



RBC Capital Markets

December 9, 2014

FibroGen, Inc

Initiating at Outperform: Anemia pill and fibrosis antibody look very promising

Our view: We believe FGEN represents a compelling long-term opportunity with two multi-billion-dollar programs: 1) Novel Phase III anemia program with Roxadustat, a safe oral drug already partnered with AstraZeneca and Astellas via one of largest pharma/biotech partnerships, and 2) wholly owned Phase II anti-fibrosis antibody, FG-3019 for IPF and other diseases, which is almost a free call option at these levels.

Key points:

We are buyers of FibroGen on the heels of significant value creation potential over next couple years with a safe and oral anemia pill, and attractive call optionality on a very interesting anti-fibrosis antibody that has shown signs of reversal of lung fibrosis. Bottom line: FibroGen is a very attractive investment thanks to its de-risked and well-funded Phase 3 oral pill for anemia that is reasonably likely to take meaningful share or expand the current \$6B market dominated by ESAs. IPF antibody is another multi-billion call option, exemplified by Roche's recent acquisition of InterMune for \$8.3B that could provide more catalysts over the next 12-24 months.

- **The primary value driver, Roxadustat for anemia, is straight-forward and simple:** It does all the same things Amgen/JNJ's \$6B EPO drugs (ESAs) do but in an easy-to-administer oral pill. Data through Phase 2 shows similar efficacy and potentially better safety than ESAs - without signs of cardiovascular risk. The drug is fairly de-risked with clear efficacy and good safety through hundreds of patients treated to date, with estimated launch in mid-2017 (China) and 2018/2019 (EU/US).
- **Two major global pharma partnerships with AstraZeneca (US, China) and Astellas (EU, Japan) provide major resources** via one of the largest pharma/biotech deals we have seen, validating and funding this blockbuster program all the way through. In essence, FibroGen is eligible for ~20%-25% royalties and over \$1.5B in clinical and commercial milestones — including \$762M in upfronts combined. We model \$3.5B peak sales for Roxadustat WW with conservative 40%-70% probability of success. Of note, FibroGen's management is also working closely with regulatory authorities to bring Roxadustat to China where the oral administration provides significant logistical advantages (estimate \$500M+ potential sales in 2020), and where the Street is likely to undervalue this opportunity.
- **Separately, we will be keenly watching Phase II FG-3019 for fibrotic diseases.** This is a separate, wholly owned anti-fibrotic antibody with a differentiated MOA (anti-CTGF). It is in a randomized controlled Phase IIb for treating orphan lung disease IPF (idiopathic pulmonary fibrosis); Phase IIa data showed signs of reversal of fibrosis, and a separate Phase II has shown promising efficacy in pancreatic cancer. The \$8B acquisition of ITMN by Roche for IPF, and high interest in GILD's simtuzumab antibody for IPF and NASH supports what we think will be growing interest in FibroGen's off-the-radar fibrosis antibody.

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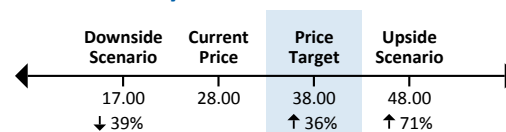
Outperform

Speculative Risk

NASDAQ: FGEN; USD 28.00

Price Target USD 38.00

Scenario Analysis*



*Implied Total Returns

Key Statistics

Shares O/S (MM):	47.4	Market Cap (MM):	1,327
Dividend:	0.00	Yield:	0.0%
		P/NAVPS:	NM
		P/BVPS:	NM
		Avg. Daily Volume:	NA

RBC Estimates

FY Dec	2014E	2015E	2016E	
Revenue	136.5	155.0	190.5	
EPS, Adj Basic	(1.12)	(2.69)	(2.97)	
Revenue	Q1	Q2	Q3	Q4
2014	53.9A	53.9A	13.7A	15.0E
EPS, Adj Basic				
2014	0.48A	0.17A	(0.84)A	(0.81)E

All values in USD unless otherwise noted.

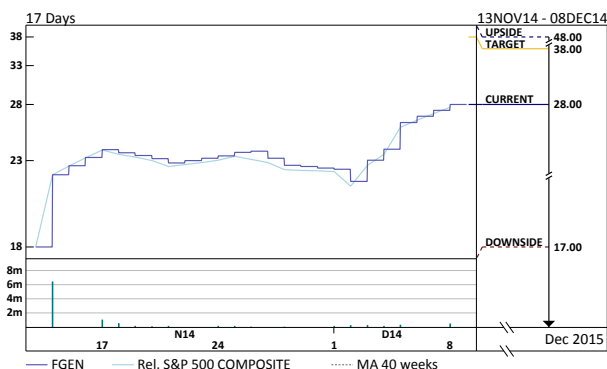
Priced as of prior trading day's market close, EST (unless otherwise noted).

For Required Conflicts Disclosures, see Page 33.



Target/Upside/Downside Scenarios

Exhibit 1: FibroGen, Inc



Source: Bloomberg and RBC Capital Markets estimates for Upside/Downside/Target

Target price/base case

Our base case of \$38/share is a SOTP of 1) Roxadustat successfully penetrating the anemia market (both dialysis and non-dialysis) as a safe first-in-class oral drug and achieving \$3B+ peak WW sales. We apply conservative ~45% prob. to market, which yields \$25/share; 2) FG-3019 is developed for IPF and becomes a \$1.5B+ WW drug by 2024 and applying 27% probability yields \$8/share; and 3) small credit to FG-3019's potential opportunity in other indications such as pancreatic cancer with additional peak sales ~\$500M, 4x peak sales and 15% prob. discounted back yields \$2/share. We use a 10% discount rate consistently across the three SOTP components.

Upside scenario

Our upside scenario of \$48 assumes 1) higher probability of success of 60% for Roxadustat, which yields \$34/share, 2) higher prob. of 32% for FG-3019 in IPF, yielding \$10/share, 3) maintain same \$2/share for FG-3019's potential in pancreatic cancer, and 4) small credit to its fourth pipeline drug, FG-5200 in development for corneal blindness, which if it works in China could become a peak \$300M drug, adding \$2/share at 20% probability.

Downside scenario

Our downside scenario of \$17 assumes 1) lower 20% probability to market for Roxadustat taking into consideration the great risk remaining in running a long and large phase III and the high bar on safety with new agents for anemia post removal of Omontys from the market in 2013. This yields \$17/share solely on Roxadustat. We do not include any valuation for other pipeline drugs such as FG-3019 and FG-5200 given the early stage of development or lack of controlled data.

Investment summary

We believe FibroGen represents a compelling long-term opportunity due to two major pipeline programs with proven multi-billion-dollar opportunities. First (Roxadustat) is a novel Phase III program for anemia that could be a significant competitor as the only oral drug in a \$6B+ class of EPO drugs. It is already partnered with AstraZeneca and Astellas through one of the largest pharma/biotech deals we have seen for any biotech product, validating its huge opportunity. The second (FG-3019) is a Phase II anti-fibrosis antibody program for IPF and other diseases, and almost a free call option at this point.

Potential catalysts to our thesis

Several publications in peer reviewed medical journals in H1:15: More detailed Phase II data could further establish safety and efficacy profile of roxadustat. and FG-3019.

Advancement of pipeline in 2015: FGEN will initiate Phase II studies in dialysis and non-dialysis settings for China, further advancing their global development program for anemia. In addition, we expect interim Phase II data in pancreatic cancer (on top of abraxane + gemcitabine) in H2:15, as well as Phase II efficacy data in liver fibrosis (associated with HBV in Hong Kong) during 2015.

Risks and price target impediments

Failure to develop Roxadustat into safe and efficacious drug for anemia: FGEN is currently launching an extensive, global Phase II program that will include almost 8,000 CKD patients with either incident dialysis, stable dialysis or no dialysis. Phase II data to date look clean, but there is no guarantee that this will be replicated in the larger, global Phase III program.

Failure to develop FG-3019 for fibrotic diseases: This program is in Phase IIB for treating lung IPF. While Phase II data has shown promising signs of reversal of fibrosis and promising efficacy in pancreatic cancer, and there is growing interest in anti-fibrosis antibodies, there is the risk that further clinical development could fail.

Lack of major near-term catalysts: Emerging biotech stocks with no commercial products primarily trade based on newsflow or catalysts regarding its pipeline drugs. Fibrogen's two major pipeline assets are in mid-to-late stage trials with key topline data not expected until 2016 or later. This may not create the urgency for investors to buy Fibrogen stock in the near term given the opportunity cost analysis.



Key questions

Our view

1) What advantages could FGEN bring to the anemia market?

With a de-risked and well-funded Phase III program, FGEN's Roxadustat/ FG-4592 is a serious competitive threat to AMGN's IV/subQ drugs: 1. Roxadustat is an attractive oral anemia pill that does not require IV iron supplementation; 2. unlike ESAs, Roxadustat does not seem to pose CV risk (which led to declined ESA utilization); 3. besides taking meaningful share from ESAs, roxadustat can further expand the current anemia market via treating pre-dialysis CKD and other undertreated anemia patients (e.g. cancer, inflammation).

2) Are there cardiovascular risks associated with Roxadustat or other safety concerns such as carcinogenesis?

In contrast to ESAs, Roxadustat has not been associated with increased CV events, new/worsening hypertension, increased platelet counts, prolonged QT interval, or thrombosis that could lead to stroke. In fact, Phase II studies suggested that Roxadustat may help lower total cholesterol, improve the average HDL/LDL ratio, and even reduce the need for concomitant medications such as statins. Furthermore, Roxadustat treatment did not increase EPO beyond physiologic levels, and liver enzyme tests did not show any hepatotoxicity. Despite the association between HIF activity and angiogenesis, Roxadustat did not increase cancer risk (via tumor initiation, development, or metastasis) or otherwise adversely affect rodent mortality in 12 carcinogenicity studies conducted so far. Final two-year carcinogenicity results should be available YE, and help to further de-risk Roxadustat.

3) What is the commercial opportunity in China and what regulatory path will FGEN pursue in China?

FGEN is planning their first global launch in China, as a drug intended antihypertension/ ESA/ IV iron. With a large, undertreated population, the China represents a large unmet opportunity. FGEN is pursuing a domestic regulatory approval pathway via FibroGen China, launching Phase III trials in H1:15 for potential approval in mid-2017; AZN would be responsible for commercialization/distribution. The Chinese government's growing interest in addressing CKD (expanded reimbursement programs, dialysis facility build-outs) and in recombinant collagen for corneal blindness (FG-5200 tied to anemia pursuits) may help with regulatory approval in China. A post-marketing observational study would be required, and reimbursement delays may last 6-12+ months.

4) Are there other anemia opportunities for Roxadustat to target beyond CKD-related indications?

With the progression of CKD, the prevalence of anemia rises, since healthy kidneys produce the Epogen. However, anemia may also be brought on by other conditions, such as liver disease, cancers (myelodysplastic syndrome MDS), chemotherapy, chronic inflammation (lupus, rheumatic arthritis), genetic conditions (sickle cell anemia, enzyme deficiencies), or iron/ vitamin B12/ folic acid deficiencies. These represent further upside options for Roxadustat – e.g., ESAs do not work in patients with inflammatory diseases such as Crohn's or lupus.

5) How is FibroGen's Roxadustat differentiated from Akebia's AKB-6548, which is also an oral HIF-inhibitor?

