anti-takeover measure results in a change in Ownership of greater than fifty percent (50%) of the total voting power of the Company.

10. EXERCISE.

(a) You may exercise the vested portion of your option (and the unvested portion of your option if your Grant Notice so permits) during its term by (i) delivering a Notice of Exercise (in a form designated by the Company) or completing such other documents and/or procedures designated by the Company for exercise and (ii) paying the exercise price and any applicable withholding taxes to the Company's Secretary, stock plan administrator, or such other person as the Company may designate, together with such additional documents as the Company may then require.

(b) By exercising your option you agree that, as a condition to any exercise of your option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any tax withholding obligation of the Company arising by reason of (i) the exercise of your option, (ii) the lapse of any substantial risk of forfeiture to which the shares of Common Stock are subject at the time of exercise, or (iii) the disposition of shares of Common Stock acquired upon such exercise.

(c) If your option is an Incentive Stock Option, by exercising your option you agree that you will notify the Company in writing within fifteen (15) days after the date of any disposition of any of the shares of the Common Stock issued upon exercise of your option that occurs within two (2) years after the Date of Grant or within one (1) year after such shares of Common Stock are transferred upon exercise of your option.

11. TRANSFERABILITY. Except as otherwise provided in this Section 11, your option is not transferable, except by will or by the laws of descent and distribution, and is exercisable during your life only by you.

(a) Certain Trusts. Upon receiving written permission from the Board or its duly authorized designee, you may transfer your option to a trust if you are considered to be the sole beneficial owner (determined under Section 671 of the Code and applicable state law) while the option is held in the trust. You and the trustee must enter into transfer and other agreements required by the Company.

(b) Domestic Relations Orders. Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your option pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by Treasury Regulation 1.421-1(b)(2) that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this option with the Company prior to finalizing the domestic relations order or marital settlement agreement to help ensure the required information is contained within the domestic relations order or marital settlement agreement. If this option is an Incentive Stock Option, this option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

(c) Beneficiary Designation. Upon receiving written permission from the Board or its duly authorized designee, you may, by delivering written notice to the Company, in a form approved by the Company and any broker designated by the Company to handle option exercises, designate a third party who, on your death, will thereafter be entitled to exercise this option and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, your executor or administrator of your estate will be entitled to exercise this option and receive, on behalf of your estate, the Common Stock or other consideration resulting from such exercise.

12. OPTION NOT A SERVICE CONTRACT. Your option is not an employment or service contract, and nothing in your option will be deemed to create in any way whatsoever any obligation on your part to continue in the employ of the Company or an Affiliate, or of the Company or an Affiliate to continue your employment. In addition, nothing in your option will obligate the Company or an Affiliate, their respective stockholders, boards of directors, officers or employees to continue any relationship that you might have as a Director or Consultant for the Company or an Affiliate.

13. WITHHOLDING OBLIGATIONS.

(a) At the time you exercise your option, in whole or in part, and at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for (including by means of a "same day sale" pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board to the extent permitted by the Company), any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise of your option.

(b) If this option is a Nonstatutory Stock Option, then upon your request and subject to approval by the Company, and compliance with any applicable legal conditions or restrictions, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon the exercise of your option a number of whole shares of Common Stock having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the minimum amount of tax required to be withheld by law (or such lower amount as may be necessary to avoid classification of your option as a liability for financial accounting purposes). If the date of determination of any tax withholding obligation is deferred to a date later than the date of exercise of your option, share withholding pursuant to the preceding sentence shall not be permitted unless you make a proper and timely election under Section 83(b) of the Code, covering the aggregate number of shares of Common Stock acquired upon such exercise with respect to which such determination is otherwise deferred, to accelerate the determination of such tax withholding obligation to the date of exercise of your option. Notwithstanding the filing of such election, shares of Common Stock shall be withheld solely from fully vested shares of Common Stock determined as of the date of exercise of your option that are otherwise issuable to you upon such exercise. Any adverse consequences to you arising in connection with such share withholding procedure shall be your sole responsibility.

(c) You may not exercise your option unless the tax withholding obligations of the Company and/or any Affiliate are satisfied. Accordingly, you may not be able to exercise your option when desired even though your option is vested, and the Company will have no obligation to issue a certificate for such shares of Common Stock or release such shares of Common Stock from any escrow provided for herein, if applicable, unless such obligations are satisfied.

14. TAX CONSEQUENCES. You hereby agree that the Company does not have a duty to design or administer the Plan or its other compensation programs in a manner that minimizes your tax liabilities. You will not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from your option or your other compensation. In particular, you acknowledge that this option is exempt from Section 409A of the Code only if the exercise price per share specified in the Grant Notice is at least equal to the "fair market value" per share of the Common Stock on the Date of Grant and there is no other impermissible deferral of compensation associated with the option.

15. NOTICES. Any notices provided for in your option or the Plan will be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the

United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this option by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this option, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

16. GOVERNING PLAN DOCUMENT. Your option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. If there is any conflict between the provisions of your option and those of the Plan, the provisions of the Plan will control. In addition, your option (and any compensation paid or shares issued under your option) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

17. OTHER DOCUMENTS. You hereby acknowledge receipt of and the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company's policy permitting certain individuals to sell shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

18. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS. The value of this option will not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

19. VOTING RIGHTS. You will not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this option until such shares are issued to you. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this option, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

20. SEVERABILITY. If all or any part of this Option Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Option Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Option Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

21. MISCELLANEOUS.

(a) The rights and obligations of the Company under your option will be transferable to any one or more persons or entities, and all covenants and agreements hereunder will inure to the benefit of, and be enforceable by the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your option.

(c) You acknowledge and agree that you have reviewed your option in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your option, and fully understand all provisions of your option.

(d) This Option Agreement will be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Option Agreement will be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

* * *

This Option Agreement will be deemed to be signed by you upon the signing by
you of the Grant Notice to which it is attached.

