FIBROGEN INC
Form 10-K
February 29, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2015

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to .

Commission file number: 001-36740

FIBROGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware	77-0357827
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
409 Illinois Street	
San Francisco, CA	94158
(Address of principal executive offices)	(zip code)

Registrant’s telephone number, including area code:

(415) 978-1200

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Exchange on Which Registered
Common Stock, $0.01 par value	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act:

None

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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:

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the closing price as of the last business day of the registrant's most recently completed

second fiscal quarter, June 30, 2015, was approximately $1,151.1 million. Shares of Common Stock held by each executive officer and director and stockholders known by the registrant to own 10% or more of the outstanding stock based on public filings and other information known to the registrant have been excluded since such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of common stock outstanding as of January 31, 2016 was 62,074,139.

TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

This Annual Report filed on Form 10-K and the information incorporated herein by reference, particularly in the sections captioned “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” contains forward-looking statements, which involve substantial risks and uncertainties. In this Annual Report, all statements other than statements of historical or present facts contained in this Annual Report, including statements regarding our future financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “believe,” “will,” “may,” “estimate,” “continue,” “anticipate,” “contemplate,” “intend,” “tar “project,” “should,” “plan,” “expect,” “predict,” “could,” “potentially” or the negative of these terms or other similar terms or expressions that concern our expectations, strategy, plans or intentions. Forward-looking statements appear in a number of places throughout this Annual Report and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for roxadustat, 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 our initial public 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 Annual Report captioned “Risk Factors” and elsewhere in this Annual Report.

These risks are not exhaustive. Other sections of this Annual Report may include additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

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

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

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

forward-looking statements by these cautionary statements.

PART I

ITEM 1. BUSINESS

OVERVIEW

We are a 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 (“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 (“HIF-PHs”), in Phase 3 clinical development for the treatment of anemia in chronic kidney disease (“CKD”). Our second product candidate, FG-3019, is a monoclonal antibody in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis (“IPF”), pancreatic cancer, Duchenne muscular dystrophy (“DMD”) 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 (“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. The chart below is a summary of our most advanced product candidates:

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 therapies available for anemia in CKD, such as injectable erythropoiesis stimulating agents ("ESAs").

Roxadustat is currently in Phase 3 global development for the treatment of anemia in patients with CKD. Over 1,400 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 ("DD-CKD'), including hyporesponsive patients, and those who are not dialysis-dependent ("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 bowel disease, lupus and rheumatoid arthritis), myelodysplastic syndrome ("MDS"), and surgical procedures requiring transfusions.

We, along with our collaboration partners Astellas Pharma Inc. ("Astellas"), and AstraZeneca AB ("AstraZeneca"), 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 ("U.S."), the European Union ("EU"), Japan and China. Our U.S. 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 ("MACE"), composite safety endpoints that we believe will be required for approval in the U.S. 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 ("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 U.S. 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 ("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).

4

Stages of CKD and Prevalence in the United States

*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 2013 estimates by the United States Renal Data System ("USRDS") presented in the 2015 USRDS annual data report: Epidemiology of kidney disease in the United States ("2015 USRDS ADR"), using data from the National Health and Nutrition Examination Survey ("NHANES") 2007-2012 and 2013 data from the U.S. Census Bureau. The prevalence of stage 5 CKD was calculated based on 2013 data from the 2015 USRDS ADR using data from the U.S. National ESRD database, NHANES 2007-2012 and 2013 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 U.S., according to the USRDS, a majority of dialysis eligible CKD patients are currently on dialysis. According to USRDS data as of 2013, approximately 470,000 patients were receiving dialysis in the U.S., 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. Approximately 16% of U.S. NDD-CKD patients were being treated with ESAs prior to initiation of dialysis as of 2013 (2015 USRDS ADR). 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 ("IV iron"), oral iron and blood transfusions. ESAs have been used in the treatment of anemia in CKD for over 20 years and are administered intravenously or subcutaneously, typically in conjunction with IV iron. NDD-CKD patients who are not under the care of nephrologists, including those with diabetes and hypertension, do not typically receive ESAs and are often left untreated. ESAs currently on the market are all synthetic recombinant versions of human erythropoietin ("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 the label for 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 18%, 36%, 45% and 45% by the end of 2010, 2011, 2012 and 2013 respectively (2015 USRDS ADR).

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.

6

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 ("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 ("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 ("TNF-alpha"), and interleukin-6 ("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 ("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 U.S. 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 U.S.), 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.

Increased use of IV iron has been associated with increased risk of hospitalization and death. 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. However, new and purportedly safer and more effective iron supplementation therapies are being developed and introduced, and if such new therapies are accepted by patients and physicians as a superior alternative to traditional IV iron supplementation therapies, they may help maintain or increase the attractiveness of ESA therapy.

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 U.S. Food and Drug Administration ("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, the Centers for Medicare and Medicaid Services ("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 ("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, DD-CKD in the presence of inflammation, 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 circulating endogenous EPO levels at peak concentration 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.

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.

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. In Study 041, 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 ("DOPPS"), for the fourth quarter of 2011 in the U.S. (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 ("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. Cmax of endogenous EPO levels were not measured in all patients; instead the range of 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 or predictive 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.

Our preclinical studies indicate that roxadustat can overcome the direct suppressive effects of inflammatory cytokines on erythropoiesis. In addition, in our preclinical studies, we have seen an ability of roxadustat to reduce hepcidin expression, 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.

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 ("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 Cmax of 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. Refer to 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 U.S. 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 2014 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

In addition to the over 1,100 subjects who have been exposed to roxadustat in Phase 1 and Phase 2 clinical studies, including treatment of some patients for 24 weeks in Phase 2 studies and several patients for approximately 4 years in a safety extension study, our ongoing Phase 3 program, which requires a minimum treatment duration of a year, provides additional long term safety data.

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 U.S., the EU, Japan and China. Our U.S. and EU Phase 3 program has an aggregate target enrollment of approximately 7,000 to 8,000 patients worldwide. 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 U.S. 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 U.S. However, the EU requires shorter treatment duration and less overall patient exposure.

For our three roxadustat Phase 3 studies, we have reached approximately 90% of our cumulative target enrollment agreed upon with our partners. We completed patient enrollment in one of these three studies and the second should complete in early March 2016; we currently expect to complete enrollment in the third U.S. study in the third quarter of 2016. We currently anticipate filing for New Drug Application (“NDA”) approval for roxadustat in the U.S. in 2018.

Our subsidiaries, FibroGen China Anemia Holdings, Ltd. and FibroGen (China) Medical Technology Development Co., Ltd. (individually or collectively referred to as “FibroGen China”), began enrolling patients in our China Phase 3 studies in December 2015. The primary efficacy endpoint is 26 weeks for the 300 subject dialysis study and 8 weeks for the 150 subject non-dialysis study. We expect to complete enrollment of the dialysis study in the second quarter of 2016 and the non-dialysis study in the third quarter of 2016. We expect to complete enrollment of the 52 week extension study (100 subjects) in the first half of 2016.

We are operating within the context of a Class 1.1 drug approval pathway for Domestic innovative drugs, and we currently anticipate initiating the NDA process in the fourth quarter of 2016 after we have reached the primary efficacy endpoint for both studies. Given that there is little precedent in China for the approval pathway, and the China Food and Drug Administration (“CFDA”) is in the process of enacting regulatory reform, we continue to regularly consult with the CFDA. We currently do not expect to announce the interim data publicly prior to initiating the NDA process. We expect that the Beijing CFDA will conduct the manufacturing review and site inspections first, to be followed by technical review of the preclinical, clinical and Chemistry, Manufacturing and Control filing by the Center for Drug Evaluation.

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 and medical

journals. 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. Astellas' Phase 2 DD-CKD and NDD-CKD studies in Japan have been completed, and data reconciliation and analysis are in progress.

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 over 1,500 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	29		117	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
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	Up to 4 years	TIW, BIW, QW
Total			725			905		

*Final report pending, study conducted by Astellas
**7 patients remain in ongoing study

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 117 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	
	Placebo	BIW	TIW	BIW	TIW	BIW	TIW
N	23	10	12	5	5	10	11
Mean Maximum Change in Hb	0.44	0.82	1.22	1.12	0.81	1.74	2.03
Standard Error of the Mean	0.11	0.28	0.37	0.26	0.45	0.32	0.26
% Hb Responder	13 %	30 %	58 %	60 %	40 %	80 %	91 %
Median Time to Response (Days)	NA	NA	26.5	42	NA	24.5	14

BIW = twice weekly; TIW = three times weekly

Standard error of the mean (“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 ³11 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 Hb 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 Hb 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 ("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) Hb 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 hepcidin 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: Mean (+SE) Plasma EPO 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 (“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. We observed that at week 12 in excess of 90% of the patients achieved a greater than 1 g/dL increase in Hb from baseline. In addition, 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 ("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 (3.5 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: Hb 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 ("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 > 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 U.S. trials.

Study 047: 8 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 U.S. 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 Hb at the end of Week 8. The mean 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
28

Study 048: Stable Dialysis Conversion in China

In this multi-center, open-label, ESA-controlled study, 87 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 (59.1% for the low-dose, 88.9% for the mid-dose, and 100% for the high dose). 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 U.S.

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

Safety Summary

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. In January 2016, the roxadustat data safety monitoring board (“DSMB”) completed its scheduled review of the data from all active Phase 3 roxadustat clinical trials and recommended that the program proceed with no protocol changes. 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 U.S. and Europe Phase 2 studies, and determined there were no safety signals. The overall frequency and type of treatment-emergent adverse events (“TEAEs”) and serious adverse events (“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 TEAE in the Phase 2 studies were diarrhea, nausea, urinary tract infection, nasopharyngitis, peripheral edema, hyperkalemia, headache, hypertension and upper respiratory tract infection.

Of our completed Phase 2 clinical studies, four (Studies 017, 047, 040 and 048) were controlled, two with placebo and two with ESA.

For Study 017, which had a treatment period of 4 weeks, for 88 subjects on roxadustat, and 28 subjects on placebo, we observed treatment emergent SAEs ("TSAEs"), in 4 patients (4.5%) on roxadustat, with 0 cardiovascular SAEs and 0 SAEs for the composite safety endpoint. There were also TSAEs in 1 patient (3.6%) in the placebo arm of the study, including 1 cardiovascular SAE and 0 SAEs for the composite safety endpoint. The composite safety endpoint (exploratory analysis) includes death, myocardial infarction, congestive heart failure, subendocardial ischaemia, cerebrovascular accident, thrombosis (fistula), arteriovenous fistula occlusion, angina pectoris, and vascular graft thrombosis. A patient may experience more than one SAE, in which case a patient is only counted once in this analysis. TSAEs observed in patients treated with roxadustat were arteriovenous fistula site complications, dyspnea, femoral neck fracture and non-cardiac chest pain. SAEs observed in patients treated with placebo were acute renal failure and pericarditis.

For Study 047, which had a treatment period of 8 weeks, for 61 subjects on roxadustat, and 30 subjects on placebo, we observed TSAEs in 8 patients on roxadustat (13.1%), with 0 cardiovascular SAEs, and 0 SAEs for the composite safety endpoint, and TSAEs in 4 patients on placebo (13.3%), including 1 cardiovascular SAE (3.3%), and 1 SAE (3.3%) for the composite safety endpoint. TSAEs observed in patients treated with roxadustat were chronic renal failure (4), upper respiratory tract infection (1), hyperkalaemia (2) and urinary tract infection (1). TSAEs observed in patients treated with placebo were unstable angina (1), anemia (1), retinal detachment (1), pneumonia (1) and gastritis (1).

For Study 040, for those who had a treatment period of 19 weeks, for 66 subjects on roxadustat, and 23 subjects on ESAs, we observed TSAEs in 15 patients on roxadustat (22.7%), including 1 cardiovascular SAEs (1.5%), and 8 SAEs for the composite safety endpoint (12.1%), and TSAEs in 4 patients on ESAs (17.4%), including 2 cardiovascular SAEs (8.7%), and 4 SAEs (17.4%) for the composite safety endpoint. TSAEs categorized by System Organ Class, a standard event classification, observed in patients treated with roxadustat were infections and infestations (5), metabolism and nutrition disorders (2), cardiac disorders (1), gastrointestinal disorders (1), nervous system disorders (2), respiratory, thoracic and mediastinal disorders (2), skin and subcutaneous tissue disorders (1), injury, poisoning and procedural complications (2), and psychiatric disorders (1). TSAEs categorized by System Organ Class observed in patients treated with ESA were infections and infestations (3), metabolism and nutrition disorders (3), cardiac disorders (1), respiratory, thoracic and mediastinal disorders (1), blood and lymphatic system disorders (1) and vascular disorders (1).

For Study 048 which had a treatment period of 6 weeks, for 74 subjects on roxadustat, and 22 subjects on ESAs, we observed 0 TSAEs in patients on roxadustat, including cardiovascular SAEs and for the composite safety endpoint. There were also 0 TSAEs in the patients taking ESAs.

The differences in the SAE percentages described are not considered statistically significant.

The three SAEs described above that were considered by the principal investigator to be possibly related to roxadustat did not occur in these four studies.

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 ("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.

In March 2015, we received final reports for two-year rat and mouse carcinogenicity studies of roxadustat. Roxadustat treatment had no adverse effect on survival and did not cause carcinogenic effects in either species. 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 efforts for regulatory approval in the U.S. and Europe, we have continued with our partners to progress on our global Phase 3 clinical program for roxadustat. FibroGen China has also begun enrolling patients in its Phase 3 program in China, and Astellas is responsible for Phase 3 studies in Japan. Roxadustat is the first HIF-PH inhibitor to enter Phase 3 clinical trials. 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 Roxadustat Phase 3 Clinical Trials

Study Number, Enrollment Start Date	Company Sponsor	Dose Frequencies for Ongoing Trials	Comparator	Estimated # of Patients to be Enrolled	Randomization	Study Objective
For Approval in U.S. and Europe:						
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 December 2014	Astellas	TIW	Epoetin alfa or Darbepoetin alfa	750	376:200:174	Conversion
FGCL-4592-064 January 2015	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		
For Approval in China:						
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	U.S.	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	1,500 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		1H 2016

* 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 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 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.

33

- 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 for several reasons:
- Greater Hb Response While Minimizing Total Drug Exposure. Early preclinical studies in rodents with a HIF-PH inhibitor (that was not FG-4592) indicated that a greater Hb response could be achieved using a lower total weekly dose with intermittent dosing compared to daily dosing. In the studies shown below, rats were dosed with HIF-PH inhibitor using either a daily or twice weekly dosing regimen. Both a higher Hb response and a better dose response were observed in animals dosed with HIF-PH inhibitor twice weekly compared to animals that were dosed daily. Furthermore, the total weekly dose required to achieve this greater Hb response was lower than with daily dosing exposure.

In addition, our previous preclinical studies suggested that a wider therapeutic window was achieved with intermittent dosing compared with daily dosing. Preclinical observations such as these led us to conclude that intermittent dosing could enable a better Hb response with a lower overall drug exposure and offer a potentially wider therapeutic window.

- Reduce the Risk of Changing the HIF Set Point. The HIF system has a built-in negative feedback mechanism. Genes for two of the PHD enzymes that are responsible for degrading HIF under normal oxygen conditions are actually HIF target genes. Thus, while these PHD enzymes are inhibited by hypoxia (or by a HIF-PH inhibitor), the resulting HIF activation leads to an increase in the very enzymes that are responsible for its degradation following the re-oxygenation (or potentially removal of the HIF-PH inhibitor). This negative feedback mechanism is important in enabling the HIF system to reset. However, under chronically hypoxic conditions, it has been shown that the elevation in PHD enzyme levels is maintained, leading to a change in the HIF set-point. Based on this knowledge of HIF biology, it is our belief that prolonged HIF activation by a HIF-PH inhibitor drug could similarly lead to a change in the HIF set-point, which we believe may then require an increased HIF-PH inhibitor dose to elicit the same HIF response. In an effort to avoid this potential risk, and to potentially prolong drug effectiveness, we have undertaken an intermittent dosing regimen.
- Increase Intervals Between HIF Activation. The kinetics of HIF target gene induction (including genes encoding PHD enzymes) are variable, with some HIF target genes being induced very quickly after HIF activation and others requiring longer periods of HIF activation for significant induction. We believe that increasing the intervals between HIF activation using an intermittent dosing regimen has the potential to limit the HIF target gene response.
- Potential Commercial Advantages. We expect that a dosing regimen that enables dosing concurrently with hemodialysis treatment, typically administered on a thrice weekly basis, will be more commercially attractive in the dialysis market.

Our Phase 2 studies indicated that intermittent dosing 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 TSAT ³ 5% and anemic DD-CKD patients with ferritin ³ 50 ng/mL and TSAT ³ 10%, which permits the inclusion of patients who are iron deficient. Hb response was generally achieved in iron deficient NDD-CKD and DD-CKD patients (ferritin <100 ng/mL 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/mL and TSAT< 20%).

Status with Regulatory Agencies

In the last four 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.

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 U.S. 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 U.S.

Investigational New Drug and Clinical Trial Applications

Roxadustat is being studied under one Investigational New Drug Application ("IND"), and several Clinical Trial Applications ("CTAs"), all with a specified indication of treatment of anemia in CKD. We originally submitted the IND in the U.S. 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 our collaboration partners Astellas and AstraZeneca have also submitted CTAs in Europe, Latin America, Canada, Russia, and Asia, 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. In the first half of 2016, we plan on submitting a clinical trial application in China to study roxadustat in MDS. We also plan on submitting a clinical trial application in China to study roxadustat in chemotherapy induced anemia in 2016.

We investigated the effects of roxadustat in rats with cisplatin-induced acute kidney injury ("AKI"), a model of chemotherapy induced anemia. Cisplatin injection (5 mg/kg) induced AKI as reflected by an increase in serum creatinine and a significant increase in Blood Urea Nitrogen ("BUN") concentrations. Animals were treated with vehicle control (n=8) or roxadustat at 20 and 40 mg/kg (n=6/group) via oral dosing 3 times a week for 2 weeks starting at 2 hours after cisplatin administration.

Cisplatin treatment significantly decreased reticulocyte counts at day 4 and roxadustat restored the reticulocyte counts in a dose dependent fashion. By day 14, cisplatin caused significant reduction of Hb levels and roxadustat normalized Hb concentration in a dose dependent fashion in the cisplatin-treated rats. Treatment with roxadustat at the higher dose (40 mg/kg), but not at the lower dose (20 mg/kg), prevented the increase in serum creatinine and BUN levels. This study demonstrated that roxadustat, in an intermittent dosing regimen starting 2 hours before cisplatin administration, improved renal function as measured by creatinine and BUN levels in a cisplatin-induced AKI and effectively ameliorated cisplatin-induced anemia.

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 for use as cardioprotective agents or for the treatment of metabolic disease such as diabetes.

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

We are currently performing two Phase 3 trials in China to support approval of roxadustat for treatment of anemia in DD-CKD and NDD-CKD patients. Our ongoing Phase 3 trials are designed to confirm Phase 2 results and 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.

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: DD-CKD patients; Dialysis Eligible patients who need dialysis under treatment guidelines but are not dialyzed ("Dialysis Eligible NDD-CKD"); and stages 3 and 4 patients as well as stage 5 patients who are not eligible for dialysis ("Other NDD-CKD").

DD-CKD (Dialysis)

Dialysis can be delivered in the form of HD, or peritoneal dialysis ("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 U.S. 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 U.S., 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 between 2006 and 2011, from $156 billion to $357 billion. China is projected by IMS Health to become the world's second largest pharmaceutical market after the U.S. 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, the dialysis market is still in the early stages of development relative to the U.S., 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 (refer to "— 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 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 began enrollment in its Phase 3 clinical trials in China in the fourth quarter of 2015, with initial 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 late-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 (such as the recent backlog in CFDA review of pending clinical trial applications). Refer to “Risk Factors”, and particularly those risk factors under the heading “Risks 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 has completed construction and validation of its manufacturing facility in Beijing. We received a Pharmaceutical Production Permit, which is a general certification by the CFDA that the facility is deemed ready for current good manufacturing practices (“cGMP”) production in August 2014, and we expect to receive the Manufacturing Licenses that will allow the Beijing facility to manufacture roxadustat for the commercial market after NDA approval and successful completion of the registration and validation campaigns and associated CFDA inspections. (Refer to “— 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 U.S. 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.

Completed 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 EPO, 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 U.S. Refer to "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 dosed our first patients in our DD-CKD and NDD-CKD Phase 3 trials in China in December 2015. Our planned Phase 3 trials are designed to confirm Phase 2 results and 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.

42

- 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: Hb mean change from baseline averaged over Weeks 7 to 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.

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 study to demonstrate the long-term safety of roxadustat as well as provide additional information related to the quality of the manufacturing process for roxadustat. The study design and patient size 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 U.S. 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. In April 2015, a subsidiary of China Regenerative Medicine International Limited received approval for their acellular porcine cornea stroma medical device for the indication of repair of corneal ulcers in China. However, alternatives to cadaver corneas, such as synthetic corneas using collagen derived from porcine tissue or fish scales, are either experimental or to our knowledge, have not yielded satisfactory results for restoration of vision in patients with corneal blindness. 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 collagen 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 medical device we are developing in China, is designed to serve as an immediately functional replacement cornea as well as a scaffold to allow for regeneration of the native corneal tissue for the primary purpose of restoration of vision. 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 our recombinant human collagen, and substantially similar to FG-5200, 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.

FG-5200 Strategy

In January 2016, our subsidiary FibroGen China received CFDA’s written notice of classification of our FG-5200 corneal implant as a Domestic Class III medical device. This allows FibroGen to develop, and if approved, to market FG-5200 corneal implants fabricated in China without any prior reference approval outside of China.

We currently plan to manufacture FG-5200 preclinical and clinical trial material in our aseptic GMP production suite located at our Beijing manufacturing plant. We have completed process technology transfer and expect to complete the registration campaign in the second half of 2016. Materials from this campaign will be used in preclinical studies which will commence in China in the second half of this year. We expect to file a CTA at the end of 2017 and to commence the pivotal clinical trial thereafter.

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 U.S. 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 ("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 ("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 IPF, pancreatic cancer and DMD. Additionally, we are also preparing to conduct a clinical trial in liver fibrosis due to non-alcoholic steatohepatitis ("NASH"). FG-3019 has received orphan drug designation in IPF in the U.S.

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. We are also currently conducting a randomized, active-control, neoadjuvant Phase 2 trial combining FG-3019 with nab-paclitaxel plus gemcitabine in approximately 42 patients with locally advanced pancreatic cancer.

DMD is an inherited disorder of the dystrophin gene that leads to progressive muscle loss and results in early death due to pulmonary or cardiac failure. Numerous pre-clinical studies including those in the mdx model of DMD suggest that CTGF contributes to the process by which muscle is replaced by fibrosis and fat and that CTGF may also impair muscle cell differentiation during muscle repair after injury. FG-3019 treatment has improved muscle strength and exercise endurance in the mdx model of DMD. We recently began an open label single arm trial in non-ambulatory boys with DMD.

Results to date indicate that FG-3019 has broad potential to address unmet needs for the treatment of fibrotic diseases and cancers. Specifically, given our preclinical and clinical data to date, our primary focus for clinical development of FG-3019 is in IPF, DMD and pancreatic cancer. We are also preparing to conduct an exploratory clinical trial in liver fibrosis due to NASH.

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 Can Reverse 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 (refer to figure above).

Multiple biological agents and pathways have been implicated in the fibrotic process (Wynn J Pathol (2008)). Many fibrosis pathways converge on CTGF (refer to 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-ß and VEGF. CTGF expression has been demonstrated to be up-regulated in fibrotic tissues. Thus, we believe that targeting CTGF to block or inhibit its activity could 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 IPF. 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; a randomized, open label Phase 2 trial in stage 3 pancreatic cancer; and an open label single arm trial in non-ambulatory boys with DMD; In ten Phase 1 and Phase 2 clinical studies involving FG-3019 to date, including more than 375 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 conducting a randomized, double-blind, placebo-controlled Phase 2 trial of FG-3019 for first-line treatment. This protocol includes a sub-study that examines safety and efficacy of FG-3019 when combined with either pirfenidone or nintedanib, both of which are approved for treatment of IPF in the U.S. and Europe. 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 are also currently conducting a randomized, active-control, neoadjuvant Phase 2 trial combining FG-3019 with nab-paclitaxel plus gemcitabine in approximately 42 patients with locally advanced pancreatic cancer. Initial results for the first 12 subjects in the study indicated that more subjects treated on the combination arm containing FG-3019 were converted from unresectable to fully resectable status. The study continues to enroll subjects in order to confirm these early preliminary data.