While FGEN's Roxadustat is not the only HIF-PH inhibitor under development for treating anemia, it is the most advanced (entering extensive, global Phase III program). It may also be more effective than AKB-6548 at treating patients with severe anemia by primarily targeting HIF-1 instead of HIF-2. In addition, Roxadustat may be safer than AKB-6548, as three patients under AKB-6548 treatment died during the Phase IIb study (n=138) – including one "possibly related" death from ischemic heart disease. While many of the patients were quite sick with cardiovascular and other co-morbidities, these deaths raise questions about AKB-6548's safety, especially in light of the increased CV risk associated with ESAs.



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Portfolio manager's summary

We believe FibroGen represents a compelling long-term opportunity due to two major pipeline programs with proven multi-billion-dollar opportunities. First (Roxadustat) is a novel Phase III program for anemia that could be a significant competitor as the only oral drug in a \$6B+ class of EPO drugs. It is already partnered with AstraZeneca and Astellas through one of the largest pharma/biotech deals we have ever seen for any product, validating its huge opportunity. The second (FG-3019) is a Phase II anti-fibrosis antibody program for IPF and other diseases, and almost a free call option at this point.

The primary value driver, Roxadustat for anemia, is straightforward and simple: It does all the same things Amgen/JNJ's \$5B EPO drugs (ESAs) do but in an easy-to-administer oral pill (particularly for dialysis centers and non-dialysis use where there is under-treatment due to logistics and IV/subQ), and could expand the market. Data through Phase 2 shows comparable to better efficacy and potentially improved safety vs. ESAs - without signs of cardiovascular risk. The drug is fairly de-risked with clear efficacy (it clearly raises hemoglobin and works....) and good safety through hundreds of patients treated to date.

Two major global pharma partnerships with AstraZeneca (US, China) and Astellas (EU, Japan) provide major resources via one of the largest pharma/biotech deals we have ever seen, validating and funding this blockbuster program all the way through. In essence, FibroGen is eligible for ~20%-25% royalties and over \$1.5B in clinical and commercial milestones -- including \$762M in upfronts combined. We model \$3.5B peak sales for Roxadustat WW with conservative 40%-70% probability of success. Of note, FibroGen's management is also working closely with regulatory authorities to bring Roxadustat to China where the oral administration provides significant logistical advantages (estimate \$500M+ potential sales in 2020), and where the Street is likely to undervalue this opportunity.

Separately, we will be keenly watching Phase II FG-3019 for fibrotic diseases. This is a separate, wholly owned pipeline program with significant upside "optionality" via key differentiated profile as an antibody that binds CTGF and prevents fibrosis. This is in Phase IIb for treating orphan lung disease IPF (idiopathic pulmonary fibrosis); Phase IIa data showed signs of reversal of fibrosis, and a separate Phase II has shown promising efficacy in pancreatic cancer. The \$8B acquisition of ITMN by Roche for IPF, and high interest in GILD's Simtuzumab antibody for IPF and NASH supports what we think will be growing interest in FibroGen's off-the-radar anti-fibrosis antibody.

We are buyers of FibroGen on the heels of significant value creation potential over the next several years. Bottom line: FibroGen is a very attractive investment because with a de-risked and well-funded Phase 3 oral pill for treating anemia, this is reasonably likely to take meaningful share or further expand the current market dominated by ESAs such as Amgen's Epogen. IPF antibody is another multi-billion-dollar call option exemplified by Roche's recent acquisition of InterMune for \$8.3B that could provide more catalysts over next 12-24 months.



Initial Public Offering

On November 13, 2014, FibroGen issued 8.1M shares of common stock at \$18 per share, an increase by 1M shares from the original plan of 7.1M shares and at the high-end of the initial filing range of \$16 to \$19 per share. Four days later on November 17th, the company announced the full exercise of the greenshoe option, selling an additional 1.215M shares at \$18 per share. Net proceeds from the offering after deducting underwriting discount and fees are estimated to be approximately \$156M. The primary purpose of the IPO was to create a public market for the company's common stock and increase the company's visibility in the marketplace all while adding capital. Portion of the net proceeds will be used to develop and commercialize its un-partnered assets such as FG-3019 as well as for general corporate purposes.

Valuation

Base case – \$38/share

Our base case of \$38/share is a SOTP of: 1) Roxadustat successfully penetrating the anemia market (both dialysis and non-dialysis due to CKD) as a safe first-in-class oral drug and achieving \$3B+ peak in WW sales. We apply ~45% prob. to market given the need to run long and large Phase III studies, which yields \$28/share; 2) FG-3019 is developed for IPF and becomes a \$1.5B+ WW drug by 2024 and applying 27% probability yields \$8/share; and 3) small credit to FG-3019's potential opportunity in other indications such as pancreatic cancer with additional peak sales ~\$500M, 4x peak sales and 15% prob. discounted back yields \$2/share. We use a 10% discount rate consistently across the three SOTP components.

Upside scenario - \$48

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Downside scenario - \$17

Our downside scenario of \$17 assumes: 1) lower 20% probability to market for Roxadustat taking into consideration the great risk remaining in running a long and large phase III and the high bar on safety with new agents for anemia post removal of Omontys from the market in 2013. This yields \$17/share solely on Roxadustat. We do not include any valuation for other pipeline drugs such as FG-3019 and FG-5200 given the early stage of development or lack of controlled data.

Ultra-bull case - \$60/share

This assumes a more optimistic scenario across all pipeline options including: 1) higher 70% probability for Roxadustat (\$39/share); 2) higher 40% probability for FG-3019 in IPF (\$13/share) and other indications (\$5/share); 3) higher 30% probability for FG-5200 in corneal blindness (\$3/share).

Ultra-bear case - \$8/share

This assumes the worst-case scenario where its main lead candidate Roxadustat halts development due to late emergence of safety issues. This leaves all focus on FG-3019 for IPF, which we maintain at \$8/share, same as the assumption in our base case scenario.

Exhibit 2: Table of our SOTP scenarios on FGEN

		<u>Assumed Probability of Success</u>				
Roxadustat		0%	20%	46%	60%	70%
FG-3019		27%	0%	27%	32%	40%

\$/Share	Ultra Bear	Bear	Base Case	Bull	Ultra Bull
Roxadustat	\$0	\$17	\$28	\$34	\$39
FG-3019 (IPF)	\$8	\$0	\$8	\$10	\$13
FG-3019 (Other e.g. Pancreatic cancer)	\$0	\$0	\$2	\$2	\$5
FG-5200 (Corneal blindness)	\$0	\$0	\$0	\$2	\$3
	\$8	\$17	\$38	\$48	\$60

Source: RBC Capital Markets estimates

Price target impediments

Failure to develop Roxadustat into safe and efficacious drug for anemia: FGEN is currently launching an extensive, global Phase III program that will include almost 8,000 CKD patients with either incident dialysis, stable dialysis or no dialysis. Phase II data to date look clean, but there is no guarantee that this will be replicated in the larger, global Phase III program.

Failure to develop FG-3019 for fibrotic diseases: This program is in Phase IIb for treating lung IPF. While Phase II data has shown promising signs of reversal of fibrosis and promising efficacy in pancreatic cancer, and there is growing interest in anti-fibrosis antibodies, there is the risk that further clinical development could fail due to emergence of safety concerns or lack of efficacy in a controlled study.

Lack of major near-term catalysts: Emerging biotech stocks with no commercial products primarily trade based on newsflow or catalysts regarding its pipeline drugs. Fibrogen's two major pipeline assets are in mid-to-late stage trials with key topline data not expected until 2016 or later. This may not create the urgency for investors to buy Fibrogen stock in the near term given the opportunity cost analysis.

Risk of intellectual property litigations: Akebia is another company developing oral drugs to treat anemia related to CKD by targeting the same molecular pathology of HIF. Fibrogen is approximately 1 year ahead in development but the two companies are involved in patent opposition suits in Europe. Akebia filed an opposition to Fibrogen's EU patent No. 1463823 in Dec 2013. Fibrogen remains confident on the strength of their patent portfolio but the opposition proceeding could take 2-4 yrs and a new suit could open up in the US as well. This could create an overhang on the stock for investors.



Comparable companies

Exhibit 3: Valuation of small- to mid-cap biotech companies that are similar to FGEN

Comparable Company	Ticker	Price	Comparable Product/ Technology	Lead Stage	Market Cap (\$ in MM)	EV (\$ in MM)
InterMune*	ITMN	N/A	Esbriet was approved by the FDA in 2014 for the treatment of idiopathic pulmonary fibrosis. Roche acquired ITMN 2 months before FDA approval for \$8.3B.	Market	\$7,900	\$8,300
Intercept Pharmaceuticals	ICPT	\$141.77	OCA is a bile-acid analog in late-stage development as a potential anti-fibrotic agent for treatment of NASH and PBC	Mid/ Late	\$3,028	\$2,755
Acceleron Pharma	XLRN	\$42.67	Sotatercept is in Phase II development for treatment of anemia related to B-thalassemia, myelodysplastic syndromes, CKD	Mid	\$1,376	\$1,187
Portola Pharmaceuticals	PTLA	\$28.41	Betrixaban is an oral Factor Xa inhibitor in Phase III development as an anticoagulant for venous thromboembolism prophylaxis	Mid/ Late	\$1,382	\$1,157
Genfit SA	GNFTF	\$46.50	GFT505 is a small molecule oral treatment in Phase IIb development as a potential anti-fibrotic treatment of NASH	Mid	\$1,087	\$1,008
Relypsa	RLYP	\$28.06	Patiromer FOS has been submitted to the FDA for treatment of hyperkalemia (high potassium), a common complication associated with CKD	Mid/ Late	\$960	\$837
ZS Pharma	ZSPH	\$45.49	ZS-9 is an oral drug in Phase III development for the treatment of hyperkalemia (high potassium), a common complication associated with CKD	Mid/ Late	\$947	\$836
Akebia Therapeutics	AKBA	\$11.54	AKB-6548 is an oral drug in Phase II development for treatment of anemia related to CKD in both dialysis and non-dialysis setting	Mid	\$235	\$117
FibroGen	FGEN	\$28.00	Roxadustat is an oral drug in development for treatment of anemia related to CKD. FG-3019 is an anti-fibrotic antibody in development for IPF and pancreatic cancer	Mid/ Late	\$1,620	\$1,357
					Mean**	\$2,114
					Median**	\$1,232
						\$2,025
						\$1,083

*InterMune was acquired by Roche in Sept 2014 and no longer trades in the public market

**Does not include Fibrogen in the calculation

Source: Thomson, RBC Capital Markets; Priced as of market close on December 8, 2014

Expected news flow

Exhibit 4: Forecast timeline and news flow for FGEN

Time	Expected News Flow	Program
Roxadustat (Anemia)		
1H:15	Publication of Phase II results in a peer reviewed medical journal	Roxadustat (US/EU)
1H:15	Initiate Phase III studies in dialysis and non-dialysis settings for China	Roxadustat (China)
2H:16	Final Phase III data from China study	Roxadustat (China)
2H:16	Submit for regulatory approval in China	Roxadustat (China)
2H:16	Topline data from initial Phase III studies in non-dialysis setting	Roxadustat (US/EU)
2017	Final Phase III data from non-dialysis and dialysis setting	Roxadustat (US/EU)
2017/2018	Submit for regulatory approval in EU and USA	Roxadustat (US/EU)
FG-3019 (IPF, Pancreatic cancer, other fibrotic diseases)		
1H:15	Publication of Phase IIa results in a peer reviewed medical journal	FG-3019 (IPF)
2H:15	Interim data from Phase II study in pancreatic cancer on top of abraxane + gemcitabine	FG-3019 (pancreatic)
2015	Efficacy data from Phase II study in liver fibrosis associated with HBV in Hong Kong	FG-3019 (liver fibrosis)
2H:16	Topline data from Phase IIb randomized controlled study in mild-moderate IPF	FG-3019 (IPF)