ATTACHMENT II

2014 EQUITY INCENTIVE PLAN

ATTACHMENT III

NOTICE OF EXERCISE

NOTICE OF EXERCISE

FibroGen, Inc.
Attention: [Stock Plan Administrator]
409 Illinois St.
San Francisco, CA 94158

Date of Exercise:

This constitutes notice to FibroGen, Inc. (the “***Company***”) under my stock option that I elect to purchase the below number of shares of Common Stock of the Company (the “***Shares***”) for the price set forth below.

Type of option (check one):	Incentive ☐	Nonstatutory ☐
Stock option dated:		
Number of Shares as to which option is exercised:		
Certificates to be issued in name of:		
Total exercise price:	$	$
Cash payment delivered herewith:	$	$
Value of Shares delivered herewith:	$	$
Value of Shares pursuant to net exercise:	$	$
Regulation T Program (cashless exercise):	$	$

By this exercise, I agree (i) to provide such additional documents as you may require pursuant to the terms of the FibroGen, Inc. 2014 Equity Incentive Plan, (ii) to provide for the payment by me to you (in the manner designated by you) of your withholding obligation, if any, relating to the exercise of this option, and (iii) if this exercise relates to an Incentive Stock Option, to notify you in writing within fifteen (15) days after the date of any disposition of any of the Shares issued upon exercise of this option that occurs within two (2) years after the date of grant of this option or within one (1) year after such Shares are issued upon exercise of this option.

[Signature Follows]

Very truly yours,

____
Signature

____
Print Name

FIBROGEN, INC.
RESTRICTED STOCK UNIT GRANT NOTICE
(2014 EQUITY INCENTIVE PLAN)

FibroGen, Inc. (the “***Company***”), pursuant to its 2014 Equity Incentive Plan (the “***Plan***”), hereby awards to Participant a Restricted Stock Unit Award for the number of shares of the Company’s Common Stock (“***Restricted Stock Units***”) set forth below (the “***Award***”). The Award is subject to all of the terms and conditions as set forth in this notice of grant (this “***Restricted Stock Unit Grant Notice***”) and in the Plan and the Restricted Stock Unit Award Agreement (the “***Award Agreement***”), which are incorporated herein in their entirety. Capitalized terms not otherwise defined herein shall have the meanings set forth in the Plan or the Award Agreement. In the event of any conflict between the terms in the Award Agreement and the Plan, the terms of the Plan shall control.

Participant: ______________________________
ID: ______________________________
Date of Grant: ______________________________
Grant Number: ______________________________
Vesting Commencement Date: ______________________________
Number of Restricted Stock Units/Shares: ______________________________

Vesting Schedule: Subject to Section 9(c) of the Plan, the shares subject to the Award shall vest as follows: [______________________], subject to Participant’s Continuous Service on each applicable vesting date.

Issuance Schedule: Subject to any change on a Capitalization Adjustment, one share of Common Stock will be issued for each Restricted Stock Unit that vests at the time set forth in Section 6 of the Award Agreement.

Additional Terms/Acknowledgements: Participant acknowledges receipt of, and understands and agrees to, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the acquisition of the Common Stock pursuant to the Award specified above and supersede all prior oral and written agreements on the terms of this Award with the exception, if applicable, of (i) the written employment agreement or offer letter agreement entered into between the Company and Participant specifying the terms that should govern this specific Award, and (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law.

* * *

By accepting this Award, Participant acknowledges having received and read the Restricted Stock Unit Grant Notice, the Award Agreement and the Plan and agrees to all of the terms and conditions set forth in these documents. Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

OTHER AGREEMENTS: ____

FIBROGEN, INC.		**PARTICIPANT**	
By:	____________________ Signature		____________________ Signature
Title:	____________________	Date:	____________________
Date:	____________________		

ATTACHMENTS: Award Agreement

FIBROGEN, INC.
2014 EQUITY INCENTIVE PLAN
RESTRICTED STOCK UNIT AWARD AGREEMENT

Pursuant to the Restricted Stock Unit Grant Notice (the "***Grant Notice***") and this Restricted Stock Unit Award Agreement (the "***Agreement***"), FibroGen, Inc. (the "***Company***") has awarded you ("***Participant***") a Restricted Stock Unit Award (this "***Award***") pursuant to Section 6(b) of the Company's 2014 Equity Incentive Plan (the "***Plan***") for the number of Restricted Stock Units/shares indicated in the Grant Notice. Capitalized terms not explicitly defined in this Agreement or the Grant Notice shall have the same meanings given to them in the Plan. The terms of your Award, in addition to those set forth in the Grant Notice, are as follows.

1. GRANT OF THE AWARD. This Award represents the right to be issued on a future date one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 below) as indicated in the Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the "***Account***") the number of Restricted Stock Units/shares of Common Stock subject to this Award. This Award was granted in consideration of your services to the Company.

2. VESTING. Subject to the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice, provided that vesting will cease upon the termination of your Continuous Service. Upon such termination of your Continuous Service, the Restricted Stock Units/shares of Common Stock credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in or to such underlying shares of Common Stock.

3. NUMBER OF SHARES. The number of Restricted Stock Units/shares subject to your Award may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan. Any additional Restricted Stock Units, shares, cash or other property that becomes subject to this Award pursuant to this Section 3, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Restricted Stock Units and shares covered by your Award. Notwithstanding the provisions of this Section 3, no fractional shares or rights for fractional shares of Common Stock shall be created pursuant to this Section 3. Any fraction of a share will be rounded down to the nearest whole share.

4. SECURITIES LAW COMPLIANCE. You may not be issued any Common Stock under your Award unless the shares of Common Stock underlying the Restricted Stock Units are either (i) then registered under the Securities Act, or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award must also comply with other applicable laws and regulations governing the Award, and you shall not receive such Common Stock if the Company determines that such receipt would not be in material compliance with such laws and regulations.

5. TRANSFER RESTRICTIONS. Prior to the time that shares of Common Stock have been delivered to you, you may not transfer, pledge, sell or otherwise dispose of this Award or the shares issuable in respect of your Award, except as expressly provided in this Section 5. For example, you may not use shares that may be issued in respect of your Restricted Stock Units as security for a loan. The restrictions on transfer set forth herein will lapse upon delivery to you of shares in respect of your vested Restricted Stock Units.

