William Blair

FibroGen, Inc.

Initiating Coverage With an Outperform Rating

December 9, 2014
Basic Report (14-154)

Stock Rating:	**Outperform**
Company Profile:	**Aggressive Growth**
Symbol:	FGEN (NASDAQ)
Price:	$23.84 (52-Wk.: $20–$25)
Market Value (mil.):	$1,353
Fiscal Year End:	December
Dividend/Yield:	None

Estimates	2013A	2014E	2015E
EPS FY	-$0.32	-$1.12	-$1.55
Revenue (mil.)	$102	$136	$191

Trading Data	
Shares Outstanding (mil.)	56.7
Average Daily Volume	771,000

Financial Data	
Cash (mil.)	~$340
Enterprise Value (mil.)	$1,010

We are initiating coverage of FibroGen with an Outperform rating and an Aggressive Growth company profile. FibroGen has adroitly parlayed its extensive technical experience in hypoxia-inducible factors (HIFs) and fibrosis biology to generate multiple compounds targeting a number of therapeutic areas, which we outline in exhibit 1. Our bullish investment outlook on FibroGen is based on a variety of factors, including the strength of lead product candidates roxadustat (under development for the treatment of anemia) and FG-3019 (designed to inhibit connective tissue growth factor [CTGF] and being tested in fibrotic disease and cancer); an economically rich, globally collaborative framework with Astellas Pharma Inc. and AstraZeneca PLC; and a strong balance sheet, which collectively hold the potential to significantly expand the size of the company.

We believe that FibroGen's lead product candidate roxadustat could be highly disruptive to current treatment paradigms for anemia, given its distinctive mechanism of action and strong clinical profile to date. We estimate that the total anemia market is now about $8.6 billion globally, despite the limitations of currently available therapies. FibroGen's roxadustat inhibits a molecular pathway that results in mirroring the normal adaptive physiological response following exposure to high-altitude hypoxic conditions, which may offer a safer approach to anemia correction compared with the current standard of care using erythropoiesis-stimulating agents (ESAs). Roxadustat is undergoing Phase III clinical trials involving 7,000 to 8,000 patients globally, making it the largest anemia Phase III program in pharmaceutical history; we anticipate pivotal data in second half 2016.

We believe FibroGen's shares represent an attractive value. Recognizing development risks that are common to the biotechnology industry (e.g., clinical, regulatory, and capital risks), we view FibroGen shares as an attractive value at current price levels. Trading at $23.84 with an estimated $340 million in cash, the current enterprise value is roughly $1.0 billion. In addition, we emphasize that FibroGen benefits from an economically rich, collaborative framework for roxadustat that holds the potential to infuse an additional $1.9 billion of nondilutive funding, which could extend our cash runway estimation to the commercialization of roxadustat. Based on our estimates, we believe that the company has sufficient capital to sustain itself for at least two years.

FibroGen is a San Francisco-based biopharmaceutical company focused on the discovery, development, and commercialization of novel therapeutics to treat serious unmet medical needs. The lead product candidate, roxadustat, is in Phase III clinical study with pivotal data expected in the second half of 2016.

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Portfolio Manager Summary

We believe that FibroGen offers investors the opportunity to own a stake in a well-managed company with a distinctive clinical pipeline that could disrupt a number of treatment paradigms in a broad range of therapeutic settings. Specifically, the company has skillfully leveraged its deep technical knowledge and experience in HIFs and fibrosis to build an exciting collection of compounds targeting anemia, fibrotic disease, and cancer. In addition, we view FibroGen's global licensing strategy to develop, commercialize, and ultimately, maximize the value of lead product candidate roxadustat as highly differentiated and economically rich. A distinctive feature of the collaborative framework is focused on establishing a significant market presence in China as an attractive means of return on investors' capital. Exhibit 1 profiles the company's clinical development pipeline; we highlight that each of these candidates is the product of the FibroGen drug discovery effort, and with the exception of roxadustat, are all wholly owned.

Exhibit 1
FibroGen, Inc.
Product Portfolio

Drug	Description	Preclinical	Phase I	Phase II	Phase III	Market	Indication
HIF Platform							
Roxadustat	HIF-PH inhibitor	U.S.[1] / Europe[2]					Anemia in chronic kidney disease
		China[1]					
		Japan					
FG-6874	HIF-PH inhibitor						Hematopoietic stem cell mobilization
FG-8205	Selective HIF-PH inhibitor						Heart failure after myocardial infarction
Fibrotic Disease Platform							
FG-3019	Anti-CTGF antibody						Pancreatic cancer
							Idiopathic pulmonary fibrosis
							Liver fibrosis
							Duchenne muscular dystrophy

Device		Pilot	Pivotal	Market	Description
Recombinant Human Collagen Platform					
FG-5200	Type III recombinant human collagen scaffold	China			Corneal blindness

HIF-PH=hypoxia-inducible factor-prolyl hydroxylase. CTGF=connective tissue growth factor.
[1]Partnered with AstraZeneca
[2]Partnered with Astellas
Sources: FibroGen, Inc. reports

Roxadustat is undergoing global Phase III clinical testing to evaluate its potential in correcting anemia in dialysis-dependent (DD) and nondialysis-dependent (NDD) patients suffering from chronic kidney disease (CKD). The World Health Organization's criteria for anemia (established over 40 years ago) is less than 13 g/dL of hemoglobin (Hb) in men and 12 g/dL of hemoglobin in women. We believe that roxadustat stands to meaningfully affect the worldwide anemia markets by stimulating erythropoiesis through biological processes that more closely mimic a normal physiological response (e.g., compensating for low oxygen at high altitude), which thus far in clinical testing has

proved safe, even when targeting near normal Hb levels. On the contrary, with the current standard of care of administering ESAs, several large clinical trials suggest that dosing at or above the physiological Hb range may contribute to significant safety issues.

By our estimation, the anemia markets served by ESAs are largely composed of patients with kidney disease and cancer and represent an $8.6 billion opportunity worldwide. Safety concerns that emerged with the ESA class between 2005 and 2010 had a profound and negative impact on the use of the drugs, and we believe that there is a significant opportunity for an easier-to-administer, safer, and more effective alternative to considerably expand the overall market. For example, in the nephrology setting, while ESAs are primarily used to treat anemia in DD-CKD patients, we believe roxadustat could penetrate the NDD-CKD market, which represents a larger patient population. Outside of nephrology, we believe that there are large pockets of anemia patients who are underserved as a result of the safety and efficacy limitations of ESAs; these individuals may present long-term development targets for FibroGen and its collaborators. Given the shortcomings of standard-of-care treatment of anemia and roxadustat's distinctive clinical profile, we hope to see positive clinical results showing roxadustat's superior efficacy and safety compared with traditional ESA-based regimens. Branded ESAs are commercialized globally by Amgen Inc., Roche Holding AG, and Johnson & Johnson, addressing various disease settings and totaling $5.7 billion in commercial opportunity, which we outline in exhibit 2. It is our opinion that biosimilar forms of this class will become broadly accepted in Europe and the United States over the next few years.

Exhibit 2
FibroGen, Inc.
Branded Erythropoiesis-Stimulating Agents
(sales in millions)

Brand	Company	Indications	2013 Sales
Epogen	Amgen	Anemia in CKD, HIV, and chemotherapy	$1,953
Aranesp	Amgen	Anemia in CKD and chemotherapy	$1,911
Eprex	Johnson & Johnson	Anemia in CKD, chemotherapy, and elective surgery	$1,364
Procrit	Johnson & Johnson	Anemia in CKD, HIV, and chemotherapy	
Mircera	Roche	Anemia in CKD	$478
		Total Sales	**$5,706**

Sources: Amgen, Johnson & Johnson, and Roche reports

Roxadustat is under worldwide development and commercialization agreements with Astellas and AstraZeneca in geographically defined and economically rich collaborations. While the two collaborations are independent of each other, we believe they stand to maximize the value of roxadustat when we consider the overall framework. Moreover, we believe that, from an economic perspective, it represents one of industry's richest collaborative frameworks to date with over $700 million received thus far, and the potential of additional milestone payments of up to $1.9 billion. We will discuss the mechanics of the collaborations later in this report; however, we highlight that FibroGen maintains attractive "back-end" economics, including commercial participation in the United States and in China. In the context of the collaboration, we believe roxadustat is uniquely positioned for a strong global commercial launch with follow-on clinical development plans that should maximize the asset's value.

The value proposition of roxadustat over the current standard of care was the basis for the rich collaborative agreements. We see five key areas in which roxadustat is clinically differentiated; we highlight these below and in exhibit 3.

1. **An improved cardiovascular safety profile.** Unlike ESAs, which are associated with cardiovascular events and increased risk for hypertension and stroke, safety analysis of Phase II trials with roxadustat did not reveal any association between increase in Hb levels and rates of cardiovascular events or hypertension.