Source: Company reports, RBC Capital Markets

FGEN's product pipeline

Exhibit 5: FGEN's pipeline products

Drug	Mechanim of action	Indication	Stage				Est time to market
			Pre-clinical	Phase I	Phase II	Phase III	
HIF Platform							
roxadustat (FG-4592)	HIF-PH inhibitor	anemia	US:				2019
			EU:				2018
			China:				2H:17
			Japan:				2019+
FG-6874	HIF-PH inhibitor	stem cell mobilization					2019+
FG-8205	HIF-PH inhibitor	heart failure after myocardial infarction					2019+
Fibrotic Diseases							
FG-3019	anti-CTGF antibody	pancreatic cancer					2019
		Idiopathic Pulmonary Fibrosis					2019
		liver fibrosis					2019
		Duchenne Muscular Dystrophy					2019+
rhCOLLAGEN III Scaffold							
				Pilot	Pivotal		
FG-5200	corneal implant	corneal blindness					2017+

 Partnered
  Wholly-owned

Source: Company reports, RBC Capital Markets

Roxadustat – On the heels of a blockbuster

FibroGen's most advanced drug candidate, Roxadustat (FG-4592), is an oral anemia pill under Phase III development, with patients currently enrolling in the US and EU, as well as a China study to be initiated soon. **Anemia is a common global blood disorder that is characterized by low levels of healthy red blood cells (RBCs) and/or hemoglobin (Hb).** According to the World Health Organization, anemia affects over 1.6 billion people worldwide (~25% of global population). Currently, anemia is a proven \$6B+ blockbuster market with unmet medical needs. FibroGen is currently pursuing Phase III development of Roxadustat for treating anemia in chronic kidney disease, but FGEN management is in discussions to pursue additional indications, since anemia can be caused by a variety of other factors including chemotherapy, cancer, and inflammation.

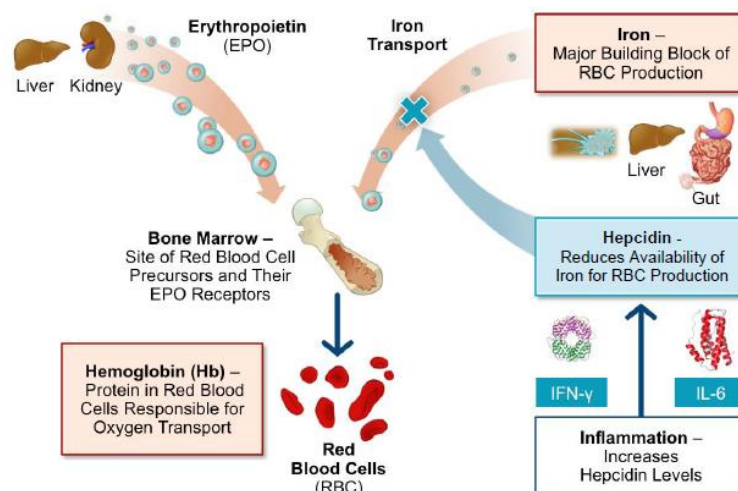
Limited current treatment options for anemia demonstrate unmet needs

ESAs such as Amgen's Epogen and Aranesp resemble naturally occurring erythropoietin (EPO), a hormone that controls RBC production (erythropoiesis). Anemia patients are prescribed ESAs in order to maintain Hb at the lowest level that minimizes transfusions and that best meets individual patient needs. However, ESAs are not recommended for mild or moderate anemia. Treating anemia with ESAs is limited by their IV/subQ administration of doses well above physiologic range, and by the requirement of IV iron for dialysis patients. This is important, as normal RBC production requires both EPO hormones and normal levels of iron – while EPO is the stimulator that drives erythropoiesis, iron is a vital ingredient for that process; in fact, the mere presence of iron and EPO hormones is not adequate, as the timing of their presence in the bone marrow has to be coordinated for optimal RBC production. Furthermore, ESAs increase the risk of CV-related death and tumor progression/recurrence, which led to a black box warning in March 2007.

Targeting anemia via CKD

Anemia is a common complication of CKD, since healthy kidneys produce the EPO hormone. Fibroblasts in the kidneys produce most of the EPO during adulthood, while perisinusoidal liver cells produce most of the EPO during the fetal and perinatal periods. EPO is a protein signaling molecule for erythrocyte precursors in the bone marrow. As an aside, EPO is also involved in the brain's response to neuronal injury and in wound healing.

Exhibit 6: A healthy kidney is essential for normal RBC production in the presence of iron



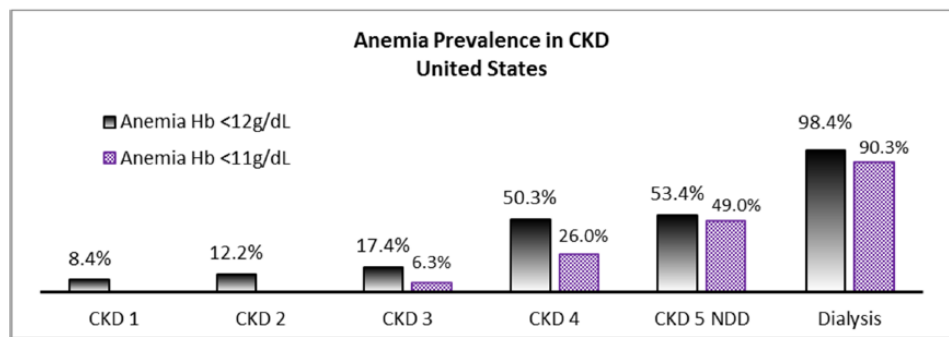
Source: Company reports

In CKD, there are low levels of erythropoietin and/or iron in the body:

1. Low levels of EPO may result from impaired EPO production by damaged kidneys.
2. Iron deficiency may be exacerbated in CKD, as early-stage kidney disease patients are advised to reduce their protein intake (because damaged kidneys lose the ability to remove protein waste products).
3. Furthermore, the inability of damaged kidneys to efficiently remove toxins and waste products results in a buildup in the bloodstream, which can shorten the lifespan of existing RBCs.

Therefore, as CKD progresses, the prevalence of anemia increases in CKD patients. Almost all end stage renal disease (ESRD) patients – CKD stage 5 patients who require dialysis or a transplant for permanent renal replacement therapy – suffer from anemia. Hence it is not surprising that anemia is also associated with worse outcome in CKD.

Exhibit 7: Anemia prevalence increases with CKD progression, and anemia is associated with worse CKD outcome



Sources: USRDS ADR 2013; NHANES 2005-2010; KDIGO Clinical Practice Guidelines 2012/2000 CKD; Stauffer and Fan, PLoSOne (2014); Goodkin, JASN (2011)

Source: Company reports

Roxadustat tackles anemia through enhancing natural RBC production

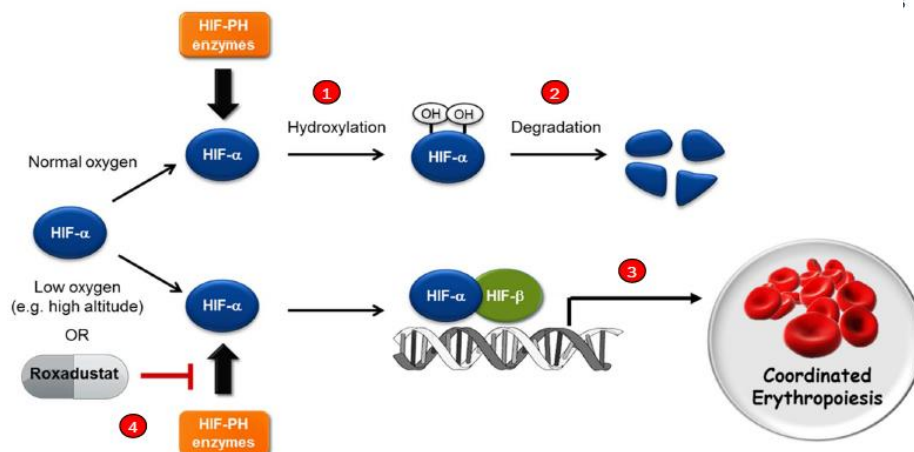
The body's natural response to higher altitudes (lower oxygen availability) turns on the hypoxia-inducible factor (HIF), which subsequently turns on erythropoietin (EPO) production and iron mobilization in order to increase RBCs and ultimately oxygen delivery. Therefore, turning on HIF activity may be a novel form of treating anemia. This is especially promising, since HIF activity is part of a natural feedback circuit.

HIFs are DNA-binding proteins called transcription factors that respond to hypoxia (low levels of cellular oxygen). In humans, HIF-1 is a key protein that regulates genes involved in iron absorption from the intestine, iron transport to bone marrow cells, and iron mobilization, in addition to stimulating the EPO hormone. HIF-1 is composed of an alpha and a beta subunit. At normal oxygen levels, the alpha subunit is found in the cytoplasm and becomes rapidly degraded, while the beta subunit is found in the nucleus of the cell. Only under low oxygen levels will the alpha subunit accumulate in the cytoplasm, and then translocate to the nucleus to form the HIF-1 complex with the beta subunit. The HIF-1 protein then induces production of EPO, which subsequently increases RBC production.

This process is regulated by enzymes called HIF prolyl-hydroxylases (HIF-PH), which mark HIF-1 alpha subunits for degradation through hydroxylation at proline residues. If HIF-PH is turned off – either through lack of oxygen (since these enzymes need oxygen as cosubstrate),

or through direct inhibition (such as by a drug) – then HIF-1 alpha subunits are not degraded and allowed to accumulate in the body. FGEN chose Roxadustat from its library of HIF-PH inhibitors based on its ability to stabilize HIF-1 (and HIF-2, another main form of HIF protein). **Roxadustat takes advantage of the natural feedback circuit for erythropoiesis by stabilizing HIF-1 alpha through HIF-PH inhibition.**

Exhibit 8: FGEN's Roxadustat takes advantage of the body's natural HIF feedback circuit in order to stimulate RBC production



Source: Company reports

Roxadustat Phase II data shows promising efficacy with low safety concerns

FGEN has completed six Phase II trials of Roxadustat in CKD patients with anemia. Out of a total of 669 trial patients, 545 have been treated with Roxadustat. Consistent efficacy and safety results were seen in trials conducted within the US as well as outside (two Phase II studies in China). The primary efficacy endpoints – change in hemoglobin from baseline or % HB responders – are based on hemoglobin (Hb) measurements, as Hb is the iron-containing oxygen-transporter within RBCs.