(a) Death. Your Award is transferable by will and by the laws of descent and distribution. At your death, vesting of your Award will cease and your executor or administrator of your estate shall be entitled to receive, on behalf of your estate, any Common Stock or other consideration that vested but was not issued before your death.

(b) Domestic Relations Orders. Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your right to receive the distribution of Common Stock or other consideration hereunder, pursuant to a domestic relations order or marital settlement agreement that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this Award with the Company's stock plan administrator prior to finalizing the domestic relations order or marital settlement agreement to verify that you may make such transfer, and if so, to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

6. DATE OF ISSUANCE.

(a) Subject to the satisfaction of the withholding obligations set forth in Section 11 of this Agreement and subject to Section 6(b) below, in the event that one or more Restricted Stock Units vests, the Company shall issue to you, on the applicable vesting date (subject to any adjustment under Section 3 above), one share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date; *provided*, that if such date falls on a date that is not a business day, delivery will instead occur on the next business day.

(b) Notwithstanding the foregoing, shares will be delivered on a date later than the applicable vesting date or its next following business day, if, to the extent applicable at a vesting date, (i) any shares covered by your Restricted Stock Units are scheduled to be delivered on a date (the "***Original Distribution Date***") that does not occur: (A) during an open "window period" applicable to you, as determined by the Company in accordance with the Company's then-effective policy on trading in Company securities (the "***Policy***"); (B) on a date on which you are permitted to sell shares of Common Stock pursuant to a written plan that meets the requirements of Rule 10b5-1 under the Exchange Act, as determined by the Company in accordance with the Policy; (C) on a date when you are otherwise permitted to sell shares of Common Stock on the open market; or (D) during any applicable lock-up period under any lock-up agreement or market standoff agreement covering shares of Common Stock held by you; and (ii) the Company elects not to satisfy its tax withholding obligations by withholding shares pursuant to one of the methods permitted under Section 11, withholding from other compensation otherwise payable to you by the Company, or by permitting you to pay your Withholding Taxes in cash, then such shares will not be delivered on such Original Distribution

Date and will instead be delivered on the first business day when you are not prohibited from selling shares of the Company's Common Stock in the open public market, but in no event later than the date that is the 15th day of the third calendar month of the year following the year in which the shares of Common Stock under this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).

(c) Delivery of the shares pursuant to the provisions of this Section 6 is intended to comply with the requirements for the short-term deferral exemption available under Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such manner.

(d) If the Company elects to issue you cash in part or in full satisfaction of the shares of Common Stock issuable upon vesting of your Restricted Stock Units, then the foregoing provisions of this Section 6 will not apply and such cash will be paid to you in a lump sum at any time on after the vesting date of your Restricted Stock Units, but in no event later than the 15th day of the third calendar month of the year following the year in which the shares of Common Stock under the Restricted Stock Units are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).

(e) The form of delivery (e.g., a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

7. DIVIDENDS. You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment.

8. RESTRICTIVE LEGENDS. The shares of Common Stock issued under your Award shall be endorsed with appropriate legends as determined by the Company.

9. EXECUTION OF DOCUMENTS. You hereby acknowledge and agree that the manner selected by the Company by which you indicate your consent to your Grant Notice is also deemed to be your execution of your Grant Notice and of this Agreement. You further agree that such manner of indicating consent may be relied upon as your signature for establishing your execution of any documents to be executed in the future in connection with your Award.

10. AWARD NOT A SERVICE CONTRACT.

(a) Nothing in this Agreement (including, but not limited to, the vesting of your Award or the issuance of the shares subject to your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

(b) The Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a "***reorganization***"). Such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. This Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with the Company's right to conduct a reorganization.

11. WITHHOLDING OBLIGATIONS.

(a) On the vesting date, and on or before the date on which you receive a distribution of the shares underlying your Restricted Stock Units, and at any other time as reasonably requested by the Company in accordance with applicable tax laws, you hereby authorize any required withholding from the Common Stock issuable to you and/or otherwise agree to make adequate provision in cash for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate that arise in connection with the vesting and settlement of your Award (the "***Withholding Taxes***"). The Company or any Affiliate may, in its sole discretion, satisfy all or any portion of the Withholding Taxes obligation relating to your Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company; (ii) causing you to tender a cash payment; (iii) permitting you to enter into a "same day sale" commitment, if applicable, with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***") whereby you irrevocably elect to sell a portion of the shares to be delivered in connection with your Restricted Stock Units to satisfy the Withholding Taxes and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Taxes directly to the Company and/or its Affiliates; or (iv) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to you in connection with the Award with a Fair Market Value (measured as of the date shares of Common Stock are issued to pursuant to Section 6) equal to the amount of such Withholding Taxes; *provided*, *however*, that the number of such shares of Common Stock so withheld will not exceed the amount necessary to satisfy the Company's required tax withholding obligations using the minimum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income; and *provided*, further, that to the extent necessary to qualify for an exemption from application of Section 16(b) of the Exchange Act, if applicable, such share withholding procedure will be subject to the express prior approval of the Company's Compensation Committee.

(b) Unless the tax withholding obligations of the Company and/or any Affiliate are satisfied, the Company shall have no obligation to deliver to you any shares of Common Stock in settlement of any vested portion of your Award.

(c) In the event the Company's obligation to withhold arises prior to the delivery to you of Common Stock or it is determined after the delivery of Common Stock to you that the amount of the Company's withholding obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

12. TAX CONSEQUENCES. The Company has no duty or obligation to minimize the tax consequences to you of this Award and shall not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by signing the Grant Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so. You understand that you (and not the Company) shall be responsible for your own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

13. UNSECURED OBLIGATION. Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue shares or other property pursuant to this Agreement. You shall not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 6 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

14. NOTICES. Any notice or request required or permitted hereunder shall be given in writing to each of the other parties hereto and shall be deemed effectively given on the earlier of (i) the date of personal delivery, including delivery by express courier, or delivery via electronic means, or (ii) the date that is five (5) days after deposit in the United States Post Office (whether or not actually received by the addressee), by registered or certified mail with postage and fees prepaid, addressed at the following addresses, or at such other address(es) as a party may designate by ten (10) days' advance written notice to each of the other parties hereto:

COMPANY:
FibroGen, Inc.
Attn: General Counsel
409 Illinois Street
San Francisco, CA 94158

PARTICIPANT:
Your address as on file with the Company
at the time notice is given

15. HEADINGS. The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.

16. MISCELLANEOUS.

(a) The rights and obligations of the Company under your Award shall be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by, the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

(c) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award and fully understand all provisions of your Award.