2. **The ability to correct anemia within near-physiological levels.** ESAs typically require dosing above the physiological range to achieve clinical effect. In contrast, clinical experience with roxadustat suggests the compound corrects anemia while maintaining erythropoietin (EPO) levels within the normal physiological range. The findings corroborate roxadustat's proposed mechanism of action, which involves mimicking a human's adaptive response to replenish hematocrits following blood donation or exposure to high-altitude conditions. Roxadustat's inhibition of hypoxia-inducible factor prolyl hydroxylase (HIF-PH) culminates in a coordinated erythropoietic response, including increased absorption and transport of iron in the gastrointestinal tract, production of endogenous EPO primarily from the kidney, and up-regulation of EPO-receptor expression on erythroid progenitor cells. We believe that by eliciting an endogenous physiological response, roxadustat provides distinguished efficacy and safety characteristics over injectable recombinant ESAs.

3. **Anemia correction in patients who are hyporesponsive to ESAs.** A portion of anemic patients are ESA-treatment resistant, or hyporesponders, and higher doses are necessary to reach target Hb levels, which increases the risk of adverse events and higher medical expenses. Moreover, in some patients, target Hb levels are not achieved despite aggressive ESA dosing. Phase II trials with roxadustat in incident dialysis patients (those who have initiated dialysis within the past four months) with elevated inflammatory markers (associated with ESA hyporesponsiveness) provided results similar to patients with other baseline characteristics (e.g., nonincident [longer-term] or no elevated inflammation markers).

4. **Anemia correction without the need for intravenous (IV) iron administration.** Unlike ESAs, roxadustat has demonstrated the ability to correct anemia without the need for concomitant administration of intravenous iron. Notably, intravenous iron has been associated with numerous risks including hypersensitivity, which could potentially be fatal; hypotension; gastrointestinal distress; and infection.

5. **Potential advantages in the commercial setting.**

    - ***Reimbursement.*** In the dialysis setting, ESAs are reimbursed under Medicare Part B and included in a bundled payment. Therefore, they represent a cost to the provider. The ability to treat patients without iron could be a source of cost savings to dialysis centers.

    - ***Convenience.*** Roxadustat is an oral therapy that we expect to be subject to Medicare Part D, which lowers the economic prescribing risk to providers, in our view.

Exhibit 3
FibroGen, Inc.
Roxadustat Opportunity in Dialysis

Market Dynamics	Opportunity for Roxadustat
Dialysis care is dominated by two large dialysis organizations (LDOs): Fresenius SE & Co. and DaVita Healthcare Partners (>60% share in the United States)	Collaboration framework in place to conduct a large Phase III program
Centralized decision on the anemia therapy at LDOs	Opportunity for rapid market conversion with strong safety profile
ESAs typically need IV iron	Potential to demonstrate safety benefit with MACE endpoint; no blood pressure increase
Dialysis is given three times a week (TIW)	Likely given during dialysis since it is dosing TIW and is not affected by dialysis
End-stage renal disease (ESRD) patients are typically on 15-20 medications	Potential to reduce need for concomitant medications, e.g., antihypertensives, antiplatelets, anticoagulants
	Upstream initiation at predialysis

MACE=major adverse cardiac events.
Sources: Fibrogen, Inc. reports

Key 12- to 24-Month Potential Value-Creating Catalyst Events

We see the potential for several value-creating inflection points over the next 12 to 24 months. Given FibroGen's enterprise value of about $1.0 billion, or $17.81 per share, we believe that many of the catalysts could have a material and positive impact on FibroGen shares. We highlight upcoming events in exhibit 4.

Exhibit 4
FibroGen, Inc.
Timeline

Date	Product	Event
2015	Roxadustat	Phase III trial initiation in anemia associated with chronic kidney disease (CKD) in China (1H).
	FG-3019	Phase II trial initiation in stage IV pancreatic cancer (1H).
	FG-3019	Phase II trial interim results in stage III pancreatic cancer (2H).
	FG-5200	Potential regulatory submission in corneal blindness as a result of partial thickness corneal damage in China (2H).
2016	Roxadustat	Potential regulatory submission in anemia associated with CKD in China (2H).
	Roxadustat	Phase III trial results in anemia associated with CKD in China (2H).
	FG-3019	Phase IIb trial results in idiopathic pulmonary fibrosis (2H).
2017	Roxadustat	Potential regulatory approval in anemia associated with CKD in China (1H).
	Roxadustat	Phase III global trial results in anemia associated with chronic kidney disease that is nondialysis dependent (1H).

Sources: FibroGen, Inc. reports

Valuation and Financial Analysis

Our Outperform rating on FibroGen shares is based on our belief that the stock represents an attractive value at current price levels. Recognizing the difficulty in precision valuation of developmental-stage biotechnology companies, we have taken a three-pronged approach that includes a sum-of-the-parts evaluation, comparable analysis, and attribution of value to technology and pipeline to FibroGen, which we believe elucidates the company's value. FibroGen shares are trading at about $1.0 billion in enterprise value; we see significant potential for upside in FibroGen shares.

Sum-of-the-Parts Evaluation
We performed a net present value analysis using a conservative set of criteria in which we attribute all of the company's value to roxadustat. At current price levels, we believe that roxadustat plus cash easily justifies the valuation. Therefore, we believe that FG-3019, additional pipeline candidates, and the platform represent significant value that is not reflected in the stock price. In the following bullets, we outline our assumptions to perform the sum-of-parts analysis.

Roxadustat assumptions

- We rely heavily on the experience with current standard-of-care treatments with ESA. We assume roxadustat will be priced at parity with regimens consisting of ESA and IV iron, which has a total cost of about $6,500 annually per patient. Consistent with pricing trends associated with marketing pharmaceuticals in other global markets, we assume roxadustat will be priced at a 20% discount to the U.S. price in Japan and Europe, while the price in China will be 50% relative to the U.S. price.

- We used the conservative end of the aforementioned criteria when evaluating roxadustat, with promotional discounts ranging from low double digits to mid-double digits and market penetration rates capped at 15% for the four targeted geographies.

- As a result of the elaborate collaborative framework for global development and commercialization, there are a number of revenue and expense considerations, which we reflect in our financial projections (exhibit 16, on page 24).

FG-3019 assumptions

- We assume FG-3019 will be priced comparably with similar drugs that are used to treat idiopathic pulmonary fibrosis (IPF), which is estimated to cost roughly $70,000 annually per patient in the United States and $40,000 in Europe, with promotional discounts ranging from low-double digits to mid-double digits.

- Recognizing increasing participation of R&D efforts from other biotechnology companies focused on IPF therapeutics, we apply a conservative peak penetration of 10% for both the U.S. and European markets.

- While not a direct consideration in our quantitative valuation methods, we believe that an important qualitative observation is the recent acquisition of InterMune (a leading participant in the IPF category) by Roche for $8.3 billion (exhibit 13, on page 19).

Comparable Analysis
Recognizing that the biotechnology sector is extremely heterogeneous, we compiled a list of companies that we believe have comparable attributes to FibroGen, as shown in exhibit 5. As is often the case with comparable analysis in biotechnology, there are no perfect comparisons for FibroGen. However, we believe that when compared with many of the companies in our analysis, FibroGen appears inexpensive, particularly on the basis of enterprise value.

Exhibit 5
FibroGen, Inc.
Analysis of Comparable Companies
(dollars in millions except share price)

Company	Share Price	Market Cap	Enterprise Value	Rating
Companywide Comps				
Incyte Corporation	$74.66	$12,613.20	$7,665.71	
Nektar Therapeutics	$15.76	$2,024.24	$1,338.10	Outperform
Theravance Biopharma, Inc.	$13.43	$1,549.41	$3,473.83	
Hypoxia-Inducible Factor/Platform Comps				
Akebia Therapeutics	$10.70	$217.65	$90.25	
Ironwood Pharmaceuticals, Inc.	$14.09	$1,967.42	$1,326.38	
Pharmacyclics, Inc.	$139.33	$10,524.87	$7,518.21	Outperform
Puma Biotechnology, Inc.	$197.67	$5,959.36	$2,887.01	
Seattle Genetics, Inc.	$37.41	$4,634.78	$4,475.36	Outperform
Connective Tissue Growth Factor Comps				
Chimerix,Inc.	$36.58	$1,428.60	$191.63	Outperform
Intercept Pharmaceuticals, Inc.	$137.00	$2,926.28	$1,086.09	
Onconova Therapeutics, Inc.	$4.24	$91.98	$22.11	
Ophthotech Corporation	$43.29	$1,456.76	$80.65	
FibroGen, Inc.	$23.02	$1,353.00	$1,010.00	Outperform

Source: FactSet

Attribution of Value to Technology and Platform, Earlier Pipeline Candidates, and Partnerships
FibroGen has two global partnerships with Astellas and AstraZeneca to move roxadustat through clinical testing and into the market. The amount from the two partners totals $1.9 billion in potential future cash payments to FibroGen. In addition, we believe that the next two years hold great promise for organic and inorganic value creation inflection points for FibroGen (exhibit 6). In our view, FibroGen possesses two promising compounds that address meaningful global unmet medical needs with significant intermediate- and long-term potential.