We conducted a randomized placebo-controlled study of FG-3019 in subjects with liver fibrosis due to hepatitis B who were about to start anti-viral treatment with entecavir. This study tested two doses of FG-3019. The primary endpoint was improvement in liver fibrosis. Interim data indicated that the rate of liver fibrosis improvement in the placebo group that received entecavir alone was much higher than expected (54% compared to 30% expected). Based on this analysis, we determined that the trial was unlikely to be successful and the trial was closed. Based on the safety data in that study we are planning to conduct a trial of FG-3019 in subjects with advanced liver fibrosis due to NASH, for which there is no effective therapy.

In January 2016, we dosed the first patients in an exploratory single arm trial of the safety and efficacy of FG-3019 in non-ambulatory subjects with DMD. The primary endpoint is change in forced vital capacity; other endpoints include changes in arm function and in muscle and heart fibrosis.

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. Also refer to “Risk Factors,” and particularly those risk factors under the heading “Risks Related to the Development and Commercialization of Our Product Candidates.”

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 150**
'067 Sub-study	Double-blind, active-controlled (2:1)	30 mg/kg	Every 3 weeks	24 weeks	Target 60**
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 42**
Phase 2—Liver Fibrosis, due to HBV, FGCL-3019-	Double-blind,	15 or 45	Every 3 weeks	45 weeks	114

801	placebo-controlled (2:1)				
Phase 2 – Duchenne muscular dystrophy, non-ambulatory FGCL-3019-079	Open-label, single arm	45	Every 2 weeks	45 weeks	22**
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, which destroys the structure and function of the lungs. As tissue scarring progresses in the lungs, transfer of oxygen into the bloodstream is increasingly impaired. Average life expectancy at the time of confirmed diagnosis of IPF is estimated to be between 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, ("HRCT"), imaging technology have enabled more reliable diagnosis of IPF without the need for a lung biopsy more clear 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 U.S. and Europe in 2020.

Pirfenidone has been approved to treat IPF in Europe, Canada, Japan and the U.S. 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 ("FVC") with an annual decline in FVC of 235 mL compared to 428 mL for placebo. Nintedanib has also been approved to treat IPF in the U.S. and the EU and has similar modest effect with an annual decrease in FVC of approximately 115 mL compared to approximately 240 mL for placebo. To our knowledge, neither pirfenidone nor nintedanib has been shown to reverse pulmonary fibrosis. We believe that FG-3019 has the potential to stabilize or reverse lung fibrosis in a subset of IPF patients and if approved, improve the prognosis for patients with IPF.

Phase 2 Clinical Trial 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. TEAE 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. After 45 weeks of dosing, subjects whose FVC declined less than predicted were allowed to continue dosing in an extension study until they had disease progression. Nineteen patients from Cohort 1 (35.8%) and 13 patients from Cohort 2 (36.1%) entered the extension study. Efficacy endpoints are pulmonary function assessments, extent of pulmonary fibrosis as measured by quantitative imaging and measures of health-related quality of life. A total of 16 patients (4 from cohort 1 and 12 from cohort 2) remain in the extension study, 2.8 to 4.6 years after enrolling in the original study.

HRCT is typically used to diagnose IPF based on visual assessments of computed tomography ("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			
	FVC % Predicted	Severe < 55% N	Moderate 55% to 80%	Mild > 80%	Total	Severe < 55% N	Moderate 55% to 80%	Mild > 80%	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 mild to moderate 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 a subset of IPF patients. Stable fibrosis has been considered the only achievable favorable outcome in IPF. The table below sets forth the number of patients who showed stable or improved fibrosis at Weeks 24 and 48 compared to the amount of fibrosis at the start of the trial.

Changes in Fibrosis in Patients with Mild to Moderate IPF Treated with 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 as reticular fibrosis 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 mild to moderate 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

50

The FVC changes observed in mild to moderate patients 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 (or 48 Weeks, as applicable)					
	Baseline FVC% Predicted	N				
	Pbo/Active	Pbo/Active	Placebo	Active	Difference	%
Pirfenidone I*		174/174	-350	-181	169	48.3%
Pirfenidone II*		173/171	-274	-220	54	19.7%
Pirfenidone III	68.6/67.8	238/223	-428	-235	193	45.1%
Nintedanib I	80.5/79.5	204/307	-240	-115	125	52.1%
Nintedanib II	78.1/80.0	217/327	-207	-114	93	44.9%
FG-3019	71.8**	0/65 ***	—	-128		

* Week 48, FVC (rank ANCOVA w/ imputation)

** Safety population (n=69)

*** Full analysis set

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 IPF patients with mild to moderate disease (baseline FVC percentage predicted between 55% and 90%). 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. This trial was initially a placebo-only controlled study targeting 90 subjects. We expanded the trial to enable enrollment of both first-line and second-line treatment. The presence of approved therapies has made enrollment in this first-line, placebo-controlled arm of the trial more challenging, and because the approved therapies have only recently become available, few patients have

enrolled for second-line treatment. Hoffmann-La Roche's ("Roche's") pirfenidone is approved for marketing in Europe, Canada, Japan and the U.S. and Boehringer Ingelheim's nintedanib is approved for marketing in Europe and the U.S. Consequently we are focused on the first-line patients and are currently over two-thirds enrolled toward the requisite 90 patients. We are also expanding this trial to include 60 subjects to test FG-3019 in combination with therapies approved for IPF. We expect to report topline data of FG-3019 vs. placebo in the first half of 2017. Reaching the target enrollment of 90 subjects in the first half of 2016 is dependent upon our enrolling patients at sites in countries outside the U.S. where approved therapies do not exist or have not fully penetrated the market. We are enrolling subjects in Canada, New Zealand, India, South Africa, Australia, Bulgaria, and Romania.

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 U.S. According to the World Health Organization (“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. There are 47,000 new cases of pancreatic cancer per year in U.S. Fifty percent of patients with pancreatic cancer have no detectable metastases at presentation, and are thus classified as clinically localized (50%). In one third (8,225) the nature of the cancer precludes resection, in two thirds (15,275) the tumors are potentially resectable, For those with non-resectable tumors, 50% survive 8 to 12 months post-diagnosis, and few report 5-year survival; similar to metatastatic cases. For those with resectable tumors, 50% survive 17 to 27 months post-diagnosis and ~20% report 5-year survival.

Pancreatic cancer is aggressive and typically not diagnosed until it is largely incurable. Most patients are diagnosed after the age of 45, and according to the American Cancer Society, 94% of patients die within five years from diagnosis. The majority of patients are treated with chemotherapy, but pancreatic cancer is highly resistant to chemotherapy. Approximately 15% to 20% of patients are treated with surgery; however, even for those with successful surgical resection, the median survival is approximately two years, with a five year survival rate of 15% to 20% (Neesse et al. Gut (2011)). Radiation treatment may be used for locally advanced diseases, but it is not curative.

The duration of effect of approved anti-cancer agents to treat pancreatic cancer is limited. Gemcitabine demonstrated improvement in median overall survival from approximately four to six months, and erlotinib in combination with gemcitabine demonstrated an additional ten days of survival. Nab-paclitaxel in combination with gemcitabine was recently approved by the FDA for the treatment of pancreatic cancer, having demonstrated median survival of 8.5 months. The combination of folinic acid, 5-fluorouracil, irinotecan and oxaliplatin (FOLFIRINOX) was reported to increase survival to 11.1 months from 6.8 months with gemcitabine. These drugs illustrate that progress in treatment for pancreatic cancer has been modest, and there remains a need for substantial improvement in patient survival and quality of life.

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

Pancreatic cancers are generally resistant to powerful chemotherapeutic agents, and there is now growing interest in the use of an anti-fibrotic agent to diminish the supportive role of stroma in tumor cell growth and metastasis. The anti-tumor effects observed with FG-3019 in preclinical models indicate that it has the potential to inhibit tumor expansion through effects on tumor cell proliferation and apoptosis as well as reduce metastasis.

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

*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

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 continue to enroll an open-label, randomized (2:1) Phase 2 trial (FGCL-3019-069) of FG-3019 combined with gemcitabine plus nab-paclitaxel chemotherapy versus the chemotherapy regimen alone in patients with inoperable locally advanced pancreatic cancer that has not been previously treated. Approximately 42 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, or resectable, cancer. Tumor removal is the only chance for cure of pancreatic cancer, but only 15% to 20% of patients are eligible for surgery. The patients are then followed for disease progression and overall survival. We reported on the first eight evaluable patients at the 2016 American Society of Clinical Oncology GastroIntestinal Cancer Meeting. Of the four patients randomized to FG-3019 plus standard of care (gemcitabine and nab-paclitaxel), one discontinued therapy due to a serious adverse event unrelated to study drug and three were converted to operable cancer; two having complete resection (R0) and one having an R1 resection (microscopic evidence of residual tumor cells at the resection margins). Of the four patients randomized to gemcitabine and nab-paclitaxel alone, two experienced progressive disease, one remained inoperable and one was converted to operable cancer having an R0 resection. After 2 cycles of treatment in the first 12 subjects, plasma levels of CA19.9, a non-specific tumor marker, showed a mean reduction of 78.3% with FG-3019 plus chemotherapy compared to 48.7% with chemotherapy alone. Patients with locally advanced unresectable pancreatic cancer have median survival of less than 12 months, only slightly better than patients with metastatic pancreatic cancer, whereas patients with resectable pancreatic cancer have a much better prognosis with median survival of approximately 23 months and some patients being cured. If FG-3019 in combination with chemotherapy continues to demonstrate an enhanced rate of conversion from unresectable cancer to resectable cancer, it will support the possibility that FG-3019 could provide a substantial survival benefit for locally advanced pancreatic cancer patients, and we will explore the clinical and regulatory path for approval.

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 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 U.S. Treating the underlying cause of disease may stabilize or reverse fibrosis, but only liver transplantation can treat fibrosis that has advanced to cirrhosis.

Reversal of fibrosis after anti-viral therapy is largely observed in patients with mild to moderate fibrosis in hepatitis B and is slow in hepatitis C. 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 U.S. 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

We conducted a randomized, double-blind, placebo-controlled Phase 2 clinical trial with FG-3019 in 113 patients with HBV-associated liver fibrosis in Hong Kong and Thailand, where the prevalence of HBV is high. Subjects were eligible if they had biopsy-proven liver fibrosis and were starting anti-viral therapy with entecavir. The trial tested two doses of FG-3019, 15 mg/kg and 45 mg/kg, administered every three weeks for 45 weeks. The primary endpoint of the trial was change in fibrosis as assessed in liver biopsies. We designed the trial based on the expectation that liver fibrosis improved slowly in subjects who are starting entecavir and that no more than 30% of subjects assigned to the control placebo arm of entecavir alone would have improved liver fibrosis after one year of treatment. An interim data analysis revealed that 54% of subjects on the control arm had reduced liver fibrosis after one year of entecavir. The trial was not designed to demonstrate benefit of FG-3019 in the setting of such a high background improvement rate and the trial was closed early. Although there were no significant efficacy results, there were trends for dose related improvements in fibrosis and Fib-4, a non-invasive marker of liver fibrosis. For patients who received a full course of FG-3019 at 15 mg/kg, were switched mid-course from 15 to 45 mg/kg or received a full course at 45 mg/kg, a 1 point or more improvements in Ishak fibrosis score was seen in 55.6% (N=20), 60% (N=6) or 66.7% (N=2) respectively, compared to 54.2% (N=13) of placebo-treated patients. Similarly, for patients who received a full course of FG-3019 at 15 mg/kg, were switched mid-course from 15 to 45 mg/kg or received a full course at 45 mg/kg, a 10% or greater reduction in Fib-4 was seen in 44.7% (N=21), 80% (N=8) or 83.3% (N=5) respectively, compared to 63.6% (N=21) of placebo-treated patients. The proportion of subjects who had grade 3 or 4 adverse events was similar between the FG-3019 arm and the placebo arm. No deaths were reported in this study. Overall there were no safety signals or change in the safety profile of FG-3019 from the results of this trial.

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 for mild to moderate disease because clinical manifestations of liver disease do not become apparent until fibrosis is advanced. As with HRCT for pulmonary fibrosis, the imaging technologies and other 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, has 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 and function.

We are assessing the potential study design and timing of a randomized, double-blind, placebo controlled Phase 2 trial of FG-3019 for treatment of advanced liver fibrosis due to NASH. We are also evaluating the potential of a trial of FG-3019 in patients with advanced liver fibrosis due to Hepatitis C particularly where it appears that fibrosis may not resolve after cure of hepatitis C with the latest antiviral agents.

FG-3019 for Duchenne Muscular Dystrophy

Understanding DMD and the Limitations of Current Therapies

In the U.S., 1 in 3,500 boys have 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.

Clinical Development of FG-3019 for DMD

In 2015 we filed an IND for DMD which was approved in July 2015. In January 2016, we dosed the first patients in the first study under this IND, a 22 patient open-label trial of FG-3019 in non-ambulatory patients. The primary endpoint is change in pulmonary function compared to each individual subject's historical decline in lung function. Other endpoints include assessments of cardiac fibrosis and function assessed by magnetic resonance imaging ("MRI"), upper arm muscle fibrosis and fat assessed by MRI and upper body strength. Clinical sites began screening subjects for eligibility in late 2015 and the first subjects were enrolled in January 2016. We plan to meet with the FDA to discuss development of FG-3019 for further treatment of DMD including in ambulatory subjects.

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, hepatoma
- Lung — scleroderma lung disease
- Radiation induced fibrosis
- Muscular dystrophies other than Duchenne muscular dystrophy
- 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 U.S. 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 U.S. for the treatment of locally advanced or metastatic pancreatic cancer under an IND that we submitted to the FDA in September 2004. FG-3019 is being studied in the U.S. for the treatment of DMD under an IND that we submitted to the FDA in June 2015. We have an IND number for treatment of liver fibrosis due to NASH and in October 2015 we held a pre-IND meeting with the FDA to discuss our development plans.

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 U.S. 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 December 31, 2015 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 equity 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 (the "China Agreement"), and one for the U.S. and all other countries not previously licensed to Astellas (the "U.S./RoW Agreement"). Under these agreements we provided AstraZeneca the right to develop and commercialize roxadustat for anemia in these territories. We share responsibility with AstraZeneca for clinical development activities required for United States regulatory approval of roxadustat.

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

In China, our subsidiary FibroGen 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, a portion of which we have received and the remainder of which we expect to receive in various amounts through 2016, including a $62.0 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 December 31, 2015 totals $355.2 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.

AstraZeneca purchased 1,111,111 shares of our common stock at the initial public offering ("IPO") price for an aggregate purchase price of $20.0 million in a private placement concurrent with our IPO. In connection with the purchase of our shares of common stock in the private placement, AstraZeneca has also entered into a standstill agreement which provides that, until November 2019, 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 private placement for the two-year period following

such purchase and to limitations on the volume of its sales of such shares thereafter.

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

Under the China Agreement, which is conducted through FibroGen China, 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 any regulatory filings and approvals for roxadustat in the affected territories that they may hold under our agreements, grant us licenses and conduct certain transition activities.

Additional Information Related to Collaboration Agreements

Of the $1,113.5 million in development and regulatory milestones payable in the aggregate under our Astellas and AstraZeneca collaboration agreements, $425.0 million is payable upon achievement of milestones relating to the submission and approval of roxadustat in DD-CKD and NDD-CKD in the U.S. and Europe.

Information about collaboration partners that accounted for more than 10% of our total revenue or accounts receivable for the last three fiscal years is set forth in Note 14 to our consolidated financial statements under Item 8 of this Annual Report.

COMPETITION

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

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

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 U.S., Procrit ® marketed by Johnson & Johnson, Inc. in the U.S., and Erypo®/Eprex ® also marketed by Johnson & Johnson in other markets and Espo ® marketed by Kyowa Hakko Kirin (“KHK”), in Japan and China), darbepoetin (Aranesp® marketed by Amgen in the U.S. and Europe, and by KHK in Hong Kong; NESP ® marketed by KHK in Japan, Korea, Singapore, Taiwan, Thailand), as well as Mircera ® (marketed by Roche in various markets including Europe and Japan, and marketed by

Galenica in the U.S.) and NeoRecormon ® /Epogin ® (marketed by Roche in Japan and certain other markets). In addition, several biosimilar versions of currently marketed ESAs are available for sale in the EU and many other markets, and, in the U.S., a few BLAs for epoetin alpha biosimilars are currently under review by the U.S. FDA, and if approved, could alter the competitive and pricing landscape of anemia therapy in dialysis patients under the ESRD bundle. ESAs have been used 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. NDD-CKD patients who are not under the care of nephrologists, including those with diabetes and hypertension, do not typically receive ESAs and are often left untreated. Physicians and patients currently treated with ESAs 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 therapies currently in clinical development for the treatment of anemia in CKD patients, including those patient segments not currently addressed by ESAs. In addition to our roxadustat programs, several companies, including GlaxoSmithKline plc ("GSK"), Bayer Corporation ("Bayer"), and Akebia Pharmaceuticals, Inc. ("Akebia") are currently in clinical development of their HIF-PH inhibitors. While roxadustat was the only HIF-PH inhibitor in Phase 3 development for the past few years, Akebia began its first Phase 3 study of its HIF-PH inhibitor in NDD-CKD in December 2015. The company also plans to consult with the U.S. FDA regarding its Phase 3 DD-CKD program. Bayer and GSK are both in Phase 2 development of their respective HIF-PH inhibitor product candidates for anemia in CKD indications. In Japan, while Daiichi Sankyo terminated its HIF-PH inhibitor program at Phase 1, Japan Tobacco Inc. has advanced to Phase 2b development. We may face competition for patient recruitment and enrollment for clinical trials and potentially in commercial sales by some of those HIF-PH inhibitors.

In addition, there are other companies developing biologic therapies for treatment of other anemia indications, including MDS. In MDS, current therapeutic options are limited, and many patients are exposed to multiple RBC transfusions. Despite lack of regulatory approvals for MDS (except for Japan where darbepoetin is approved for MDS), ESA therapy is recommended for anemia treatment in MDS patients with low serum EPO levels. If roxadustat is approved for MDS, it would compete with ESA and potentially with the new biologic therapies currently under development. For example, Celgene Corporation, in partnership with Acceleron Pharma Inc. is initiating Phase 3 development of protein therapeutic candidates to treat anemia and associated complications in patients with ß-thalassemia and certain type of MDS, and has received orphan drug status from the EMA and FDA for these indications. Noxxon Pharma AG is developing an anti-hepcidin Spiegelmer ® lexaptepid pegol (NOX-H94), a mirror image of a natural oligonucleotide, which is in Phase 2 development in cancer patients for the treatment of anemia associated with chronic disease, as well as in ESA-hyporesponsive patients on dialysis.

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. We may also face competition by HIF-PH inhibitors from other companies such as Akebia, GSK, and Bayer. Akebia announced in December 2015 that it has entered into a development and commercialization partnership with Mitsubishi Tanabe Pharmaceutical Corporation for vadadustat, one of its HIF-PH inhibitor in Japan, Taiwan, South Korea, India and certain other countries in Asia. 3SBio Inc. also plans on beginning a Phase 1 clinical trial of a HIF-PH inhibitor for the China market in 2016.

The currently marketed ESA products are 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.

In the U.S., two of the largest operators of dialysis clinics, DaVita Healthcare Partners Inc. ("DaVita") and Fresenius Medical Care AG & Co. KGaA ("Fresenius"), collectively provide dialysis care to approximately 70% of the dialysis market, and therefore have historically won long-term contracts including rebate terms with Amgen. DaVita's contract with Amgen that began in January 2012 includes an exclusive relationship through 2018. Fresenius' contract with Amgen is non-exclusive and expired in 2015. Fresenius is now administering Mircera ® in a significant portion of its U.S. dialysis patients since Mircera was made available by Galenica. Successful penetration in this market may require a significant agreement with at least either Fresenius or DaVita, on favorable terms and on a timely basis.

FG-3019

We are currently in Phase 2 development of FG-3019 to treat DMD, 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 Roche (through its acquisition of InterMune) and Boehringer Ingelheim Pharma GmbH & Co. KG, who have received approval for product candidates for the treatment of IPF in the U.S., have successfully developed and commercialized drugs in various indications and have built sales organizations that we do not currently have; both have more resources and more established relationships when competing with us for patient recruitment and enrollment for clinical trials or, if we are approved, in the market.

Idiopathic Pulmonary Fibrosis

If approved to treat IPF, FG-3019 would compete with pirfenidone, which is approved for marketing in Europe, Canada and Japan. As of October 2014, Roche (through its acquisition of InterMune) has obtained approval in the U.S. for pirfenidone for the treatment of IPF and Boehringer Ingelheim has obtained approval in the U.S. and the EU for nintedanib for the treatment of IPF. We believe that if FG-3019 can be shown to safely stabilize or reverse lung fibrosis in a subset of IPF patients, 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 Bristol-Myers Squibb's BMS-986020 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 U.S. and Europe in 2013 and 2014, respectively, and was the first drug approved in this disease in nearly a decade. 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. For example, 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®), Abbvie's Viekira Pak™, entecavir (Baraclude®), adefovir (Hepsera ®), lamivudine (Epivir ®), simeprevir (Olysio ®), tenofovir (Viread ®), telbivudine (Tyzeka ®), 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, including NASH, include Gilead's simtuzumab and Intercept Pharmaceuticals, Inc.'s obeticholic acid.

Duchenne Muscular Dystrophy

Currently, no disease modifying drugs have received full approval to treat DMD, and no disease modifying products are commercially available outside of the European Economic Area. If approved and launched commercially to treat DMD, FG-3019 may face competition for some patients from Sarepta Therapeutics, Inc., as well as BioMarin, and PTC Therapeutics, Santhera Pharmaceuticals, Pfizer, Summit plc and Tivorsan Pharmaceuticals. BioMarin, along with Sarepta have entered clinical development with therapeutics based on exon-skipping technology which seeks to help patients produce functioning forms of the dystrophin protein. The lead molecules for both BioMarin (drisapersen) and Sarepta (eteplirsen) focus on skipping exon-51. Therapies skipping exon-51 target only approximately 13% of the patients who have DMD. To reach other DMD patients with their technology BioMarin and Sarepta would need to generate a new clinical candidate for each type of mutation in the dystrophin gene. PTC Therapeutics' product ataluren (Translarna ™) received conditional approval in Europe in 2014.Translarna targets a different set of DMD patients from those being targeted by BioMarin's and Sarepta's therapeutics that skip exon-51; however, it is also limited to a subset of patients who carry a specific mutation. Conversely, FG-3019 is intended to treat DMD patients without limitation to type of mutation. Santhera Pharmaceuticals recently reported positive Phase 3 data with its drug idebenone (Raxone ® /Catena ®) in a trial measuring changes in lung function for DMD patients. Idebenone is a synthetic short-chain benzoquinone and a cofactor for the enzyme NAD(P)H:quinone oxidoreductase (NQO1). Pfizer's product candidate, which is in Phase 2 development, is an antibody targeting myostatin which is a protein that regulates muscle growth. The goal of the program is to increase muscle growth and muscle strength in patients with

DMD. Summit plc and Tivorsan Pharmaceuticals are both working on drugs involving the utrophin pathway. The goal of these programs is to increase the production the utrophin protein to compensate for the nonfunctional dystrophin protein produced by DMD patients. Utrophin is a protein similar to dystrophin. Summit is conducting a Phase 1b trial and Tivorsan is conducting preclinical work.

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 (collectively "WuXi STA," and "Catalent Pharma Solutions," or "Catalent"). WuXi STA is located in China and currently supplies our active pharmaceutical ingredient ("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 U.S. 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 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 several metric tons 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 is manufactured at the FibroGen China manufacturing facility in Beijing. Until our FibroGen China manufacturing facility is qualified and licensed for manufacture of roxadustat for the China market, we will continue to rely on external contract manufacturers for both API and drug product manufacturing. We plan to use drug product from our FibroGen China manufacturing facility upon commercialization. We plan on using API from contract manufacturers or our own facility for commercial supply, depending on evolving manufacturing and environmental regulations.

Irix Pharmaceuticals, Inc.

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

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, we freeze-dry the material in our U.S. facility. We are still determining any facility licensing requirements for this step. The final step is the production of FG-5200, which will be done in a qualified aseptic manufacturing suite at the FibroGen China manufacturing facility. After completion of the final validation of the sterile process (currently in progress), implants will be manufactured there for product registration testing, clinical testing, as well as for commercial use in the future.

GOVERNMENT REGULATION

The clinical testing, manufacturing, labeling, storage, distribution, record keeping, advertising, promotion, import, export and marketing, among other things, of our product candidates are subject to extensive regulation by governmental authorities in the U.S. and other countries. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations, including in Europe and China, requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the applicable regulatory authority to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by FDA and the Department of Justice, or other governmental entities.