(d) This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

17. GOVERNING PLAN DOCUMENT. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Your Award (and any compensation paid or shares issued under your Award) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to voluntarily terminate employment upon a resignation for "good reason," or for a "constructive termination" or any similar term under any plan of or agreement with the Company.

18. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS. The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating benefits under any employee benefit plan (other than the Plan) sponsored by the Company or any Affiliate except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any or all of the employee benefit plans of the Company or any Affiliate.

19. CHOICE OF LAW. The interpretation, performance and enforcement of this Agreement shall be governed by the law of the State of Delaware without regard to that state's conflicts of laws rules.

20. SEVERABILITY. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

21. OTHER DOCUMENTS. You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act. In addition, you acknowledge receipt of the Company's Policy.

22. AMENDMENT. This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that, except as otherwise expressly provided in the Plan, no such amendment materially adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the Award as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.

23. COMPLIANCE WITH SECTION 409A OF THE CODE. This Award is intended to comply with the "short-term deferral" rule set forth in Treasury Regulation Section 1.409A-1(b)(4). Notwithstanding the foregoing, if it is determined that the Award fails to satisfy the requirements of the short-term deferral rule and is otherwise deferred compensation subject to Section 409A, and if you are a "Specified Employee" (within the meaning set forth in Section 409A(a)(2)(B)(i) of the Code) as of the date of your "separation from service" (within the meaning of Treasury Regulation Section 1.409A-1(h) and without regard to any alternative definition thereunder), then the issuance of any shares that would otherwise be made upon the date of the separation from service or within the first six (6) months thereafter will not be made on the originally scheduled date(s) and will instead be issued in a lump sum on the date that is six (6) months and one day after the date of the separation from service (or the date of your death, if earlier), with the balance of the shares issued thereafter in accordance with the original vesting and issuance schedule set forth above, but if and only if such delay in the issuance of the shares is necessary to avoid the imposition of adverse taxation on you in respect of the shares under Section 409A of the Code. Each installment of shares that vests is intended to constitute a "separate payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2).

* * * * *

This Restricted Stock Unit Award Agreement shall be deemed to be signed by the Company and the Participant upon the signing by the Participant of the Restricted Stock Unit Grant Notice to which it is attached.

Exhibit 10.5

FIBROGEN, INC.

2014 EMPLOYEE STOCK PURCHASE PLAN

ADOPTED BY THE BOARD OF DIRECTORS: SEPTEMBER 09, 2014
APPROVED BY THE STOCKHOLDERS: SEPTEMBER 30, 2014

1. GENERAL; PURPOSE.

(a) The Plan provides a means by which Eligible Employees of the Company and certain designated Related Corporations may be given an opportunity to purchase shares of Common Stock. The Plan permits the Company to grant a series of Purchase Rights to Eligible Employees under an Employee Stock Purchase Plan.

(b) The Company, by means of the Plan, seeks to retain the services of such Employees, to secure and retain the services of new Employees and to provide incentives for such persons to exert maximum efforts for the success of the Company and its Related Corporations.

2. ADMINISTRATION.

(a) The Board will administer the Plan unless and until the Board delegates administration of the Plan to a Committee or Committees, as provided in Section 2(c).

(b) The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine how and when Purchase Rights will be granted and the provisions of each Offering (which need not be identical).

(ii) To designate from time to time which Related Corporations of the Company will be eligible to participate in the Plan.

(iii) To construe and interpret the Plan and Purchase Rights, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan, in a manner and to the extent it deems necessary or expedient to make the Plan fully effective.

(iv) To settle all controversies regarding the Plan and Purchase Rights granted under the Plan.

(v) To suspend or terminate the Plan at any time as provided in Section 12.

(vi) To amend the Plan at any time as provided in Section 12.

(vii) Generally, to exercise such powers and to perform such acts as it deems necessary or expedient to promote the best interests of the Company and its Related Corporations and to carry out the intent that the Plan be treated as an Employee Stock Purchase Plan.

(viii) To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Employees who are foreign nationals or employed outside the United States.

(c) The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revest in the Board some or all of the powers previously delegated. Whether or not the Board has delegated administration of the Plan to a Committee, the Board will have the final power to determine all questions of policy and expediency that may arise in the administration of the Plan.

(d) All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

3. SHARES OF COMMON STOCK SUBJECT TO THE PLAN.

(a) Subject to the provisions of Section 11(a) relating to Capitalization Adjustments, the maximum number of shares of Common Stock that may be issued under the Plan will not exceed 4,000,000 shares of Common Stock, plus the number of shares of Common Stock that are automatically added on January 1 of each year, commencing on (and including) January 1, 2016 and ending on (and including) January 1, 2024, in an amount equal to the lesser of (i) 1.0% of the total number of shares of Capital Stock outstanding on December 31 of the preceding fiscal year, and (ii) 3,000,000 shares of Common Stock. Notwithstanding the foregoing, the Board may act prior to the first day of any fiscal year to provide that there will be no January 1 increase in the share reserve for such fiscal year or that the increase in the share reserve for such fiscal year will be a lesser number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence.

(b) If any Purchase Right granted under the Plan terminates without having been exercised in full, the shares of Common Stock not purchased under such Purchase Right will again become available for issuance under the Plan.

(c) The stock purchasable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market.