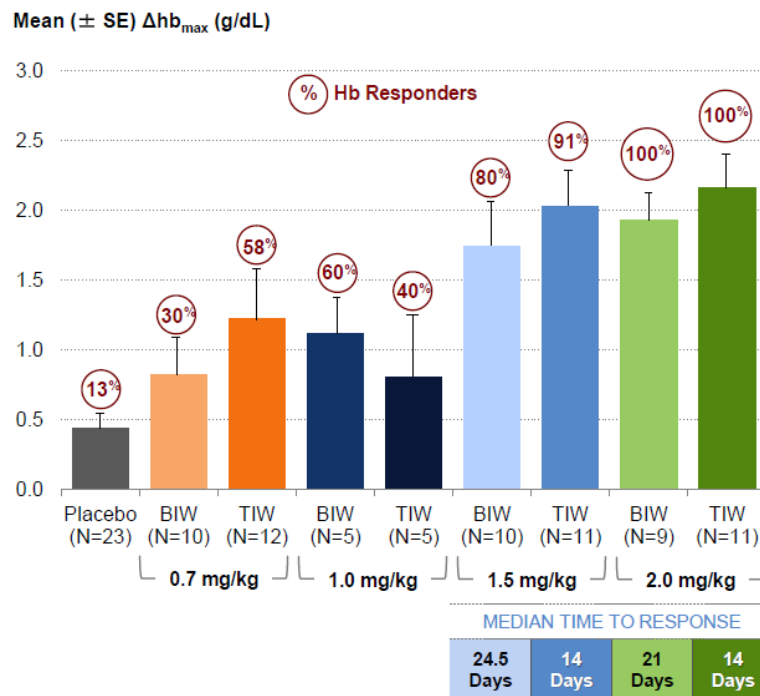
Exhibit 9: FGEN has completed multiple Phase II CKD Studies with 650+ patients

Study	Location	CKD Pt Type	N	#roxa	#ESA	#pbo	Study Objective	Dosing	#wks treatment
FGCL-4592-017	US	NDD	116	88		28	correction, PK	TIW, BIW	4
FGCL-4592-040	US	stable dialysis	161	117	40	4	conversion, maintenance	TIW	6; 19
FGCL-4592-041	US	NDD	145	145			correction, maintenance	TIW, BIW, QW	16; 24
FGCL-4592-047	China	NDD	91	61		30	correction	TIW	8
FGCL-4592-048	China	stable dialysis	96	74	22		conversion, PK	TIW	6
FGCL-4592-053	Russia, US, HK	incident dialysis	60	60			correction	TIW	12

Source: Company reports, RBC Capital Markets estimates

In pre-dialysis patients (NDD-CKD), Study 017 provided POC for the treatment of anemia with Roxadustat. Patients were randomized to placebo or Roxadustat (BIW or TIW) at doses ranging from 0.7 to 2.0mg/kg for four weeks. Compared to placebo, anemia patients treated with Roxadustat showed statistically significant increases in Hb. The presence of a dose response for Roxadustat is encouraging, as it implies true efficacy by the drug. The highest dose of 2.0mg/kg even achieved 100% Hb response rates and lowered hepcidin levels, which is consistent with the mechanism of Roxadustat.

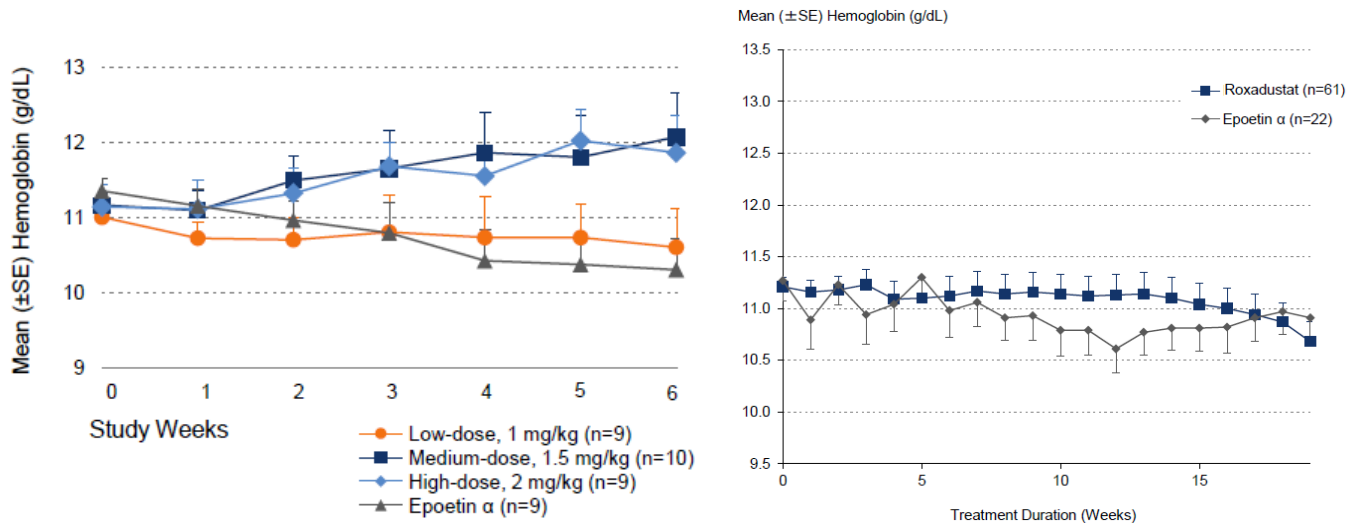
Exhibit 10: Roxadustat increases Hb levels and the number of Hb responders



Source: Company reports

Study 040 was the first single-blind study of patients on hemodialysis treatment, and established the conversion dose relationship between ESAs and Roxadustat to be used in Phase III trials. This study was divided into two parts, one that tested the impact of switching from epoetin alpha to Roxadustat, and a second part that established the optimal conversion dose. The primary endpoint was met in study 040a at week 6, demonstrating that 1.5mg/kg or higher doses of Roxadustat were better than epoetin alfa at maintaining Hb. However, there was minimal difference between dose 1.5mg/kg and 2mg/kg, raising questions about the lack of improvement at higher doses (which would have been expected, since only 80% of patients maintained Hb at 1.5mg/kg and so drug efficacy should not have plateaued yet). Study 040b also met the primary endpoint at week 19, demonstrating that Roxadustat is capable of maintaining Hb long term without IV iron. As seen with other studies, dialysis patients who switched from ESA treatment to Roxadustat saw reduced serum hepcidin levels, since hepcidin levels are inversely correlated to serum iron levels.

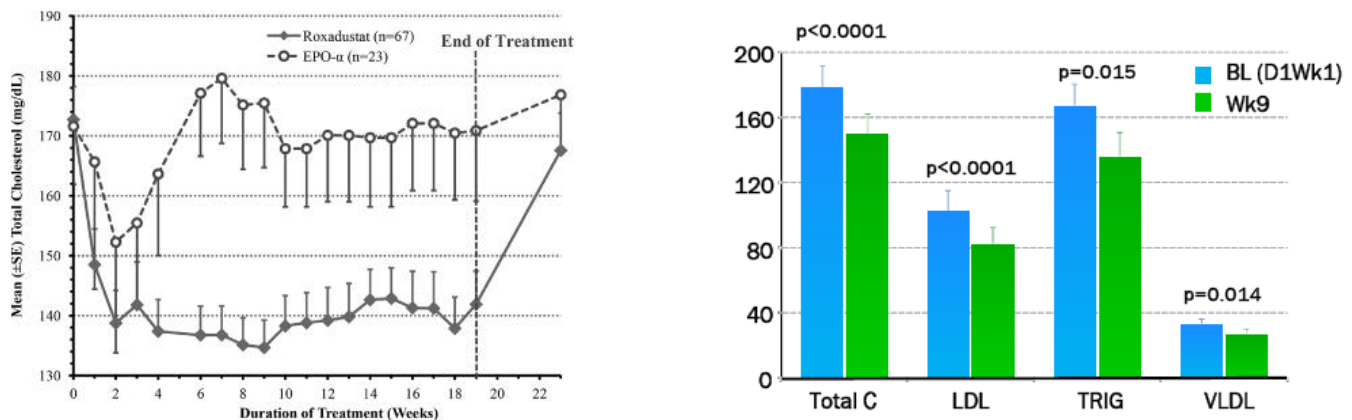
Exhibit 11: Roxadustat appears effective in dialysis patients by increasing Hb levels after conversion from ESAs



Source: Company reports

As an added benefit, Roxadustat may even reduce total cholesterol levels in CKD patients with anemia. In a post-hoc analysis of study 040, patients on Roxadustat had much lower mean total cholesterol levels than those treated with epoetin alfa. Total cholesterol levels jumped back up to baseline levels within two weeks of the end of treatment, suggesting that Roxadustat is responsible for conferring protective, cholesterol-lowering benefits on patients. This is encouraging, since recent use of ESAs has been overshadowed by increased cardiovascular risk. High levels of LDL cholesterol may lead to atherosclerosis and raise the risk of heart attacks and ischemic stroke. Thus Roxadustat may also help CKD patients with cardiovascular-related co-morbidities, and reduce concomitant use of statins and other medications.

Exhibit 12: Roxadustat confers cardiovascular benefits to anemia patients by lowering total and LDL cholesterol levels



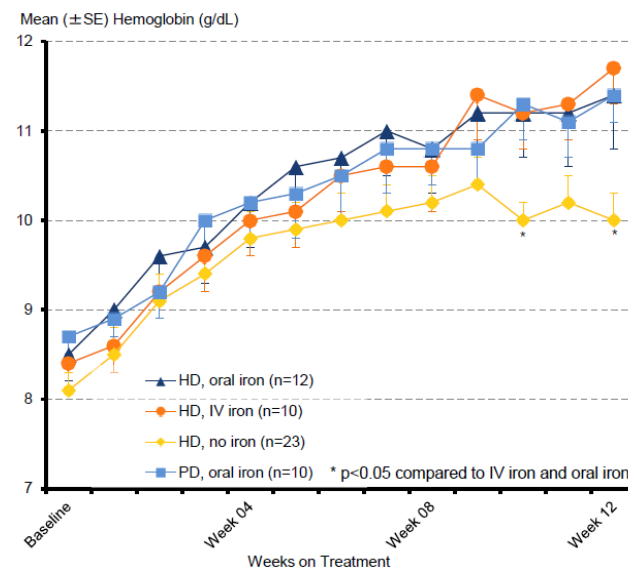
Source: Company reports

In newly initiated (incident) dialysis patients, Roxadustat met the primary endpoint by raising Hb levels for all treatment groups (study 053). Dialysis patients face the highest risk of mortality and serious cardiovascular events during the first few months of dialysis initiation (as opposed to stable dialysis), and thus require higher doses of ESAs along with IV iron supplementation. FGEN's 053 incident dialysis study was important for the following reasons:

- Roxadustat treatment alone was effective at raising Hb levels in the harder to treat incident dialysis subpopulation;
- Roxadustat was effective with similar treatment doses for both incident and stable dialysis patients (median weekly dose of 4.0mg/kg in study 053 was comparable to 4.45mg/kg in study 040);
- Roxadustat was enhanced by iron supplementation via either oral or IV administration – in contrast to ESA treatment, which requires IV iron – thus providing ease of treatment even with supplementation.

As seen in both nondialysis and stable dialysis studies, Roxadustat treatment reduced hepcidin levels in patients, especially those not receiving IV iron supplementation, and thus supplying more iron for RBC production.