U.S. Product Approval Process

In the U.S., the FDA regulates drugs and biological products, or biologics, under the Public Health Service Act, as well as the FDCA which is the primary law for regulation of drug products. Both drugs and biologics are subject to the regulations and guidance implementing these laws. Pharmaceutical products are also subject to regulation by other governmental agencies, such as the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services, the Consumer Product Safety Commission and the Environmental Protection Agency. The clinical testing, manufacturing, labeling, storage, distribution, record keeping, advertising, promotion, import, export and marketing, among other things, of our product candidates are subject to extensive regulation by governmental authorities in the U.S. and other countries. The steps required before a drug or biologic may be approved for marketing in the U.S. generally include:

- Preclinical laboratory tests and animal tests conducted under Good Laboratory Practices.
- The submission to the FDA of an IND for human clinical testing, which must become effective before each human clinical trial commence.
- Adequate and well-controlled human clinical trials to establish the safety and efficacy of the product and conducted in accordance with Good Clinical Practices.
- The submission to the FDA of an NDA, in the case of a small molecule drug product, or a BLA, in the case of a biologic product.
- FDA acceptance, review and approval of the NDA or BLA, as applicable.
- Satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made to assess compliance with cGMPs.

The testing and approval process requires substantial time, effort and financial resources, and the receipt and timing of any approval is uncertain. The FDA may suspend clinical trials at any time on various grounds, including a finding

that the subjects or patients are being exposed to a potentially unacceptable health risk.

Preclinical studies include laboratory evaluations of the product candidate, as well as animal studies to assess the potential safety and efficacy of the product candidate. Preclinical studies must be conducted in compliance with FDA regulations regarding GLPs. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of the IND, which includes the results of preclinical testing and a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase or phases of the clinical trial lends themselves to an efficacy determination. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the trials as outlined in the IND prior to that time. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. The IND must become effective before clinical trials may be commenced.

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

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

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

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

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

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

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

Review of Application

Once the NDA or BLA submission has been accepted for filing, which occurs, if at all, 60 days after submission, the FDA informs the applicant of the specific date by which the FDA intends to complete its review. This is typically 12 months from the date of submission. The review process is often extended by FDA requests for additional information or clarification. The FDA reviews NDAs and BLAs to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to

assure and preserve the product's identity, strength, quality and purity. Before approving an NDA or BLA, the FDA may inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facility complies with cGMPs and will also inspect clinical trial sites for integrity of data supporting safety and efficacy. During the approval process, the FDA also will determine whether a risk evaluation and mitigation strategy ("REMS"), is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the application must submit a proposed REMS; the FDA will not approve the application without an approved REMS, if required. A REMS can substantially increase the costs of obtaining approval. The FDA may also convene an advisory committee of external experts to provide input on certain review issues relating to risk, benefit and interpretation of clinical trial data. The FDA may delay approval of an NDA if applicable regulatory criteria are not satisfied and/or the FDA requires additional testing or information. The FDA may require post-marketing testing and surveillance to monitor safety or efficacy of a product. FDA will issue either an approval of the NDA or BLA or a Complete Response Letter detailing the deficiencies and information required in order for reconsideration of the application.

Pediatric Exclusivity and Pediatric Use

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

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

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

Post-Approval Requirements

Even after approval, drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to continuous regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

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

In addition, entities involved in the manufacture and distribution of approved drugs and biologics are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require

investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

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

- Restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls.
- Fines, warning letters or holds on post-approval clinical trials.

- Refusal of the FDA to approve pending NDAs or BLAs or supplements to approved NDAs or BLAs, or suspension or revocation of product license approvals.
- Product seizure or detention, or refusal to permit the import or export of products.
- Injunctions or the imposition of civil or criminal penalties.

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

Prescription Drug Marketing Act

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

Federal and State Fraud and Abuse and Data Privacy and Security and Transparency Laws and Regulations

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

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any good, facility, item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and our practices may not in all cases meet all of the criteria for a statutory exception or safe harbor protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 (collectively "PPACA"), to a stricter intent standard such that a person or entity no longer needs to have actual knowledge of this statute or the specific intent to violate it in order to have committed a violation. In addition, PPACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of

the civil False Claims Act (discussed below). Further, civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal false claims laws prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses. The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party 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 ("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.

66

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 U.S. and foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations as we begin to directly commercialize our products. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state level that seek to reduce healthcare costs. If a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”). The MMA imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval. However, any negotiated prices for our future products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain from non-governmental 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 U.S. to fundamental change. Initiatives to reduce the federal budget and debt and to reform healthcare coverage are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative healthcare benefits, controls on healthcare spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups, price controls on pharmaceuticals and other fundamental changes to the healthcare delivery system. Any proposed or actual changes could limit or eliminate our spending on development projects and affect our ultimate profitability. In March 2010, PPACA was signed into law. PPACA has the potential to substantially change the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, PPACA established: an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents; revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; and extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations. In the

future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit the prices we are able to charge for our products, or the amounts of reimbursement available for our products. If future legislation were to impose direct governmental price controls and access restrictions, it could have a significant adverse impact on our business. Managed care organizations, as well as Medicaid and other government agencies, continue to seek price discounts. Some states have implemented, and other states are considering, price controls or patient access constraints under the Medicaid program, and some states are considering price-control regimes that would apply to broader segments of their populations that are not Medicaid-eligible. Due to the volatility in the current economic and market dynamics, we are unable to predict the impact of any unforeseen or unknown legislative, regulatory, 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 U.S. 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 API 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 ("PPP"), as well as cGMP 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 cGMP certification for the commercial production of roxadustat at our Beijing manufacturing facility. Only after the issuance of the cGMP 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 ("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 cGMP 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. In January 2016, we received CFDA's approval of our device classification application 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 U.S., we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, manufacturing, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the U.S. apply similarly in the context of other countries we are seeking approval in, including Europe and China, the approval process varies between countries and jurisdictions and can involve different amounts of product testing and additional administrative review periods. For example, in Europe, a sponsor must submit a 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 U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to 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 U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves applications for any patent term extension or restoration. In the future, we expect to apply for restoration of patent term for patents relating to each of our product candidates in order to add patent life beyond the current expiration date of such patents, depending on the length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications of companies seeking to reference another company’s NDA or BLA. The Hatch-Waxman Act provides a 5-year period of exclusivity to any approved NDA for a product containing a 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 (“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 U.S. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the U.S., or if it affects more than 200,000 individuals in the U.S. there is no reasonable expectation that the cost of developing and making a drug product available in the U.S. for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

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

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

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

Our worldwide patent portfolio encompasses over 200 granted patents and 150 pending patent applications, including multiple granted and pending patent applications relating to roxadustat (FG-4592) and FG-3019. Currently granted patents relating to composition-of-matter for roxadustat and for FG-3019 are expected, for each product candidate, to expire in 2024 or 2025, in each case without any patent term extension that may be available due to regulatory delay. Two U.S. patents, and corresponding foreign patents if granted, relating to crystalline forms of roxadustat are expected to expire in 2033, without extension that may be available. Additional patents and patent applications relating to manufacturing processes, formulations, and various therapeutic uses, including treatment of specific indications and improvement of clinical parameters provide further protection for product candidates.

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

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

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

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

Roxadustat (FG-4592) Patent Portfolio

Our roxadustat patent portfolio includes multiple granted U.S. patents offering protection for roxadustat, including protection for roxadustat composition-of-matter, for pharmaceutical compositions containing roxadustat, and for methods for treating anemia using roxadustat or its analogs. Exclusive of any patent term extension, the granted U.S. patents relating to the composition-of-matter of roxadustat are due to expire in 2024 or 2025. Corresponding patents have been granted in Europe and in multiple territories worldwide. Exclusive of any patent term extension, these granted foreign patents, and any pending patent applications, if granted are due to expire in 2024. Two crystalline forms patents issued by the U.S. Patent and Trademark Office are due to expire in 2033, as would patents granted from the corresponding foreign patent applications currently pending worldwide.

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. Refer to "Government Regulation — Regulatory Exclusivity for Approved Products — U.S. Patent Term Restoration."

We also hold various U.S. and foreign granted patents and pending patent applications directed to manufacturing processes 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.

Roxadustat China Patent Portfolio

Our Chinese patent portfolio relating to roxadustat includes at least five granted Chinese patents covering roxadustat composition-of-matter and pharmaceutical compositions and uses thereof, as well as 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 pending Chinese patent applications relating to 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.

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. Refer to "Government Regulation — Regulatory Exclusivity for Approved Products — Foreign Country Data Exclusivity"

HIF Anemia-related Technologies Patent Portfolio

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

This 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 EPO 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 ("TSAT%").
- To overcome iron deficiency through effects on iron regulatory factors such as ferroportin and hepcidin.
- To provide coordinated erythropoiesis resulting in increased reticulocyte Hb content ("CHr"), and increased mean corpuscular volume ("MCV").
- To improve kidney function.

74

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

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

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

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 at least three granted U.S. patents providing composition-of-matter protection for FG-3019 and related antibodies, and for methods of using such 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 patent has been granted in Europe and 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. Refer to “Government Regulation — Regulatory Exclusivity for Approved Products.”

We also hold additional granted U.S. and foreign patents and pending patent applications directed to the use of FG-3019 to treat IPF, DMD, pancreatic cancer, liver fibrosis and other disorders.

Trade Secrets and Know-How

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

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

In-Licenses

Dana-Farber Cancer Institute

Effective March 2006, we entered into a license agreement with the Dana-Farber Cancer Institute ("DFCI"), under which we obtained an exclusive license to certain patent applications, patents and biological materials for all uses. The patent rights relate to inhibition of prolyl hydroxylation of the alpha subunit of hypoxia-inducible factor (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 ("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 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 ("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 ("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., 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 January 31, 2016, we had 353 full-time employees, 87 of whom held Ph.D. or M.D. degrees, 276 of whom were engaged in research and development and 77 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. 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.

FINANCIAL INFORMATION

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

Research and development expenses for fiscal years ended December 31, 2015, 2014 and 2013 were $214.1 million, $150.8 million, and $85.7 million, respectively. We expect our research and development expenses to continue to increase in the future as we advance our product candidates through clinical trials and expand our product candidate portfolio.

Our revenue to date has been generated primarily from our collaboration agreements with Astellas and AstraZeneca for the development and commercialization of roxadustat. For fiscal years ended December 31, 2015, 2014 and 2013, substantially all of our revenue was related to our collaboration agreements.

AVAILABLE INFORMATION

Our internet website address is www.fibrogen.com. In addition to the information about us and our subsidiaries contained in this Annual Report, information about us can be found on our website. Our website and information included in or linked to our website are not part of this Annual Report.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), are available free of charge through our website as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission (“SEC”). The public may read and copy the materials we file with the SEC at the SEC’s Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC’s website is www.sec.gov.

CORPORATE INFORMATION

We were incorporated in 1993 in Delaware. Our headquarters are located at 409 Illinois Street, San Francisco, California 94158 and our telephone number is (415) 978-1200. Our website address is www.FibroGen.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated into, this Annual Report.

Our subsidiaries consist of the following: 1) FibroGen Europe Oy (“FibroGen Europe”), a majority owned entity incorporated in Finland in 1996; 2) Skin Sciences, Inc., a majority owned entity incorporated in the State of Delaware in 1995; 3) FibroGen International (Cayman) Limited, a wholly owned entity incorporated in the Cayman Islands in 2011; 4) FibroGen China Anemia Holdings Ltd., a majority owned entity incorporated in the Cayman Islands in 2012; 5) FibroGen International (Hong Kong) Limited, a majority owned entity incorporated in Hong Kong in 2011; and 6) FibroGen (China) Medical Technology Development Co., Ltd., a majority owned entity incorporated in China in 2011.

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

Until the end of 2015, we were an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012 (”JOBS Act”). Based on the aggregate market value of the outstanding common stock held by non-affiliates as of June 30, 2015, the Company meets the criteria for a large accelerated filer. Beginning with this Annual Report on Form 10-K, we are no longer exempt, as an “emerging growth company,” from various reporting requirements applicable to other public companies, however through a permitted transition period until the third anniversary of our IPO, we may still choose to take advantage of the exemption from the requirements of holding a nonbinding advisory vote on executive compensation.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below in addition to the other information included or incorporated by reference in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Although we have discussed all known material risks, the risks described below are not the only ones that we may face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to Our Financial Condition and History of Operating Losses

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future and may never achieve or sustain profitability. We may require additional financings in order to fund our operations.

We are a clinical-stage biopharmaceutical company with two lead product candidates in clinical development, roxadustat in anemia in CKD, and FG-3019 in IPF, pancreatic cancer, DMD, 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 ("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, 2015, 2014 and 2013 was approximately $85.8 million, $59.5 million and $14.9 million, respectively. As of December 31, 2015, we had an accumulated deficit of $408.1 million. As of December 31, 2015, we had capital resources consisting of cash, cash equivalents and short-term investments of $181.2 million plus $131.7 million of long-term investments classified as available for sale securities. Despite contractual development and cost coverage commitments from our collaboration partners, AstraZeneca, and Astellas, and the potential to receive milestone and other payments from these partners, 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, 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 our initial public offering ("IPO"), our existing cash, cash equivalents and short-term investments and expected third party collaboration revenues will allow us to fund our operating plans through at least the next 12 months. Our operating plans or third party collaborations may change as a result of many factors, 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 ("U.S."), 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;
- regulatory compliance costs; 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 earned from collaboration partners for our product candidates under development.

During the years ended December 2015, 2014 and 2013, substantially all of our revenues recognized were from our collaboration partners.

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.

81

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 over 1,400 subjects have participated and for which we reported favorable primary and secondary safety and efficacy endpoint results. Based on our discussions with the U.S. FDA ("FDA"), we believe that we have an acceptable plan for the conduct of our 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, DMD, and liver fibrosis. FG-3019 requires substantial further development and investment. 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, pancreatic cancer, DMD, and liver fibrosis;
- 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 U.S. and in other countries where we intend to develop and, if approved, market any product candidates. Before obtaining regulatory approval for the commercial sale of any product candidate, we must demonstrate through extensive preclinical trials and clinical trials that the product candidate is safe and effective for use in each indication for which approval is sought. The regulatory review and approval process is expensive and requires substantial resources and time, and in general very few product candidates that enter development receive regulatory approval. In addition, our collaboration partners for roxadustat have final control over development decisions in their respective territories and they may make decisions with respect to development or regulatory authorities that delay or limit the potential approval of roxadustat, or increase the cost of development or commercialization. Accordingly, we may be unable to successfully develop or commercialize roxadustat or 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 take actions or impose requirements that 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 CKD or that FG-3019 is safe and effective in treating IPF, pancreatic cancer, DMD 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, (“CROs”), that conduct clinical trials on our behalf may take actions outside of our control that materially adversely impact our clinical trials;
- we or third party contractors manufacturing our product candidates may not maintain current good manufacturing practices (“cGMP”), successfully pass inspection or meet other applicable manufacturing regulatory requirements;
- regulatory authorities may not agree with our interpretation of the data from our preclinical trials and clinical trials;

- 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 (“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 U.S. 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 ("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.

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

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical and early clinical trials, which are often highly variable and use small sample sizes, may not be predictive of similar results in humans or in larger, controlled clinical trials, and successful results from 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 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 ("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 performed additional clinical pharmacology studies to evaluate if the effect of any such interaction could be minimized or eliminated by a modification of the dosing schedule that would separate the administration of roxadustat and the statin, however, such studies showed no minimization of effect. 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 ("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 low-density lipoprotein ("LDL"), and reduce the ratio of LDL to high-density lipoprotein ("HDL"), 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 preclinical and 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.

Success in preclinical and early clinical trials, which are often highly variable and use small sample sizes, may not be predictive of similar results in humans or in larger, controlled clinical trials, and successful results from early or small clinical trials may not be replicated or show as favorable an outcome, even if successful. 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, a Phase 2 dose finding trial of FG-3019 combined with gemcitabine plus erlotinib in 75 patients with pancreatic cancer and a randomized double-blind placebo controlled study for liver fibrosis in subjects with hepatitis B. 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 ("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 suggest 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 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 ("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. Refer to "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 labeling changes or withdrawal of ESAs 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 or quality, 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.

For example, we have a limited amount of FG-3019 in storage and there are long lead times required to manufacture and scale-up the manufacture of additional supply. If we are unable to manufacture sufficient quantities of FG-3019 on a timely basis, it may limit our ability to replenish inventory or delay our development of FG-3019 in some or all indications. 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. Refer to "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 ("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 have initiated 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.

In addition, in order for any Phase 3 clinical trial to support an NDA submission for approval, the FDA and foreign regulatory authorities require compliance with regulations and standards, including good clinical practices ("GCP") requirements for designing, conducting, monitoring, recording, analyzing and reporting the results of clinical trials to ensure that the data and results from trials are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Although we rely on third parties to conduct our clinical trials, we as the sponsor remain responsible for ensuring that each of these clinical trials is conducted in accordance with its general investigational plan and protocol under legal and regulatory requirements, including GCP. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If 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 exclude the use of patient data from our clinical trials not conducted in compliance with GCP or 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 or that our results may be used in support of our regulatory submissions.

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 any of them may fail to devote the necessary resources and attention to sell and market our products, if any, effectively. If they are not successful in commercializing our product candidates, our business and financial condition would suffer.

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

The development and commercialization of new pharmaceutical products is highly competitive. Our future success depends on our ability to achieve and maintain a competitive advantage with respect to the development and commercialization of our product candidates. Our objective is to discover, develop and commercialize new products with superior efficacy, convenience, tolerability and safety. We expect that in many cases, the products that we

commercialize will compete with existing, market-leading products of companies that have large, established commercial organizations.

If roxadustat is approved and launched commercially, competing drugs are expected to include ESAs, particularly in those patient segments where ESAs are used. Currently available ESAs include epoetin alfa (EPOGEN®, commercialized by Amgen Inc. in the U.S., Procrit® and Erypo®/Eprex®, commercialized by Johnson & Johnson Inc.), darbepoetin (Amgen/KHK's Aranesp® and NESP®) and Mircera ® commercialized by Hoffmann-La Roche ("Roche") outside of the U.S., and by Galenica, a Roche licensee in the U.S. and Puerto Rico, as well as biosimilar versions of these currently marketed ESA products. ESAs have been used in the treatment of anemia in CKD for over 20 years, serving a significant majority of DD-CKD 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 the treatment of anemia in CKD patients, including those patient segments not currently addressed by ESAs. Companies such as GlaxoSmithKline plc ("GSK"), Bayer Corporation ("Bayer"), Akebia Pharmaceuticals, Inc. ("Akebia"), and Japan Tobacco, who are currently developing HIF PH inhibitors, 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. Akebia recently announced that it has initiated its first Phase 3 study in NDD-CKD patients in December 2015, and is in discussion with the U.S. FDA regarding its DD-CKD program. GSK and Bayer are currently in Phase 2 development globally, and Japan Tobacco is in Phase 2b in Japan. 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. In addition, there are other companies developing biologic therapies for treatment of other anemia indications that we may also seek to pursue in the future, including MDS, for which we plan to submit a Clinical Trial Application in China in the first half of 2016 and may pursue in broader markets.

Introduction of biosimilar ESAs into the U.S. market may alter the pricing landscape for anemia therapies where ESAs are used.

The introduction of biosimilar ESAs into the market in the U.S. may occur by the time roxadustat enters the market and may alter the competitive and pricing landscape of anemia therapy in dialysis patients under the end stage renal disease bundle. 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 ("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 ("EU"), and the final material patents expired in May 2015 in the U.S. Several biosimilar versions of currently marketed ESAs are available for sale in the EU, China and other territories. In the U.S., a few ESA biosimilars are currently under development or regulatory review, including Retacrit™, an EPOGEN and Procrit biosimilar, which has been marketed by Hospira (now part of Pfizer) in Europe.

Large dialysis providers such as Fresenius and DaVita may expect us to enter into a sales-purchase contract which may impact usage and revenues for roxadustat, if approved and commercialized.

The majority of the current CKD anemia market focuses on dialysis patients, who visit dialysis centers on a regular basis, typically three times a week, and anemia therapies are administered as part of the visit. Two of the largest operators of dialysis clinics in the U.S., DaVita Healthcare Partners Inc. ("DaVita"), and Fresenius Medical Care AG & Co. KGaA ("Fresenius"), collectively, provide dialysis care to approximately 70% of the U.S. dialysis patients, and therefore have historically won long-term contracts including rebate terms with Amgen. DaVita's contract with Amgen that began in January 2012 includes an exclusive relationship through 2018. Fresenius' contract with Amgen is non-exclusive and expired in 2015. Fresenius is now administering Mircera ® in a significant portion of its U.S. dialysis patients since Mircera was made available by Galenica. Successful penetration of this market may require AstraZeneca to reach a significant agreement with Fresenius or DaVita, the two largest dialysis clinics in the U.S., 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 Roche's pirfenidone, which is approved for marketing in Europe, Canada, Japan and the U.S., and Boehringer Ingelheim's nintedanib which has been approved in the U.S. and 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 Bristol-Myers Squibb's BMS-986020 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 NewLink Genetics Corporation, Merrimack Pharmaceuticals, Inc., Momenta 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, and was the first drug approved in this disease in nearly a decade. On October 22, 2015, Merrimack Pharmaceuticals Inc., announced that it had received FDA approval for the use of ONIVYDE (irinotecan liposome injection) for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy.

If FG-3019 is approved and launched commercially to treat DMD, FG-3019 may face competition for some patients from Sarepta Therapeutics, Inc, as well as BioMarin, and PTC Therapeutics, Santhera Pharmaceuticals, Pfizer, Summit plc and Tivorsan Pharmaceuticals. BioMarin along with Sarepta, have entered clinical development with therapeutics based on exon-skipping technology which seeks to help patients produce functioning forms of the dystrophin protein. The lead molecules for both BioMarin (drisapersen) and Sarepta (eteplirsen) focus on skipping exon-51. Therapies skipping exon-51 target only approximately 13% of the patients who have DMD. To reach other DMD patients with their technology BioMarin and Sarepta would need to generate a new clinical candidate for each type of mutation in the dystrophin gene. PTC Therapeutics' product ataluren (Translarna™) received conditional approval in Europe in 2014. Translarna targets a different set of DMD patients from those being targeted by BioMarin's and Sarepta's existing exon-skipping therapeutics; however it is also limited to a subset of patients who carry a specific mutation. Conversely, FG-3019 is intended to treat DMD patients without limitation to type of mutation. Santhera Pharmaceuticals recently reported positive Phase 3 data with its drug idebenone (Raxone ® /Catena ®) in a trial measuring changes in lung function for DMD patients. Idebenone is a synthetic short-chain benzoquinone and a cofactor for the enzyme NAD(P)H:quinone oxidoreductase (NQO1). Pfizer's product candidate, which is in Phase 2 development, is an antibody targeting myostatin which is a protein that regulates muscle growth. The goal of the program is to increase muscle growth and muscle strength in patients with DMD. Summit plc and Tivorsan Pharmaceuticals are both working on drugs involving the utrophin pathway. Utrophin is a protein similar to dystrophin. Summit is conducting a Phase 1b trial and Tivorsan is conducting preclinical work.

If FG-5200 is approved and launched to treat corneal blindness resulting from partial thickness corneal damage in China, it is likely to compete with other products designed to treat corneal damage. For example, in April 2015, a subsidiary of China Regenerative Medicine International Limited received approval for their acellular porcine cornea stroma medical device to treat patients in China with corneal ulcers.

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.

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 third party reimbursement 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.

Price controls may limit the price at which products such as roxadustat, if approved, are sold. For example, reference pricing is used by various EU 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 CROs to assist in undertaking, managing, monitoring and executing our ongoing clinical trials, including those for roxadustat. We expect to continue to rely on CROs, clinical data management organizations, medical institutions and clinical investigators to conduct our development efforts in the future,

including our Phase 3 development program for roxadustat. We compete with many other companies for the resources of these third parties, and large pharmaceutical companies often have significantly more extensive agreements and relationships with such third party providers, and such third party providers may prioritize the requirements of such large pharmaceutical companies over ours. The third parties on whom we rely may terminate their engagements with us at any time, which may cause delay in the development and commercialization of our product candidates. If any such third party terminates its engagement with us or fails to perform as agreed, we may be required to enter into alternative arrangements, which would result in significant cost and delay to our product development program. Moreover, our agreements with such third parties generally do not provide assurances regarding employee turnover and availability, which may cause interruptions in the research on our product candidates by such third parties.