4. GRANT OF PURCHASE RIGHTS; OFFERING.

(a) The Board may from time to time grant or provide for the grant of Purchase Rights to Eligible Employees under an Offering (consisting of one or more Purchase Periods) on an Offering Date or Offering Dates selected by the Board. Each Offering will be in such form and will contain such terms and conditions as the Board will deem appropriate, and will comply with the requirement of Section 423(b)(5) of the Code that all Employees granted Purchase Rights will have the same rights and privileges. The terms and conditions of an Offering shall be incorporated by reference into the Plan and treated as part of the Plan. The provisions of separate Offerings need not be identical, but each Offering will include (through incorporation of the provisions of this Plan by reference in the document comprising the Offering or otherwise) the period during which the Offering will be effective, which period will not exceed 27 months beginning with the Offering Date, and the substance of the provisions contained in Sections 5 through 8, inclusive.

(b) If a Participant has more than one Purchase Right outstanding under the Plan, unless he or she otherwise indicates in forms delivered to the Company: (i) each form will apply to all of his or her Purchase Rights under the Plan, and (ii) a Purchase Right with a lower exercise price (or an earlier-granted Purchase Right, if different Purchase Rights have identical exercise prices) will be exercised to the fullest possible extent before a Purchase Right with a higher exercise price (or a later-granted Purchase Right if different Purchase Rights have identical exercise prices) will be exercised.

(c) The Board will have the discretion to structure an Offering so that if the Fair Market Value of a share of Common Stock on the first Trading Day of a new Purchase Period within that Offering is less than or equal to the Fair Market Value of a share of Common Stock on the Offering Date for that Offering, then (i) that Offering will terminate immediately as of that first Trading Day, and (ii) the Participants in such terminated Offering will be automatically enrolled in a new Offering beginning on the first Trading Day of such new Purchase Period.

5. ELIGIBILITY.

(a) Purchase Rights may be granted only to Employees of the Company or, as the Board may designate in accordance with Section 2(b), to Employees of a Related Corporation. Except as provided in Section 5(b), an Employee will not be eligible to be granted Purchase Rights unless, on the Offering Date, the Employee has been in the employ of the Company or the Related Corporation, as the case may be, for such continuous period preceding such Offering Date as the Board may require, but in no event will the required period of continuous employment be equal to or greater than two years. In addition, the Board may provide that no Employee will be eligible to be granted Purchase Rights under the Plan unless, on the Offering Date, such Employee's customary employment with the Company or the Related Corporation is more than 20 hours per week and more than five months per calendar year or such other criteria as the Board may determine consistent with Section 423 of the Code.

(b) The Board may provide that each person who, during the course of an Offering, first becomes an Eligible Employee will, on a date or dates specified in the Offering which coincides with the day on which such person becomes an Eligible Employee or which occurs thereafter, receive a Purchase Right under that Offering, which Purchase Right will thereafter be deemed to be a part of that Offering. Such Purchase Right will have the same characteristics as any Purchase Rights originally granted under that Offering, as described herein, except that:

(i) the date on which such Purchase Right is granted will be the “Offering Date” of such Purchase Right for all purposes, including determination of the exercise price of such Purchase Right;

(ii) the period of the Offering with respect to such Purchase Right will begin on its Offering Date and end coincident with the end of such Offering; and

(iii) the Board may provide that if such person first becomes an Eligible Employee within a specified period of time before the end of the Offering, he or she will not receive any Purchase Right under that Offering.

(c) No Employee will be eligible for the grant of any Purchase Rights if, immediately after any such Purchase Rights are granted, such Employee owns stock possessing five percent or more of the total combined voting power or value of all classes of stock of the Company or of any Related Corporation. For purposes of this Section 5(c), the rules of Section 424(d) of the Code will apply in determining the stock ownership of any Employee, and stock which such Employee may purchase under all outstanding Purchase Rights and options will be treated as stock owned by such Employee.

(d) As specified by Section 423(b)(8) of the Code, an Eligible Employee may be granted Purchase Rights only if such Purchase Rights, together with any other rights granted under all Employee Stock Purchase Plans of the Company and any Related Corporations, do not permit such Eligible Employee’s rights to purchase stock of the Company or any Related Corporation to accrue at a rate which exceeds $25,000 of Fair Market Value of such stock (determined at the time such rights are granted, and which, with respect to the Plan, will be determined as of their respective Offering Dates) for each calendar year in which such rights are outstanding at any time.

(e) Officers of the Company and any designated Related Corporation, if they are otherwise Eligible Employees, will be eligible to participate in Offerings under the Plan. Notwithstanding the foregoing, the Board may provide in an Offering that Employees who are highly compensated Employees within the meaning of Section 423(b)(4)(D) of the Code will not be eligible to participate.

6. PURCHASE RIGHTS; PURCHASE PRICE.

(a) On each Offering Date, each Eligible Employee, pursuant to an Offering made under the Plan, will be granted a Purchase Right to purchase up to that number of shares of Common Stock purchasable either with a percentage or with a maximum dollar amount, as designated by the Board, but in either case not exceeding 15% of such Employee’s earnings (as defined by the Board in each Offering) during the period that begins on the Offering Date (or such later date as the Board determines for a particular Offering) and ends on the date stated in the Offering, which date will be no later than the end of the Offering.

(b) The Board will establish one or more Purchase Dates during an Offering on which Purchase Rights granted for that Offering will be exercised and shares of Common Stock will be purchased in accordance with such Offering.

(c) In connection with each Offering made under the Plan, the Board may specify (i) a maximum number of shares of Common Stock that may be purchased by any Participant on any Purchase Date during such Offering, (ii) a maximum aggregate number of shares of Common Stock that may be purchased by all Participants pursuant to such Offering and/or (iii) a maximum aggregate number of shares of Common Stock that may be purchased by all Participants on any Purchase Date under the Offering. If the aggregate purchase of shares of Common Stock issuable upon exercise of Purchase Rights granted under the Offering would exceed any such maximum aggregate number, then, in the absence of any Board action otherwise, a pro rata (based on each Participant's accumulated Contributions) allocation of the shares of Common Stock available will be made in as nearly a uniform manner as will be practicable and equitable.