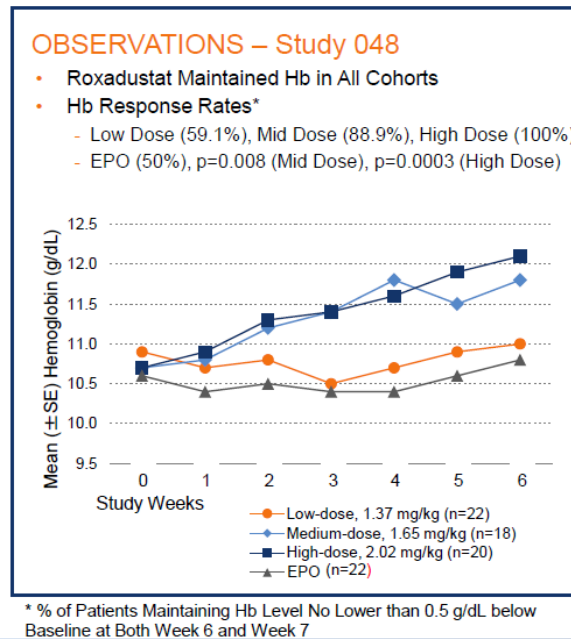
Exhibit 13: Roxadustat is effective even in harder to treat incident dialysis patients



Source: Company reports

Roxadustat has consistently raised Hb levels, not just across dialysis subpopulations, but also across regions. While approximately half of the Phase II studies were conducted in US patients, study 053 met its primary endpoint and included patients from Russia and HK. Two Phase II studies that were conducted solely in China also showed results similar to those seen in the US trials. For example, in study 048 with stable dialysis patients, FG-4592 (Roxadustat's name within China) at the mid- and high-doses raised Hb levels with statistical significance, as compared to epoetin alfa. Hb levels dropped after FG-4592 treatment ended at week 6, which is expected for drug-induced effects.

Exhibit 14: Mid- and high-doses treatments with FG-4592 raise Hb in Phase II China study



Source: Company reports

Exhibit 15: Ongoing Phase II CKD studies cover both NDD and DD patients

Study	Location	CKD Pt Type	N	#roxa	#ESA	#pbo	Study Objective	Dosing	#wks treatment
FGCL-4592-059	US	NDD, DD	15	15			longterm safety, maintenance	TIW, BIW, QW	260+
1517-CL-303	Japan	NDD	100	75		25	correction (Astellas)	TIW, QW	24
1517-CL-304	Japan	DD	120	90	30		maintenance (Astellas)	TIW	24

Source: Company reports, RBC Capital Markets estimates

De-risked by multiple safety studies: Reduced cardiovascular events, no liver toxicity, and no tumor growth

Unlike ESAs, which have been linked to increased risk of major cardiovascular events and resulted in a black box warning, Roxadustat has not raised safety concerns of CV events, new onset or worsening hypertension, increased platelet counts, or thrombosis (blood clotting that could lead to stroke). On the contrary, Phase II patients actually experienced reductions in total cholesterol and improvements in their average HDL/LDL ratio. This is an additional benefit, as many CKD patients suffer from cardiovascular-related co-morbidities as a result of high cholesterol levels. Thus, Roxadustat may even enable CKD patients to reduce concomitant use of other medications such as statins and anti-hypertensives. In particular, Phase II studies seemed to show that fewer patients on Roxadustat treatment experienced serious cardiovascular adverse events, as compared to patients on placebo or EPO treatment. Even at a high dose of 5mg/kg (4x average maintenance dose in non-dialysis patients), Roxadustat did not appear to affect the QT interval, which would have been an indicator for ventricular arrhythmias. Almost 1.4k patients/healthy volunteers have already been treated with Roxadustat as part of their clinical programs.



As another benefit, Roxadustat takes advantage of the HIF feedback circuit without exceeding physiologic EPO levels. Importantly, Roxadustat is able to act uniformly across CKD patients with anemia, regardless of their dialysis or inflammation status. These benefits can be conferred even without iron supplementation by IV. FGEN believes that the advantages of Roxadustat over current standard-of-care ESAs are a result of the following distinctions:

1. Roxadustat can overcome suppressive effects from inflammatory cytokines;
2. Roxadustat can increase iron absorption from the gastrointestinal tract;
3. Roxadustat can promote the release of stored iron and its transport to the bone marrow;
4. Roxadustat is an oral agent, whereas ESAs such as AMGN's Epogen have to be injected under the skin or via IV.

Exhibit 16: Roxadustat appears superior to ESAs in three considerations - efficacy, safety, administration

		ROXADUSTAT	ESAs
EASE	Oral Agent	✓	
	Raises Hb	✓	✓
	No Iron Needed in Pre-dialysis Patients and No IV Iron Needed in Dialysis	✓	
EFFICACY	Increases Iron Absorption	✓	
	Typically Raises Hb in Presence of Inflammation	✓	
	Lowers Hepcidin	✓	
	Within or Near Physiologic EPO Levels	✓	
SAFETY	Reduction in Platelet Elevations	✓	
	Lowers Cholesterol	✓	
	No Blood Pressure Increase	✓	
	Safety Risk	No Safety Signals to Date	Black Box

Source: Company reports

Exhibit 17: Roxadustat appears to have positive cardiovascular benefits, which is actually the opposite of ESAs such as EPO

Placebo-Controlled Phase 2 Trials (Anemia correction in non-dialysis patients)

	Protocol 017 4 Weeks		Protocol 047 8 Weeks	
	Roxadustat	Placebo	Roxadustat	Placebo
Number of subjects	88	28	61	30
SAEs	4 (4.5%)*	1 (3.6%)	8 (13.1%)*	4 (13.3%)
Cardiovascular SAEs	0	1 (3.6%)	0	1 (3.3%)
CSE**	0	0	0	1 (3.3%)

EPO-Controlled Phase 2 Trials (Conversion study in dialysis patients)

	Protocol 048 6 Weeks		Protocol 040b 19 Weeks	
	Roxadustat	EPO	Roxadustat	EPO
Number of subjects	74	22	66	23
SAEs	0	0	15 (22.7%)*	4 (17.4%)
Cardiovascular SAEs	0	0	2 (3.0%)	2 (8.7%)
CSE**	0	0	8 (12.1%)	4 (17.4%)

*No SAEs were attributed to roxadustat in completed trials. No statistically significant differences from comparators.

**CSE=death, myocardial infarction, congestive heart failure, subendocardial ischaemia, cerebrovascular accident, thrombosis (fistula), arteriovenous fistula occlusion, angina pectoris, and vascular graft thrombosis.

Source: Company reports

From a safety perspective, it should be noted that HIF inhibitors are under investigation for anti-cancer effects. While HIF stabilization may increase erythropoiesis and even enhance memory, HIF activity has also been implicated in angiogenesis (new blood vessel formation), which may promote the growth of malignant cancer tumors. Therefore, any treatments that alter the activity of HIF proteins need to be monitored for unintended side effects

Reassuringly, FGEN has conducted extensive preclinical carcinogenicity studies, which have not shown any tumor risk yet. Out of 12 tumor studies in rodents, there has not been any evidence associating Roxadustat with any increased cancer risk. In fact, none of the other five HIF-PH inhibitors from FGEN's library seemed to initiate tumor growth, promote cancer development, lead to cancer metastasis, or otherwise adversely affect rodent mortality. FGEN has completed the in-life portion of their two-year rat and mouse carcinogenicity studies (average rodent lifespan is one-two years) without any red flags, and expects to have final results with statistical analysis by the end of this year.

Furthermore, in accordance with current FDA guidelines, liver enzymes were monitored for hepatotoxicity. The independent data-monitoring committee has concluded that currently there is no concern for liver toxicity.

However, as a note of caution, we point out that in the past, one of FGEN's earlier generation anemia product candidates triggered a safety signal during Phase II trials, which resulted in a clinical hold for that earlier generation product candidate as well as Roxadustat. While the clinical hold was lifted for both product candidates with subsequent data submission to the FDA, this incidence **highlights the potential for safety concerns to emerge at any time of research and development as more patients are treated.** In yet another example, within a year of receiving FDA approval for their injectable anemia drug Omontys (peginesatide, an ESA), Affymax and partner Takeda Pharmaceuticals recalled their drug after three patients reportedly died from fatal drug reactions. Even though the overall rate of hypersensitivity

reactions was fairly low at 0.2%, their potential to cause life-threatening anaphylaxis led to the termination of Affymax and Takeda's partnership for Omontys. Therefore, there is a potential risk that, as with any drug candidate, even if no safety concerns emerge during Phase III testing of Roxadustat, broader use over time after potentially winning regulatory approval could unveil post-marketing safety concerns. However, as explained above, Phase II data show Roxadustat to be fairly safe and - importantly - unlike Affymax's failed Omontys, Roxadustat is not an injectable ESA but an oral HIF-PH inhibitor.

Development Path – On third base, on track to touch home base in next 2-3 years

FibroGen is launching an extensive, global Phase III program for Roxadustat for the treatment of anemia that will include almost 8,000 CKD patients with either incident dialysis, stable dialysis or no dialysis. FGEN is currently enrolling patients in the US for a Phase III program and a China study (conducted by FibroGen China) to be initiated next year. FGEN's partner Astellas will also be conducting Phase III Roxadustat studies in Japan upon completing the current Phase II studies. US/EU Phase III enrollment is expected to complete by H1/16, with initial data to be read out in 2017. FGEN's planned extensive program will enable further safety evaluations and de-risking of Roxadustat, since the program will include previously tested dosing regimens and composite safety endpoints called MACE (major adverse cardiac events, which FGEN management believes will be required for FDA approval of all new anemia drugs).




Exhibit 18: Planned design for the large, global Phase III program of FG-4592/ Roxadustat in anemia

Study	Location	Company	N	#US	#EU	#China	Study Objective	Comparator	Drug:Comparator	Dosing	#wks treatment	est completion/read-out
STABLE DIALYSIS												
CL-613	EU, Middle East, Africa	Astellas	750	(same pts)			conversion	epoetin alpha/darbepoetin alfa	376:200:174	TIW	US: 52+ wks EU: 36+ wks	Sep-16
FG-064	US +/- global	FGEN	up to 750	(same pts)			conversion	epoetin alpha	1:1 randomization	TIW	US: 52+ wks EU: 36+ wks	Jun-17
FG-806	China	FGEN	150			300	correction & conversion	epoetin alpha	2:1 randomization	TIW	China: 26-52 wks	H2:16
INCIDENT DIALYSIS												
FG-063	Global	FGEN	up to 750	(same pts)			correction	epoetin alpha	1:1 randomization	TIW	US: 52+ wks EU: 36+ wks	Oct-16
INCIDENT AND STABLE DIALYSIS												
AZ-002	US	AZN	1425	1425			correction & conversion	epoetin alapha	1:1 randomization	TIW	US: 52+ wks	Feb-17
NON-DIALYSIS												
FG-060	US/Asia/Latin America	FGEN	up to 600	(same pts)			correction	placebo	2:1 randomization	TIW, BIW, QW	US: 52+ wks EU: 36+ wks	Feb-16
CL-0608	EU, Middle East, Africa	Astellas	450-600	(same pts)			correction	placebo	2:1 randomization	TIW, BIW, QW	US: 52+ wks EU: 36+ wks	Jun-16
FG-808	China	FGEN	150			150	correction	placebo	2:1 randomization	TIW	China: 26-52 wks	H2:16
AZ-001	Global	AZN	~2,600	2600			correction	placebo	1:1 randomization	TIW	US: 52+ wks	Mar-17
CL-0610	EU, Middle East, Africa	Astellas	570		570		correction	darbepoetin alfa	2:1 randomization	TIW, BIW, QW	EU: 36+ wks	Jul-17

Source: Company reports, RBC Capital Markets estimates



Exhibit 19: FGEN is pursuing global regulatory approval, potentially launching Roxadustat in 2018 in China/EU and 2019 in USA

REGULATORY AUTHORITIES	US 	EUROPE 	CHINA 
# of P3 Studies to Support Regulatory Approval	7**	6**	2
# of P3 Patients to Support Regulatory Approval	~7,500**	Up to 4,000**	450
Minimum Duration	52+ weeks	36+ weeks	26-52 weeks (100 for 1 yr)
Average Duration	1.3 to 1.5 years	1 year	6-12 months
Estimated Patient Years	~10,000	~3,600	~275
Mandatory Post-Approval Safety Study (China)	None at this time	None at this time	~2,000 patients
Pharma Partners	AstraZeneca	Astellas	AstraZeneca

* Excludes Japan where Phase 2 studies are being completed and Phase 3 plans will be finalized in 2015.