Moreover, while our reliance on these third parties for certain development and management activities will reduce our control over these activities, it will not relieve us of our responsibilities. For example, the FDA and foreign regulatory authorities require compliance with regulations and standards, including GCP requirements for designing, conducting, monitoring, recording, analyzing and reporting the results of clinical trials to ensure that the data and results from trials are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Although we rely on third parties to conduct our clinical trials, we, as the sponsor, remain responsible for ensuring that each of these clinical trials is conducted in accordance with its general investigational plan and protocol under legal and regulatory requirements, including GCP. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If 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 exclude the use of patient data from our clinical trials not conducted in compliance with GCP requirements or 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 or that our results may be used in support of our regulatory submissions.

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 clinical studies and 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 or our collaboration partners' specifications, or the regulatory requirements of the FDA or other regulatory authorities, we may not be able to secure and/or maintain regulatory approval for our product candidates and our development or commercialization plans may be delayed. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. In addition, although our longer-term agreements are expected to provide for requirements to meet our quantity and quality requirements to manufacture our products candidates for clinical studies and commercial sale, we will have minimal direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel and we expect to rely on our audit rights to ensure that those qualifications are maintained to meet our requirements. If our contract manufacturers' facilities do not pass inspection by regulatory authorities, or if regulatory authorities do not approve these facilities for the manufacture of our products, or withdraw any such approval in the future, we would need to identify and qualify alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products, if approved. Moreover, any failure of our third party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us or adverse regulatory consequences, including clinical holds, warnings or untitled letters, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which would be expected to significantly and adversely affect supplies of our products to us and our collaboration partners.

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 ingredients ("APIs") or drug products. With respect to roxadustat, AstraZeneca and Astellas have certain rights to assume manufacturing of roxadustat and the existence of those rights may limit our ability to enter into favorable long-term supply agreements, if at all, with other third party manufacturers. In addition, our product candidates and any products that we may develop may compete with other product candidates and products for access and prioritization to manufacture. Certain third party manufacturers may be contractually prohibited from manufacturing our product due to non-compete agreements with our competitors or a commitment to grant another party priority relative to our products. There are a limited number of third party manufacturers that operate under cGMP and that might be capable of manufacturing to meet our requirements. Due to the limited number of third party manufacturers with the contractual freedom, expertise, required regulatory approvals and facilities to manufacture our products on a commercial scale, identifying and qualifying a replacement third party manufacturer would be expensive and time-consuming and may cause delay or interruptions in the production of our product candidates or products, which in turn may delay, prevent or impair our development and commercialization efforts.

We have a letter agreement with IRIX Pharmaceuticals, Inc. ("IRIX"), a third party manufacturer that we have used in the past, pursuant to which we agreed to negotiate a single source manufacturing agreement that included a right of first negotiation for the cGMP manufacture of HIF-PH inhibitors, including roxadustat, provided that IRIX is able to match any third party bids within 5%. The exclusive right to manufacture extends for five years after approval of an NDA for those compounds, and any agreement would provide that no minimum amounts would be specified until appropriate by forecast and that we and a commercialization partner would have the rights to contract with independent third parties that exceed IRIX's internal manufacturing capabilities or in the event that we or our commercialization partner determines for reasons of continuity of supply and security that such a need exists, provided that IRIX would supply no less than 65% of the product if it is able to provide this level of supply. Subsequent to the letter agreement, we and IRIX have entered into several additional service agreements. IRIX has requested in writing that we honor the letter agreement with respect to the single source manufacturing agreement, and

if we were to enter into any such exclusive manufacturing agreement, there can be no assurance that IRIX will not assert a claim for right to manufacture roxadustat or that IRIX could manufacture roxadustat successfully and in accordance with applicable regulations for a commercial product and the specifications of our collaboration partners. In 2015, Patheon Pharmaceuticals Inc., a business unit of DPx Holdings B.V., acquired IRIX.

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

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trade secret protection and contractual arrangements to protect the intellectual property related to our technologies. We will only be able to protect our products and proprietary information and technology by preventing unauthorized use by third parties to the extent that our patents, trade secrets, and contractual position allow us to do so. Any disclosure to or misappropriation by third parties of our trade secrets or confidential information could compromise our competitive position. Moreover, we are involved in, have in the past been involved in, and may in the future be involved in legal or administrative proceedings involving our intellectual property initiated by third parties, and which proceedings can result in significant costs and commitment of management time and attention. As our product candidates continue in development, third parties may attempt to challenge the validity and enforceability of our patents and proprietary information and technologies.

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

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

Biotechnology and pharmaceutical product patents involve highly complex legal and scientific questions and can be uncertain. Any patent applications that we own or license may fail to result in issued patents. Even if patents do successfully issue from our applications, third parties may challenge their validity or enforceability, which may result in such patents being narrowed, invalidated, or held unenforceable. Even if our patents and patent applications are not challenged by third parties, those patents and patent applications may not prevent others from designing around our claims and may not otherwise adequately protect our product candidates. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, competitors with significantly greater resources could threaten our ability to commercialize our product candidates. Discoveries are generally published in the scientific literature well after their actual development, and patent applications in the U.S. and other countries are typically not published until 18 months after filing, and in some cases are never published. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or patent applications, or that we or our licensors were the first to file for patent protection covering such inventions. Subject to meeting other requirements for patentability, for U.S. patent applications filed prior to March 16, 2013, the first to invent the claimed invention is entitled to receive patent protection for that invention while, outside the U.S., the first to file a patent application encompassing the invention is entitled to patent protection for the invention. The U.S. moved to a “first to file” system under the Leahy-Smith America Invents Act (“AIA”), effective March 16, 2013. The effects of this change and other elements of the AIA are currently unclear, as the U.S. Patent and Trademark Office (“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 U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property globally. If we are unable to prevent unauthorized disclosure of our intellectual property related to our product candidates and technology to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business and operations.

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

Our commercial success may depend on our avoiding infringement of the patents and other proprietary rights of third parties as well as on enforcing our patents and other proprietary rights against third parties. Pharmaceutical and biotechnology intellectual property disputes are characterized by complex, lengthy and expensive litigation over patents and other intellectual property rights. We may initiate or become 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 (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, and while loss 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, 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 U.S. or other countries. Third parties may use our technologies in territories in which we have not obtained patent protection to develop their own products and, further, may infringe our patents in territories which provide inadequate enforcement mechanisms, even if we have patent protection. Such third party products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

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

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

- Others may be able to make compounds that are the same as or similar to our current or future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- The prosecution of our pending patent applications may not result in granted patents.
- Granted patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product.
- Our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale

in markets where we intend to market our product candidates.

99

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 or used for research under the same or similar names, or similar mechanism of action or product class, but which are sold without proper licenses or approvals. Such products may be used for indications or purposes that are not recommended or approved or for which there is no data or inadequate data with regard to safety or efficacy. Such products divert sales from genuine products, 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 or used for research result in adverse events or side effects to consumers, we may be associated with any negative publicity resulting from such incidents. Consumers may buy counterfeit pharmaceuticals that are in direct competition with our pharmaceuticals, which could have an adverse impact on our revenues, business and results of operations. In addition, the use of counterfeit products could be used in non-clinical or clinical studies, or could otherwise produce undesirable side effects or adverse events that may be attributed to our products as well, which could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. With respect to China, although the government has recently been increasingly active in policing counterfeit pharmaceuticals, there is not yet an effective counterfeit pharmaceutical regulation control and enforcement system in China. As a result, we may not be able to prevent third parties from selling or purporting to sell our products in China. The proliferation of counterfeit pharmaceuticals has grown in recent years and may continue to grow in the future. The existence of and any increase in the sales and production of counterfeit pharmaceuticals, or the technological capabilities of counterfeiters, could negatively impact our revenues, brand reputation, business and results of operations.

Risks Related to Government Regulation

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

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions. 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 U.S. where the standard of care is potentially different from that in the U.S.;
- the insufficiency of data collected from clinical trials of our present or future product candidates to support the submission and filing of an NDA or other submission or to obtain regulatory approval;

- disapproval of the manufacturing processes or facilities of either our manufacturing plant or third party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or other regulatory authorities may require more information, including additional preclinical or clinical data to support approval, 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 U.S. include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
    - federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent;
- 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 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 the PPACA, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the 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; and
- foreign and state law equivalents of each of the above federal laws, such as the U.S. Foreign Corrupt Practices Act (“FCPA”), anti-kickback and false claims laws that may apply to items or services reimbursed by any third party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing

the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

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 U.S. 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 U.S. and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

In the U.S., the 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 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, if approved, will be included in the payment bundle. Under MIPPA, agents that have no IV equivalent in the bundle are currently expected to be excluded from the bundle until 2025. If roxadustat were included in the bundle, it may reduce the price that could be charged for roxadustat, and therefore potentially limit our profitability. Based on roxadustat’s differentiated mechanism of action and therapeutic effects, and discussions with our collaboration partner, we currently believe that roxadustat might not be included in the bundle. If roxadustat is reimbursed outside of the bundle, it may potentially limit or delay market penetration of roxadustat.

More recently, the 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 U.S. 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 U.S. 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 failure to:

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

Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions, delays in clinical trials, or serious harm to our reputation. We have adopted a code of conduct for our directors, officers and employees (“Code of Business Conduct and Ethics”), but it is not always possible to identify and deter employee misconduct. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could harm our business, results of operations, financial condition and cash flows, including through the imposition of significant fines or other sanctions.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our

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

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

Risks Related to Our International Operations

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

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

- different regulatory requirements for drug approvals in foreign countries;
- different standards of care in various countries that could complicate the evaluation of our product candidates;
- different U.S. and foreign drug import and export rules;
- reduced protection for intellectual property rights in certain countries;
- 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 U.S.;
- 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. Refer to “Business — Government Regulation — Regulation in China” for a discussion of the regulatory requirements that are applicable to our current and planned business activities in China. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. 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 we 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 of our study results may lead the 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 planning on using our own manufacturing facility in China to produce roxadustat drug product, and possibly API, and corneal implants. As an organization, we have limited experience in the construction, licensure, 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.

In 2014, we recently received a Pharmaceutical Production Permit for our facility in China in which we intend to manufacture roxadustat. The Pharmaceutical Production Permit allowed us to produce the NDA registration campaign of roxadustat according to cGMP. However, we have not yet received a license for commercial manufacture of roxadustat. 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.

We would require separate approval for the manufacture of FG-5200. In addition, we may convert our existing manufacturing process of FG-5200 to a semi-automated process which may 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. Certain equipment, records and other materials located in these facilities would be difficult to replace or would require substantial replacement lead time that would impact our ability to successfully commercialize our product candidates in China. The occurrence of any such event could materially and adversely affect our business, financial condition, results of operations, cash flows and prospects.

105

Our decision to seek approval in China for roxadustat prior to approval in the U.S. or Europe is largely unprecedented and could be subject to significant risk, delay and expense.

Our subsidiaries, FibroGen China Anemia Holdings, Ltd. and FibroGen (China) Medical Technology Development Co., Ltd. (individually or collectively referred to as "FibroGen China"), plan to seek approval for roxadustat in China as a Domestic Class 1.1 Drug, which we believe, if approved, would be the first CFDA approval of a first in class drug candidate while Phase 3 trials are ongoing in the U.S. and Europe. Because of this largely novel regulatory pathway, the CFDA approval process may take longer than we currently expect, or the CFDA may require us to submit additional data including data from the U.S. or European Phase 3 trials. In addition, negative data from the U.S. or European Phase 3 trials could impact the CFDA approval process. Any such development delays would result in significant delay in our commercialization plans for roxadustat in China. Elements of our plan for approval of roxadustat and other product candidates in China are based on communications with the CFDA, some of which are not reflected in formal written communications, 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, or that additional or different clinical data must be generated, 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. It is possible that other unforeseen delays in the China regulatory process could have a material adverse effect on our development and commercialization of roxadustat in China. For example, some of our clinical trial sites recently received permission from the Ministry of Science and Technology, under a new approval process, to obtain routine blood and urine samples that contain genetic information. Such applications are reviewed only on a quarterly basis, thus studies to be performed at additional clinical trial sites could be delayed until they receive approval.

In addition, there are evolving environmental and manufacturing regulations in China. Final regulations and the application thereof, and any further changes to these regulations may impact our API manufacturing location or strategy. It is possible that we may be able to produce API at contract manufacturers or we may be required to move our API manufacturing to another facility that we must build outside of Beijing. The exact impact of these regulations are yet to be determined, however, it is possible that they could adversely affect the cost or, potentially, the timeline of our commercial manufacturing plan and timing of our commercialization 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 Kyowa Hakko Kirin Brewery Co., Ltd. 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. Refer to "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 ("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.

Even if FG-5200 can be manufactured successfully and achieve regulatory approval, we may not achieve commercial success.

We have not yet received a license to manufacture FG-5200 in our China manufacturing facility or at scale, and 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.

107

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

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

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

We plan to conduct all of our business in China through FibroGen Beijing. We may rely on dividends and royalties paid by FibroGen Beijing for a portion of our cash needs, including the funds necessary to service any debt we may incur and to pay our operating expenses. The payment of dividends by FibroGen Beijing is subject to limitations. Regulations in China currently permit payment of dividends only out of accumulated profits as determined in accordance with accounting standards and regulations in China. FibroGen Beijing is not permitted to distribute any profits until losses from prior fiscal years have been recouped and in any event must maintain certain minimum capital requirements. FibroGen Beijing is also required to set aside at least 10.0% of its after-tax profit based on Chinese accounting standards each year to its statutory reserve fund until the cumulative amount of such reserves reaches 50.0% of its registered capital. Statutory reserves are not distributable as cash dividends. In addition, if FibroGen Beijing incurs debt on its own behalf in the future, the agreements governing such debt may restrict its ability to pay dividends or make other distributions to us. As of December 31, 2015, approximately $26.6 million of our cash and cash equivalents is held in China.

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

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

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

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

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

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

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

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

In addition, we and our foreign subsidiaries have various intercompany transactions. We may not be able to obtain certain benefits under relevant tax treaties to avoid double taxation on certain transactions among our subsidiaries. If we are not able to avail ourselves of the tax treaties, we could be subject to additional taxes, which could adversely affect our financial condition 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 pursuing patent applications in China and other countries, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. We currently have at least 5 granted patents relating to roxadustat in China. Refer to "Business — Intellectual Property." We note that, the filing of a patent application does not mean that we will be granted a patent, or that any patent eventually granted will be as broad as requested in the patent application or will be sufficient to protect our technology. There are a number of factors that could cause our patents, if granted, to become invalid or unenforceable or that could cause our patent applications not to be granted, including known or unknown prior art, deficiencies in the patent application, or lack of originality of the technology. Furthermore, the terms of our patents are limited. The patents we hold and patents that may be granted from our currently pending patent applications have, absent any patent term adjustment or extension, a twenty-year protection period starting from the date of application.

Intellectual property rights and confidentiality protections in China may not be as effective as those in the U.S. or other countries for many reasons, including lack of procedural rules for discovery and evidence, low damage awards, and lack of judicial independence. Implementation and enforcement of 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, 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 U.S. to comply with certain accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

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

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

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

As we expand our operations in China and other jurisdictions internationally, we will need to increase the scope of our compliance programs to address the risks relating to the potential for violations of the FCPA and other anti-bribery and anti-corruption laws. Our compliance programs will need to include policies addressing not only the FCPA, but also the provisions of a variety of anti-bribery and anti-corruption laws in multiple foreign jurisdictions, including

China, provisions relating to books and records that apply to us as a public company, and include effective training for our personnel throughout our organization. The creation and implementation of anti-corruption compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required. Violation of the FCPA and other anti-corruption laws can result in significant administrative and criminal penalties for us and our employees, including substantial fines, suspension or debarment from government contracting, prison sentences, or even the death penalty in extremely serious cases in certain countries. The SEC also may suspend or bar us from trading securities on U.S. exchanges for violation of the FCPA's accounting provisions. Even if we are not ultimately punished by government authorities, the costs of investigation and review, distraction of 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.

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

The legal system of China is a civil law system primarily based on written statutes. Unlike in a common law system, prior court decisions may be cited for reference but are not binding. Because the China legal system continues to rapidly evolve, the interpretations of many laws, regulations and rules are not always uniform and enforcement of these laws, regulations and rules involve uncertainties, which may limit legal protections available to us. Moreover, decision makers in the China judicial system have significant discretion in interpreting and implementing statutory and contractual terms, which may render it difficult for FibroGen Beijing to enforce the contracts it has entered into with our business partners, customers and suppliers. Different government departments may have different interpretations of certain laws and regulations, and licenses and permits issued or granted by one government authority may be revoked by a higher government authority at a later time. Navigating the uncertainty and change in the China legal system will require the devotion of significant resources and time, and there can be no assurance that our contractual and other rights will ultimately be enforced.

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

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 Beijing's liquidity, access to capital and its ability to conduct business in China. Any failure on our part to comply with changing government regulations and policies could result in the loss of our ability to develop and commercialize our product candidates in China.

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.

Risks Related to the Operation of Our Business

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

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, commercialization and administration capabilities or contract with third parties to provide these capabilities for us. As our operations expand and we continue to undertake the efforts and

expense to operate as a public reporting company, we expect that we will need to increase the responsibilities on members of management in order to manage any future growth effectively. Our failure to accomplish any of these steps could prevent us from successfully implementing our strategy and maintaining the confidence of investors in 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 B. 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 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

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

In general, pharmaceutical, biotechnology and other life sciences company stocks have been highly volatile in the current market. The volatility of pharmaceutical, biotechnology and other life sciences company stocks is sometimes unrelated to the operating performance of particular companies and biotechnology and life science companies stocks often respond to trends and perceptions rather than financial performance. In particular, the market price of shares of our common stock could be subject to wide fluctuations in response to the following factors:

- results of clinical trials of our product candidates, including roxadustat and 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 U.S. 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 continue to publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of 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 January 31, 2016, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 26.02% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after such date and shares issuable upon settlement of restricted stock units that will vest within 60 days after such date. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. The interests of this group may differ from those of other stockholders and they may vote their shares in a way that is contrary to the way other stockholders vote their shares. This concentration of ownership could have the effect of entrenching our management and/or the board of directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

114

Until the end of 2015, we were an "Emerging Growth Company," and any decision on our part to comply only with certain reduced disclosure requirements applicable to us could make our common stock less attractive to investors.

Until the end of 2015, we were an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). As an "emerging growth company," we were able to take advantage of certain exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies." These exemptions include, but are not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Through a permitted transition period until the third anniversary of our IPO, we may still choose to take advantage of the exemption from the requirement of holding a nonbinding advisory vote on executive compensation.

We cannot predict if investors will find our common stock less attractive given that we have chosen to rely on certain exemptions available to "emerging growth companies" in the past, and may continue to do so through the transition period as permitted. If some investors find our common stock less attractive as a result of any choices to reduce disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

Additional remedial measures that may be imposed in the 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 consolidated 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 ("CSRC"). 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. In February 2015, the Chinese affiliates of the "big four" accounting firms each agreed to a censure and to pay a fine to the SEC to settle the dispute and avoid suspension of their ability to practice before the SEC and audit U.S.-listed companies. The settlement required the firms to follow detailed procedures and to seek to provide the SEC with access to Chinese firms' audit documents via the CSRC. If future document productions fail to meet specified criteria, the SEC retains authority to impose a variety of additional remedial measures on the firms depending on the nature of the failure.

We cannot predict if the SEC will further review the four firms' compliance with specified criteria or if such further review would result in the SEC imposing additional penalties such as suspensions or commencing any further administrative proceedings. 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 Exchange Act. Such a determination could ultimately lead to the delisting of our shares from the NASDAQ Global Select Market or deregistration from the SEC, or both, which would substantially reduce or effectively terminate the

trading of our stock.

We are incurring significant compliance costs as a result of operating as a public company and our management is required to devote substantial resources to public company compliance programs.

As a newly public company, we are incurring 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 are currently and intend to continue 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, particularly now that we are no longer an "emerging growth company". 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 may 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 now required to comply with the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act ("Section 404"). 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. In addition, we are required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with this Annual Report on Form 10-K since we have lost our status as an "emerging growth company". 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 consolidated 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 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.

117

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 ("Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses ("NOLs") or tax credits ("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 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 U.S. federal and state taxable income. As described above under "— Risks Related to Our Financial Condition 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 U.S. federal or state taxable income necessary to utilize our NOLs or credits. A full valuation allowance has been provided for all of our NOLs and credits.

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

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

We are also subject to non-income taxes, such as payroll, sales, use, value-added, net worth, property and goods and services taxes in the U.S. and various foreign jurisdictions. We are subject to audit and assessments by tax authorities with respect to these non-income taxes and may have exposure to additional non-income tax liabilities which could have an adverse effect on our results of operations and financial condition.

Our amended and restated certificate of incorporation designates the state or federal courts located in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the state and federal courts located in the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated by-laws, or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate and research and development operations are located in San Francisco, California, where we lease approximately 234,000 square feet of office and laboratory space with approximately 35,000 square feet subleased. The lease for our San Francisco headquarters expires in 2023. 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. This lease and associated subleases expired in February 2015. 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.

ITEM 3. LEGAL PROCEEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information for Common Stock

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

The following table sets forth for the indicated periods the high and low closing sales prices of our common stock as reported on the NASDAQ.

	High	Low
2015:		
Quarter ended March 31, 2015	$36.23	$27.48
Quarter ended June 30, 2015	30.99	17.36
Quarter ended September 30, 2015	29.76	21.66
Quarter ended December 31, 2015	31.36	20.53
2014:		
Quarter ended December 31, 2014 (1)	$31.48	$20.10

(1) Beginning on November 14, 2014

Stock Price Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return for our common stock since November 14, 2014, which is the date our common stock first began trading on the NASDAQ Global Select Market, to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes an initial investment of $100 on November 14, 2014, in our common stock, the stocks comprising the NASDAQ Composite Index, and the stocks comprising the NASDAQ Biotechnology Index. The stockholder return shown in the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

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

Dividend Policy

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

Stockholders

As of January 31, 2016, there were 329 registered stockholders of record for our common stock. This number of registered stockholders does not include stockholders whose shares are held in street name by brokers and other nominees, or may be held in trust by other entities. Therefore, the actual number of stockholders is greater than this number of registered stockholders of record.

Use of Proceeds from Initial Public Offering of Common Stock

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

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated results of operations data for the years ended December 31, 2015, 2014 and 2013, and the consolidated balance sheet data as of December 31, 2015 and 2014 should be read together with Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in conjunction with the consolidated financial statements, related notes, and other financial information included elsewhere in this Annual Report. The selected consolidated results of operations data for the year ended December 31, 2012 and the consolidated balance sheet data as of December 31, 2013 and 2012 have been derived from audited financial statements not included herein. Our historical results are not necessarily indicative of the results to be expected in the future.

	Years Ended December 31,			
	2015	2014	2013	2012
	(in thousands, except for per share data)			
Result of Operations				
Revenue:				
License and milestone revenue	$148,093	$117,191	$94,961	$62,845
Collaboration services and other revenue	32,735	20,410	7,209	3,088
Total revenue	180,828	137,601	102,170	65,933
Operating expenses:				
Research and development (1)	214,089	150,794	85,710	74,222
General and administrative (1)	44,364	36,909	24,409	18,934
Total operating expenses	258,453	187,703	110,119	93,156
Loss from operations	(77,625)	(50,102)	(7,949)	(27,223)
Total interest and other, net	(7,912)	(9,402)	(6,994)	(5,448)
Loss before income taxes	(85,537)	(59,504)	(14,943)	(32,671)
Provision for (benefit from) income taxes	242	—	—	(100)
Net loss	$(85,779)	$(59,504)	$(14,943)	$(32,571)
Net loss per share—basic and diluted	$(1.42)	$(3.17)	$(1.13)	$(2.48)
Weighted-average number of common shares used in net loss per share— basic and diluted	60,337	18,775	13,186	13,128

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

	Years Ended December 31,

	2015	2014	2013	2012
	(in thousands)			
Research and development	$16,987	$10,893	$1,925	$2,277
General and administrative	10,694	7,805	1,519	2,284
Total stock-based compensation expense	$27,681	$18,698	$3,444	$4,561

122

	December 31,			
	2015	2014	2013	2012
	(in thousands)			
Balance Sheet Data:				
Cash and cash equivalents	$153,324	$165,455	$76,332	$38,872
Short-term and long-term investments	159,567	158,633	61,833	82,630
Working capital	133,383	135,484	106,164	29,125
Total assets	470,574	483,528	296,952	265,588
Deferred revenue	97,860	70,206	36,649	5,764
Lease financing obligations	97,445	97,221	96,809	92,902
Product development obligations	15,085	16,465	18,257	17,152
Senior preferred stock	—	—	168,436	168,436
Junior preferred stock	—	—	136,313	136,313
Accumulated deficit	(408,062)	(322,283)	(262,779)	(247,836)
Total stockholders' equity (deficit)	177,554	221,405	(88,708)	(73,952)
Non-controlling interests	19,271	19,271	27,875	27,700
Total equity (deficit)	$196,825	$240,676	$(60,833)	$(46,252)

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes and other financial information included in Item 15 of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, international operations and product candidates, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this Annual Report for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

BUSINESS OVERVIEW

We were incorporated in 1993 in Delaware and 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 ("HIF"), biology to generate multiple programs targeting various therapeutic areas. 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 our monoclonal antibody in Phase 2 clinical development for the treatment of idiopathic pulmonary fibrosis ("IPF"), pancreatic cancer, Duchenne muscular dystrophy ("DMD") 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 ("China").