(d) The purchase price of shares of Common Stock acquired pursuant to Purchase Rights will be not less than the lesser of:

(i) an amount equal to 85% of the Fair Market Value of the shares of Common Stock on the Offering Date; and

(ii) an amount equal to 85% of the Fair Market Value of the shares of Common Stock on the applicable Purchase Date.

7. PARTICIPATION; WITHDRAWAL; TERMINATION.

(a) An Eligible Employee may elect to authorize payroll deductions as the means of making Contributions by completing and delivering to the Company, within the time specified in the Offering, an enrollment form provided by the Company. The enrollment form will specify the amount of Contributions not to exceed the maximum amount specified by the Board. Each Participant's Contributions will be credited to a bookkeeping account for such Participant under the Plan and will be deposited with the general funds of the Company except where applicable law requires that Contributions be deposited with a third party. If permitted in the Offering, a Participant may begin such Contributions with the first payroll occurring on or after the Offering Date (or, in the case of a payroll date that occurs after the end of the prior Offering but before the Offering Date of the next new Offering, Contributions from such payroll will be included in the new Offering). If permitted in the Offering, a Participant may thereafter reduce (including to zero) or increase his or her Contributions. If specifically provided in the Offering, in addition to making Contributions by payroll deductions, a Participant may make Contributions through the payment by cash or check prior to a Purchase Date.

(b) During an Offering, a Participant may cease making Contributions and withdraw from the Offering by delivering to the Company a withdrawal form provided by the Company. The Company may impose a deadline before a Purchase Date for withdrawing. Upon such withdrawal, such Participant's Purchase Right in that Offering will immediately terminate and the Company will distribute to such Participant all of his or her accumulated but unused

Contributions and such Participant's Purchase Right in that Offering shall thereupon terminate. A Participant's withdrawal from that Offering will have no effect upon his or her eligibility to participate in any other Offerings under the Plan, but such Participant will be required to deliver a new enrollment form to participate in subsequent Offerings.

(c) Purchase Rights granted pursuant to any Offering under the Plan will terminate immediately if the Participant either (i) is no longer an Employee for any reason or for no reason (subject to any post-employment participation period required by law) or (ii) is otherwise no longer eligible to participate. The Company will distribute to such individual all of his or her accumulated but unused Contributions.

(d) During a Participant's lifetime, Purchase Rights will be exercisable only by such Participant. Purchase Rights are not transferable by a Participant, except by will, by the laws of descent and distribution, or, if permitted by the Company, by a beneficiary designation as described in Section 10.

(e) Unless otherwise specified in the Offering, the Company will have no obligation to pay interest on Contributions.

8. EXERCISE OF PURCHASE RIGHTS.

(a) On each Purchase Date, each Participant's accumulated Contributions will be applied to the purchase of shares of Common Stock, up to the maximum number of shares of Common Stock permitted by the Plan and the applicable Offering, at the purchase price specified in the Offering. No fractional shares will be issued unless specifically provided for in the Offering.

(b) If any amount of accumulated Contributions remains in a Participant's account after the purchase of shares of Common Stock and such remaining amount is less than the amount required to purchase one share of Common Stock on the final Purchase Date of an Offering, then such remaining amount will be held in such Participant's account for the purchase of shares of Common Stock under the next Offering under the Plan, unless such Participant withdraws from or is not eligible to participate in such Offering, in which case such amount will be distributed to such Participant after the final Purchase Date, without interest. If the amount of Contributions remaining in a Participant's account after the purchase of shares of Common Stock is at least equal to the amount required to purchase one whole share of Common Stock on the final Purchase Date of an Offering, then such remaining amount will not roll over to the next Offering and will instead be distributed in full to such Participant after the final Purchase Date of such Offering without interest.

(c) No Purchase Rights may be exercised to any extent unless the shares of Common Stock to be issued upon such exercise under the Plan are covered by an effective registration statement pursuant to the Securities Act and the Plan is in material compliance with all applicable federal, state, foreign and other securities and other laws applicable to the Plan. If on a Purchase Date the shares of Common Stock are not so registered or the Plan is not in such compliance, no Purchase Rights will be exercised on such Purchase Date, and the Purchase Date will be delayed until the shares of Common Stock are subject to such an effective registration statement and the Plan is in material compliance, except that the Purchase Date will in no event be more than 6 months from the Offering Date. If, on the Purchase Date, as delayed to the maximum extent permissible, the shares of Common Stock are not registered and the Plan is not in material compliance with all applicable laws, no Purchase Rights will be exercised and all accumulated but unused Contributions will be distributed to the Participants without interest.

9. COVENANTS OF THE COMPANY.

The Company will seek to obtain from each federal, state, foreign or other regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Purchase Rights and issue and sell shares of Common Stock thereunder. If, after commercially reasonable efforts, the Company is unable to obtain the authority that counsel for the Company deems necessary for the grant of Purchase Rights or the lawful issuance and sale of Common Stock under the Plan, and at a commercially reasonable cost, the Company will be relieved from any liability for failure to grant Purchase Rights and/or to issue and sell Common Stock upon exercise of such Purchase Rights.

10. DESIGNATION OF BENEFICIARY.

(a) The Company may, but is not obligated to, permit a Participant to submit a form designating a beneficiary who will receive any shares of Common Stock and/or Contributions from the Participant’s account under the Plan if the Participant dies before such shares and/or Contributions are delivered to the Participant. The Company may, but is not obligated to, permit the Participant to change such designation of beneficiary. Any such designation and/or change must be on a form approved by the Company.

(b) If a Participant dies, in the absence of a valid beneficiary designation, the Company will deliver any shares of Common Stock and/or Contributions to the executor or administrator of the estate of the Participant. If, to the knowledge of the Company, no executor or administrator has been appointed, the Company, in its sole discretion, may deliver such shares of Common Stock and/or Contributions to the Participant’s spouse, dependents or relatives, or if no spouse, dependent or relative is known to the Company, then to such other person as the Company may designate.

11. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; CORPORATE TRANSACTIONS.