** Plan to support US regulatory approval with 7 studies (4 DD and 3 NDD), 5 of which (3DD and 2 NDD) will also be used in the European package that contains a total of 6 studies (3 DD and 3 NDD)

Source: Company reports

Competition – First in class and best in class, simple

Roxadustat may be safer and more effective than competitors, plus farthest along

While FGEN is not unique in targeting anemia through the body's natural HIF pathway, clinical development for Roxadustat appears to be further advanced than that for competing drug candidates from AKBA, GSK and Bayer. Furthermore, Roxadustat's mechanism of action may be more effective and safer, as it was selected from FGEN's library for targeting HIF-1. In contrast, Akebia's AKB-6548 primarily induces the HIF-2 alpha response. HIF-1 is prominently activated under extremely low oxygen conditions (hypoxia), while HIF-2 is activated under moderate increases of altitude. Thus, Roxadustat may be more effective than AKB-6548 at treating patients with severe anemia.

In addition, Roxadustat may be safer than AKB-6548, as three patients under AKB-6548 treatment died during the Phase IIb study (n=138) – including one “possibly related” death. The “possibly related” case involved a patient who was found dead at home and whose death was attributed to ischemic heart disease, but no autopsy was available for further conclusions. The two other deaths, deemed “not related”, involved a 71-year-old obese male, who was a stage 4 CKD patient who had completed five weeks of dosing and passed away from a sudden cardiac event, and a 54-year-old female smoker with hypertension and diabetes, who also died from cardiac arrest. While many of the patients were quite sick with cardiovascular and other co-morbidities, these deaths raise questions about AKB-6548's safety, especially in light of the increased CV risk associated with ESAs.

Exhibit 20: Competing HIF anemia drug candidates are not as advanced as FGEN's Roxadustat

Company	Compound	Stage	CKD Pt Type	dosing	#wks treatment	Location	Est. Timeline
AKBA	AKB-6548	Phase IIb	NDD	oral, QD	20	US	completed, present in 2015
		Phase IIb	DD (open-label)	oral, QD	16	US	results in Q3:15
		Phase III	anemia secondary to CKD, NDD			global	initiate in 2015
GSK	GSK1278863	Phase IIb	DD (active-controlled)	oral, QD	4, 24	US	complete in Jan '15
			NDD	oral, QD	24	US	complete in Jan '15
Bayer	molidustat (BAY85-3934)	Phase II	NDD (naïve, pbo-controlled)	oral	12-16	EU/Asia/Australia	complete in Q1:16
			NDD (maintenance, open-label, Aranesp+)		16		complete in Q4:15
			NDD (long-term extension, open-label)		144		complete in Q4:18
		Phase II	DD (maintenance, open-label, ESA+)	oral	12-16	US/Japan	complete in Q4:15
			DD (long-term extension, open-label, ESA+)		144		complete in Q3:18

Source: Company reports, RBC Capital Markets estimates

Pursuing the anemia market in China – don't underestimate this golden opportunity

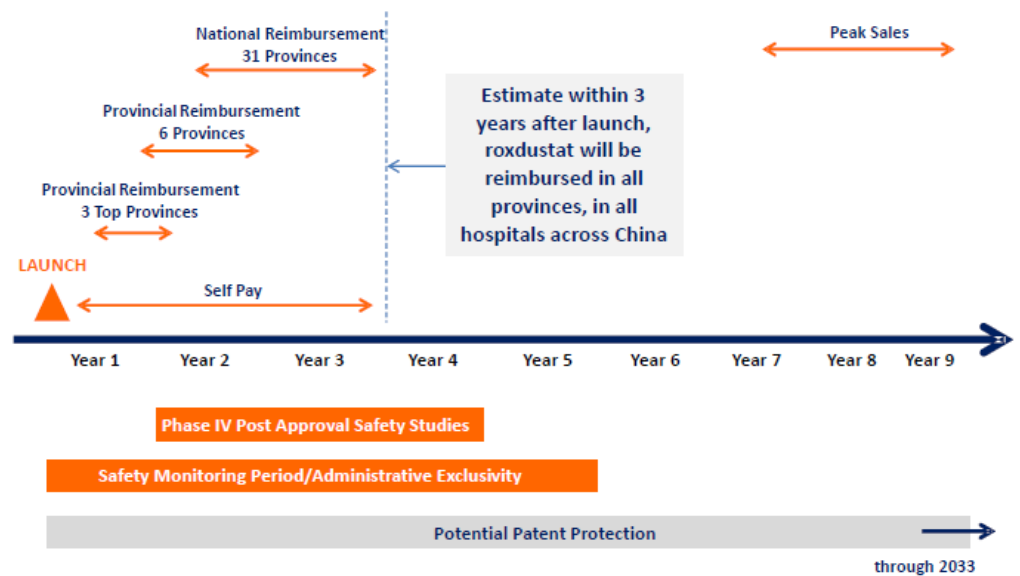
While there are differences between the anemia markets in the US and China, we believe the Chinese market represents a large unmet opportunity. In fact, the differences may actually enhance FG-4592's success in China:

- Given a much larger total population, the prevalence of CKD patients is higher in China – ~119.5M patients as of Sept 2010 (Zhang et al., *Lancet* 2012);
- CKD is undertreated in China, as many dialysis-eligible patients (~60% of dialysis eligible patients according to FGEN estimates) are not receiving treatment due to a shortage of treatment centers – with the Chinese central government's growing interest in addressing CKD, anemia drug candidates like FG-4592 could benefit through expanded government reimbursement programs and dialysis facility build-outs (which would help bring CKD patients to treatment);
- CKD under-treatment also manifests in advanced stage, pre-dialysis patients, as they are only receiving traditional Chinese medicine and iron supplementation;
- Despite current under-treatment, ESA sales still totaled \$145M in 2013 (IMS Health) – with a more compelling safety profile and ease of administration, FG-4592 has the potential to replace ESA use and become a blockbuster drug over time; and
- As part of its anemia pursuits, FGEN was required to conduct a five-year human corneal study of FG-5200 – the Chinese government's interest in recombinant collagen for treating corneal blindness (as opposed to human cadaver tissues used in the US/Europe) may help with regulatory approval for FG-4592 in China, and may also lead to corneal markets across Asian countries, Latin America or even the US/EU.

FGEN is pursuing a domestic regulatory approval pathway in China through its subsidiary, FibroGen China, which has completed several Phase I and Phase II clinical trials in China. FibroGen China expects to launch Phase III trials in China in H1:15, with potential data a year and a half later that could lead to drug approval in China in mid-2017. FGEN intends to price FG-4592 at \$1.5k-\$3k, as a drug intended to replace three therapies (antihypertension, ESA, IV iron); the large range in pricing is due to self-titration in the China market.

This is a new paradigm, as the first global launch would be in China. If approved, AZN will not book revenues, but will be responsible for commercialization and distribution of FG-4592 in China. FGEN's proposed domestic regulatory pathway for China would require it to conduct a post-marketing observational study with 2,000 patients, as the China Food and Drug Administration requires a five-year monitoring surveillance period. Another challenge of penetrating the anemia market in China is the slower, delayed launch – there is an initial lag time of six-12 months between launch and securing the right to sell in China; in addition, FGEN will have to pursue provincial reimbursement one-by-one (starting with Beijing, Guangzhou and Shanghai), until FG-4592 could receive national reimbursement in all 31 provincial-level divisions in Year 3 after launch. FGEN's estimate of six-12 months initial lag time may actually be an overly optimistic estimate, as it may take 15 months or more to actually obtain market access in China: FGEN will have to secure approval of drug price (three months for the registration province, another one-two months for other provinces), enter provincial bidding (three-five months for each province), and obtain listing by hospitals (three-five months). However, the slower, prolonged drug launch may be alleviated by the presence of a self-pay market in China.

Exhibit 21: FG-4592 could launch first in China in mid-2017, but would face 6mo+ delays



Source: Company reports

Anemia – A well-established \$6B+ market that was at one point \$8B+ before the emergence of safety concerns with ESAs

The primary market opportunity for Roxadustat is in anemia patients with chronic kidney disease. In the US, ~13%-14% of adults suffer from CKD – that corresponds to 32M-34M patients in the US alone. The prevalence rate is similar for the EU at 10%, which corresponds to 55M+ CKD patients in the EU.

Currently, there is a \$6B+ market worldwide for anemia, primarily through ESA treatment of dialysis patients with CKD. Peak ESA sales used to be \$8B+ in 2006, but safety concerns have discouraged ESA use (cardiovascular events, new onset/worsening hypertension, mortality and anaphylaxis risks from IV iron supplementation).

With a better safety profile (no serious CV events, may even reduce total cholesterol and diminish the need for concomitant medications) and ease of administration (oral, no need for IV iron), Roxadustat seems superior to ESAs and could easily target the existing CKD market. There is also an opportunity for Roxadustat in non-dialysis CKD, a subpopulation that may be understated and untreated. In addition to approaching CKD patients through nephrologists and large dialysis organizations (Fresenius, DaVita in the US), Roxadustat could also target anemia patients with secondary CKD through endocrinologists (diabetic patients, a new market), and cardiologists (hypertension patients, another new market). There are further upside options for Roxadustat through cancer-/chemo-induced anemia and anemia caused by inflammation (yet another new market, as ESAs are ineffective in inflammatory diseases). Reimbursement limitations (MIPPA bundled payment system) also make ESA treatment economically unattractive, further encouraging usage of new treatments such as oral Roxadustat.





Exhibit 22: Modest peak 23%-30% penetration into existing CKD-related anemia market yields \$1B prob-adjusted peak sales estimate for Roxadustat. Anemia related to other conditions represent upside opportunities for our model.