Exhibit 6
FibroGen, Inc.
Potential Two-Year Value Drivers

Organic	Inorganic
Phase II interim results with FG-3019 in stage III pancreatic cancer	Sustained growth in dialysis population worldwide
Regulatory submission with FG-5200 in corneal blindness in China	Elevated focus to establish dialysis infrastructure by the central government in China
Regulatory submission with roxadustat in anemia associated with chronic kidney disease in China	Increase appetite for low-cost options among private and public payors
Phase IIb trial results with FG-3019 in IPF	Expanding healthcare spending in developing countries
Additional collaborations	Increased diagnosis and treatment rate due to higher rates of disease awareness

Sources: FibroGen, Inc. reports

Risk Factors

We view FibroGen as a speculative investment since the company has no approved products; therefore, the company is likely to burn cash until it is successful in marketing roxadustat. Still, given that FibroGen can leverage its economically rich global collaborative framework, we believe the risk profile of the company is substantially mitigated compared with a typical development-stage biotechnology firm. We have outlined key risks for FibroGen over the next two to three years.

Clinical
While we believe that FibroGen's two lead clinical programs have shown promising results in early stage clinical trials, there is always the risk of clinical trial failure or an unexpected safety event. Any setbacks that occur could threaten the company's prospects of obtaining regulatory approval and ultimately weigh heavily on the stock. Roxadustat has previously been studied in over 1,400 patients and to date has demonstrated attractive safety profiles; we believe it carries a reduced risk compared with FibroGen's other potential compounds.

Regulatory
We believe that all development candidates in the biotechnology industry carry some level of regulatory risks. In addition, it must be noted that FibroGen has not previously developed a drug through the regulatory process, and the plan to gain approval in four separate regulatory pathways (United States, European Union, China, and Japan) increases the complexity of the process. However, the corporate partnerships in place with roxadustat will provide support and expertise in global regulatory affairs to help facilitate the approval process. We also take comfort in the large scale of the planned Phase III studies for roxadustat, with over 7,000 patients across eight studies, which we believe should be sufficient to mitigate the risk of any regulatory concerns regarding efficacy and safety.

Financial
Although FibroGen is well capitalized because of its lucrative corporate partnerships involving roxadustat, it is currently not a profitable company. Because of the large expense associated with R&D, clinical trials, regulatory submissions, and commercialization, it may be necessary for FibroGen to raise additional capital before reaching profitability. Capital can come into companies from a variety of sources, including strategic collaborations and equity financing.

Competitive
FibroGen's lead product, roxadustat, is in a highly competitive market with entrenched and well-funded competition. Although we believe the safety profile and dosing regimen of roxadustat gives it the potential to become the best-in-class drug for the treatment of anemia in patients with CKD, the prevalence of competing therapies may hinder the market share growth of roxadustat, if approved. In addition, other companies are developing compounds to target the same unmet clinical needs as FibroGen. For example, Akebia Therapeutics is also developing an HIF-PH inhibitor for the treatment of anemia secondary to CKD.

Company Management

FibroGen is led by an experienced management team whose executives have successful track records. In exhibit 7, we summarize key experience of top executives.

Exhibit 7
FibroGen, Inc.
Management Team

Management	Position	Previous Experience
Thomas B. Neff	Chief Executive Officer and Chairman of the Board	Director, Kolltan Pharmaceuticals Founder and general partner, Three Arch Bay Health Science Fund Founder, Pharmaceutical Partners I and II (Royalty Pharma) Investment banker, PaineWebber Incorporated
Frank H. Valone, M.D.	Chief Medical Officer	Executive vice president, Titan Pharmaceuticals Chief medical officer and executive vice president, Dendreon
K. Peony Yu, M.D.	Vice President of Clinical Development	Vice president, Anesiva, Inc. Director of research, ALZA Corporation Pain Therapeutics Elan Pharmaceuticals
Pat Cotroneo	Chief Financial Officer	Controller, SyStemix Controller, Genetic Therapy Inc. Deloitte L.L.P

Sources: FibroGen, Inc. reports

Company Background

Company History

FibroGen is a San Francisco-based company with 317 employees that was founded in 1993 by current Chairman and Chief Executive Officer Thomas Neff. The company's focus is the discovery, development, and commercialization of novel therapeutic agents to treat serious unmet medical needs. FibroGen's extensive experience in HIF and fibrosis biology has proved to be a productive means of drug discovery, as evidenced by the generation of three clinical assets in three distinctive therapeutic areas. The company's distinctive capital structure is owed in large part to the monetization of roxadustat in global collaborations with Astellas and AstraZeneca; we estimate the cash balance for FibroGen to be approximately $340 million. Maintaining a strong balance sheet has enabled FibroGen to advance its other clinical assets, FG-3019 in IPF, pancreatic cancer, and liver fibrosis and FG-5200 as a corneal implant. Moreover, we believe that the combination of its strong balance sheet and collaborative framework have enabled the company to take more of a global approach to the development and future commercialization of its assets, including a highly differentiated and distinctive approach in China.

Current Approach to Anemia Leaves Significant Room for Improvement

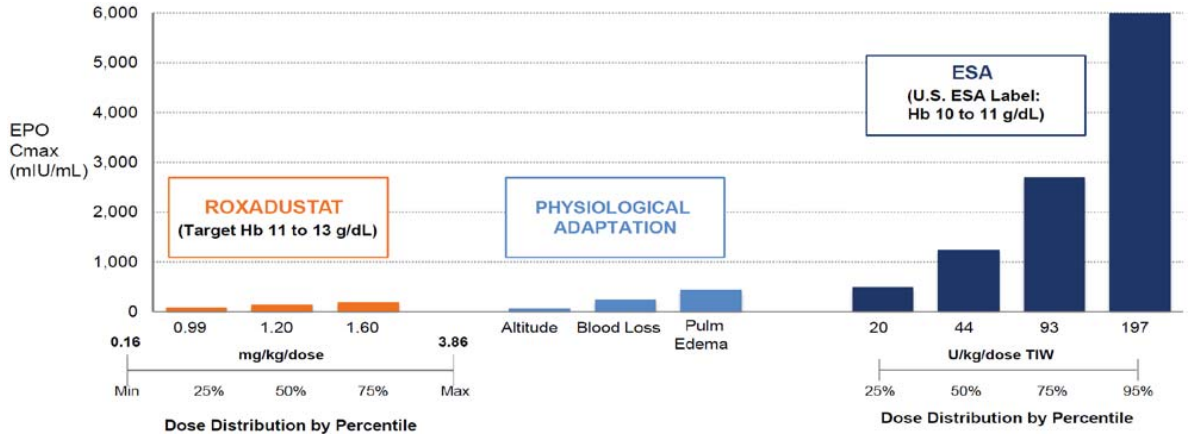
The development and eventual availability of ESAs as supportive care in treating anemia in the CKD and oncology settings was viewed as a major treatment advance for patients and physicians alike. The commercialization of ESAs in the United States began in June 1989, and the initial regulatory approvals were not based on placebo-controlled trials. In the dialysis setting, the kidney dialysis

quality outcomes initiative (KDOQI) supported increasing target hemoglobin levels, as patients appeared to do better with higher hematocrits. During this time and until 2006, ESAs were also a source of revenue for dialysis providers.

The 2006 to 2009 time frame was a formative one for the ESA class, as industry sponsors undertook a series of large studies designed to confirm that targeting higher versus lower hemoglobin levels was associated with better patient outcomes. These studies included the Correction of Hemoglobin in Outcomes and Renal Insufficiency (CHOIR), Cardiovascular Risk Reduction by Early Anemia Treatment with Epoetin Beta (CREATE), and Trial to Reduce Cardiovascular Events with Aranesp Therapy (TREAT). ***The risk elucidated in the CHOIR and TREAT trials was cardiovascular in nature and dose associated***. Specifically, CHOIR illustrated that patients with the lowest cardiovascular risk achieved target hemoglobin with the lowest ESA dose. There has subsequently been significant emphasis placed on the risk profile of hyporesponders to ESAs. Ultimately, warnings regarding these risks have been integrated into treatment guidelines and have had a measurable and negative effect on ESA use.

We believe that the consistency of the exposure and response relationship with roxadustat will be a key differentiating feature of the compound. Based on the current product profile, we see potential for the drug to do well in the existing markets and believe it is likely to expand into the anemia management space over time. Within the current base of ESA use in kidney disease, we estimate that 10% of the population are hyporesponders. In a worst-case scenario, doses may be 40-fold higher in these patients than in individuals who are ESA-responsive. Hyporesponsiveness to ESAs may be particularly problematic in the incident dialysis cases where low kidney function and other co-morbidities, including inflammation, may amplify the problem. Pro-inflammatory cytokines such as tumor necrosis factors (TNFs) have been implicated in the suppression of red blood cell formation. Moreover, interleukin 6 (IL-6) may elevate hepcidin, which interferes with the regulation of iron metabolism and results in functional iron deficiency. We illustrate in exhibit 8 that the physiological concentration of EPO in hyporesponsive patients is significantly above normal levels.