(a) In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a), (ii) the class(es) and maximum number of securities by which the share reserve is to increase automatically each year pursuant to Section 3(a), (iii) the class(es) and number of securities subject to, and the purchase price applicable to outstanding Offerings and Purchase Rights, and (iv) the class(es) and number of securities that are the subject of the purchase limits under each ongoing Offering. The Board will make these adjustments, and its determination will be final, binding and conclusive.

(b) In the event of a Corporate Transaction, then: (i) any surviving corporation or acquiring corporation (or the surviving or acquiring corporation’s parent company) may assume or continue outstanding Purchase Rights or may substitute similar rights (including a right to acquire the same consideration paid to the stockholders in the Corporate Transaction) for outstanding Purchase Rights, or (ii) if any surviving or acquiring corporation (or its parent company) does not assume or continue such Purchase Rights or does not substitute similar rights for such Purchase Rights, then the Participants' accumulated Contributions will be used to purchase shares of Common Stock within ten business days prior to the Corporate Transaction under the outstanding Purchase Rights, and the Purchase Rights will terminate immediately after such purchase.

12. AMENDMENT, TERMINATION OR SUSPENSION OF THE PLAN.

(a) The Board may amend the Plan at any time in any respect the Board deems necessary or advisable. However, except as provided in Section 11(a) relating to Capitalization Adjustments, stockholder approval will be required for any amendment of the Plan for which stockholder approval is required by applicable law or listing requirements, including any amendment that either (i) materially increases the number of shares of Common Stock available for issuance under the Plan, (ii) materially expands the class of individuals eligible to become Participants and receive Purchase Rights, (iii) materially increases the benefits accruing to Participants under the Plan or materially reduces the price at which shares of Common Stock may be purchased under the Plan, (iv) materially extends the term of the Plan, or (v) expands the types of awards available for issuance under the Plan, but in each of (i) through (v) above only to the extent stockholder approval is required by applicable law or listing requirements.

(b) The Board may suspend or terminate the Plan at any time. No Purchase Rights may be granted under the Plan while the Plan is suspended or after it is terminated.

(c) Any benefits, privileges, entitlements and obligations under any outstanding Purchase Rights granted before an amendment, suspension or termination of the Plan will not be materially impaired by any such amendment, suspension or termination except (i) with the consent of the person to whom such Purchase Rights were granted, (ii) as necessary to comply with any laws, listing requirements, or governmental regulations (including, without limitation, the provisions of Section 423 of the Code and the regulations and other interpretive guidance issued thereunder relating to Employee Stock Purchase Plans) including without limitation any such regulations or other guidance that may be issued or amended after the date the Plan is adopted by the Board, or (iii) as necessary to obtain or maintain favorable tax, listing, or regulatory treatment. To be clear, the Board may amend outstanding Purchase Rights without a Participant's consent if such amendment is necessary to ensure that the Purchase Right and/or the Plan complies with the requirements of Section 423 of the Code.

13. EFFECTIVE DATE OF PLAN.

The Plan will become effective immediately prior to and contingent upon the IPO Date. No Purchase Rights will be exercised unless and until the Plan has been approved by the stockholders of the Company, which approval must be within 12 months before or after the date the Plan is adopted (or if required under Section 12(a) above, materially amended) by the Board.

14. MISCELLANEOUS PROVISIONS.

(a) Proceeds from the sale of shares of Common Stock pursuant to Purchase Rights will constitute general funds of the Company.

(b) A Participant will not be deemed to be the holder of, or to have any of the rights of a holder with respect to, shares of Common Stock subject to Purchase Rights unless and until the Participant's shares of Common Stock acquired upon exercise of Purchase Rights are recorded in the books of the Company (or its transfer agent).

(c) The Plan and Offering do not constitute an employment contract. Nothing in the Plan or in the Offering will in any way alter the at will nature of a Participant's employment or be deemed to create in any way whatsoever any obligation on the part of any Participant to continue in the employ of the Company or a Related Corporation, or on the part of the Company or a Related Corporation to continue the employment of a Participant.

(d) The provisions of the Plan will be governed by the laws of the State of California without resort to that state's conflicts of laws rules.

15. DEFINITIONS.

As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

(a) "***Board***" means the Board of Directors of the Company.

(b) "***Capital Stock***" means each and every class of common stock of the Company, regardless of the number of votes per share.

(c) "***Capitalization Adjustment***" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Purchase Right after the date the Plan is adopted by the Board without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other similar equity restructuring transaction, as that term is used in Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(d) "***Code***" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(e) "***Committee***" means a committee of one or more members of the Board to whom authority has been delegated by the Board in accordance with Section 2(c).

(f) "***Common Stock***" means, as of the IPO Date, the common stock of the Company.

(g) "***Company***" means FibroGen, Inc., a Delaware corporation.

(h) ***"Contributions***" means the payroll deductions and other additional payments specifically provided for in the Offering that a Participant contributes to fund the exercise of a Purchase Right. A Participant may make additional payments into his or her account if specifically provided for in the Offering, and then only if the Participant has not already had the maximum permitted amount withheld during the Offering through payroll deductions.

(i) "***Corporate Transaction***" means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of at least 90% of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(j) "***Director***" means a member of the Board.

(k) "***Eligible Employee***" means an Employee who meets the requirements set forth in the document(s) governing the Offering for eligibility to participate in the Offering, provided that such Employee also meets the requirements for eligibility to participate set forth in the Plan.

(l) "***Employee***" means any person, including an Officer or Director, who is "employed" for purposes of Section 423(b)(4) of the Code by the Company or a Related Corporation. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan.

(m) "***Employee Stock Purchase Plan***" means a plan that grants Purchase Rights intended to be options issued under an "employee stock purchase plan," as that term is defined in Section 423(b) of the Code.

(n) "***Exchange Act***" means the Securities Exchange Act of 1934, as amended and the rules and regulations promulgated thereunder.

(o) "***Fair Market Value***" means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock will be the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in such source as the Board deems reliable. Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing sales price on the last preceding date for which such quotation exists.

(ii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith in compliance with applicable laws and in a manner that complies with Sections 409A of the Code.