Price of therapy in US (\$/month)	\$400	Prob. of Phase III Success	70%							
Price Growth	3%	Prob of Regulatory Approval	65%							
Gross to net	12%	Prob. of Getting to Market	46%							
Price of therapy in EU (\$/month)	\$320									
Price Growth	0%									
Gross to net	15%									
Price of therapy in China (\$/month)	\$175	US Peak Revenue Estimate (\$M) EU Peak Revenue Estimate (\$M) China Peak Revenue Estimate (\$M) Total Peak Revenue Estimate (\$M)	Prob. Adjusted							
Price Growth	1%		\$1,298\$591							
Gross to net	15%		\$1,212\$552							
			\$1,071\$487							
			\$3,581\$1,630							
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
Total REVENUE - USA (\$M)	\$ -	\$ 97	\$ 328	\$ 484	\$ 704	\$ 940	\$ 1,111	\$ 1,177	\$ 1,248	\$ 1,298
Total REVENUE - EU (\$M)	\$ 68	\$ 391	\$ 740	\$ 894	\$ 993	\$ 1,074	\$ 1,157	\$ 1,188	\$ 1,200	\$ 1,212
Total REVENUE - China (\$M)	\$ 8	\$ 94	\$ 247	\$ 446	\$ 653	\$ 814	\$ 920	\$ 966	\$ 1,016	\$ 1,071
TOTAL WW REVENUE (\$M)	\$ 76	\$ 582	\$ 1,315	\$ 1,824	\$ 2,349	\$ 2,829	\$ 3,188	\$ 3,332	\$ 3,464	\$ 3,581
Prob. Adjusted Revenue Estimates										
Total REVENUE - USA (\$M)	\$ -	\$ 44	\$ 149	\$ 220	\$ 320	\$ 428	\$ 505	\$ 536	\$ 568	\$ 591
Total REVENUE - EU (\$M)	\$ 31	\$ 178	\$ 337	\$ 407	\$ 452	\$ 489	\$ 526	\$ 541	\$ 546	\$ 552
Total REVENUE - China (\$M)	\$ 4	\$ 43	\$ 112	\$ 203	\$ 297	\$ 370	\$ 419	\$ 440	\$ 462	\$ 487
TOTAL WW REVENUE (\$M)	\$ 31	\$ 222	\$ 486	\$ 627	\$ 772	\$ 917	\$ 1,032	\$ 1,077	\$ 1,114	\$ 1,142
US Market (AstraZeneca)	2018	2019	2020	2021	2022	2023	2024	2025	2026	2026
Dialysis CKD										
CKD Prevalence	34,271,401									
dialysis eligible	3%									
% Treated	45%									
Growth Rate	1.0%									
# Eligible Patients	441,329	445,742	450,200	454,702	459,249	463,841	468,480	473,165	477,896	482,675
Roxadustat Market Share (%)	0%	5%	12%	15%	20%	25%	30%	30%	30%	30%
Duration of therapy (in months)	0	12	12	12	12	12	12	12	12	12
# Pts treated on Roxadustat	0	22,287	54,024	68,205	91,850	115,960	140,544	141,949	143,369	144,803
Non-dialysis CKD										
non-dialysis treated market	171,357									
diagnosed, untreated ND pts	200,000									
additional potential pts	300,000									
Roxadustat Market Share (%)	0%	0%	5%	10%	15%	20%	21%	22%	23%	23%
Duration of therapy (in months)	0	12	12	12	12	12	12	12	12	12
# Pts treated on Roxadustat	0	0	21,302	43,031	65,192	87,792	93,103	98,512	104,020	105,060
Anemia by other conditions										
anemia caused by cancer	200,000									
anemia induced by chemo	500,000									
MDS	137,086									
Roxadustat Market Share (%)	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Duration of therapy (in months)	0	12	12	12	12	12	12	12	12	12
# Pts treated on Roxadustat	0	0	0	0	0	0	0	0	0	0

Source: Company reports, RBC Capital Markets estimates

FGEN is partnering with AZN for the US and China markets, and partnering with Astellas for the EU and Japan markets (partnership deals total \$2.5B+). FGEN is eligible for 20%-25% royalties ex-China (low 20% net sales royalty/ transfer price from Astellas, and low-mid 20% from AZN; 50% profit sharing with AZN in China), and over \$2.5B in clinical and commercial milestones, including \$762M total upfront payments (to date, FGEN has received \$580M upfront cash). This is one of the largest pharma/ biotech deals we have ever seen, providing validation and funding for FGEN's blockbuster anemia program all the way through. FGEN is only liable for shared development costs up to \$116.5M, with the remaining development costs funded by AZN and all commercialization costs covered by territorial partners. If Roxadustat is approved for treating anemia in the US/EU, FGEN will receive royalty in the low to mid 20% from its partners.

Exhibit 23: FGEN is partnered with AZN and Astellas in one of the largest pharma/biotech deals – further validation for the anemia blockbuster program

		 		
\$ Millions		JAPAN, EU, ETC.	U.S., CHINA, ROW	CASH RECEIVED TO DATE
PAYMENTS TO FIBROGEN	Equity Investment in FibroGen	\$81	\$20 at IPO	\$81
	Upfront, Non-Contingent	\$360	\$402	\$360 + \$220
	Development & Reg. Milestones	\$543	\$571	\$103+ \$0
	Commercial Milestones	\$15	\$653	\$0
	POTENTIAL TOTAL	\$918 M	\$1,626 M	\$683 M of \$2,543 M
Low 20% (Astellas) – Low-Mid 20% (AstraZeneca) Net Sales Royalty / Transfer Price				
DEVELOPMENT FUNDING	FibroGen ex-China Costs Capped at \$116.5 M (Cost-Share < 50% of Planned CKD Anemia Development Costs)			
LAUNCH FUNDING	Commercialization Costs Are Covered by Partners in All Territories Ex-China			

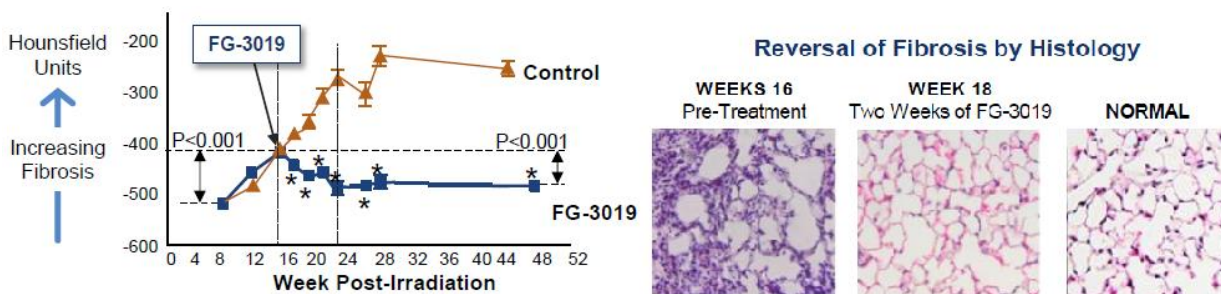
China Partnership:
50% Profit Sharing and 50% Development and Launch Cost Responsibility

Source: Company reports

FG-3019: Plenty of upside opportunities with this interesting anti-fibrotic antibody

FibroGen's second drug candidate, FG-3019, is in Phase II development for fibrotic diseases such as IPF (idiopathic pulmonary fibrosis) and early clinical data looks promising. The drug actually ties back to the original foundation of the company, which was to discover drugs targeting fibrotic diseases and hence the name "FibroGen". FG-3019 is a fully human monoclonal antibody that inhibits the activity of Connective Tissue Growth Factor (CTGF), a key mediator of the fibrotic cascade. CTGF has been found to be elevated in multiple fibrotic tissue and organs. In a preclinical study in radiation induced fibrosis in mice, treatment with FG-3019 showed statistically significant improvement in fibrosis as measured by HRCT.

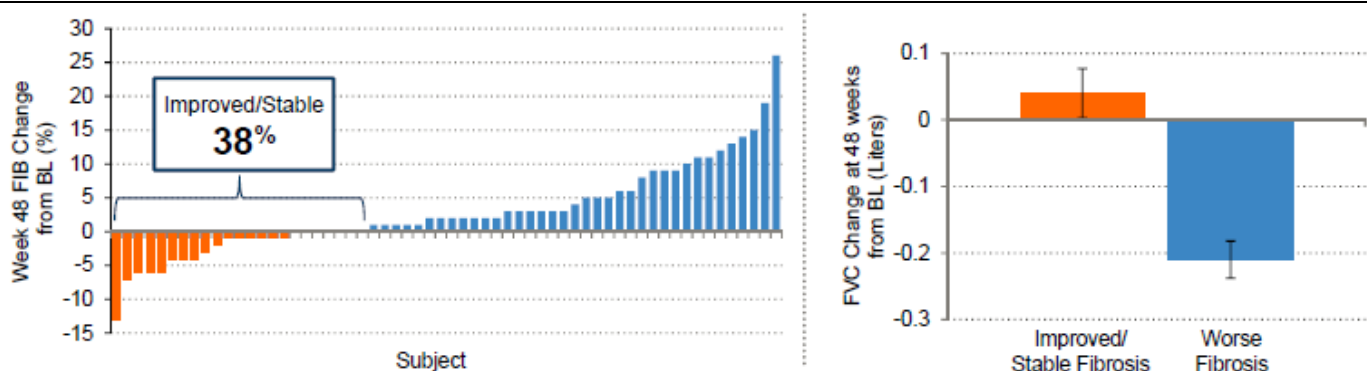
Exhibit 24: Pre-clinical study shows treatment with FG-3019 leads to resolution of fibrosis both on HRCT and histology evaluation



Source: Company reports.

Early clinical data suggests FG-3019 could potentially become the first fibrosis-reversing therapy for IPF, an orphan pulmonary disease only recently addressed by two therapies (pirfenidone, nintedanib) with modest efficacy. In an open-label Phase IIa trial (N~89), FG-3019 showed it can improve lung function in a substantial number of IPF patients. Most strikingly, the drug showed evidence of fibrosis stabilization or even reversal in 30%-40% of IPF patients. It is difficult to interpret the true benefit from this data as it was an open-label uncontrolled trial. However, analysis showing that benefit in fibrosis correlated with clinical benefit in lung function (FVC) provides support to the promise in the data (Exhibit 25). **A Phase IIb randomized, controlled trial is on-going and expected to report data in the second half of 2016.** Further understanding whether there are predictive biomarkers to identify responders vs. non-responders would be helpful as IPF population is quite a heterogeneous pool.