Exhibit 8
FibroGen, Inc.
Physiological Concentration of EPO in Hyporesponsive Patients Is Significantly Above Normal Levels



Sources: Adapted from FibroGen, Inc. reports

To that end, one of the many benefits of roxadustat is the drug's ability to increase hemoglobin in the absence of IV iron. Assessment of iron status is indicated in the ESA labels, and physicians routinely administer IV iron to ensure that patients are replete before ESA administration.

Market for Anemia Drugs
ESAs are used predominantly in the CKD and oncology settings. Epogen, Amgen's short-acting ESA, is perhaps the best-known agent in the class and is marketed by Amgen in the dialysis setting. Sales of Epogen were $2.0 billion in 2013. Amgen also markets Aranesp, a longer-acting ESA, which, in nephrology, is used predominantly by NDD-CKD patients, as well as in the oncology setting, where anemia most commonly occurs as the result of ablative therapies to treat cancer. In Europe, the key drugs are Aranesp, which is broadly used in the nephrology and oncology settings, and Mircera, a pegylated form of epoetin marketed by Roche. Notably in Europe, there are biosimilar ESAs, which have enjoyed limited success as a result of the area's history with pure red cell aplasia. Over time, we expect biosimilar ESAs to play a more prominent role globally; however, the clinical limitations of the class will likely limit overall patient growth. Fiscal 2013 sales of Aranesp, Epogen, Eprex, Procrit, and Mircera were $5.7 billion, as illustrated in exhibit 2, on page 3.

Given the limitations of ESAs, which as described previously are driven by both patient safety and clinical issues, we see the opportunity for a safe, effective, easy-to-use drug to garner share from the existing market and expand the overall market for anemia correction. We believe that FibroGen has embarked on an approach with roxadustat that has the potential to offer a safer, more effective, more convenient, and more accessible alternative to ESAs.

Key Program Analysis—Roxadustat

Roxadustat Background and Clinical Settings
To date, there have been over 1,770 patients enrolled in more than 30 roxadustat clinical trials globally, including roughly 1,400 who have been dosed with the drug. Across the clinical experience, the drug appears to be well tolerated, with some patients on therapy for over 2.5 years. Based on robust clinical trial results, FibroGen and its partners have designed a global Phase III trial program geared toward supporting regulatory filings in patients with CKD who are not on dialysis, as well as people with CKD who are on dialysis. We expect the Phase III trials to enroll between 7,000 and 8,000 patients globally, making it the largest anemia Phase III program in pharmaceutical history. We project the global Phase III CKD trial in NDD patients will likely be reported in 2017 with regulatory filing in 2018. The company is also conducting a broad clinical program in China, which we describe later in this report.

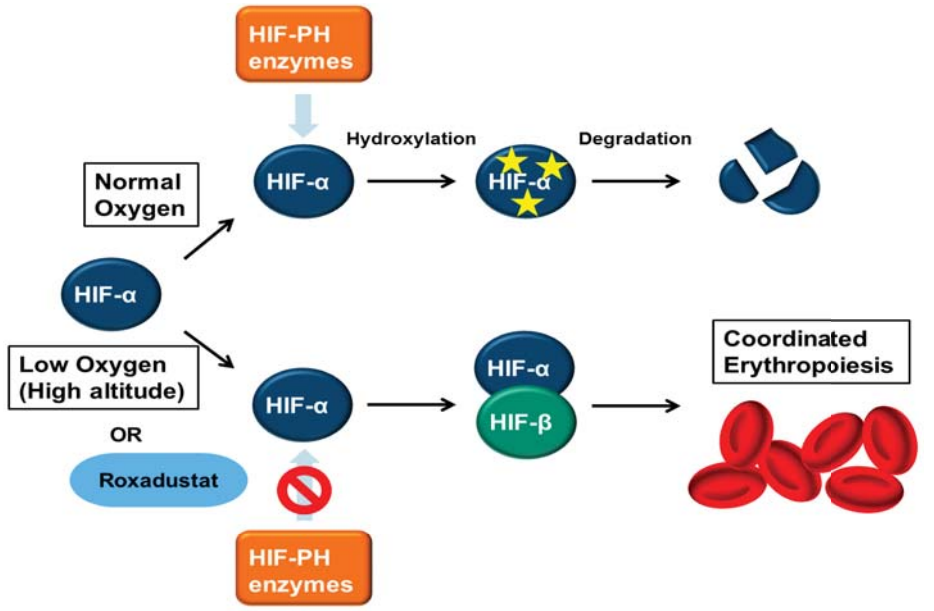
Our enthusiasm for the roxadustat program is grounded in the distinctive clinical profile that was elucidated during the Phase II experience. Several objectives were satisfied during Phase II clinical trials that we believe answer important clinical, regulatory, and commercial questions. Those objectives include:

- Dose optimization and efficacy in a diverse set of CKD patients including dialysis, nondialysis, incident dialysis, and switches from ESAs without the need for iron therapy
- Substantial and consistent safety database with over 1,400 patients
- Reduction in cholesterol observed in post-hoc analysis and potential for treatment of anemia in a significant subset of patients with inflammation

Scientific Rationale for Small Molecule Inhibition of HIF-PH
Oxygen is intricately linked to the survival of higher order multicellular organisms. In mammals, a protein responsible for the regulation of oxygen levels called HIF can also trigger a variety of cellular responses to restore oxygen concentration to normal levels, as shown in exhibit 9. One of the

most important countermeasures elicited by HIF is to trigger the production of additional red blood cells, or erythropoiesis. The increased number of red blood cells can, in turn, provide the oxygen necessary to reestablish oxygen equilibrium in the body.

Exhibit 9
FibroGen, Inc.
Control of HIF Levels by Prolyl Hydroxylation



Sources: Adapted from FibroGen, Inc. reports and William Blair & Company, L.L.C.

Under normal oxygen levels, an oxygen-sensing enzyme called HIF-PH places hydroxyl functional groups to HIF (indicated by gold stars in exhibit 9), and the chemical signature acts as a signal to target HIF for degradation. In contrast, without ample levels of oxygen, HIF-PH becomes inactive, which consequently leads to functional HIF proteins (illustrated by bound HIF-α and HIF-β in exhibit 9) coordinating genes necessary for the process of erythropoiesis.

Roxadustat is a small molecule inhibitor of HIF-PH. By interrupting HIF-PH's cellular function, Roxadustat could mimic hypoxic conditions and induce erythropoiesis. We believe that by using innate physiological pathways responsible for human adaptation, the natural response could lead to improved therapeutic effects and safety profiles.

Key Differentiating Features of the Roxadustat Clinical Profile

An interesting finding, albeit in a small subset of patients, that could have relevant clinical implications is that roxadustat is associated with lower circulating hepcidin levels than patients treated with Epogen, thereby enabling the maintenance of regular iron levels. Additional key differences are highlighted in exhibit 10. We list what we view as the three most significant differentiating features of roxadustat versus ESAs below.

- Oral administration and potential to simplify anemia management
- Potential for reduced hepcidin levels and anemia correction without IV iron
- Potential for numerous health economic advantages

Exhibit 10
FibroGen, Inc.
Roxadustat's Potential Clinical Differentiation From ESAs

	Clinical Differentiator	Roxadustat	ESAs
Ease	Oral agent	√	
Efficacy	Raises Hb	√	√
	No iron needed in predialysis patients and no IV iron needed in dialysis	√	
	Increases iron absorption	√	
	Typically raises Hb in presence of inflammation	√	
	Lowers hepcidin	√	
Safety	Within or near physiologic EPO levels	√	
	Reduction in platelet elevations	√	
	Lowers cholesterol	√	
	No blood pressure increase	√	
	Reduced safety risk	√	

Sources: FibroGen, Inc. reports

The Commercial Opportunity for Roxadustat Is Estimated to Be at Least $8 Billion Globally
We believe that there is a significant opportunity for roxadustat to play a key role in the existing market, as well as to meaningfully grow the market. Specifically, we believe that there are large populations of people suffering from anemia who are not served by ESAs, including the majority of people suffering from CKD anemia who are not on dialysis. The leading causes of secondary CKD are diabetes and hypertension, and we estimate that over a third of the diabetes population and one-fifth of the hypertensive CKD patients are anemic.

The Opportunity for Roxadustat in the Chinese Market
FibroGen's opportunity in China is highly differentiated, with significant potential for investors. We believe that FibroGen has skillfully created a framework in which to participate in the Chinese market with partner AstraZeneca, which we describe in detail later in the report. The basis for our excitement about the opportunity in China is the drug profile, which we believe is well suited for the market. The implementation of a healthcare reform plan in 2009 has expanded the population eligible for reimbursement, which, in turn, has doubled national healthcare expenditures over the past five years. The increase in healthcare spending has been evident in the sale of ESAs. This is not particularly surprising given China's aging population and growing prevalence of diabetes. According to IMS Health, ESA sales grew at a compound annual rate of 25% between 2006 and 2013, to $145 million.