Financial Highlights

	Years Ended December 31,		
	2015	2014	2013
	(in thousands, except for per share data)		
Result of Operations			
Revenue	$180,828	$137,601	$102,170
Operating expenses	258,453	187,703	110,119
Net loss	(85,779)	(59,504)	(14,943)
Net loss per share - basic and diluted	$(1.42)	$(3.17)	$(1.13)

	December 31,	
	2015	2014
Balance Sheet		
Cash and cash equivalents	$153,324	$165,455
Short-term and long-term investments	$159,567	$158,633
Accounts receivable	$15,405	$13,453

Our revenue for the year ended December 31, 2015 increased compared to the prior year primarily due to an upfront payment of $120.0 million and a development milestone payment of $15.0 million received in the second quarter of 2015 under the collaboration agreements with AstraZeneca AB ("AstraZeneca"), as compared to an upfront payment of $110.0 million received from AstraZeneca in 2014. The increase in operating expenses for the year ended December 31, 2015 resulted primarily from the progression of our clinical trials and expenses to support our new requirements as a public company. During the year ended December 31, 2015, we had a net loss of $85.8 million, or net loss per basic and diluted share of $1.42. The increase in net loss for the year ended December 31, 2015 compared to the prior year

is primarily due to higher operating expenses, partially offset by an increase in revenue. The decrease in net loss per basic and diluted share for the year ended December 31, 2015 compared to the prior year is primarily due to an increase in the weighted average number of common shares outstanding as a result of the initial public offering ("IPO").

Cash and cash equivalents, short-term and long-term investments and accounts receivable were $153.3 million, $159.6 million and $15.4 million, respectively, at December 31, 2015, a total decrease of $9.2 million from December 31, 2014, primarily due to cash used in operations partially offset by payments received from AstraZeneca.

Our research and development expenses were $214.1 million, $150.8 million and $85.7 million for the years ended December, 31, 2015, 2014 and 2013, respectively. Since inception and through December 31, 2015, we have incurred a total of $1,132.5 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 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.

As of December 31, 2015, the $116.5 million cap on our share of development costs for roxadustat has been reached. As such, all future development and commercialization costs for roxadustat for the treatment of anemia in CKD in the United States (“U.S.”), Europe, Japan and all other markets outside of China will be paid by Astellas Pharma Inc. (“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, refer to “Risk Factors.”

Programs

During 2015, we continued to make progress in the development of our major programs.

Roxadustat is the first HIF-PH inhibitor to enter Phase 3 clinical development and acts by stimulating the body’s natural pathway of erythropoiesis, or red blood cell production. We, along with our collaboration partners Astellas and AstraZeneca, continue to advance roxadustat through our global Phase 3 program, conducting seven studies designed to support regulatory approval of roxadustat in both dialysis-dependent CKD (“DD-CKD”) patients and CKD patients who are not dialysis-dependent (“NDD-CKD”) in multiple geographies. For the three FibroGen roxadustat Phase 3 studies, we have reached approximately 90% of our cumulative target enrollment agreed upon with our partners. We currently anticipate submitting a New Drug Application (“NDA”) for roxadustat in the U.S. in 2018 and initiating the NDA process for roxadustat in China in the fourth quarter of 2016. Our subsidiary FibroGen (China) Medical Technology Development Co., Ltd. (“FibroGen Beijing”) began enrolling patients in our China Phase 3 studies in December 2015.

FG-3019 is our fully-human monoclonal antibody that inhibits the activity of connective tissue growth factor, a critical common element in the progression of fibrosis and associated serious diseases. 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 stage 3 pancreatic cancer; and an open label single arm trial in non-ambulatory boys with DMD. Additionally, we are also preparing to conduct an exploratory clinical trial in liver

fibrosis due to non-alcoholic steatohepatitis.

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

Collaboration Partnerships For Roxadustat

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

Astellas

In June 2005, we entered into a collaboration agreement with Astellas for 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"). Under these agreements, we provided Astellas the right to develop and commercialize roxadustat for anemia in these territories.

We share responsibility with Astellas for clinical development activities required for U.S. and the European Union ("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 to us the relevant trademarks used with the products in the Astellas territories. Under certain terminations, Astellas is also obligated to pay us a termination fee.

Consideration under these agreements includes a total of $360.1 million in upfront and non-contingent payments, and milestone payments totaling $557.5 million, of which $542.5 million are development and regulatory milestones, and $15.0 million are commercial-based milestones. Total consideration, excluding development cost reimbursement and product sales-related payments, could reach $917.6 million. The aggregate amount of such consideration received through December 31, 2015 totals $462.6 million.

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

In addition, as of December 31, 2015, Astellas has separately invested $80.5 million in the equity of FibroGen, Inc.

AstraZeneca

In July 2013, we entered into a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in the U.S. and all territories not previously licensed to Astellas, except China ("U.S./RoW Agreement"). In July 2013, through our China subsidiary and related affiliates, we entered into a collaboration agreement with AstraZeneca for roxadustat for the treatment of anemia in China ("China Agreement"). Under these agreements we provided AstraZeneca the right to develop and commercialize roxadustat for anemia in these territories. We share responsibility with AstraZeneca for clinical development activities required for U.S. regulatory approval of roxadustat.

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

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

Under the AstraZeneca agreements, we will receive upfront and subsequent non-contingent payments totaling $402.2 million, a portion of which we have received and the remainder of which we expect to receive in various amounts through 2016, including a $62.0 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 December 31, 2015 totals $355.2 million.

During the second quarter of 2015, we received an upfront payment of $120.0 million and a development milestone payment of $15.0 million under the U.S./RoW Agreement. The development milestone payment resulted from the finalization of our two audited pre-clinical carcinogenicity study reports.

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

Concurrent with our IPO, AstraZeneca purchased 1,111,111 shares of our common stock at the IPO price for an aggregate purchase price of $20.0 million in a private placement.

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

Under the China Agreement, which is conducted through FibroGen China, 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 Beijing has achieved profitability. At that time, AstraZeneca will recoup 50% of their historical launch costs out of initial roxadustat profits in China.

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

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

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

Additional Information Related to Collaboration Agreements

Of the $1,113.5 million in development and regulatory milestones payable in the aggregate under our Astellas and AstraZeneca collaboration agreements, $425.0 million is payable upon achievement of milestones relating to the submission and approval of roxadustat in DD-CKD and NDD-CKD in the U.S. and Europe.

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

Total cash consideration received through December 31, 2015 and potential cash consideration, other than development cost reimbursement, transfer price payments, royalties and profit share, pursuant to our existing collaboration agreements are as follows:

	Cash Received Through December 31, 2015	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:			
U.S. / RoW Agreement	327,000	922,000	1,249,000
China Agreement	28,200	348,500	376,700
Total AstraZeneca	355,200	1,270,500	1,625,700
Total revenue	$817,793	$ 1,725,500	$ 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.

RESULTS OF OPERATIONS

Revenue

	Years Ended December 31,			Change 2015 vs. 2014		Change 2014 vs. 2013	
	2015	2014	2013	$	%	$	%
	(dollars in thousands)						
Revenue:							
License and milestone revenue	$148,093	$117,191	$94,961	$30,902	26 %	$22,230	23 %
Collaboration services and other revenue	32,735	20,410	7,209	12,325	60 %	13,201	183 %
Total revenue	$180,828	$137,601	$102,170	$43,227	31 %	$35,431	35 %

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

Under our revenue recognition policy, license revenue includes amounts from upfront, non-refundable license payments and amounts allocated pursuant to the 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 82%, 85% and 93% of total revenues for the years ended December 31, 2015, 2014 and 2013, 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, 2015, 2014 and 2013. Collaboration services and other revenues represented 18%, 15% and 7% of total revenues for the years ended December 31, 2015, 2014 and 2013, respectively.

We have not generated any revenues based on the sale of U.S. Food and Drug Administration or China Food and Drug Administration approved 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.

Total revenue increased by $43.2 million, or 31% for the year ended December 31, 2015 compared to the year ended December 31, 2014, and increased by $35.4 million, or 35%, for the year ended December 31, 2014 compared to the year ended December 31, 2013 for the reasons discussed in the sections below.

License and Milestone Revenue

	Years Ended December 31,			Change 2015 vs. 2014		Change 2014 vs. 2013	
	2015	2014	2013	$	%	$	%
	(dollars in thousands)						
License and milestone revenue:							
Astellas	$18,701	$14,453	$22,326	$4,248	29 %	$(7,873)	(35)%
AstraZeneca	129,392	102,738	72,635	26,654	26 %	30,103	41 %
Total license and milestone revenue	$148,093	$117,191	$94,961	$30,902	26 %	$22,230	23 %

Comparison of the years ended December 31, 2015 and 2014

License and milestone revenue increased by $30.9 million, or 26% for the year ended December 31, 2015 compared to the year ended December 31, 2014. License and milestone revenue recognized under our collaboration agreements with both Astellas and AstraZeneca increased compared to the year ended December 31, 2014 primarily due to an increase in reimbursable co-development costs allocated to license and milestone revenues. In addition, license and milestone revenue recognized under our collaboration agreements with AstraZeneca increased due to an upfront payment of $120.0 million and a development milestone payment of $15.0 million received and fully recognized during the second quarter of 2015 compared to an upfront payment of $110.0 million received during the second quarter of 2014. A portion of each of the upfront payments received under the collaboration agreements with AstraZeneca were deferred as a result of applying the relative selling price method and assessing the timing of the provision of various deliverables. The milestone payment was recognized in its entirety upon receipt.

Comparison of the years ended December 31, 2014 and 2013

License and milestone revenue increased by $22.2 million, or 23%, for the year ended December 31, 2014 compared to the year ended December 31, 2013. This increase was primarily driven by license revenue recognized in connection with our collaboration agreements signed in July 2013 with AstraZeneca, partially offset by the decrease in milestone revenue recognized in connection with our collaboration agreement with Astellas during the year ended December 31, 2014. The amount of license revenue recognized for each of the years ended December 31, 2014 and December 31, 2013 was comprised principally of the receipt of a $110.0 million time-based payment in June 2014 and up-front payments of $98.2 million in July 2013, respectively, 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 December 31, 2014 and December 31, 2013 approximately $16.4 million and $18.3 million, respectively (which relate to the co-development, information sharing and committee services unit of accounting), and $14.9 million and $13.3 million, respectively (which relate to the China unit of accounting), of these payments were deferred. The application of the relative selling price method to the reimbursements for co-development payments from both Astellas and AstraZeneca contributed to $19.0 million of the $22.2 million increase in license and milestone revenue for the year ended December 31, 2014 compared to the year ended December 31, 2013. 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

	Years Ended December 31,

	2015	2014	2013	Change 2015 vs. 2014 $	Change 2015 vs. 2014 %	Change 2014 vs. 2013 $	Change 2014 vs. 2013 %
	(dollars in thousands)						
Collaboration services revenue:							
Astellas	$2,895	$3,535	$3,335	$(640)	(18)%	$200	6 %
AstraZeneca	29,731	16,820	3,843	12,911	77 %	12,977	338 %
Total collaboration services revenue	32,626	20,355	7,178	12,271	60 %	13,177	184 %
Other revenue	109	55	31	54	98 %	24	77 %
Total collaboration services and other revenue	$32,735	$20,410	$7,209	$12,325	60 %	$13,201	183 %

Comparison of the years ended December 31, 2015 and 2014

Collaboration services and other revenue increased $12.3 million, or 60%, for the year ended December 31, 2015 compared to the year ended December 31, 2014, primarily due to the allocation of the upfront payment of $120.0 million received during the second quarter of 2015 under the AstraZeneca collaboration agreements and an increase in reimbursable co-development costs under our collaboration agreements with AstraZeneca.

Comparison of the years ended December 31, 2014 and 2013

Collaboration services and other revenue increased $13.2 million, or 183%, for the year ended December 31, 2014 compared to the year ended December 31, 2013 primarily due to an increase in expenses subject to reimbursement following our entry into our agreements with AstraZeneca.

Operating Expenses

	Years Ended December 31,			Change 2015 vs. 2014		Change 2014 vs. 2013	
	2015	2014	2013	$	%	$	%
	(dollars in thousands)						
Operating expenses							
Research and development	$214,089	$150,794	$85,710	$63,295	42 %	$65,084	76 %
General and administrative	44,364	36,909	24,409	7,455	20 %	12,500	51 %
Total operating expenses	$258,453	$187,703	$110,119	$70,750	38 %	$77,584	70 %

Total operating expenses increased by $70.8 million, or 38%, for the year ended December 31, 2015 compared to December 31, 2014, and increased by $77.6 million, or 70%, for the year ended December 31, 2014 compared to the year ended December 31, 2013, for the reasons discussed in the sections below.

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 (“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, 2015, 2014 and 2013:

		Years Ended December 31,		
		2015	2014	2013
Product Candidate	Phase of Development	(dollars in thousands)		
Roxadustat	Phase 3	$151,342	$94,969	$43,620
FG-3019	Phase 2	35,651	25,381	20,103
FG-6874	Phase 1	1,425	3,048	1,979
FG-5200	Preclinical	5,620	4,284	3,154
Other research and development expenses		20,051	23,112	16,854
Total research and development expenses		$214,089	$150,794	$85,710

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

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

Comparison of the years ended December 31, 2015 and 2014

Research and development expenses increased by $63.3 million, or 42%, for the year ended December 31, 2015 compared to the year ended December 31, 2014. The increase was primarily due to increases in clinical trial, outside services and drug development related costs of $47.3 million, stock-based compensation expense of $6.1 million, employee-related costs of $6.5 million and depreciation expense of $0.6 million. Clinical trial, outside services and drug development related costs increased as a result of the progression of the Phase 3 trials for FG-4592 and the ongoing Phase 2 trials for FG-3019. Stock-based compensation expense increased primarily due to expense related to our Employee Stock Purchase Plans (“ESPP”), a higher valuation for stock option grants and the delay in the timing of granting annual awards in 2014. Employee-related costs increased as a result of higher average compensation level.

Comparison of the years ended December 31, 2014 and 2013

Research and development expenses increased by $65.1 million, or 76%, for the year ended December 31, 2014 compared to the year ended December 31, 2013. The increase was due to an increase in personnel related costs of $18.6 million, of which $9.7 million related to an increase in headcount and related expenses and $9.0 million related to an increase in stock-based compensation expenses associated with new grants. We also experienced an increase in outside services expenses of $28.4 million primarily related to clinical trial costs for roxadustat and FG-3019 trials and an increase in drug development expenses of $5.4 million due to increased supply required for these trials. In addition, our overall clinical trials expenses increased $11.1 million, as a result of our increased use of CROs as well as costs for data management. Furthermore, facilities expense increased $0.6 million due to the costs associated with our facility in China.

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.

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 and ceasing to be an emerging growth 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.

Comparison of the years ended December 31, 2015 and 2014

General and administrative expenses increased $7.5 million, or 20%, for the year ended December 31, 2015 compared to the year ended December 31, 2014. The increase was primarily due to increases in facility expenses of $3.7 million, stock-based compensation expense of $2.9 million, outside services of $2.0 million, employee-related costs of $0.7 million. Facility expenses increased primarily due to the additional assessed property tax during the fourth quarter of 2015. Stock-based compensation expense increased primarily due to expense related to ESPP, a higher valuation for stock option grants and the delay in the timing of granting annual awards in 2014. Outside services expenses increased for the nine months ended September 30, 2015 compared to the same period a year ago primarily as a result of incremental maintenance costs associated with our intellectual property portfolio and expenses related to being a publicly traded company. Employee-related costs increased primarily as a result of additional headcount and other costs to support being a public company.

Comparison of the years ended December 31, 2014 and 2013

General and administrative expenses increased $12.5 million, or 51%, for the year ended December 31, 2014 compared to the year ended December 31, 2013. The increase was primarily due to an increase in personnel related costs of $9.1 million, of which $2.6 million related to an increase in headcount and related expenses, $0.3 million under our corporate bonus program, and $6.3 million related to an increase in stock-based compensation expenses associated with new grants. In addition, professional fees increased $2.6 million due to increase in audit, tax, recruiting and other outside services costs. Furthermore, facilities expense increased $0.9 million due to the costs

associated with our facility in China.

Operating Expenses for Roxadustat Covered Under Collaboration Agreements

We share responsibility with AstraZeneca for clinical development activities required for U.S. regulatory approval of roxadustat. As of December 31, 2015, the $116.5 million cap on our share of development costs for roxadustat has been reached. As such, all future development and commercialization costs for roxadustat for the treatment of anemia in CKD in the U.S., Europe, Japan and all other markets outside of China will be paid by Astellas and AstraZeneca. In China, our subsidiary FibroGen China will conduct the development work for CKD anemia and will hold all of the regulatory licenses issued by China regulatory authorities, through its subsidiary FibroGen Beijing, and be primarily responsible for regulatory, clinical and manufacturing. All development and commercialization costs for roxadustat in China will be shared equally with AstraZeneca.

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. In addition, we had a leased facility located in South San Francisco, California, covering approximately 106,000 square feet of space that was fully subleased. This lease and associated subleases expired in February 2015. For the years ended December 31, 2015, 2014 and 2013, we had sublease income of $3.4 million, $5.0 million and $4.5 million, respectively.

Interest Expense and Other, Net

	Years Ended December 31,			Change 2015 vs. 2014		Change 2014 vs. 2013	
	2015	2014	2013	$	%	$	%
	(dollars in thousands)						
Interest and other, net:							
Interest expense	$(11,033)	$(11,108)	$(10,702)	$75	(1)%	$(406)	4 %
Interest income and other, net	3,121	1,706	3,708	1,415	83 %	(2,002)	(54)%
Total interest and other, net	$(7,912)	$(9,402)	$(6,994)	$1,490	(16)%	$(2,408)	34 %

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 (“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 the relevant period. 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 (“TEKES”), product development obligations (see Note 6 to the consolidated financial statements).

Comparison of the years ended December 31, 2015 and 2014

Interest expense stayed relatively flat for the year ended December 31, 2015 compared to the year ended December 31, 2014.

Comparison of the years ended December 31, 2014 and 2013

Interest expense increased $0.4 million, or 4%, for the year ended December 31, 2014 compared to the year ended December 31, 2013 primarily due to the lease financing obligations for the facility in China.

Interest and Other Income, Net

Interest and other income, net primarily include interest income earned on our cash, cash equivalents and investments, foreign currency transaction gains (losses), remeasurement of certain monetary assets and liabilities in non-functional currency of our subsidiaries into the functional currency, and realized gains (losses) on sales of investments.

Comparison of the years ended December 31, 2015 and 2014

Interest and other income, net increased $1.4 million, or 83%, for the year ended December 31, 2015 compared to the year ended December 31, 2014 primarily due to higher average balances of cash equivalents and investments and foreign currency translation adjustments on our cash and cash equivalent accounts denominated in currencies other than our functional currency.

Comparison of the years ended December 31, 2014 and 2013

Interest and other income, net decreased $2.0 million, or 54%, for the year ended December 31, 2014 compared to the year ended December 31, 2013 due to a decrease of $1.9 million in bond interest related to the maturity and call of bonds.

Provision for Income Taxes

	Years Ended December 31,		
	2015	2014	2013
	(dollars in thousands)		
Loss before income taxes	$(85,537)	$(59,504)	$(14,943)
Provision for income taxes	242	—	—
Effective tax rate	(0.3)%	0.0 %	0.0 %

Our income tax provision is $0.2 million for the year ended December 31, 2015 compared to $0 for the prior year. The tax provision for 2015 was primarily due to the tax expense related to an uncertain tax position for permanent establishment in a foreign jurisdiction as well as foreign withholding taxes.

We continue to maintain a full valuation allowance against our deferred tax assets as we do not currently believe that realization of these assets is more-likely-than-not, which is based upon the weight of available evidence including our historical operating performance, reported cumulative net losses since inception and expected continuing net loss.

SELECTED QUARTERLY FINANCIAL DATA

The following tables presenting our unaudited quarterly results of operations should be read in conjunction with the consolidated financial statements and notes included in Item 8 of this Annual Report on Form 10-K. We have prepared the unaudited information on the same basis as our audited consolidated financial statements. Our operating results for any quarter are not necessarily indicative of results for any future quarters or for a full year.

The following tables present unaudited quarterly results for 2015 and 2014. These tables include all adjustments, consisting only of normal recurring adjustments that we consider for the fair statement of our consolidated financial position and operating results for the quarters presented. Payments from our collaboration partners have caused, and are likely to continue to cause, fluctuations in our quarterly results.

2015	Fourth Quarter	Third Quarter	Second Quarter	First Quarter
	(in thousands, except for per share data)			
Revenue (a)	$24,442	$ 19,538	$ 120,550	$ 16,298
Operating expenses	72,889	63,308	61,235	61,021
Net income (loss)	(51,369)	(45,098)	57,055	(46,367)
Net income (loss) per share attributable to common stockholders (b):				
Basic	(0.83)	(0.74)	0.95	(0.78)
Diluted	$(0.83)	$ (0.74)	$ 0.83	$ (0.78)

2014	Fourth Quarter	Third Quarter	Second Quarter	First Quarter
	(in thousands, except for per share data)			
Revenue (a)	$16,105	$ 13,662	$ 89,958	$ 17,876
Operating expenses	64,079	50,757	40,785	32,082
Net income (loss)	(50,560)	(39,535)	46,831	(16,240)
Net income (loss) attributable to common stockholders:				
Basic	(50,560)	(39,535)	18,123	(16,240)
Diluted	(50,560)	(39,535)	21,597	(16,240)

Net income (loss) per share attributable to common stockholders (b):				
Basic	$(1.45)	(2.93)	1.36	(1.23)
Diluted	(1.45)	(2.93)	0.58	(1.23)

(a) Revenue for the second quarter in both 2015 and 2014 was higher compared to other quarters due to revenue recognized on non-contingent upfront payments based on our revenue recognition methodology as explained in Note 2 in the notes to our consolidated financial statements.

(b) Basic and diluted earnings per share are computed independently for each of the quarters presented. Therefore, the sum of quarterly basic and diluted per share information may not equal annual basic and diluted earnings per share.

We determined that $8.5 million which had been classified in cash and cash equivalents should have been classified within the short-term investments line item in our unaudited condensed consolidated balance sheet as of September 30, 2015; such classification has been corrected as of December 31, 2015. The misclassification also resulted in our investing cash flows for the nine months ended September 30, 2015 being overstated by $8.5 million; such amounts have been corrected in the statement of cash flows for the year ended December 31, 2015. We will revise the investing cash flow amounts for the nine months ended September 30, 2015 when the related statement of cash flows is included in the September 30, 2016 Form 10-Q. We concluded that the impact of this error was not material to the previously filed financial statements.

LIQUIDITY AND CAPITAL RESOURCES

Financial Conditions

We have historically funded our operations principally from the sale of convertible preferred stock and common stock and from the execution of certain collaboration agreements involving license payments, milestones and reimbursement for development services. On November 19, 2014, we closed our initial public offering and concurrent private placement in which we issued and sold a total of 10,426,111 shares of common stock, resulting in net proceeds of approximately $171.8 million, after deducting underwriting discounts and commissions of $11.7 million and offering expenses of $4.1 million for our initial public offering. Upon the closing of our initial public offering, all FibroGen, Inc. convertible preferred stock outstanding automatically converted into 33,919,954 shares of common stock, based on the shares of convertible preferred stock outstanding as of November 18, 2014.

During the year ended December 31, 2015, we received a $120.0 million upfront payment and a $15.0 million development milestone payment under the U.S./RoW Agreement. The development milestone payment was related to the finalization of our two audited pre-clinical carcinogenicity study reports.

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. Although our share of expenses for roxadustat will decrease as a result of AstraZeneca funding all non-China collaboration expenses not reimbursed by Astellas, we expect our research and development expenses to continue to increase as we invest in our other programs. We are subject to all the risks related to the development and commercialization of novel therapeutics, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. As a newly public company, 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.

As of December 31, 2015, we had cash and cash equivalents of approximately $153.3 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 December 31, 2015 we had short-term and long-term investments of approximately $27.8 million and $131.7 million, respectively. As of December 31, 2015, a total of $27.2 million of our cash and cash equivalents was held outside of the U.S. in our foreign subsidiaries to be used primarily for our China operations.