(iii) Notwithstanding the foregoing, for any Offering that commences on the IPO Date, the Fair Market Value of the shares of Common Stock on the Offering Date will be the price per share at which shares are first sold to the public in the Company's initial public offering as specified in the final prospectus for that initial public offering.

(p) "***IPO Date***" means the date of the underwriting agreement between the Company and the underwriter(s) managing the initial public offering of the Common Stock, pursuant to which the Common Stock is priced for the initial public offering.

(q) "***Offering***" means the grant to Eligible Employees of Purchase Rights, with the exercise of those Purchase Rights automatically occurring at the end of one or more Purchase Periods. The terms and conditions of an Offering will generally be set forth in the "***Offering Document***" approved by the Board for that Offering.

(r) "***Offering Date***" means a date selected by the Board for an Offering to commence.

(s) "***Officer***" means a person who is an officer of the Company or a Related Corporation within the meaning of Section 16 of the Exchange Act.

(t) "***Participant***" means an Eligible Employee who holds an outstanding Purchase Right.

(u) "***Plan***" means this FibroGen, Inc. 2014 Employee Stock Purchase Plan.

(v) "***Purchase Date***" means one or more dates during an Offering selected by the Board on which Purchase Rights will be exercised and on which purchases of shares of Common Stock will be carried out in accordance with such Offering.

(w) "***Purchase Period***" means a period of time specified within an Offering, generally beginning on the Offering Date or on the first Trading Day following a Purchase Date, and ending on a Purchase Date. An Offering may consist of one or more Purchase Periods.

(x) "***Purchase Right***" means an option to purchase shares of Common Stock granted pursuant to the Plan.

(y) “***Related Corporation***” means any “parent corporation” or “subsidiary corporation” of the Company whether now or subsequently established, as those terms are defined in Sections 424(e) and (f), respectively, of the Code.

(z) “***Securities Act***” means the Securities Act of 1933, as amended.

(aa) “***Trading Day***” means any day on which the exchange(s) or market(s) on which shares of Common Stock are listed, including but not limited to the NYSE, Nasdaq Global Select Market, the Nasdaq Global Market, the Nasdaq Capital Market or any successors thereto, is open for trading.

Exhibit 10.32

FIBROGEN, INC.

CHANGE IN CONTROL AND SEVERANCE AGREEMENT

This Change in Control and Severance Agreement (this “Agreement”) is dated as of [__________], 2014, 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 termination of Executive’s employment in connection with a Change in Control 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.

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. 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 option 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. Benefits upon a Termination in Connection with or Following a Change in Control.

(a) Severance Benefits. 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 eighteen (18) months following the effective date of a Change in Control, and provided such termination constitutes a "separation from service" (within the meaning of Treasury Regulation Section 1.409A-1(h), a "Separation from Service"), and further provided that Executive delivers an effective release of claims as required under Section 3 below, then Executive shall be entitled to the following severance benefits (the "Severance Benefits"):

(i) The Company shall pay Executive an amount equal to [twelve/eighteen/twenty-four (12/18/24)] months of Executive's then current base salary, ignoring any decrease in base salary that forms the basis for Good Reason, less all applicable withholdings and deductions, paid [in a lump sum/over such twelve/eighteen/twenty-four (12/18/24) month period] immediately following the Separation from Service in accordance with the Company's regular payroll practices, on the schedule described in Section 3 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 (the "Change in Control COBRA Payment Period"); provided however that any Company obligation under this Section 2(a)(ii) 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 Change in Control COBRA Payment Period.

(iii) All outstanding stock options 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 2(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 or the Change in Control Benefits, subject to the applicable terms and conditions thereof.

(b) 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; (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. 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.

4. 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 4.

(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 4. 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.

5. 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.

6. 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.

7. 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 9(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.

8. 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 9(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 reduction of Executive's then current base salary; (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 this Agreement or any other written agreement between the Company and the Participant; or (v) the failure by any successor to the Company to assume this Agreement and any obligations under this Agreement; 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.

9. 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 and Invention Assignment 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 2 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 affected Participant 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, including Executive's eligibility to be a Participant in the Policy; 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.

(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 9(j).

(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.

[OFFICER NAME]

____

Date: ____________________________

FIBROGEN, INC.

By: ____________________________
Name: ____________________________
Title: ____________________________

Date: ____________________________

For Executive Age 40 or Older
Group Termination

EXHIBIT A

RELEASE AGREEMENT

In consideration of receiving certain benefits under my Change in Control and Severance Agreement with Fibrogen, Inc. (the "Company") dated [________, 2014] (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 and Invention Assignment 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, 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

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[1] Will need to revise for other states, as applicable.

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 a Company stock option or stock 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 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.

[OFFICER NAME]

Name: ______________________________

Date: ______________________________

For Executive Age 40 or Older
Individual Termination

EXHIBIT B

RELEASE AGREEMENT

In consideration of receiving certain benefits under my Change in Control and Severance Agreement with Fibrogen, Inc. (the "Company") dated [________, 2013] (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 and Invention Assignment 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, 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 a Company stock option or stock 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.

[OFFICER 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 [________, 2014] (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 and Invention Assignment 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, 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 a Company stock option or stock 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.

[OFFICER NAME]

Name: ______________________________

Date: ______________________________

Exhibit 21.1

List of Subsidiaries of FibroGen, Inc.

Subsidiaries	Incorporation
FibroGen (China) Medical Technology Development Co., Ltd.	China
FibroGen China Anemia Holdings, Ltd.	Cayman Islands
FibroGen Europe Corporation	Finland
FibroGen International (Cayman) Limited	Cayman Islands
FibroGen International (Hong Kong) Limited	Hong Kong
Skin Sciences, Inc.	Delaware, USA

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the use in this Registration Statement on Form S-1 of Fibrogen Inc. of our report dated June 11, 2014, relating to the consolidated financial statements of Fibrogen, Inc., which appears in such Registration Statement. We also consent to the reference to us under the heading “Experts” in such Registration Statement.

/s/ PricewaterhouseCoopers LLP
San Jose, California

October 24, 2014