Because of its large, aging population and growing incidence of diabetes, the prevalence of CKD in China is estimated to be 120 million people, or 10.8% of the population. By comparison, the population prevalence in the United States is estimated to be 14%. We estimate that there are between one and two million people living in China who are eligible for dialysis; however, only between 300,000 and 400,000 are currently dialysis patients. Compared with U.S. or Japanese standards, less than 20% of requisite dialysis capacity has been built, and we believe that capacity expansion is growing at over 25% per year, driven in part by government liberalized regulations on private ownership of healthcare facilities. Notably, between 2011 and 2013, we estimate that the installed base of hemodialysis machines increased from 30,053 to 41,271. Given that the Chinese government placed the development of innovative medicines as a strategic priority, we expect this growth trajectory to continue.

The anemia market in China is significantly underpenetrated, with 85% of ESAs used being locally manufactured. Those patients who are dialysis eligible and not on dialysis, as well as the large population of predialysis patients, are managed with oral iron and traditional Chinese medicine. As described earlier in this report, there are significant drawbacks to ESAs, such as dosing modality and expense, which may be amplified in the Chinese market. Ultimately, we believe roxadustat has a very strong potential in the Chinese market based on the factors previously discussed and expect that the collaboration with AstraZeneca in China will provide significant value to FibroGen.

Global Collaborative Framework With Astellas and AstraZeneca

Roxadustat is under development in two key global collaborations, which have infused more than $700 million of capital into the company to date. The initial collaboration was with Astellas, and more recently, the company partnered additional geographies of the world with AstraZeneca. The combination of the two transactions creates a broad-reaching development and commercial framework, which, in our view, should maximize the value of roxadustat. Exhibit 11 provides summary terms of the transaction.

Collaboration with Astellas. FibroGen has provided Astellas with the right to develop and commercialize roxadustat for anemia under two separate agreements in Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa. As a part of the agreement, FibroGen shares the responsibility and cost with Astellas for clinical development activities required for U.S. and European regulatory approval. For other territories, Astellas will be responsible for clinical development activities as well as the associated costs required for regulatory filings. FibroGen is responsible for providing development and commercial supplies for roxadustat either directly or through contract manufacturers.

Consideration under these agreements includes a total of $360.1 million in up-front and noncontingent 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 received through June 30, 2014, totaled $462.6 million.

In terms of commercialization, Astellas will be entirely responsible for the costs accrued in its territories. In addition, Astellas will provide FibroGen with a transfer price in the low 20% range for the manufacturing and delivery of roxadustat, based on net sales.

Collaboration with AstraZeneca. FibroGen has also provided AstraZeneca with the right to develop and commercialize roxadustat for anemia under two separate agreements in China, the United States, and all other countries not previously licensed to Astellas ("Rest of World"). As a part of the agreement, FibroGen shares the responsibility and cost with AstraZeneca for clinical development activities required for regulatory approval in the United States. Moreover, AstraZeneca will be responsible for all the development costs incurred by FibroGen under the agreed development plan for roxadustat in the United States and Europe, to the extent those costs are not covered by Astellas, after an initial 50% development cost-sharing period, in which the funding obligation is limited to a total of $116.5 million. Thereafter, AstraZeneca will be solely responsible for additional development costs. In China, the company's subsidiary, FibroGen China, will conduct development work for CKD anemia, hold all of the regulatory licenses issued by Chinese regulatory authorities, and be primarily responsible for regulatory, clinical, and manufacturing terms. Development costs are split, and AstraZeneca is responsible for 100% of development expenses in all other licensed territories excluding China. Similar to the agreement with Astellas, FibroGen is responsible for providing development and commercial supplies for roxadustat either directly or through contract manufacturers.

Under the AstraZeneca agreements, FibroGen received up-front and subsequent noncontingent payments totaling $402.2 million, which the company expects to receive in various amounts through 2015, and including a $62 million time-based development milestone, which became noncontingent

as of July 30. The agreement could total $1.2 billion, of which $571 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 received through June 30, 2014, totaled $220.2 million.

In addition, AstraZeneca agreed to pay for all commercialization costs in the United States and Rest of World with FibroGen undertaking specified promotional activities in the end-stage renal disease (ESRD) segment. The company will receive a transfer price for delivery of the commercial product based on a percentage of net sales in the low- to midsingle-digit range, and AstraZeneca will provide a tiered royalty rate in the low 20% range, based on net sales of roxadustat.

China-specific collaborative framework. Under the China agreement through FibroGen China, the commercial collaboration is structured as a split profit share. AstraZeneca will conduct commercialization activities in China and serve as the main distributor for roxadustat. In addition, AstraZeneca will fund the roxadustat launch until FibroGen China has achieved profitability, which will trigger AstraZeneca to recoup 50% of the historical launch costs from roxadustat profits in China. In addition, FibroGen is eligible to receive an aggregate amount of about $328.5 million in potential payments, which include $15 million after achieving specified development milestone events, $146 million after reaching specified regulatory events, and $167.6 million after accomplishing specified commercial sales events.

Exhibit 11
FibroGen, Inc.
Roxadustat Collaboration Summary
(revenues in millions)

Astellas	Cash received through June 30, 2014	Additional potential cash payments under agreements	Total potential cash payments under agreements
Up-front, noncontingent	$360.1		$360.1
Regulatory/development milestones	102.5	440.0	542.5
Commercial milestones		15.0	15.0
Total Astellas	**$462.6**	**$455.0**	**$917.6**
Astellas Equity Investment	**$80.5**		**$80.5**

AstraZeneca	Cash received through June 30, 2014	Additional potential cash payments under agreements	Total potential cash payments under agreements
Up-front, noncontingent	$220.2	182.0	$402.2
Regulatory/development milestones		571.0	571.0
Commercial milestones		652.5	652.5
Total AstraZeneca	**$220.2**	**$1,405.5**	**$1,625.7**
AstraZeneca Equity Investment		**$20.0**	**$20.0**
Total Collaborative Payments	**$763.3**	**$1,880.5**	**$2,643.8**

	Astellas	AstraZeneca
Net Sales Royalty/Transfer Price**	Low 20%	Low- to Mid-20%
China Partnership	50% profit share 50% development cost and launch responsibility	
Development Funding	FibroGen excl. China capped at $116M	
Commercialization Funding	Commercialization costs covered by partners in all territories except China***	

**FibroGen bears manufacturing costs excluding China

***AZ advances launch costs in China

Sources: FibroGen, Inc. reports

Roxadustat Competitive Landscape

While roxadustat is the only HIF-PH inhibitor in Phase III development, we acknowledge that Akebia Pharmaceuticals, Bayer Corporation, and GlaxoSmithKline plc are conducting Phase II studies with their respective compounds. In a smaller subset of anemia patients suffering from beta thalassemia (β-thalassemia) and myelodysplastic syndrome, Celgene Corporation, together with partner Acceleron Pharma, Inc., is evaluating sotatercept in a Phase II development program. Furthermore, Noxxon Pharma AG is investigating the potential of a structured mirror-image RNA oligonucleotide, NOX-H94, to treat anemia associated with chronic disease in a Phase II study.

Recently, Akebia released top-line results from a Phase IIb trial with its HIF-PH inhibitor, AKB-6548, in patients with anemia secondary to CKD not requiring dialysis. After 20 weeks of treatment, 54.9% of patients on AKB-6548 met the primary endpoint of hemoglobin level maintenance of ≥ 11 g/dL or hemoglobin change over baseline ≥ 1.2 g/dL, which was significantly higher than the percentage of patients receiving a placebo to meet the primary endpoint (10.3%, p<0.0001). *However, the group of patients receiving AKB-6548 also had a higher incidence of serious adverse events versus the placebo group at 23.9% and 15.3%, respectively, including one patient death in which the drug dosing cannot be eliminated as a factor.*

In our view, the introduction of biosimilars for ESAs into the U.S. market may also increase the competition for roxadustat. Under current regulations, a biosimilar product sponsor must wait 12 years after the existing, patent-protected product was approved for the compound to be reviewed by the FDA. The patents for Epogen expired in 2004 in Europe, and in the United States, the remaining patents will expire by 2015. Several biosimilar candidates of currently marketed ESAs are available for sale in Europe and many other markets, and several biosimilar versions of epoetin alfa are currently under development, including in the United States. In China, biosimilars of epoetin alfa are commercialized by Chinese pharmaceutical companies, such as EPIAO by 3SBio Inc. and Xue Da Sheng by Hayao Biological.