We believe that our existing cash and cash equivalents, short-term and long-term investments and accounts receivable will be sufficient to meet our anticipated cash requirements for at least the next 12 months. However, our liquidity assumptions may change over time, and we could utilize our available financial resources sooner than we currently

expect. In addition, we may elect to raise additional funds at any time through equity, equity-linked or debt financing arrangements. Our future capital requirements and the adequacy of available funds will depend on many factors, including those set forth under Part I, Item 1A “Risk Factors” in this Annual Report on Form 10-K. We may not be able to secure additional financing to meet our operating requirements on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, the ownership of our existing stockholders will be diluted. If we raise additional financing by the incurrence of indebtedness, we will be subject to increased fixed payment obligations and could also be subject to restrictive covenants, such as limitations on our ability to incur additional debt, and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to obtain needed additional funds, we will have to reduce our operating expenses, which would impair our growth prospects and could otherwise negatively impact our business.

Cash Sources and Uses

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

	Years Ended December 31,		
	2015	2014	2013
	(in thousands)		
Net cash provided by (used in):			
Operating activities	$(18,571)	$22,414	$25,918
Investing activities	(5,868)	(107,289)	10,778
Financing activities	12,346	174,092	680
Effect of exchange rate changes on cash and cash equivalents	(38)	(94)	84
Net change in cash and cash equivalents	$(12,131)	$89,123	$37,460

Operating Activities

Net cash used in operating activities was $18.6 million for the year ended December 31, 2015, which consisted primarily of net loss of $85.8 million adjusted for non-cash items of $36.3 million and a net increase in operating assets and liabilities of $31.0 million. The significant non-cash items included stock-based compensation expense of $27.7 million, depreciation expense of $5.7 million and amortization of the premium on investments of $3.0 million. The significant items in the changes in operating assets and liabilities included increases resulted from deferred revenue of $27.7 million, other long-term liabilities of $4.2 million and accounts payable of $2.0 million, partially offset by decreases results from accounts receivable of $2.0 million and accrued liabilities of $2.1 million. The change in deferred revenue relate to the timing of the receipt of upfront payments and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca. The changes in accounts payable, accounts receivable and other long-term liabilities is driven by the timing of payments. The change in accrued liabilities is driven by clinical trial activity primarily related to our Phase 3 trials for roxadustat and the timing of payments.

Net cash provided by operating activities was $22.4 million for the year ended December 31, 2014, which consisted primarily of net loss of $59.5 million adjusted for non-cash items of $23.8 million and a net increase in operating assets and liabilities of $58.1 million. The significant non-cash items included stock-based compensation expense of $18.7 million, depreciation expense of $4.5 million and amortization of bond premium/discount of $0.7 million. The significant items in the changes in operating assets and liabilities included increases resulted from deferred revenue of $33.6 million, accounts payable and accrued expenses of $22.4 million, and a accounts receivable of $4.0 million, partially offset by decreased resulted from prepaid expenses of $1.6 million. The increase in deferred revenue and decrease in accounts receivable relates to the timing of upfront payments and recognition of revenues under our collaboration agreements with Astellas and AstraZeneca. The increase in accounts payable and accrued expenses is driven by the increase in clinical trial activity related to ongoing Phase 3 trials for roxadustat.

Net cash provided by operating activities was $25.9 million for the year ended December 31, 2013, which consisted primarily of a net loss of $14.9 million adjusted for non-cash items of $9.1 million and a net increase in operating assets and liabilities of $31.8 million. The significant non-cash items included depreciation expense of $5.1 million, stock-based compensation expense of $3.4 million and amortization of bond premium/discount of $0.8 million. The significant items in the changes in operating assets and liabilities included increases resulted from deferred revenue of $30.9 million and accrued expenses of $11.3 million, partially offset by decreases resulted from accounts receivable of $8.7 million and accounts payable of $2.0 million. 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.

Investing Activities

Investing activities primarily consist of purchases of fixed assets, purchases of investments, and proceeds from the maturity and sale of investments.

Net cash used in investing activities for the year ended December 31, 2015 was $5.9 million, which consisted of $41.7 million in purchases of investments and $2.0 million in purchases of fixed assets, offset by proceeds from maturities and sales of investments of $37.8 million.

Net cash used in investing activities for the year ended December 31, 2014 was $107.3 million, which consisted of $144.7 million in purchases of investments and $8.1 million in purchases of fixed assets, offset by proceeds from maturities of investments of $45.5 million.

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

Financing Activities

Financing activities primarily consist of issuance of our common stock, repayments of our lease liability and payments of deferred offering costs associated with the planned public offering of our securities.

Net cash provided by financing activities for the year ended December 31, 2015 was $12.3 million, which consisted of $12.7 million in proceeds from the issuance of common stock upon exercise of stock options, offset by $0.4 million of repayments on our lease liability.

Net cash provided by financing activities for the year ended December 31, 2014 was $174.1 million, which consisted of $175.9 million in proceeds from our initial public offering, net of offering costs, and the concurrent private placement of shares of our common stock with AstraZeneca, and $1.7 million in proceeds from the issuance of common stock upon exercise of stock options, offset by $3.1 million of deferred offering costs (costs paid associated with the planned public offering of our securities) and $0.4 million of repayments on our lease liability.

Net cash provided by financing activities for the year ended December 31, 2013 was $0.7 million, which 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. During the years ended December 31, 2013, we also drew down and fully repaid amounts on our credit facility of $11.5 million

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. As a newly public company, 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 that our existing cash and cash equivalents, short-term and long-term investments and accounts receivable will be sufficient to meet our anticipated cash requirements for at least the next 12 months. 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 U.S., 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.

Off-Balance Sheet Arrangements

During the year ended December 31, 2015, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements.

Indemnification Agreements

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

Contractual Obligations and Commitments

Contractual Obligations

At December 31, 2015, our contractual obligations were as follows:

	Payments Due In				
	Less Than 1 Year	1 - 3 Years	3 - 5 Years	More Than 5 Years	Total
	(In thousands)				
Operating lease obligations	$128	$84	$—	$—	$212
Lease financing obligations	13,699	28,282	29,157	41,378	112,516
Total contractual obligations	$13,827	$28,366	$29,157	$41,378	$112,728

The contractual obligations table excludes uncertain tax benefits of approximately $24.2 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, 2015, we have several on-going clinical studies in various stages. Under agreements with various CROs, and clinical study sites, we incur expenses related to clinical studies of our product candidates and potential other clinical candidates. The timing and amounts of these disbursements are contingent upon the achievement of certain milestones, patient enrollment and services rendered or as expenses are incurred by the CROs or clinical trial sites. Therefore we cannot estimate the potential timing and amount of these payments and they have been excluded from the table above. Although our material contracts with CROs are cancellable, we have historically not cancelled such contracts.

Product Development Obligations

As of December 31, 2015, our FibroGen Europe subsidiary had $10.3 million of principal outstanding and $4.8 million of interest accrued related to the TEKES loans, respectively, which have been included as product development obligations on our consolidated balance sheet.

There is no stated maturity date related to these loans and each loan may be forgiven if the research work funded by TEKES does not result in an economically profitable business or does not meet its technological objectives. In addition, we are not a guarantor of the TEKES loans, and these loans are not repayable by FibroGen Europe until it has distributable funds. We do not expect FibroGen Europe to have such funds for at least the next five years. For the foregoing reasons, we cannot estimate the potential timing and the amounts of repayments (if required) or forgiveness. As a result, the TEKES loans have been excluded from the table above.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

We prepared our consolidated financial statements in accordance with accounting principles generally accepted in the U.S. (“GAAP”). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and related disclosures. We

evaluate our estimates and assumptions on an ongoing basis. Our estimates are based on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Our actual results could differ from these 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 Annual Report, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Substantially all of our revenues to date have been generated from our collaboration agreements.

Our collaboration agreements include multiple 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 ("VSOE"), (ii) third-party evidence ("TPE"), or (iii) best estimate of selling price ("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. We record a valuation allowance to reduce our deferred tax assets to reflect the net amount that we believe is more likely than not to be realized. Realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. The valuation allowance requires an assessment of both positive and negative evidence when determining whether it is more likely than not that deferred tax assets are recoverable; such assessment is required on a jurisdiction by jurisdiction basis. Based upon the weight of available evidence at December 31, 2015, we continue to maintain a full valuation allowance against all of our deferred tax assets after management considered all available evidence, both positive and negative, including but not limited to our historical operating results, income or loss in recent periods, cumulative income in recent years, forecasted earnings, future taxable income, and significant risk and uncertainty related to forecasts.

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 evaluate uncertain tax positions on a quarterly basis and adjust the liability for changes in facts and circumstances, such as new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, significant amendment to an existing tax law, or resolution of an examination. To the extent that the final tax outcome of these matters is different than the amounts recorded, such differences will impact the income tax provision in the period in which such determination is made. The resolution of our uncertain income tax positions is dependent on uncontrollable factors such as law changes, new case law, and the willingness of the income tax authorities to settle, including the timing thereof and other factors. Although we do not anticipate significant changes to our uncertain income tax positions in the next twelve months, items outside of our control could cause our uncertain income tax positions to change in the future, which would be recorded in our consolidated statements of operations. Interest and/or penalties related to income tax matters are recognized as a component of income tax expense as incurred.

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.

JOBS Act Accounting Election

Until the end of 2015, we were 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. We had, prior to ceasing to be an “emerging growth company,” irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, continue to be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recently Issued and Adopted Accounting Guidance

In November 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. This guidance requires reporting entities to classify deferred income taxes as non-current on the consolidated balance sheets, which simplifies the presentation of deferred income taxes. This guidance is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods, with early adoption permitted. We early adopted this guidance effective December 31, 2015 on a prospective basis. The adoption of this guidance had no impact on our financial position, results of operations or cash flows.

Recently Issued Accounting Guidance Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). Under this guidance, an entity is required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. This guidance offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. This guidance is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, and requires a modified retrospective adoption, with early adoption permitted. We are currently evaluating the impact on our consolidated financial statements upon the adoption of this guidance.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments-Overall (Subtopic 825-10), which requires equity investments that are not accounted for under the equity method of accounting to be measured at fair value with changes recognized in net income, simplifies the impairment assessment of certain equity investments, and updates certain presentation and disclosure requirements. This guidance is effective for annual reporting periods beginning after December 15, 2017 and interim periods within those annual periods. We are currently evaluating the impact on our consolidated financial statements upon the adoption of this guidance.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. This guidance requires management to evaluate, at each interim and annual reporting period, whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date the financial statements are issued, and provide related disclosures. This guidance will be effective for annual period ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. We do not expect a material impact on our consolidated financial statements upon the adoption of this guidance.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in ASC 605, Revenue Recognition. This guidance 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. This guidance 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. This guidance can be adopted either retrospectively to each prior reporting period presented, or retrospectively with a cumulative-effect adjustment recognized as of the date of adoption. The original effective date of this guidance for public entities was for annual reporting periods beginning after December 15, 2016. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606), to defer the effective date of this guidance by one year, to the annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. A reporting entity may choose to early adopt the

guidance as of the original effective date. We do not anticipate an early adoption, and are currently evaluating the impact on our consolidated financial statements upon the adoption of this guidance.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in foreign currency exchange rates. The functional currency of our FibroGen Europe subsidiary is the local currency. Most of our revenue from collaboration agreements are denominated in U.S. dollars, and therefore our revenue is not currently subject to significant foreign currency risk. Our operating expenses are denominated in the currencies of the countries in which our operations are located, which are primarily in the United States, China, and Europe. Our consolidated results of operations and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates.

As of December 31, 2015, we had EUR 4.2 million of cash and cash equivalent and EUR 13.8 million of short-term investment that are subject to fluctuation in the exchange rate with the U.S. dollar. The effect of a hypothetical 10% change in foreign currency exchange rates would have resulted in a gain or loss on foreign currency of approximately $2.0 million for the year ended December 31, 2015.

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.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of

FibroGen, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of comprehensive 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 at December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management’s Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements, on the financial statement schedule, and on the Company's internal control over financial reporting based on our audits (which was an integrated audit in 2015). We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

San Jose, California

February 29, 2016

FIBROGEN, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share amounts)

	December 31, 2015	2014
Assets		
Current assets:		
Cash and cash equivalents	$153,324	$165,455
Short-term investments	27,847	14,364
Accounts receivable ($4,455 and $5,033 from a related party)	15,405	13,453
Prepaid expenses and other current assets	3,988	4,966
Total current assets	200,564	198,238
Restricted cash	7,254	7,254
Long-term investments	131,720	144,269
Property and equipment, net	129,020	132,171
Other assets	2,016	1,596
Total assets	$470,574	$483,528
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$6,521	$4,551
Accrued liabilities ($2,045 and $4,594 to related parties)	47,932	48,985
Deferred revenue	12,728	9,218
Total current liabilities	67,181	62,754
Long-term portion of lease financing obligations	97,042	96,818
Product development obligations	15,085	16,465
Deferred rent	4,702	5,131
Deferred revenue, net of current	85,132	60,988
Other long-term liabilities	4,607	696
Total liabilities	273,749	242,852
Commitments and Contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 125,000 shares authorized at December 31, 2015 and 2014; no shares issued and outstanding at December 31, 2015 and 2014	—	—
Common stock, $0.01 par value; 225,000 shares authorized at December 31, 2015 and December 31, 2014; 61,985 and 59,046 shares issued and outstanding at December 31, 2015 and December 31, 2014	620	590

Additional paid-in capital	586,647	546,247
Accumulated other comprehensive loss	(1,651)	(3,149)
Accumulated deficit	(408,062)	(322,283)
Total stockholders' equity	177,554	221,405
Non-controlling interests	19,271	19,271
Total equity	196,825	240,676
Total liabilities, stockholders' equity and non-controlling interests	$470,574	$483,528

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

FIBROGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Years Ended December 31,		
	2015	2014	2013
Revenue:			
License and milestone revenue (includes $18,701, $14,453 and $22,326 from a related party)	$148,093	$117,191	$94,961
Collaboration services and other revenue (includes $2,895, $3,535 and $3,335 from a related party)	32,735	20,410	7,209
Total revenue	180,828	137,601	102,170
Operating expenses:			
Research and development	214,089	150,794	85,710
General and administrative	44,364	36,909	24,409
Total operating expenses	258,453	187,703	110,119
Loss from operations	(77,625)	(50,102)	(7,949)
Interest and other, net			
Interest expense	(11,033)	(11,108)	(10,702)
Interest income and other, net	3,121	1,706	3,708
Total interest and other, net	(7,912)	(9,402)	(6,994)
Loss before income taxes	(85,537)	(59,504)	(14,943)
Provision for income taxes	242	—	—
Net loss	$(85,779)	$(59,504)	$(14,943)
Net loss per share - basic and diluted	$(1.42)	$(3.17)	$(1.13)
Weighted average number of common shares used to calculate net loss per share - basic and diluted	60,337	18,775	13,186

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

FIBROGEN, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Years Ended December 31,		
	2015	2014	2013
Net loss	$(85,779)	$(59,504)	$(14,943)
Other comprehensive income (loss):			
Foreign currency translation adjustments	1,662	2,082	(665)
Available-for-sale investments:			
Unrealized gain (loss) on investments, net of tax effect	30	(965)	(1,936)
Reclassification from accumulated other comprehensive loss	(194)	(758)	(740)
Net change in unrealized loss on available-for-sale investments	(164)	(1,723)	(2,676)
Other comprehensive income (loss), net of taxes	1,498	359	(3,341)
Comprehensive loss	$(84,281)	$(59,145)	$(18,284)

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 data)

	Senior Preferred Stock		Junior Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive		Non Controlling	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Loss	Accumulated Deficit	Interests	Tota
e at mber 31,	38,340,182	$168,436	46,460,057	$136,313	13,167,138	$132	$37,606	$(167)	$(247,836)	$27,700	$(46
s	—	—	—	—	—	—	—	—	(14,943)	—	(14
e in alized ments	—	—	—	—	—	—	—	(2,676)	—	—	(2,
n cy dation tments	—	—	—	—	—	—	—	(665)	—	—	(66
ce of eferred to ntrolling ests	—	—	—	—	—	—	—	—	—	175	17
options ised	—	—	—	—	34,126	—	84	—	—	—	84
based pensation	—	—	—	—	—	—	3,444	—	—	—	3,4
e at mber 31,	38,340,182	168,436	46,460,057	136,313	13,201,264	132	41,134	(3,508)	(262,779)	27,875	(60
s	—	—	—	—	—	—	—	—	(59,504)	—	(59
e in alized ments	—	—	—	—	—	—	—	(1,723)	—	—	(1,
n cy	—	—	—	—	—	—	—	2,082	—	—	2,0

lation tments											
options cised	—	—	—	—	539,971	5	1,689	—	—	—	1,6
based pensation	—	—	—	—	—	—	18,698	—	—	—	18
rsion of rred mmon ovember in ection nitial ring	(38,340,182)	(168,436)	(46,460,057)	(136,313)	33,919,954	339	304,410	—	—	—	16
nge of oGen e rred mmon ovember in ection nitial ring	—	—	—	—	958,996	10	8,594	—	—	(8,604)	—
Public ring, net rwriting unts, mission nce costs	—	—	—	—	9,315,000	93	151,733	—	—	—	15
Zeneca ent	—	—	—	—	1,111,111	11	19,989	—	—	—	20
e at mber 31,	—	—	—	—	59,046,296	590	546,247	(3,149)	(322,283)	19,271	24
s	—	—	—	—	—	—	—	—	(85,779)	—	(8

148

FIBROGEN, INC.

CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND EQUITY (DEFICIT)

(CONTINUED)

(In thousands, except share data)

	Senior Preferred Stock		Junior Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Non Controlling Interests	Total
	Shares	Amount	Shares	Amount	Shares	Amount					
Change in unrealized loss on investments	—	—	—	—	—	—	—	(164)	—	—	(164)
Foreign currency translation adjustments	—	—	—	—	—	—	—	1,662	—	—	1,662
Stock options exercised	—	—	—	—	2,361,633	24	10,088	—	—	—	10,112
Shares issued upon vesting of restricted stock units and purchases made under the employee stock purchase plan	—	—	—	—	456,355	5	2,590	—	—	—	2,595
True up of issuance costs related to initial public offering and common stock sold by FibroGen Europe	—	—	—	—	—	—	42	—	—	—	42
Stock-based compensation	—	—	—	—	—	—	27,681	—	—	—	27,681

Warrants exercised	—	—	—	—	120,795	1	(1)	—	—	—	—
Balance at December 31, 2015	—	$ —	—	$ —	61,985,079	$ 620	$ 586,647	$ (1,651)	$ (408,062)	$ 19,271	$ 196,825

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,		
	2015	2014	2013
Operating activities			
Net loss	$(85,779)	$(59,504)	$(14,943)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation	5,679	4,470	5,084
Amortization of premium on investments	2,997	658	841
Loss (gain) on disposal of property and equipment	98	(10)	(1)
Stock-based compensation	27,681	18,698	3,444
Realized gain on sales of available-for-sale securities	(203)	—	(301)
Changes in operating assets and liabilities:			
Accounts receivable ($578, $979 and $2,772 from related party)	(1,952)	4,041	(8,711)
Prepaid expenses and other current assets	978	(1,628)	791
Other assets	(420)	(795)	(547)
Accounts payable	1,970	3,485	(2,041)
Accrued liabilities ($(2,549), $1,828 and $1,644 from related party)	(2,126)	18,878	11,307
Deferred revenue	27,654	33,557	30,885
Lease financing liability	627	814	690
Other long-term liabilities	4,225	(250)	(580)
Net cash provided by (used in) operating activities	(18,571)	22,414	25,918
Investing activities			
Purchases of property and equipment	(1,977)	(8,118)	(6,806)
Proceeds from sale of property and equipment	2	10	2
Purchases of available-for-sale securities	(41,736)	(144,727)	—
Proceeds from sales of available-for-sale securities	15,342	—	16,582
Proceeds from maturities of available-for-sale securities	22,501	45,546	1,000
Net cash provided by (used in) investing activities	(5,868)	(107,289)	10,778
Financing activities			
Borrowings under credit facility	—	—	11,500
Repayments under credit facility	—	—	(11,500)
Repayments of capital lease obligations	—	—	(329)
Repayments of lease liability	(403)	(403)	(403)
Proceeds from lease financing liability	—	—	553
Proceeds from convertible promissory note	—	—	600
Proceeds from non-controlling interest	—	—	175
Proceeds from initial public offering, net of underwriting discounts and	—	155,933	—

commission costs			
Proceeds from AstraZeneca private placement	—	20,000	—
Proceeds from issuance of common stock, net	12,749	1,697	84
Payments of deferred offering costs	—	(3,135)	—
Net cash provided by financing activities	12,346	174,092	680
Effect of exchange rate change on cash and cash equivalents	(38)	(94)	84
Net increase (decrease) in cash and cash equivalents	(12,131)	89,123	37,460
Cash and cash equivalents at beginning of period	165,455	76,332	38,872
Cash and cash equivalents at end of period	$153,324	$165,455	$76,332
Supplemental cash flow information:			
Interest payments	335	377	433
Purchases of property and equipment in accounts payable and accrued liabilities	931	280	1,655
Assets acquired under facility lease	—	—	3,067
Deferred offering costs recorded in accounts payable and accrued liabilities	—	974	—

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

FIBROGEN, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. The Company

FibroGen, Inc. ("FibroGen" or the "Company") was incorporated in 1993 in Delaware and is a research-based biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics agents to treat serious unmet medical needs. The Company's focus in the areas of fibrosis and hypoxia-inducible factor ("HIF") biology has 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, Duchenne muscular dystrophy ("DMD") 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 ("China").

On November 19, 2014, the Company closed the initial public offering ("IPO") of its common stock. In its IPO, the Company sold 9,315,000 shares of its common stock at a public offering price of $18.00 per share. Net proceeds from the Company's IPO and concurrent private placement were $171.8 million, after deducting underwriting discounts and commissions of $11.7 million and offering expenses of $4.1 million. Concurrent with the closing of the IPO, AstraZeneca AB ("AstraZeneca"), one of the Company's collaboration partners, purchased shares of FibroGen common stock in a private placement at a price per share equal to the IPO price for an aggregate purchase price of $20.0 million. Upon the closing of the IPO, all outstanding shares of the Company's convertible preferred stock automatically converted into 33,919,954 shares of common stock and 958,996 shares of FibroGen Europe convertible preferred stock were converted into shares of FibroGen common stock. The Company's proceeds from the sale of the common stock sold in the concurrent private placement were $20.0 million.

2. Summary of Significant Accounting Policies

Basis of Presentation and Liquidity

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The consolidated financial statements include the accounts of the Company, its wholly owned subsidiaries and its majority-owned subsidiaries, FibroGen Europe and FibroGen China Anemia Holdings, Ltd. ("FibroGen China"). All inter-company transactions and balances have been eliminated in consolidation. The Company operates in one segment — the discovery, development and commercialization of novel therapeutics to treat serious unmet medical needs. 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 (“U.S.”) dollar. The functional currency of FibroGen Europe is the Euro. The assets and liabilities of FibroGen Europe are translated to U.S. dollars at exchange rates in effect at the balance sheet date. All income statement accounts are translated at monthly average exchange rates. Resulting foreign currency translation adjustments are recorded directly in accumulated other comprehensive income (loss) as a separate component of stockholders’ equity.

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

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Concentration of Credit Risk and Other Risks and Uncertainties

The Company is subject to risks associated with concentration of credit for cash and cash equivalents. 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 U.S., Finland, China and the Cayman Islands. At times, such deposits may be in excess of insured limits. The Company has not experienced any loss on its deposits of cash and cash equivalents. Included in current assets are significant balances of accounts receivable as follows:

	As of December 31,	
	2015	2014
Astellas Pharma Inc. (“Astellas”)—Related party	29 %	37 %
AstraZeneca AB (“AstraZeneca”)	71 %	63 %

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, 2015, and 2014 totaled $7.3 million and $7.3 million, respectively. As of December 31, 2015, a total of $27.2 million of the Company’s cash and cash equivalents is held outside of the U.S. in the Company’s foreign subsidiaries to be used primarily for the Company’s China operations.

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.

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

Fair Value of Financial Instruments

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

Property and Equipment

Property and equipment (except for costs of construction of certain long-lived assets — refer to 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 ("ASC") Topic 605-25, Revenue Recognition—Multiple-Element Arrangements, ("ASC 605-25"), which:

- 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 ("VSOE"), (ii) third-party evidence ("TPE"), or (iii) best estimate of selling price ("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 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 Consolidated Statements of Operations.

Stock-Based Compensation

The Company maintains equity incentive plans under which incentive and nonqualified stock options are granted to employees and non-employee consultants. Compensation expense relating to non-employee stock options has not been material for the years ended December 31, 2015, 2014 and 2013.

The Company measures and recognizes compensation expense for all stock options and restricted stock units ("RSUs") granted to its employees and directors based on the estimated fair value of the award on the grant date. The Company uses the Black-Scholes valuation model to estimate the fair value of stock option awards. The fair value is recognized as expense, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award, on a straight-line basis. The Company believes that the fair value of stock options granted to non-employees is more reliably measured than the fair value of the services received. As such, the fair value of the unvested portion of the options granted to non-employees is re-measured each period. The resulting increase in value, if any, is recognized as expense during the period the related services are rendered on a straight-line basis. The determination of the grant date fair value of options using an option pricing model is affected by the Company's estimated Common Stock fair value and requires management to make a number of assumptions including the expected life of the option, the volatility of the underlying stock, the risk-free interest rate and expected dividends.

Comprehensive Income (Loss)

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

Recently Issued and Adopted Accounting Guidance

In November 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. This guidance requires reporting entities to classify deferred income taxes as non-current on the consolidated balance sheets, which simplifies the presentation of deferred income taxes. This guidance is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods, with early adoption permitted. The Company early adopted this guidance effective December 31, 2015 on a prospective basis. The adoption of this guidance had no impact on the Company's financial position, results of operations or cash flows.

Recently Issued Accounting Guidance Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). Under this guidance, an entity is required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing

arrangements. This guidance offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. This guidance is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, and requires a modified retrospective adoption, with early adoption permitted. The Company is currently evaluating the impact on its consolidated financial statements upon the adoption of this guidance.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments-Overall (Subtopic 825-10), which requires equity investments that are not accounted for under the equity method of accounting to be measured at fair value with changes recognized in net income, simplifies the impairment assessment of certain equity investments, and updates certain presentation and disclosure requirements. This guidance is effective for annual reporting periods beginning after December 15, 2017 and interim periods within those annual periods. The Company is currently evaluating the impact on its consolidated financial statements upon the adoption of this guidance.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. This guidance requires management to evaluate, at each interim and annual reporting period, whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date the financial statements are issued, and provide related disclosures. This guidance will be effective for annual period ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. The Company does not expect a material impact on its consolidated financial statements upon the adoption of this guidance.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in ASC 605, Revenue Recognition. This guidance 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. This guidance 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. This guidance can be adopted either retrospectively to each prior reporting period presented, or retrospectively with a cumulative-effect adjustment recognized as of the date of adoption. The original effective date of this guidance for public entities was for annual reporting periods beginning after December 15, 2016. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606), to defer the effective date of this guidance by one year, to the annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. A reporting entity may choose to early adopt the guidance as of the original effective date. The Company does not anticipate an early adoption, and is currently evaluating the impact on its consolidated financial statements upon the adoption of this guidance.

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. A clinical milestone payment of $12.5 million was received in 2013. The Company evaluated the criteria under ASC 605-28 and concluded that the aforementioned milestone was substantive.

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. 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 (and concluded that each of those milestones was substantive. Under the Europe Agreement, Astellas committed to fund 50% of joint development costs for Europe and North America, and all territory-specific costs. The Europe Agreement also provides for tiered payments based on net sales of product (as defined) in the low 20% range.

156

AstraZeneca Agreements

U.S./Rest of World Agreement

Effective July 30, 2013, the Company entered into a collaboration agreement with AstraZeneca for the development and commercialization of roxadustat for the treatment of anemia in the U.S. and all other countries in the world, other than China, not previously licensed under the Astellas Europe and Astellas Japan Agreements ("U.S./RoW Agreement"). It also excludes China, which is covered by a separate agreement with AstraZeneca described below. Under the terms of the U.S./RoW Agreement, AstraZeneca 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 $312.0 million was received as of December 31, 2015. The remaining payment of $62.0 million is contingent upon the occurrence of a specified event and accordingly is also not considered fixed or determinable. In addition, the U.S./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. During the second quarter of 2015, the Company received a $15.0 million development milestone payment as a result of the finalization of its two audited pre-clinical carcinogenicity study reports. The Company evaluated the criteria under ASC 605-28 and concluded that the aforementioned milestone was substantive.

Under the U.S./RoW Agreement, the Company and AstraZeneca will share equally in the development costs of roxadustat not already paid for by Astellas, up to a total of $233.0 million. 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 (such amounts were fully 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), 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 cumulative co-development billings of $124.1 million (for Europe Agreement) as of December 31, 2015.

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.
- Manufacturing rights. In the case of the Japan Agreement, the Company retained manufacturing rights largely because of the way the parties chose for FibroGen to be compensated under the agreement. At the time the agreement was signed, the Company believed that it was more advantageous upon commercialization to have a transfer price revenue model in place as opposed to a traditional sales-based model. The 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 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 Astellas 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.

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.

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.

Accounting for the AstraZeneca Agreements

The Company evaluated whether the U.S./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 with the presumption that two or more agreements executed with a single customer at or around the same time should be presumed to be a single arrangement. 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 U.S./RoW and China Agreements based on their relative fair values.

The Company 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 U.S./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 implied royalty rate on the transaction would equal the target return for the investment). This results in an upper bound estimation of the magnitude of royalties that a hypothetical acquirer would reasonably pay for the forecasted cash flow stream. The Company's cash flow forecasts were derived from probability-adjusted revenue and expense projections. Such projections included consideration of taxes and cash flow adjustments. The probability adjustments were made after considering the likelihood of technical success at various stages of clinical trials and regulatory approval phases. The second step involved applying the implied royalty rate, which was determined to be 40%, against the probability-adjusted projected net revenues by territory and determining the value of the license as the net present value of future cash flows after adjusting for taxes. The discount rate utilized was 17.5%.

U.S./RoW Agreement:

The 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 U.S./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 U.S./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 U.S./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 terms of the U.S./RoW Agreement, AstraZeneca has agreed to pay upfront, non-contingent and time-based payments totaling $374.0 million, which we expect to receive in various amounts through June 2016, of which $82.0 million was received as of December 31, 2013 and was 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, were 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 is determined on the basis of applying the relative selling price method to each of the units of accounting underlying the agreement. 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.

Under the U.S./RoW Agreement, the Company is also eligible to receive from AstraZeneca an aggregate of approximately $875.0 million in potential milestone payments, comprised of (i) up to $65.0 million in 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 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 was 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, is not considered to be fixed or determinable upon the execution of the agreement. This payment of $12.0 million was received as of March 31, 2014.

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 U.S./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.

Summary of revenue recognized under the collaboration agreements

The table below summarizes the accounting treatment for the various deliverables pursuant to each of the Astellas and AstraZeneca agreements. 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 under the Japan Agreement are shown below (in thousands):

Agreement	Deliverable	Years Ended December 31, 2015	2014	2013
Japan	License	$1,024	$518	$566
	Milestones	—	—	12,500
	Total license and milestone revenue	$1,024	$518	$13,066
	Collaboration services revenue*	$198	$356	$433

* 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.

The total arrangement consideration has been allocated to each of the following deliverables under the Japan Agreement, along with any associated deferred revenue as follows (in thousands):

	Cumulative Revenue Through December 31, 2015	Deferred Revenue at December 31, 2015	Total Consideration Through December 31, 2015
License	$ 42,245	$ —	$ 42,245
When and if available compounds	14	28	42
Manufacturing--clinical supplies	1,966	—	1,966
Committee services	16	—	16
Total license and collaboration services revenue	$ 44,241	$ 28	$ 44,269

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

Agreement	Deliverable	Years Ended December 31, 2015	2014	2013
Europe	License	$17,677	$13,935	$9,260
	Milestones	—	—	—
	Total license and milestone revenue	$17,677	$13,935	$9,260
	Collaboration services revenue*	$2,697	$3,179	$2,902

* 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. The total arrangement consideration has been allocated to each of the following deliverables under the Europe Agreement, along with any associated deferred revenue as follows (in thousands):

	Cumulative Revenue Through December 31, 2015	Deferred Revenue at December 31, 2015	Total Consideration Through December 31, 2015
License	$ 401,316	$ —	$ 401,316
When and if available compounds	332	432	764
Manufacturing--clinical supplies	9,612	—	9,612
Development services--in progress	32,154	—	32,154
Committee services	278	—	278
Total license and collaboration services revenue	$ 443,692	$ 432	$ 444,124

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

Agreement	Deliverable	Years Ended December 31, 2015	2014	2013
U.S. / RoW and China	License	$114,392	$102,738	$72,635
	Milestones	15,000	—	—
	Total license and milestone revenue	$129,392	$102,738	$72,635
	Collaboration services revenue*	$29,731	$16,820	$3,843
	China single unit of accounting**	$—	$—	$—

*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.

The total arrangement consideration has been allocated to each of the following deliverables under the U.S./RoW and China Agreements, along with any associated deferred revenue as follows (in thousands):

	Cumulative Revenue Through December 31, 2015	Deferred Revenue at December 31, 2015	Total Consideration Through December 31, 2015
License	$ 289,766	$ —	$ 289,766
Co-development, information sharing & committee services	50,162	37,936	88,098
Manufacturing--clinical supplies	232	70	302
China-single unit of accounting	—	59,394	59,394
Total license and collaboration services revenue	$ 340,160	$ 97,400	$ 437,560

Other Revenues

Other revenues consist of royalty payments received, which are recorded on a monthly basis as they are reported to the company and collagen feasibility sales. Other revenues were immaterial for each of the three years ended December 31, 2015.

Deferred Revenue

Deferred revenue represents amounts billed to the Company's collaboration partners for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met. The current portion of deferred revenue represents the amount to be recognized within one year from the balance sheet date based on the estimated performance period of the underlying 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.

4. Fair Value Measurements

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

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

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

Level 3: Unobservable inputs.

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

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

	December 31, 2015			
	Level 1	Level 2	Level 3	Total
Corporate bonds	$—	$126,103	$ —	$126,103
Bond and mutual funds	25,052	—	—	25,052
Equity investments	197	—	—	197
Money market funds	77,639	—	—	77,639
Certificate of deposits	—	8,215	—	8,215
Total	$102,888	$134,318	$ —	$237,206

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
Corporate bonds	$—	$158,432	$ —	$158,432
Equity investments	201	—	—	201
Money market funds	13,802	—	—	13,802
Total	$14,003	$158,432	$ —	$172,435

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

December 31, 2015

	Level 1	Level 2	Level 3	Total
Lease financing obligations	$—	$—	$97,445	$97,445

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
Cease-use liability	$—	$—	$184	$184
Lease financing obligations	—	—	97,221	97,221
Total	$—	$—	$97,405	$97,405

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.

There were no transfers of assets or liabilities between levels for the years ended December 31, 2015, 2014 or 2013.

5. Balance Sheet Components

Cash and Cash Equivalents

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

	December 31,	
	2015	2014
Cash	$75,685	$151,653
Money market funds	77,639	13,802
Total cash and cash equivalents	$153,324	$165,455

Property and Equipment

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

	December 31,	
	2015	2014
Laboratory equipment	$18,233	$17,114
Computer equipment	5,701	5,106
Furniture and fixtures	5,361	5,082
Leasehold improvements	93,380	92,790
Building shell (Refer to Note 8)	53,879	53,879
Construction in progress	193	519
Total property and equipment	$176,747	$174,490
Less: accumulated depreciation	(47,727)	(42,319)
Property and equipment, net	$129,020	$132,171

Depreciation expense for the years ended December 31, 2015, 2014 and 2013 was $5.7 million, $4.5 million, and $5.1 million, 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, 2015			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Corporate bonds	$126,522	$ 54	$ (473)	$126,103

Certificate of deposits	8,217	—	(2)	8,215
Bond and mutual funds	25,052	—	—	25,052
Equity investments	126	71	—	197
Total investments	$159,917	$ 125	$ (475)	$159,567

	December 31, 2014			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Corporate bonds	$158,692	$ 254	$ (514)	$158,432
Equity investments	124	77	—	201
Total investments	$158,816	$ 331	$ (514)	$158,633

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

	December 31, 2015
Within one year	$ 12,797
After one year through four years	121,521
Total debt investments	134,318
Bond and mutual funds	25,052
Equity investments	197
Total investments	159,567

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 within accumulated other comprehensive income (loss).

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2015	2014
Preclinical and clinical trial accruals	$27,973	$25,418
Payroll and related accruals	13,535	15,608
Professional services	1,662	2,401
Other	4,762	5,558
Total accrued liabilities	$47,932	$48,985

6. Product Development Obligations

The Technology Development Center of the Republic of Finland ("TEKES") product development obligations consist of 11 separate advances (each in the form of a note agreement) received by FibroGen Europe between 1996 and 2008 from TEKES. These advances are granted on a project by project basis to fund various product development efforts undertaken by FibroGen Europe only. Each separate note 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, 2015 and 2014, the Company had $10.3 million and $11.5 million of principal outstanding, respectively, and $4.8 million and $5.0 million of interest accrued, respectively, which were presented in the product development obligations line on the consolidated balance sheets.

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

7. Convertible Note Payable

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.

8 Commitments and Contingencies
Operating Leases

Future minimum lease payments under all non-cancelable operating lease obligations as of December 31, 2015 are as follows (in thousands):

Year Ending	Operating Leases
2016	$ 128
2017	84
Total minimum payments	$ 212

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.

In addition, the Company had a leased facility located in South San Francisco, California, which was used as its corporate headquarters prior to moving to its current facility in 2008. The South San Francisco facility is approximately 106,000 square feet and was fully subleased. This lease and associated subleases terminated in February 2015.

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, on a consolidated basis, under the Company's facility lease financing obligations as of December 31, 2015 are as follows (in thousands):

Year Ending	Lease financing obligations
2016	$ 13,699
2017	14,030
2018	14,252
2019	14,468
2020	14,689
Thereafter	41,378
Total minimum payments	$ 112,516

Apart from the property leases with Alexandria and BDA Management Committee, rent expense for leased facilities under operating lease commitments was $2.7 million, $2.9 million, and $3.0 million for the years ended December 31, 2015, 2014 and 2013, respectively. The Company received sublease income of $3.4 million, $5.0 million, and $4.5 million for the years ended December 31, 2015, 2014 and 2013, 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.

9. Redeemable Convertible Preferred Stock and Equity (Deficit)
Convertible Preferred Stock ("Preferred Stock")

As of December 31, 2013 and immediately prior to the initial public offering, the Company had authorized 125,000,000 shares of Preferred Stock. All shares of Preferred Stock had a par value of $0.01 per share.

Upon the closing of the IPO, all outstanding shares of the Company's convertible preferred stock automatically converted into 33,919,954 shares of common stock. As of December 31, 2015 and 2014, there was no outstanding convertible preferred stock.

Subsidiary Stock and Non-Controlling Interests

FibroGen Europe

As of December 31, 2015 and 2014, respectively, FibroGen Europe had a total of 42,619,022 shares of Preferred Stock outstanding, of which there were 1,700,845 shares of Series A Preferred Stock, 1,875,000 shares of Series B Preferred Stock, 1,599,503 shares of Series C Preferred Stock, 1,520,141 shares of Series D Preferred Stock, 459,565 shares of Series E Preferred Stock, 5,714,332 shares of Series F Preferred Stock, 9,927,500 shares of Series G Preferred Stock and 19,822,136 shares of Series H Preferred Stock, all of which shares no longer have any right to be exchanged for FibroGen, Inc. Common Stock.

The holders of FibroGen Europe's shares of Preferred Stock ("Preferred Shares") have the following rights, preferences and privileges:

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

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

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

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

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

- Voluntary conversion right: Preferred Shares can be converted into common shares upon the written request of a shareholder provided that the conversion is feasible within the maximum and minimum amounts of shares of classes of FibroGen Europe as set forth in its Articles of Association. Such request can be withdrawn before the notification of conversion is filed with the Finnish Trade Register.
- Compulsory conversion right: Preferred Shares will be converted into common shares if (i) FibroGen Europe's shares are listed in a stock exchange or other trading system in the European Economic Area, or (ii) FibroGen Europe's recombinant collagen and gelatin production technology is being put into commercial use in the area of 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 license fees, development financing, milestone payments or income from test products or equipment used in research. The board of directors of FibroGen Europe shall notify the shareholders of the compulsory conversion in writing, and the shareholders shall request to convert their shares within the timeframe provided in the notification. Should the shareholders fail to make the conversion request within the time limit, FibroGen Europe may redeem the shares of such shareholders.

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

FibroGen China

FibroGen China had 6,758,000 Series A Preference Shares outstanding as of December 31, 2015 and 2014, respectively. The holders of the FibroGen China Series A Preference Shares have the following rights, preferences and privileges:

Liquidation — In the event of liquidation, dissolution, or winding up of the Company, either voluntary or involuntary, including by means of a merger, the holders of FibroGen China Series A Preference Shares are entitled to be paid an amount equal to the product of the number of shares held by a holder of shares of FibroGen China Series A Preference Shares and the original issue price of $1.00 (subject to equitable adjustment for any stock dividend, combination, split, reclassification, recapitalization) plus all declared and unpaid dividends thereon.

Conversion — Each share of FibroGen China Series A Preference Shares is convertible into the number of fully paid and non-assessable shares of Common Stock of FibroGen China that results from dividing the original issue price by the

conversion price in effect at the time of the conversion, subject to adjustments for stock splits, stock dividends, reclassifications and like events. The FibroGen China Series A Preference Shares have a conversion price that is equal to the original issuance price such that the conversion ratio to FibroGen China Common Stock is 1:1 as of all periods presented.

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

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

Non-Controlling Interests

Non-controlling interest positions related to the issuance of subsidiary stock as described above are reported as a separate component of consolidated equity from the equity attributable to the Company's stockholders at December 31, 2015 and 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. Upon the initial public offering and as described above, all eligible FibroGen Europe preferred shares were exchanged for 958,996 shares of FibroGen Common Stock. No other FibroGen Europe shares have the right to be exchanged for FibroGen, Inc. Common Stock.

Common Stock

Each share of Common Stock is entitled to one vote. The holders of Common Stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding.

Shares of Common Stock outstanding, shares of stock plans outstanding and shares reserved for future issuance related to stock options and RSUs grant and Employee Stock Purchase Plan ("ESPP") purchases are as follows (in thousands):

	December 31,	
	2015	2014
Common stock outstanding	61,985	59,046
Stock options outstanding	13,583	14,427
RSUs outstanding	865	560
Common stock warrants outstanding	7	173
Shares reserved for future stock options and RSUs grant	3,394	5,358
Shares reserved for future ESPP offering	1,285	1,600
Total shares of common stock reserved	81,119	81,164

Stock Plans

Stock Option and RSU Plans

Under the Company's Amended and Restated 2005 Stock Plan ("2015 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. Upon the effective date of the registration statement related to the Company's initial public offering, the 2005 Plan was amended to cease the grant of any additional awards thereunder, although the Company will continue to issue common stock upon the exercise of previously granted stock options under the 2005 Plan.

In September 2014, the Company adopted a 2014 Equity Incentive Plan (the "2014 Plan") which became effective on November 13, 2014. The 2014 Plan is the successor equity compensation plan to the 2005 Plan. The 2014 Plan will

terminate on November 12, 2024. The 2014 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock awards, stock appreciation rights, performance stock awards, performance cash awards, restricted stock units and other stock awards to employees, directors and consultants. Stock options granted must be at prices not less than 100% of the fair market value at date of grant. Option vesting schedules are determined by the Company at the time of issuance and generally have a four year vesting schedule (25% vesting on the first anniversary of the vesting base date and quarterly thereafter over the next 3 years). Options generally expire ten years from the date of grant unless the optionee is a 10% stockholder, in which case the term will be five years from the date of grant. Unvested options exercised are subject to the Company's repurchase right. As of December 31, 2015, the Company has reserved 3,393,948 shares of its common stock for issuance under the 2014 Plan, and shares reserved for issuance will increase January 1 of each year commencing on January 1, 2016 and ending on January 1, 2024 by the lesser of (i) the amount equal to 4% of the number of shares issued and outstanding on December 31 immediately prior to the date of increase or (ii) such lower number of shares as may be determined by the board of directors.

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

Certain Common Stock option holders have the right to exercise unvested options, subject to a right held by the Company to repurchase the stock, at the original exercise price, in the event of voluntary or involuntary termination of employment of the stockholder. The shares are generally released from repurchase provisions ratably over four years. The Company accounts for the cash received in consideration for the early exercised options as a liability. At December 31, 2015 and 2014, no shares of Common Stock were subject to repurchase by the Company.

Stock option transactions, including forfeited options granted under the 2014 Plan as well as prior plans, are summarized below:

	Shares (In thousands)	Weighted Average Exercise per Share	Weighted Average Remaining Contractual Life (In Years)	Aggregate Intrinsic Value (In thousands)
Outstanding at December 31, 2014	14,427	$ 7.10		
Granted	1,891	27.27		
Exercised	(2,362)	4.28		
Expired	(29)	3.68		
Forfeited	(344)	18.08		
Outstanding at December 31, 2015	13,583	10.12	6.07	$ 276,401
Vested and expected to vest, December 31, 2015	13,321	9.84	6.01	274,820
Exercisable at December 31, 2015	10,029	$ 6.13	5.11	$ 244,134

The total intrinsic value of options exercised during the years ended December 31, 2015, 2014, and 2013 was $48.7 million, $6.5 million, and $0.3 million, respectively.

The following table summarizes restricted stock unit activity:

	Number of Shares	Fair Value at Grant
Unvested at December 31, 2014	559,582	$ 18.00
Granted	586,008	29.66
Vested	(241,497)	18.00
Forfeited	(39,244)	25.08
Unvested at December 31, 2015	864,849	$ 25.58

The estimated weighted-average fair value of the awards granted during the years ended December 31, 2015 and 2014 was $29.66 and $18.00, respectively. The Company did not grant any RSUs prior to January 1, 2014. There were no RSUs that were settled or exercised during the year ended December 31, 2015.

ESPP

In September 2014, the Company adopted a 2014 Employee Stock Purchase Plan (the “2014 Purchase Plan”) which became effective on November 13, 2014. The 2014 Purchase Plan is designed to enable eligible employees to periodically purchase shares of the Company’s common stock at a discount through payroll deductions of up to 15% of their eligible compensation, subject to any plan or IRS limitations ($25,000.00 for 2015). At the end of each offering period, employees are able to purchase shares at 85% of the lower of the fair market value of the Company’s common stock on the first trading day of the offering period or on the last day of the offering period. Purchases are accomplished through participation in discrete offering periods. The 2014 Purchase Plan is intended to qualify as an ESPP under Section 423 of the Internal Revenue Code. The Company has reserved 1,600,000 shares of its common stock for issuance under the 2014 Purchase Plan and shares reserved for issuance will increase January 1 of each year commencing January 1, 2016 by the lesser of (i) a number of shares equal to 1% of the total number of outstanding shares of common stock on December 31 immediately prior to the date of increase; (ii) 1,200,000 shares or (iii) such number of shares as may be determined by the board of directors. There were no shares purchased by employees under the 2014 Purchase Plan for the year ended December 31, 2014. There were 315,385 shares purchased by employees under the 2014 Purchased Plan for the year ended December 31, 2015.

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

Stock-Based Compensation

Stock-based compensation related to options granted is allocated to research and development and general and administrative expense for the years ended December 31, 2015, 2014, and 2013 was as follows (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Research and development	$16,987	$10,893	$1,925
General and administrative	10,694	7,805	1,519
Total stock-based compensation expense	$27,681	$18,698	$3,444

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 Company, in making its determinations of the fair value of its Common Stock, considered a variety of quantitative and qualitative factors, including (i) net present value of the Company's projected earnings, (ii) fair market value of the stock of comparable publicly-traded companies, (iii) any third party transactions involving the Company's convertible preferred stock, (iv) liquidation preferences of the Company's preferred stock and the likelihood of conversion of the preferred stock, (v) changes in the Company's business operations, financial condition and results of operations over time, including cash balances and burn-rate, (vi) the status of new product development, and (vii) general financial market conditions. Subsequent to the IPO, the fair market value of common stock is based on the closing price of the Company's common stock as reported on the NASDAQ Global Select Market on the date of the grant.

The fair value of employee stock 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 as well as contractual terms of the instruments.