We acknowledge that Akebia recently challenged patent claims by FibroGen in multiple geographies. Based on information disclosed in Akebia's Form S-1, in 2011 and 2013, FibroGen was granted patent claims associated with the use of a heterocyclic carboxamide compound that inhibits HIF-PH and selected from a group consisting of pyridine carboxamides, quinolone carboxamides, isoquinoline carboxamides, cinnoline carboxamides, and beta-carboline carboxamides, which were awarded by the Japan Patent Office and European Patent Office, respectively. We acknowledge that in December 2013 and June, Akebia filed opposition proceedings to challenge the validity of FibroGen's patent claims. Given FibroGen's long history of studying HIF biology and its expansive patent estate, we view the chances of a successful patent challenge by Akebia as minimal.

Clinical Experience With Roxadustat

FibroGen conducted a comprehensive Phase II program aimed to identify the optimal dosing regimens for anemia correction and maintenance, demonstrate efficacy results in NDD-CKD and DD-CKD patients, and build a large and robust safety database. Data from the Phase II experience is encouraging, revealing no association between roxadustat and increased rates of cardiovascular events, increased platelet counts, thrombosis, and new onset, or exacerbation of preexisting, hypertension. An additional and interesting finding was that trial results suggest a reduction in average total cholesterol and an improvement in average HDL/LDL ratio versus baseline. We have summarized FibroGen's Phase II program with roxadustat in the following paragraphs.

Study 017: Dose Escalating Study in NDD-CKD Patients (NCT00761657). A randomized, single-blind, placebo-controlled, dose-escalation study was performed to establish the safety and efficacy of roxadustat over four different weight-based doses in NDD-CKD stage III and stage IV patients. A total of 116 patients were treated with roxadustat three to four times a week for four weeks and then monitored for 12 weeks for a primary outcome of safety and tolerability and a secondary measure

of hemoglobin (Hb) rise ≥ 1 g/dL. Patients receiving roxadustat at the 2 mg/kg dose achieved the secondary measure with a 100% response rate, without any safety concerns, therefore eliminating the need to test higher doses. The dose-dependent change in Hb from baseline in roxadustat patients was statistically significant (p=0.025) over placebo as early as day eight.

Study 040: ESA Conversion Study in DD-CKD Patients (NCT01147666). This randomized, single-blind study was the first roxadustat study in patients undergoing hemodialysis (HD) treatment. In the first part of this Phase II study, 41 patients receiving epoetin alfa treatment were randomized to one of four roxadustat dose regimens, and 13 were randomized to continue on epoetin alfa treatment. After six weeks of treatment, all but the lowest dosage of roxadustat (≥1.5 mg/kg) were better than epoetin alfa at maintaining baseline Hb levels (79.2% versus 33.0%, respectively), and even the lowest dose of roxadustat (1 mg/kg) was comparable with epoetin alfa, with 44% of patients maintaining Hb levels. In the second part of this study, designed to establish the optimal conversion dose, 67 patients currently receiving epoetin alfa were randomized to seven cohorts of roxadustat and 23 were randomized to continue on epoetin alfa. After 19 weeks of treatment, the Hb correction in all patients treated with roxadustat was maintained and comparable with epoetin alfa. The average dose of roxadustat for Hb maintenance was approximately 1.7 mg/kg, three times weekly. Of note, this study did not include the administration of iron through an IV, showing the ability of roxadustat to maintain Hb levels without the need for iron supplementation.

Study 041: Dose Finding in Pre-Dialysis (NCT01244763). In this Phase IIb study, various dosing regimens of roxadustat were used to achieve the primary outcome of Hb levels ≥11 g/dL and an increase from baseline of ≥1 g/dL. The 145 CKD patients with anemia, but not yet receiving dialysis treatment, were treated with roxadustat for either 16 weeks or 24 weeks at various initial dosing regimens with dose titration every four weeks until an Hb level ≥11 g/dL was met. Overall response rate across all dosing regimens was 92%, showing both a correction in initial Hb levels and maintenance over the course of the study. In addition, serum hepcidin levels were significantly reduced in all patients by week nine (p=0.0003 versus baseline).

Study 047: Placebo-Controlled NDD-CKD (NCT01599507). In the first of two Phase II trials in China, anemic NDD-CKD patients were randomized 2:1 to roxadustat or placebo treatment for eight weeks. Patients were allowed to receive oral iron supplementation, but IV iron was prohibited. By the end of the treatment duration, patients receiving either the low or high dose of roxadustat had significantly greater maximum Hb increases (1.6 g/dL and 2.4 g/dL, respectively) than those patients receiving placebo (0.4 g/dL, p<0.0001).

Study 048: Stable Dialysis Conversion in China (NCT01596855). This multicenter, open-label, ESA-controlled study examined the ability of roxadustat to maintain Hb levels in patients previously treated with epoetin alfa. The 87 patients, with baseline Hb from 9 to 12 g/dL, were randomized 3:1 to roxadustat or epoetin alfa treatments for six weeks. Three doses of roxadustat were tested, 1.37 mg/kg, 1.75 mg/kg, and 2.02 mg/kg, to establish optimum starting doses for Hb maintenance. The primary outcome, maintenance of Hb levels at no lower than 0.5 g/dL from baseline during weeks six and seven, was significantly greater in the medium (p=0.008) and high doses (p=0.0003) of roxadustat compared with epoetin alfa.

Study 053: Correction of Anemia in Incident Dialysis Patients (NCT01414075). During the first few months following the initiation of dialysis, patients are at an increased risk of serious cardiovascular events and death compared with stable dialysis patients. It is during this time that the highest doses of ESAs are typically administered in addition to supplemental iron. In this study, 55 incident dialysis patients were treated with roxadustat with different iron supplementation regimens to evaluate the safety and efficacy of treatment in this patient population. All patients treated with roxadustat achieved a significant increase in Hb level over baseline, the primary efficacy endpoint. In addition, patients receiving oral iron supplementation had a similar maximum

increase in Hb as those supplemented with IV iron (3.4 g/dL versus 3.5 g/dL). Roxadustat may, therefore, eliminate the necessity of IV iron administration, which has been associated with many side effects in DD-CKD patients.

Notably, roxadustat is the first HIF-PH inhibitor to enter Phase III clinical development and as described previously, works by stimulating the body's natural processes to develop red blood cells. Given the Phase II profile of roxadustat, we believe that the drug holds the potential to fundamentally change anemia treatment given its safety, efficacy, and tolerability profile.

We believe that in collaboration with Astellas and AstraZeneca, FibroGen is embarking on an expansive Phase III clinical campaign with roxadustat, which will address key regulatory requirements regarding safety and efficacy metrics. Given the checkered safety history of the ESA class, including the market withdrawal of Hematide, we expect regulators will likely establish a high safety hurdle for roxadustat. Therefore, it is notable that the roxadustat Phase III clinical initiative will be the largest anemia trial ever conducted in the dialysis setting. The size of the trial of 7,000 to 8,000 patients, with the breadth of outcomes measured, should also provide important pragmatic data that directly address relevant clinical questions. We anticipate data from the global Phase III trial results will be announced in the first half of 2017. In exhibit 12, we provide a thumbnail sketch of the roxadustat Phase III program.

Exhibit 12
FibroGen, Inc.
Ongoing and Planned Phase III Clinical Trials

Patient Population	Company Sponsor	Dose Frequencies	Comparator	Number of Enrolled Patients	Random-ization	Study Objective
United States and Europe Clinical Trials						
Nondialysis	FibroGen	TIW, BIW, and QW	Placebo	Up to 600 patients	2:1	Correction
	Astellas	TIW, BIW, and QW	Placebo	450-600 patients	2:1	Correction
	AstraZeneca	TIW	Placebo	2,600 patients	1:1	Correction
	Astellas	TIW, BIW, and QW	Darbepoetin alfa	570 patients	2:1	Correction
Dialysis	FibroGen	TIW	Epoetin alfa	Up to 750 patients	1:1	Correction
	Astellas	TIW	Epoetin alfa or darbepoetin alfa	750 patients	376:200:174	Conversion
	FibroGen	TIW	Epoetin alfa	750 patients	1:1	Conversion
	AstraZeneca	TIW	Epoetin alfa	1,425 patients	1:1	Correction and conversion
China Trials						
Nondialysis	FibroGen	TIW	Placebo	150 patients	2:1	Correction
Stable dialysis	FibroGen	TIW	Epoetin alfa	300 patients	2:1	Correction and conversion

TIW=three times weekly. BIW=twice weekly. QW=weekly.
Sources: FibroGen, Inc. reports

Key Program Analysis—FG-3019

FG-3019 Background and Potential Clinical Settings

FG-3019 is a fully human, wholly owned monoclonal antibody that inhibits connective tissue growth factor (CTGF), which is a common element in the progression of fibrosis and other serious diseases, including cancer. One of the distinctive clinical features of the compound is that in an animal model of fibrosis, FG-3019 demonstrated an ability to reverse disease. Moreover, in Phase II clinical testing in the IPF disease setting, results suggest that FG-3019 has the ability to reverse fibrosis in some patients, a first in pharmaceutical development.

Beyond fibrosis, FG-3019 has been tested in the treatment of pancreatic cancer in combination with gemcitabine and erlotinib, demonstrating dose-dependent improvement in one-year survival rates. In total, more than 340 patients have been exposed to FG-3019, and the drug has been well tolerated at multiple doses with no dose-limiting toxicity observed to date.

FG-3019 in the IPF Setting

IPF is a progressive disease of the lung characterized by abnormal scarring that leads to structural damage and function decline of the lungs. Disease prevalence in the United States is estimated to be between 44,000 and 135,000 patients, and each year, there are an estimated 21,000 newly diagnosed cases. Like many diseases that are underserved, we believe that IPF could be more prevalent than incidence data suggest. There are many examples of diseases in the United States in which disease incidence and prevalence have been underestimated before the availability of effective therapy (including paroxysmal nocturnal hemoglobinuria, multiple sclerosis, and Gaucher's disease). The IPF setting has been an area of increased focus as a result of growing clinical data and participation from leading companies, such as Gilead Sciences' simtuzumab and, more recently, the approval of Roche's Esbriet (pirfenidone) in the United States.

Before the approval of Esbriet, physicians treated IPF with corticosteroids and immunosuppressive agents, even though there is no conclusive evidence of improvement in survival or quality of life. Esbriet has been shown to have a modest effect on slowing the progression of disease as measured by a lung function test known as forced vital capacity (FVC). However, the positive impact on progressive lung function decline was observed in only a minority of patients (less than 15%); therefore, a significant unmet medical need remains.

There has been renewed investor interest in IPF, fueled by Roche's $8.3 billion merger agreement with InterMune, following the announcement of positive Phase III results with Esbriet (pirfenidone). In addition, last month, Bristol-Myers Squibb signed an exclusive agreement to acquire Galecto Biotech AB, which has a novel galectin-3 inhibitor under Phase I development for IPF, for up to $444 million in aggregative payments. Exhibit 13 shows a tabulated summary of recent business development deals in the IPF disease space. In our view, the increased interest in IPF among large biotechnology and pharmaceutical companies further validates FibroGen's market positioning with the potential to provide a differentiated product in a disease setting with an unmet medical need.

Exhibit 13
Recent Idiopathic Pulmonary Fibrosis Deals

Company	Date	Deal Size	Event
Roche & InterMune	August 24, 2014	$8.3 billion	Merger agreement
Bristol-Myers Squibb & Galecto Biotech AB	November 3, 2014	up to $440 million	Exclusive-option agreement to acquire

Sources: Roche and Bristol-Myers Squibb reports

Clinical experience with FG-3019 in the IPF setting. In September, FibroGen announced positive Phase II results demonstrating that 23% (17 of 74 patients) of patients after 24 weeks of treatment and 24% (16 of 66 patients) of patients after 48 weeks had improved fibrosis as measured by high-resolution quantitative computed tomography, which is an accurate and reproducible computer-based method to measure fibrotic changes in lung tissue. The study also found a statistical significant correlation between fibrosis and changes in FVC at both 24 and 48 weeks. In a subset of patients with improved or stabilized fibrosis, there was significant improvement in pulmonary function at week 24 (+0.03 liters versus -0.15 liters) and at week 48 (+0.04 liters versus -0.23 liters). Based on this data, we are encouraged by management's decision to commence a double-blind and placebo-controlled second Phase II trial to further elucidate FG-3019's role in IPF. A compilation of the study results is summarized in exhibit 14.

Exhibit 14
FibroGen, Inc.
Phase II Trial Results With FG-3019 in Idiopathic Pulmonary Fibrosis

	Open-Label Phase II Trial	Double-Blind Phase II Trial
Phase	Phase II (NCT01262001)	Phase II (NCT01890265)
Disease	Idiopathic pulmonary fibrosis	Idiopathic pulmonary fibrosis
Enrollment	74 patients	136 patients
Dosing	15 mg/kg or 30 mg/kg FG-3019 every three weeks for 45 weeks	30 mg/kg FG-3019 every three weeks for 45 weeks
Improved Fibrosis at 24 Weeks (measured by quantitative HRCT)	23% (17/74)	
Improved Fibrosis at 48 Weeks (measured by quantitative HRCT)	24% (16/66)	
Change in Forced Vital Capacity at 24 Weeks	Improved or stable fibrosis: +0.03 liters Worsening fibrosis: -0.15 liters	
Change in Forced Vital Capacity at 48 Weeks	Improved or stable fibrosis: +0.04 liters Worsening fibrosis: -0.23 liters	Primary endpoint
Adverse Event Rate	All patients experienced at least one event	
Serious Adverse Event Rate	None related to study treatment	

HRCT=high resolution computed tomography
Sources: FibroGen, Inc. reports

Based on encouraging data from the clinical trial of FG-3019 involving 74 patients, FibroGen is conducting a randomized, double-blind, placebo-controlled Phase IIb trial with about 136 IPF patients with mild to moderate disease severity. The Phase IIb trial compares 30 mg/kg FG-3019 given

every three weeks for 45 weeks with a placebo, with change from baseline in FVC as the primary endpoint. In addition, secondary endpoints include the extent of pulmonary fibrosis, as measured by quantitative HRCT; other pulmonary function assessments; and measures of health-related quality of life. We expect Phase IIb results with FG-3019 in IPF in the second half of 2016.

FG-3019 in the Pancreatic Cancer Setting

FibroGen is planning an open-label Phase II trial with FG-3019 with gemcitabine plus Abraxane compared with gemcitabine plus Abraxane alone to assess disease progression and survival in previously untreated metastatic pancreatic cancer. In earlier trials the addition of FG-3019 to standard therapies appeared to increase survival, and the goal of this Phase II trial is to confirm these findings.

Encouraging results from an earlier open-label Phase II trial of FG-3019 combined with gemcitabine plus erlotinib in patients with stage III (locally advanced) or stage IV (metastatic) pancreatic cancer demonstrated a dose-dependent improvement in one-year survival rates. Based on the results of this trial, a 40-patient Phase II trial, which evaluates the ability of FG-3019, with other treatments, to convert inoperable pancreatic cancer to operable cancer, is enrolling.

The annual incidence and prevalence of pancreatic cancer in the United States are sadly similar at 44,000 cases and 46,000 cases, respectively, because most patients live less than one year with the disease. Given that median survival with the disease is only six to nine months when treated with currently approved drugs, the need for improvement in care is obvious. Pancreatic cancer is fibrotic, and CTGF expression in tumor-associated fibrous tissue may promote abnormal-tumor-cell proliferation and angiogenesis. Inhibition of CTGF activity with FG-3019 in preclinical mouse models has demonstrated the ability to enhance the efficacy of chemotherapy and improve survival rates.

The standard of care for treatment of pancreatic cancer in the United States is gemcitabine plus Abraxane, particularly in the community-based oncology setting. More toxic and complex regimens are sometimes used in academic settings. An interesting means of underscoring the unmet medical need, placing clinical data into context, and articulating the commercial opportunity is through the experience of Abraxane.

Abraxane (nab-paclitaxel), which is marketed by Celgene, was tested with gemcitabine in treating metastatic pancreatic cancer. The Phase III trial enrolled 861 patients and demonstrated a significant improvement in overall survival (8.5 months versus 6.7 months in the gemcitabine-alone arm). In addition, the one-year survival rate in the Abraxane arm was 35%, compared with 22% in the gemcitabine-alone arm. Results of the Phase III trial were presented at a medical conference in early 2013, and notably, 2012 Abraxane sales of $427 million are expected to grow to nearly $900 million this year. While Abraxane is commonly used in lung cancer, we believe that the majority of the growth over the past seven quarters has been driven by increased use in the pancreatic cancer setting.

Should FG-3019 succeed, we believe that the market opportunity would be attractive for a variety of reasons. First, we believe that the mechanism of action of FG-3019 is complementary to currently marketed therapies, particularly chemotherapy (gemcitabine and Abraxane). Second, the need for new, well-tolerated, and effective therapies is clear, given the acute nature of the disease. We highlight the example of Tarceva, which demonstrated a 10-day survival benefit and was the last drug approved before Abraxane in the pancreatic cancer setting. Given the poor prognosis of the disease, we believe FG-3019 will likely have a clear regulatory pathway, pending positive results from a well-designed pivotal study.

Combined Phase II Experience of Roxadustat and FG-3019 Inspire Optimism

We believe that the Phase II experience with FibroGen's lead compounds positions the company to emerge with two compounds in late-stage development that possess blockbuster potential. In total, roxadustat has been tested in 1,400 patients, which forms the basis for our optimism regarding

safety. Moreover, clinical efficacy of the compound, as illustrated in exhibit 15, has been consistent and positive. The clinical experience with FG-3019 is less extensive by comparison; however, its emergent profile suggests that the drug may have differentiated therapeutic properties in both of the clinical settings in which it has been tested to date.