Expected Volatility. Since the Company has very little 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 assumptions used to estimate the fair value of stock options granted and ESPPs using the Black-Scholes option valuation model were as follows:

	Years Ended December 31,		
	2015	2014	2013
Stock Options			
Expected term (in years)	5.2	5.1	4.1
Expected volatility	69.9%	62.8%	71.6%
Risk-free interest rate	1.7%	1.7%	0.8%
Expected dividend yield	—	—	—
Weighted average estimated fair value	$16.12	$9.51	$6.19
ESPPs			
Expected term (in years)	1.1 - 1.3	1.2	—
Expected volatility	64.8 - 65.3%	61.7 - 65.5%	—%
Risk-free interest rate	0.3%	0.1 - 0.4%	—%
Expected dividend yield	—	—	—
Weighted average estimated fair value	$10.54	$13.22	$—

As of December 31, 2015, there was $34.1 million of total unrecognized compensation costs, net of estimated forfeitures, related to non-vested stock option awards granted that will be recognized on a straight-line basis over the weighted-average period of 2.32 years. As of December 31, 2015, there was $16.2 million of total unrecognized compensation costs, net of estimated forfeitures, related to non-vested RSUs granted that will be recognized on a straight-line basis over the weighted-average period of 2.81 years.

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, 2015:

Year of Issuance	Number of Shares	Exercise Price per Share	Reason for Issuance	Expiration Date
1996	1,600	$ 4.38	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
2000	5,538	$ 15.00	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
	7,138			

10. Net Loss Per Share

The Company applies the two-class method to calculate basic and diluted net 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 loss per share in periods of net loss because the preferred stockholders have no contractual obligation to participate in losses.

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,		
	2015	2014	2013
Senior Preferred Stock	—	—	15,336
Junior Preferred Stock	—	—	18,584
Employee stock options	13,583	14,427	11,084
RSUs outstanding	865	560	—
Warrants	7	173	173
FibroGen Europe Preferred stock	—	—	959

14,455	15,160	46,136

11 FibroGen, Inc. 401(k) Plan
Substantially all of the Company's full-time United States of America-based employees are eligible to make contributions to the Company's 401(k) Plan. Under this plan, participating employees may defer up to 60% of their pretax salary during the year, but not more than statutory limits. The Company may elect to match employee contributions; no such matching contributions were made for the year ended December 31, 2013. Matching contributions of $2.5 million and $1.9 million were made during year ended December 31, 2015 and 2014, respectively.

12. Income Taxes

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

	Years Ended December 31,		
	2015	2014	2013
Domestic	$(66,411)	$(46,998)	$(3,107)
Foreign	(19,126)	(12,506)	(11,836)
Loss before provision for income taxes	$(85,537)	$(59,504)	$(14,943)

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

	Years Ended December 31,		
	2015	2014	2013
Current:			
Federal	$—	$ —	$ —
State	2	—	—
Foreign	240	—	—
Total current	$242	$ —	$ —
Deferred:			
Federal	$—	$ —	$ —
State	—	—	—
Foreign	—	—	—
Total deferred	$—	$ —	$ —
Total provision from income taxes	$242	$ —	$ —

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

	Years Ended December 31,		
	2015	2014	2013
Tax at statutory federal rate	34.0 %	34.0 %	34.0 %
State tax	— %	— %	— %
Stock-based compensation expense	(4.6)%	(4.6)%	(5.7)%
Net operating losses not benefitted	(21.7)%	(22.4)%	(1.6)%
Foreign net operating losses benefitted	(7.6)%	(7.1)%	(26.9)%
Other	(0.4)%	0.1 %	0.2 %
Total	(0.3)%	— %	— %

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

	December 31,

	2015	2014
Federal and state net operating loss carryforwards	$53,393	$44,748
Tax credit carryforwards	26,620	24,395
Foreign net operating loss carryforwards	8,421	6,485
Stock-based compensation	8,512	5,836
Lease obligations	4,335	5,204
Reserves and accruals	4,891	5,075
Deferred revenue	10,484	3,304
Other	915	950
Subtotal	117,571	95,997
Less: Valuation allowance	(116,718)	(94,731)
Net deferred tax assets	853	1,266
Fixed assets	(853)	(1,266)
Net deferred tax liabilities	(853)	(1,266)
Total net deferred tax assets	$—	$—

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

The valuation allowance increased by $22.0 million, $21.6 million and $2.2 million for the years ended December 31, 2015, 2014 and 2013, respectively. Due to uncertainty surrounding the realization of the favorable tax attributes in the future tax returns, the Company has established a valuation allowance against its otherwise recognizable net deferred tax assets.

At December 31, 2015, the Company had net operating loss carryforwards available to offset future taxable income of approximately $185.1 million and $270.1 million for federal and state tax purposes, respectively. These carryforwards will begin to expire in 2026 for federal and 2018 for state purposes, if not utilized before these dates. The Company also had foreign net operating loss carryforwards of approximately $35.6 million which expire between 2016 and 2025 if not utilized.

At December 31, 2015, the Company had approximately $27.0 million of federal and $15.6 million of California research and development tax credit and other tax credit carryforwards available to offset future taxable income. The federal credits begin to expire in 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, 2015, the impact related to stock option benefits was approximately $15.8 million.

Federal and state tax laws impose substantial restrictions on the utilization of net operating loss and credit carryforwards in the event of an “ownership change” for tax purposes, as defined in IRC Section 382. The Company reviewed its stock ownership for year ended December 31, 2015 and concluded no ownership changes occurred which would result in a reduction of its net operating loss or in its research and development credits expiring unused. If additional ownership change occurs, the utilization of net operating loss and credit carryforwards could be significantly reduced.

Uncertain Tax Positions

The Company had unrecognized tax benefits of approximately $24.2 million as of December 31, 2015. These unrecognized tax benefits, if recognized, would not affect the effective tax rate. The interest accrued as of December 31, 2015 was immaterial. There were no interest or penalties accrued as of December 31, 2014.

A reconciliation of the beginning and ending amounts of unrecognized income tax benefits during the years ended December 31, 2013, 2014 and 2015 is as follows (in thousands):

	Federal and State
Balance as of January 1, 2013	$ 12,545
Increase due to prior positions	294
Increase due to current year position	680
Balance as of December 31, 2013	13,519
Increase due to prior positions	1,493
Increase due to current year position	4,110

Balance as of December 31, 2014		19,122
Decrease due to prior positions		(2,382)
Increase due to current year position		7,473
Balance as of December 31, 2015	$	24,213

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 2006 to 2015. The Company is not currently under audit in any tax jurisdiction.

13. Related Party Transactions

Astellas is an equity investor in the Company and considered a related party. During the years ended December 31, 2015, 2014 and 2013, the Company recorded revenue related to collaboration agreements with Astellas of $21.6 million, $18.0 million, and $25.7 million, respectively. During the years ended December 31, 2015, 2014 and 2013, the Company recorded expense related to collaboration agreements with Astellas of $9.8 million, $11.4 million and $4.0 million, respectively.

As of December 31, 2015 and 2014, accounts receivable from Astellas were $4.5 million and $5.0 million, respectively, and amounts due to Astellas were $2.0 million and $4.3 million, as of the same periods. The amounts due are included in Accrued liabilities on the consolidated balance sheets.

Julian N. Stern, a director of the Company since November 1996, is of counsel to the law firm of Goodwin Procter LLP, which he joined in 2008. He has received, and continues to receive, no compensation from Goodwin Procter LLP since joining it as of counsel. The Company retains Goodwin Procter LLP as legal counsel for various matters, primarily consisting of intellectual property matters. During the years ended December 31, 2015 and 2014, the Company made payments to Goodwin Procter LLP of $0.4 million and less than $0.1 million, respectively. As of December 31, 2014, approximately $0.3 million was included in accrued liabilities in the consolidated balance sheet for amounts due to Goodwin Procter LLP. As of December 31, 2015, the balance of accrued liability for Goodwin Procter LLP was immaterial.

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,		
	2015	2014	2013
Europe	$159,123	$119,559	$76,478
Japan (related party)	21,596	17,987	25,661
All other	109	55	31
Total revenue	$180,828	$137,601	$102,170

Geographic Long-Lived Assets

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

	December 31,	
	2015	2014
United States	$113,628	$116,099
China	15,392	16,072
Total property and equipment	$129,020	$132,171

Customer Concentration

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

	As of or for the Year Ended December 31,				
	Percentage of Revenue			Percentage of Accounts Receivable	
	2015	2014	2013	2015	2014
Astellas—Related party	12%	13%	25%	29%	37%
AstraZeneca	88%	87%	75%	71%	63%

Schedule II: Valuation and Qualifying Accounts

(in thousands)

	Balance at Beginning of Year	Charged (Credited) to Statement of Operation	Deductions, Net	Balance at End of Year
Valuation allowances for deferred tax assets				
Year ended December 31, 2015	$ 94,731	$ 21,987	$ —	$ 116,718
Year ended December 31, 2014	$ 73,144	$ 21,587	$ —	$ 94,731
Year ended December 31, 2013	$ 70,955	$ 2,189	$ —	$ 73,144

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

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

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2015, the end of the period covered by this Annual Report on Form 10-K. Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to the company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Based on management's evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of December 31, 2015 at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

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

Management, with the participation and under the supervision of our Chief Executive Officer and our Chief Financial Officer, evaluated our internal control over financial reporting as of December 31, 2015, the end of our fiscal year, using the criteria established in Internal Control - Integrated Framework (2013) set forth by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on management's evaluation of our internal control over financial reporting, management concluded that, our internal control over financial reporting was effective as of December 31, 2015.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2015 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the most recent fiscal quarter ended December 31, 2015 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our Proxy Statement for our 2016 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2015.

Code of Conduct

We have adopted a Code of Business Conduct which applies to all of our directors, officers and employees. A copy of our Code of Business Conduct can be found on our website (www.FibroGen.com) under “Corporate Governance.” The contents of our website are not a part of this report.

In addition, we intend to promptly disclose the nature of any amendment to, or waiver from, our Code of Business Conduct that applies to our principal executive officer, principal financial officer, principal accounting officer or persons performing similar functions on our website in the future.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Proxy Statement for our 2016 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2015.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our Proxy Statement for our 2016 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2015.

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

The information required by this item is incorporated by reference to our Proxy Statement for our 2016 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2015.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement for our 2016 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2015.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

1. Consolidated Financial Statements

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

2. Financial Statement Schedules

Schedule II is included on page 177. All other schedules are omitted because they are not required or the required information is included in the consolidated financial statements or notes thereto.

3. Exhibits

See Item 15(b) below.

(b) Exhibits—We have filed, or incorporated into this Annual Report on Form 10-K by reference, the exhibits listed on the Index to Exhibits immediately following the Signatures page of this Annual Report on Form 10-K.

(c) Financial Statement Schedules—See (a) 2 above. All other financial statement schedules are omitted because they are not applicable because the requested information is included in the consolidated financial statements or notes thereto.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Francisco, State of California.

FIBROGEN, INC.

Date: February 29, 2016	By:	/s/ Thomas B. Neff Thomas B. Neff Chief Executive Officer
Date: February 29, 2016	By:	/s/ Pat Cotroneo Pat Cotroneo Vice President, Finance and Chief Financial Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Thomas B. Neff and Pat Cotroneo, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Thomas B. Neff Thomas B. Neff	Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	February 29, 2016
/s/ Pat Cotroneo Pat Cotroneo	Vice President, Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	February 29, 2016
/s/ Jeffrey L. Edwards Jeffrey L. Edwards	Director	February 29, 2016
/s/ Jeffrey W. Henderson Jeffrey W. Henderson	Director	February 29, 2016
/s/ Thomas F. Kearns Jr. Thomas F. Kearns Jr.	Director	February 29, 2016
/s/ Kalevi Kurkijärvi, Ph.D. Kalevi Kurkijärvi, Ph.D.	Director	February 29, 2016
/s/ Rory B. Riggs Rory B. Riggs	Director	February 29, 2016
/s/ Roberto Pedro Rosenkranz, Ph.D. M.B.A. Roberto Pedro Rosenkranz, Ph.D. M.B.A.	Director	February 29, 2016
/s/ Jorma Routti, Ph.D. Jorma Routti, Ph.D.	Director	February 29, 2016
/s/ James A. Schoeneck James A. Schoeneck	Director	February 29, 2016
/s/ Julian N. Stern	Director	February 29, 2016

Julian N. Stern		
/s/ Toshinari Tamura, Ph.D. Toshinari Tamura, Ph.D.	Director	February 29, 2016

EXHIBIT INDEX

The following exhibits are filed as part of this Annual Report on Form 10-K or are incorporated herein by reference. Where an exhibit is incorporated by reference, the number in parentheses indicates the document to which cross-reference is made. Refer to the end of this exhibit index for a listing of cross-reference documents.

Exhibit Number	Exhibit Description	Incorporation By Reference Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of FibroGen, Inc.	8-K	001-36740	3.1	11/21/2014
3.2	Amended and Restated Bylaws of FibroGen, Inc.	S-1/A	333-199069	3.4	10/23/2014
4.1	Form of Common Stock Certificate.	8-K	001-36740	4.1	11/21/2014
4.2	Investor Rights Agreement by and among FibroGen, Inc. and certain of its stockholders, dated as of December 1995.	S-1	333-199069	4.2	10/1/2014
4.3	Investor Rights Agreement by and among FibroGen, Inc. and certain of its stockholders, dated as of February 20, 1998.	S-1	333-199069	4.3	10/1/2014
4.4	Investor Rights Agreement by and among FibroGen, Inc. and certain of its warrant holders, dated as of June 3, 1999.	S-1	333-199069	4.6	10/1/2014
4.5	Investor Rights Agreement by and among FibroGen, Inc. and certain of its warrant holders, dated as of February 8, 2000.	S-1	333-199069	4.7	10/1/2014
4.6	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.	S-1	333-199069	4.1	10/1/2014
4.7	Warrant to Purchase 11,076 Shares of Common Stock issued to Bristow Investments, L.P, dated as of February 8, 2000.	S-1	333-199069	4.12	10/1/2014
4.8	Warrant to Purchase 2,769 Shares of Common Stock issued to Laurence S. Shushan and Magdalena Shushan, Trustees of The Laurence and Magdalena Shushan Family Trust, dated as of February 8, 2000.	S-1	333-199069	4.13	10/1/2014
4.9	Shareholders' Agreement by and among FibroGen China Anemia Holdings, Ltd. and certain of its shareholders, dated as of July 11, 2012.	S-1	333-199069	4.15	10/1/2014
4.10		S-1	333-199069	4.16	10/1/2014

	Share Purchase Agreement by and among FibroGen China Anemia Holdings, Ltd. and the purchasers party thereto, dated as of July 11, 2012.				
4.11	Common Stock Purchase Agreement by and between FibroGen, Inc. and AstraZeneca AB, dated as of October 20, 2014.	S-1/A	333-199069	4.17	10/24/2014
10.1(i)+	FibroGen, Inc. Amended and Restated 2005 Stock Plan.	S-1	333-199069	10.3(i)	10/1/2014

10.1(ii)+	Forms of stock option agreement, restricted stock purchase agreement and stock appreciation right agreement under the FibroGen, Inc. Amended and Restated 2005 Stock Plan.	S-1	333-199069	10.3(ii)	10/1/2014
10.1(iii)+	Form of stock option agreement under the FibroGen, Inc. Amended and Restated 2005 Stock Plan applicable to options exchanged pursuant to FibroGen, Inc.'s 2010 amendment and exchange offer.	S-1	333-199069	10.3(iii)	10/1/2014
10.1(iv)+	Form of 2010 amendment to the form of stock option agreement under the FibroGen, Inc. Amended and Restated 2005 Stock Plan applicable to options amended pursuant to FibroGen, Inc.'s 2010 amendment and exchange offer.	S-1	333-199069	10.3(iv)	10/1/2014
10.1(v)+	Form of 2013 amendment to the form of stock option agreement under the FibroGen, Inc. Amended and Restated 2005 Stock Plan applicable to options amended or exchanged pursuant to FibroGen, Inc.'s 2010 amendment and exchange offer.	S-1	333-199069	10.3(v)	10/1/2014
10.2+	FibroGen, Inc. 2014 Equity Incentive Plan and forms of agreement thereunder.	S-1/A	333-199069	10.4	11/12/2014
10.3+	FibroGen, Inc. 2014 Employee Stock Purchase Plan.	S-1/A	333-199069	10.5	11/12/2014
10.4+	FibroGen, Inc. Non-Employee Director Compensation Policy, as amended.	10-K	001-36740	10.5	3/26/2015
10.5+	FibroGen, Inc. 2014 Employee Compensation and Bonus Plan.	S-1/A	333-199069	10.7	10/30/2014
10.6	Lease Agreement by and between FibroGen, Inc. and X-4 Dolphin LLC, dated as of September 22, 2006; as amended by First Amendment to Lease by and between FibroGen, Inc. and X-4 Dolphin LLC, dated as of October 10, 2007; as amended by Second Amendment to Lease by and between FibroGen, Inc. and X-4 Dolphin LLC, dated as of June 29, 2009; as amended by Third Amendment to Lease by and between FibroGen, Inc. and Are-San Francisco No. 43, LLC (as successor in interest to X-4 Dolphin LLC), dated as of May 19, 2011; as amended by Fourth Amendment to Lease by and between FibroGen, Inc. and Are-San Francisco No. 43, LLC, dated as of September 8, 2011.	S-1	333-199069	10.8	10/1/2014
10.7	Lease for Premises in Beijing BDA Biomedical Park by and among Beijing FibroGen Medical Technology Development Co., Ltd., Beijing Economic and Technology Investment Development Parent Company and Beijing BDA International Biological Pharmaceutical Investment Management Co., Ltd., effective as of February 1, 2013, as supplemented by the Supplementary Agreement to Lease of Premises in Beijing BDA Biomedical Park by and among Beijing FibroGen Medical Technology	S-1	333-199069	10.9	10/1/2014

Development Co., Ltd., Beijing Economic Technology Investment Development Parent Company and Beijing BDA International Biological Pharmaceutical Investment Management Co., Ltd., dated as of January 30, 2013.

10.8+	Form of Employment Offer Letter.	S-1	333-199069	10.1	10/1/2014
10.9†	Collaboration Agreement, by and between FibroGen, Inc. and Astellas Pharma Inc., effective as of June 1, 2005.	S-1	333-199069	10.11	10/1/2014
10.10†	Anemia License and Collaboration Agreement, by and between FibroGen, Inc. and Astellas Pharma Inc., effective as of April 28, 2006.	S-1	333-199069	10.12	10/1/2014
10.11†	Amendment to Anemia License and Collaboration Agreement, by and between FibroGen, Inc. and Astellas Pharma Inc., effective as of August 31, 2006.	S-1	333-199069	10.13	10/1/2014
10.12	Amendment No. 2 to Anemia License and Collaboration Agreement, by and between FibroGen, Inc. and Astellas Pharma Inc., effective as of December 1, 2006.	S-1	333-199069	10.14	10/1/2014
10.13†	Supplement to Anemia License and Collaboration Agreement, by and between FibroGen, Inc. and Astellas Pharma Inc., effective as of April 28, 2006.	S-1	333-199069	10.15	10/1/2014
10.14†	Amendment No. 3 to Anemia License and Collaboration Agreement, by and between FibroGen, Inc. and Astellas Pharma Inc., dated as of May 10, 2012.	S-1	333-199069	10.16	10/1/2014
10.15†	Amended and Restated License, Development and Commercialization Agreement (China) by and among FibroGen China Anemia Holdings, Ltd., Beijing FibroGen Medical Technology Development Co., Ltd., FibroGen International (Hong Kong) Limited and AstraZeneca AB, effective as of July 30, 2013.	S-1/A	333-199069	10.17	10/23/2014
10.16†	Amended and Restated License, Development and Commercialization Agreement by and between Registrant and AstraZeneca AB, effective as of July 30, 2013.	S-1/A	333-199069	10.18	11/12/2014
10.17†	License Agreement by and between FibroGen, Inc. and the University of Miami and its School of Medicine, dated as of May 23, 1997.	S-1	333-199069	10.19	10/1/2014
10.18†	First Amendment to May 23, 1997 License Agreement by and between FibroGen, Inc. and University of Miami, effective as of July 29, 1999.	S-1	333-199069	10.20	10/1/2014
10.19	Research and Commercialization Agreement by and among FibroGen, Inc., GenPharm International Inc., Medarex, Inc. and FibroPharma, Inc., effective as of July 9, 1998.	S-1	333-199069	10.21	10/1/2014
10.20	Amendment No. 1 to Research and Commercialization Agreement by and among FibroGen, Inc., GenPharm International Inc., Medarex, Inc. and FibroPharma, Inc., effective as of June 30, 2001.	S-1	333-199069	10.22	10/1/2014
10.21†		S-1	333-199069	10.23	10/1/2014

	Amendment No. 2 to Research and Commercialization Agreement by and among FibroGen, Inc., GenPharm International Inc., Medarex, Inc. and FibroPharma, Inc., effective as of January 28, 2002.					
10.22†	License Agreement by and between FibroGen, Inc. and the Dana-Farber Cancer Institute, Inc., effective as of March 29, 2006.	S-1	333-199069	10.24	10/1/2014	

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

10.26(ix)†	Amendment No. 7 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of January 1, 2012.	S-1	333-199069	10.28(ix)	10/1/2014
10.26(x)†	Amendment No. 8 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of July 10, 2012.	S-1	333-199069	10.28(x)	10/1/2014

10.26(xi)†	Amendment No. 9 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of November 26, 2012.	S-1	333-199069	10.28(xi)	10/1/2014
10.26(xii)†	Amendment No. 10 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of June 21, 2013.	S-1	333-199069	10.28(xii)	10/1/2014
10.26(xiii)†	Amendment No. 11 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of July 9, 2013.	S-1	333-199069	10.28(xiii)	10/1/2014
10.26(xiv)†	Amendment No. 12 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of August 1, 2013.	S-1	333-199069	10.28(xiv)	10/1/2014
10.26(xv)†	Amendment No. 13 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of March 6, 2014.	S-1	333-199069	10.28(xv)	10/1/2014
10.26(xvi)†	Amendment No. 14 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of February 5, 2014.	S-1	333-199069	10.28(xvi)	10/1/2014
10.26(xvii)†	Amendment No. 15 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of October 20, 2014.	10-Q	001-36740	10.28(xvii)	11/12/2015
10.26(xviii)†	Amendment No. 16 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of December 8, 2014.	10-Q	001-36740	10.28(xviii)	11/12/2015
10.26(xix)†	Amendment No. 17 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of December 8, 2014.	10-Q	001-36740	10.28(xix)	11/12/2015
10.26(xx)†	Amendment No. 18 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of February 15, 2015.	10-Q	001-36740	10.28(xx)	11/12/2015

10.26(xxi)†	Amendment No. 19 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of March 1, 2015.	10-Q	001-36740	10.28(xxi)	11/12/2015
10.26(xxii)†	Amendment No. 20 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of June 1, 2015.	10-Q	001-36740	10.28(xxii)	11/12/2015

10.26(xxiii)†	Amendment No. 21 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of May 29, 2015.	10-Q	001-36740	10.28(xxiii)	11/12/2015
10.26(xxiv)†	Amendment No. 23 to the Process Development and Clinical Supply Agreement by and between FibroGen, Inc. and Boehringer Ingelheim Pharma GmbH & Co. KG, effective as of September 1, 2015.	10-Q	001-36740	10.28(xxiv)	11/12/2015
10.27+	Offer Letter, by and between FibroGen, Inc. and Frank Valone, dated as of November 3, 2008.	S-1	333-199069	10.29	10/1/2014
10.28+	Offer Letter, by and between FibroGen, Inc. and K. Peony Yu, dated as of November 21, 2008.	S-1	333-199069	10.3	10/1/2014
10.29+	Offer Letter, by and between FibroGen, Inc. and Pat Cotroneo, dated as of October 23, 2000.	S-1	333-199069	10.31	10/1/2014
10.30+	Form of Change in Control and Severance Agreement by and between FibroGen, Inc. and its officers.	S-1/A	333-199069	10.32	10/24/2014
21.1	Subsidiaries of FibroGen, Inc.	S-1/A	333-199069	21.1	10/24/2014
23.1*	Consent of PricewaterhouseCoopers LLP.	—	—	—	—
24.1*	Power of Attorney (included in signature pages).	—	—	—	—
31.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a).	—	—	—	—
31.2*	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a).	—	—	—	—
32.1*	Certification of Principal Executive Officer and Principal Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)(1).	—	—	—	—
101.INS*	XBRL Instance Document	—	—	—	—
101.SCH*	XBRL Taxonomy Schema Linkbase Document	—	—	—	—
101.CAL*	XBRL Calculation Linkbase Document	—	—	—	—
101.DEF*	XBRL Definition Linkbase Document	—	—	—	—
101.LAB*	XBRL Labels Linkbase Document	—	—	—	—

101.PRE*	XBRL Taxonomy Presentation Linkbase Document	—	—	—	—

* Filed herewith.
† Confidential Treatment Requested.
+ Indicates a management contract or compensatory plan.
(1) This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of FibroGen, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.