Exhibit 15
FibroGen, Inc.
Completed Phase II Studies

Drug	Study Objective	Patient Population	Number of Patients	Treatment Duration (weeks)	Dose Frequency	Key Results
Roxadustat	Dose range finding Hb ≥ 1g/dL	NDD-CKD	88	4	TIW, BIW	100% Hb response rate at high dose
	Dose range finding Hb ≥ 1g/dL	NDD-CKD	61	8	TIW	93.1% Hb response rate at high dose
	Conversion from ESA	Stable DD-CKD	74	6	TIW	100% Hb response rate at high dose
	Conversion from ESA	Stable DD-CKD	28	6	TIW	Successful conversion, including in ESA hyporesponsive patients
	Hb correction from baseline and maintenance	NDD-CKD	145	16, 24	TIW, BIW, QW	92% Hb response rate across all dosing regimens
	HB correction with oral iron versus IV iron	Incident DD-CKD	60	12	TIW	90% Hb response rate with oral iron
FG-3019	Lung fibrosis and lung function	IPF	74	48	Q3W	38% of patients had stable or improved lung fibrosis and lung function
	Dose-dependent survival	Pancreatic cancer	75	52	QW, Q2W	Dose-related increase in survival (2 times median survival and 3 times one-year survival)

TIW=three times weekly. BIW=twice weekly. QW=weekly. Q2W=every two weeks. Q3W=every three weeks.
Sources: FibroGen, Inc. reports

Key Program Analysis—FG-5200

FG-5200 Background and Potential Clinical Settings

FG-5200 is a proprietary recombinant human collagen III scaffold being pursued for use as a biosynthetic corneal implant. Corneal blindness can be caused by a variety of factors, including scarring from infections, physical trauma, chemical injury, and genetic defects. Although the current standard of care in most countries is the implantation of a cadaver cornea, graft rejection remains a serious problem, with roughly 35% of corneal grafts failing within five years in the United States. In addition, certain patient populations have limited access to cadaver grafts because of ethical or religious reasons or limited healthcare infrastructure. These restrictions are especially apparent in China, where only 3,000 corneal grafts were performed in 2007, despite the 4 million to 5 million patients suffering from corneal blindness.

FG-5200 has the potential to provide an immediate functional replacement for patients treatable with partial thickness implants. A significant portion of the corneal extracellular matrix is composed of collagen fibers, which we believe suggests that recombinant human collagen scaffold would be a logical choice for a bioengineered corneal implant. In addition, the use of recombinant human proteins significantly reduces the chance of immunological reaction to, and eventual rejection of, the implant. Preclinical studies have shown that the graft acts as a biodegradable scaffold, facilitating the regeneration of native corneal tissue over time. However, the regenerative property has not been observed with corneal cadaver grafts, and in our opinion, FG-5200 could increase the long-term success of the collagen implant and restoration of corneal function.

Clinical Testing of Recombinant Human Collagen Corneal Implants
In an initial proof-of-concept (PoC) study performed on 10 patients with severe corneal scarring in Sweden, a recombinant human collagen graft was implanted to restore vision. At the four-year follow-up, patients had a mean corrected-visual acuity of 20/54, and gained more than five Snellen lines of vision on an eye cart. In addition, nerve regrowth and touch sensitivity were closer to healthy cornea controls and significantly better than in human donor corneas. No graft rejection was observed and immunosuppression therapy was not needed.

We believe FG-5200 is the next generation of the synthetic graft used in the PoC study, with a higher collagen protein concentration. In animal models, FG-5200 showed improved regeneration of native corneal tissue compared with the previous collagen graft, with a similar safety profile. Although these results are promising, we acknowledge that the newest iteration of collagen corneal implants must be tested in human patients to gain regulatory approval in China.

FG-5200 Strategy
Because of the concurrent development of FibroGen's infrastructure in China for the release of roxadustat and the current unmet need in the China market we outlined earlier in the report, initial focus for the development of FG-5200 will be in China. The manufacturing plant for FG-5200 is being built in the same plant used to manufacture roxadustat, and a device classification application has been submitted to the China FDA (CFDA). Completion of the manufacturing plant and CFDA designation will allow FibroGen to initiate a pivotal study with FG-5200. We view the success of FG-5200 in China as the stepping stone for future market expansion in additional international markets, such as the rest of Asia, Latin America, the United States, and Europe.

Conclusion

We believe that FibroGen offers investors the opportunity to own a stake in a well-managed company with a distinctive clinical pipeline that could disrupt a number of treatment paradigms in a broad range of therapeutic settings. The combination of a productive and validated drug-discovery effort, growing clinical pipeline, global collaborative framework, and two mid- to late-stage clinical candidates forms the basis for our enthusiasm. We see FibroGen's two lead programs, roxadustat and FG-3019, as potentially disruptive therapies and expect both to become increasingly visible in the next year. With an estimated $340 million in cash, FibroGen is well capitalized and positioned to aggressively invest in the advancement of its R&D effort, which should translate into expanded shareholder value over time. We are therefore launching coverage of FibroGen with an Outperform rating.

Exhibit 16
FibroGen, Inc.
Income Statement
(shares and dollars in thousands except EPS)

	2013A	Q1A	Q2A	Q3A	Q4E	2014E	2015E	2016E	2017E	2018E	2019E
License and milestone revenue	94,961	14,588	77,000	14,588	1,833	108,008	96,476	64,739	25,059	165,059	938,500
Collaboration services and other revenue	7,209	2,583	2,584	10,154	12,750	28,071	94,525	109,560	116,820	122,100	0
Roxadustat royalty	0	0	0	0	0	0	0	0	310	8,301	39,633
FG-3019 sales	0	0	0	0	0	0	0	0	0	0	0
Total revenues	**$102,170**	**$17,171**	**$79,584**	**$24,742**	**$14,583**	**$136,080**	**$191,001**	**$174,299**	**$142,189**	**$295,460**	**$978,133**
Cost of revenue	0	0	0	0	0	0	0	0	7,255	53,897	143,216
Gross profit	102,170	17,171	79,584	24,742	14,583	136,080	191,001	174,299	134,934	241,563	834,917
R&D	85,710	29,460	29,460	40,617	51,000	150,536	209,000	166,000	177,000	185,000	193,000
SG&A	24,409	6,974	6,974	10,140	15,000	39,088	65,000	94,000	138,000	165,000	185,000
Total operating expenses	110,119	36,434	36,434	50,757	66,000	189,624	274,000	260,000	315,000	350,000	378,000
Loss from operations	**($7,949)**	**($19,263)**	**$43,151**	**($26,015)**	**($51,417)**	**($53,544)**	**($82,999)**	**($85,701)**	**($180,066)**	**($108,437)**	**$456,917**
Total interest and other, net	(6,994)	(2,272)	(2,272)	(2,272)	(2,250)	(9,066)	(8,900)	(8,740)	(8,580)	(8,420)	(8,260)
Net loss before income taxes	(14,943)	($21,535)	$40,879	($28,287)	($53,667)	(62,610)	(91,899)	(94,441)	(188,646)	(116,857)	448,657
Income tax benefit	0	0	0	0	0	0	0	0	0	0	(102,280)
Net loss	**($14,943)**	**($21,535)**	**$40,879**	**($28,287)**	**($53,667)**	**($62,610)**	**($91,899)**	**($94,441)**	**($188,646)**	**($116,857)**	**$346,377**
Non-GAAP net loss per common share basic	($0.32)	($0.46)	$0.86	($0.60)	($0.93)	($1.12)	($1.55)	($1.52)	($2.94)	($1.76)	$5.02
Non-GAAP net loss per common share diluted	**($0.32)**	**($0.46)**	**$0.86**	**($0.60)**	**($0.93)**	**($1.12)**	**($1.55)**	**($1.52)**	**($2.94)**	**($1.76)**	**$5.02**
Non-GAAP weighted-average common shares basic	47,106	47,275	47,275	47,275	57,900	49,931	59,340	61,713	64,180	66,747	69,416
Non-GAAP weighted-average common shares diluted	47,106	47,275	47,275	47,275	57,900	49,931	59,340	61,713	64,180	66,747	69,416

Sources: FibroGen reports.

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DJIA:	17,900.10
S&P 500:	2,071.92
NASDAQ:	4,769.44

The prices of the common stock of other public companies mentioned in this report follow:

Acceleron Pharma, Inc.	$37.01
Amgen Inc. (Market Perform)	$166.55
AstraZeneca PLC	$73.94
Bristol-Myers Squibb Company (Outperform)	$58.89
Celgene Corporation (Outperform)	$113.63
Gilead Sciences, Inc. (Outperform)	$101.82
GlaxoSmithKline plc	$45.89
Johnson & Johnson	$107.56
Roche Holding AG	$37.66

Current Ratings Distribution (as of 11/30/14)

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Market Perform (Hold)	31%	Market Perform (Hold)	3%
Underperform (Sell)	1%	Underperform (Sell)	0%

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