Exhibit 25: FG-3019 showed anti-fibrotic benefit in IPF patients that also correlated with improved lung function



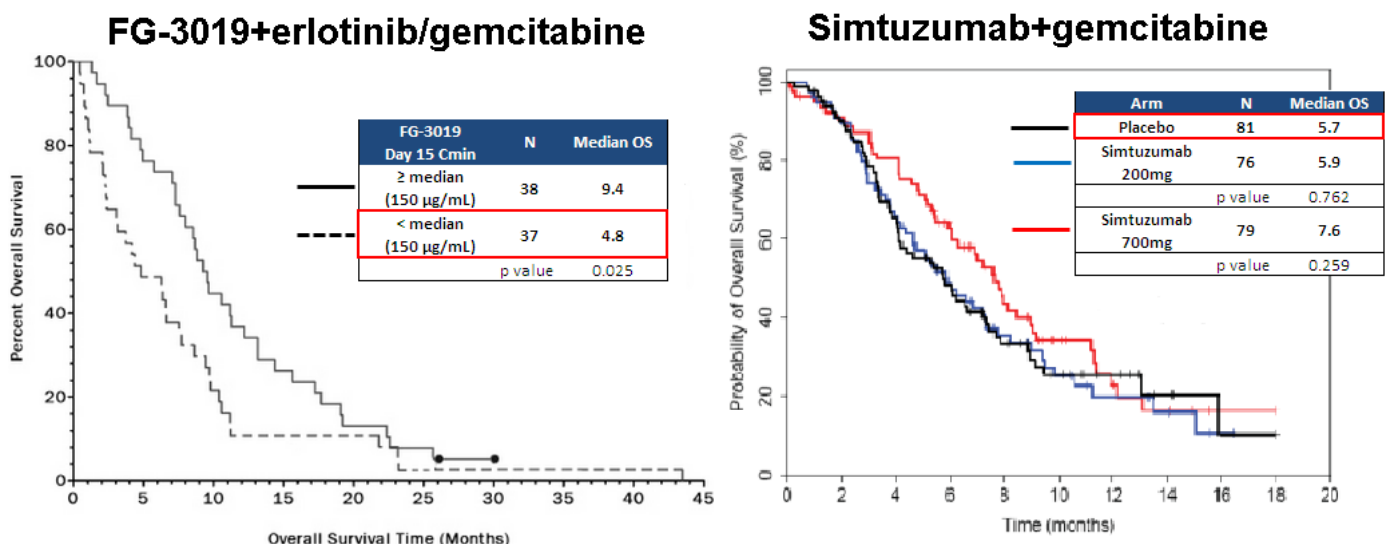
Source: Company reports

Pancreatic cancer could be another opportunity for FG-3019 but we remain somewhat cautious given the early stage, tough indication and failure by similar peers. Research suggests that CTGF is elevated in pancreatic cancer and may have a role in the proliferation and survival of tumor cells by inducing ECM (extra-cellular matrix) deposition, which in turn provides a favorable environment for tumor cell survival and metastasis. By administering FG-3019 in combination with established chemotherapy such as Abraxane and gemcitabine, it is believed that it will aid in reducing the tumor mass to surgically operable margins. However advanced pancreatic cancer is a notorious minefield of drug trial failures and just recently, Gilead's Simtuzumab also failed in a randomized Phase II study in combination with gemcitabine. In fact, Simtuzumab is a monoclonal antibody believed to have anti-fibrotic properties as well by inhibiting LOXL2, an enzyme that modifies the ECM by catalyzing the cross-linking of collagen and elastin.

Open-label Phase II study in treatment-naïve advanced pancreatic cancer showed promising signals but again, it was uncontrolled. When FG-3019 was administered on top of erlotinib and gemcitabine in 75 advanced pancreatic cancer patients, it showed a modest dose-related increase in survival although the number of patients in the first two doses were much lower (3-4 pts) vs. the later higher dose cohorts (10-13 pts). What was interesting was the data discovered through post-hoc analysis. When they divided up the patients by trough levels of plasma FG-3019 just before their second dose, they saw a statistically significant benefit in survival (median OS 9.4 vs. 4.8) for patients with Cmin ≥ 150 $\mu\text{g/mL}$ (Exhibit 26). The data is certainly intriguing as 9.4 month in median OS is much higher than 6.4 month reported in the Phase III trial for erlotinib + gemcitabine. However at the same time, several questions remain such as:

- How clinically meaningful is the trough level after just one dose when the median number of drug administered was nine?
- Was the trough level of drug correlated to dose of drug administered?
- Why did the < 150 $\mu\text{g/mL}$ group perform far inferior than previous comparable studies with gemcitabine or gemcitabine/erlotinib in similar populations? Here the median OS was 4.8 mo while the placebo/gemcitabine arm in the Simtuzumab trial showed 5.7mo, (in-line with 6.0mo in the placebo arm of erlotinib's pivotal trial).

Exhibit 26: FG-3019 in pancreatic cancer shows potential although confirmation is difficult without controlled data



Source: Company reports, ASCO 2014 Poster #4138, ESMO 2014 Poster 618



expectancy of a lethal cancer. If FG-3019's anti-fibrotic potential replicates in later controlled studies without an increase in safety issues, we believe FG-3019 could also become a \$1B+ blockbuster with the caveat that it is still early in development. If it gets to the market, we think the drug could be utilized in many different ways whether in combination with other existing drugs (similar to the treatment paradigm in other severe orphan diseases such as PAH) or as monotherapy reserved for the severe population with more advanced fibrosis. Either way, we think our currently probability-adjusted \$500M in peak sales is reasonable.

Intellectual property – Thick barricade in place but others may come knocking given the market potential

FibroGen's intellectual property is protected by a global portfolio of over 90 granted and 100 pending patent applications for Roxadustat and FG-3019, with protection likely out to 2027 or beyond. FGEN originally obtained the license to FG-3019-related antibodies from a research and commercialization agreement with Medarex, Inc. (now part of BMY). Among other protections, FGEN's granted patents include methods for treating/ preventing iron deficiency, increasing serum iron/iron absorption, and decreasing hepcidin expression via HIF-PH inhibition. If pending applications are granted, FGEN may receive patent protection until 2033 and beyond. Furthermore, FGEN estimates that with approval, Roxadustat would receive five years of patent term extension in the US under the Hatch-Waxman Act, and six years of data exclusivity and five years of market exclusivity in China as a new chemical entity. Overall, FGEN has been granted over 200 patents worldwide and has 150 pending patent applications worldwide for their entire product pipeline.

Exhibit 28: Select list of granted patents show FGEN has received a broad portfolio of global IP protection

Patent No.	Exp Expiration	Patent Title
US		
6,855,510	July 2022	Pharmaceuticals and Methods for Treating Hypoxia and Screening Methods Therefor
8,466,172	December 2022	Stabilization of Hypoxia Inducible Factor (HIF) Alpha
8,629,131	June 2024	Enhanced Erythropoiesis and Iron Metabolism
8,604,012	June 2024	Enhanced Erythropoiesis and Iron Metabolism
8,609,646	June 2024	Enhanced Erythropoiesis and Iron Metabolism
8,604,013	June 2024	Enhanced Erythropoiesis and Iron Metabolism
8,614,204	June 2026	Enhanced Erythropoiesis and Iron Metabolism
7,713,986	June 2026	Compounds and Methods for Treatment of Chemotherapy-Induced Anemia
8,318,703	February 2027	Methods for Improving Kidney Function
EU		
1,463,823	December 2022	Methods of increasing endogenous erythropoietin (epo)

Source: Company reports, RBC Capital Markets estimates

There is risk (as customary in innovative biotech) that FGEN may face intellectual property disputes with third parties that may present additional costs and/or impede FGEN's competitive position. For example, FGEN currently has a patent opposition suit with AKBA (filed in December 2013) to FGEN's EU patent# 1463823 (granted in March 2013), which covers HIF-PH inhibitory methods for treating/ pretreating/ preconditioning/ preventing EPO-associated conditions via increasing EPO, including the treatment of anemia with Roxadustat. While FGEN is confident of their EU '823 patent and believe it will be upheld in its entirety, there is inherent risk to a future ruling on the opposition, and proceedings may be both costly and time-consuming for FGEN. Surprisingly, FGEN also maintains that losing the EU '823 patent would have minimal impact on their exclusivity or operational freedom for Roxadustat; while any outcome for the EU patent may not affect the US/China/ex-EU



landscapes, it remains to be seen what potential impacts an opposition loss would have on Roxadustat in the EU.

However, FGEN does have experience protecting and prevailing in patent disputes in the past, particularly vs. AMGN. In 2007, FGEN faced an interference proceeding against their US 6855510 patent from Isis Innovation's US patent application No. 10/472595 (sub-licensed to Amgen), which predated FGEN's fundamental HIF-PH technology filings. FGEN's '510 patent covers both treatment with HIF-technology and assays for identifying HIF-PH inhibitors. Interference was suggested in September 2005 and formally declared in December 2007. The USPTO board ultimately decided in FGEN's favor over AMGN (2009), holding all of AMGN's 10/472595 claims un-patentable and assigning first-to-invent priority to FGEN. This was an important win for FGEN, as it confirmed FGEN's freedom-to-operate for HIF-PH inhibition technology.

Management

Thomas B. Neff (Chairman, Founder, and CEO)

In addition to founding FGEN and serving on FGEN's Board of Directors since 1993, Mr. Neff also founded Pharmaceutical Partners I/ Pharmaceutical Partners II (predecessors of Royalty Pharma) and Three Arch Bay Health Science Fund. He has served as director of Kolltan Pharmaceuticals since 2009, and has previously worked at Lazard Freres & Co.

Pat Cotroneo (VP, Finance, and CFO)

Mr. Cotroneo joined FGEN in 2000 as controller, and was subsequently promoted to VP of Finance and CFO. He previously worked as controller at SyStemix and Genetic Therapy (Novartis subsidiaries), and comes with experience from Deloitte & Touche.

Frank H. Valone, M.D. (CMO)

Dr. Valone comes with over 14 years of biotechnology industry experience, having served as senior VP of medical affairs at Bayhill Therapeutics, exec VP of clinical development and regulatory affairs at Titan Pharmaceuticals, and CMO at Dendreon Corporation. He has also held various clinical faculty positions at UCSF and Stanford University.

K. Peony Yu, M.D. (VP, Clinical Development)

Dr. Yu previously worked as VP of clinical research at Anesiva, and director of clinical development at ALZA Corporation (J&J subsidiary). At ALZA, she successfully led IONYSS, a drug-device combination for post-operative pain, through numerous regulatory interactions and filings that resulted in marketing approval in 25 countries.



Brief Background on anemia

Multiple illnesses may lead to anemia – multiple opportunities to target

Anemia may be brought on by the following conditions:

- Blood loss (through surgery, accidents),
- Illnesses (such as chronic kidney disease (CKD), liver disease, cancers including myelodysplastic syndrome (MDS), chronic inflammation (lupus, rheumatic arthritis)),
- Genetic conditions (sickle cell anemia, enzyme deficiencies),
- Deficiency of iron/vitamin B12/folic acid from poor dietary intake or other causes.

These causes of anemia can be broadly grouped under impaired RBC production, increased RBC destruction, blood loss and fluid overload (decreases Hb concentration). Anemia is usually diagnosed by a complete blood count, a blood panel test that measures the total number of RBCs and Hb level, as well as the cellular volume (red blood cell distribution width) of RBCs, among other factors.

The causes and symptoms of anemia can be understood by remembering that anemia is a blood disorder with low levels of RBCs and/or Hb. Hemoglobin is the iron-containing oxygen-transport protein within RBCs that carry oxygen from the lungs to cells throughout the body. Hemoglobin can also transport other molecules, such as nitric oxide (cellular signaling molecule) and carbon dioxide (byproduct of respiration). Oxygen is essential for normal metabolic processes of converting glucose (sugar) molecules from food into energy. Thus, a person with low levels of RBCs/Hb will suffer from anemic symptoms of weakness and reduced energy.

Anemia is associated with multiple, broad symptoms

Anemia symptoms can be mild and undetected. However, severe cases of anemia may affect major organs like the heart and brain, as the body increases cardiac output to compensate for the reduced oxygen-carrying capacity. Anemia patients may display a wide range of symptoms, including the following:

- Weakness,
- Fatigue,
- General malaise,
- Poor concentration,
- Dyspnea (shortness of breath) on exertion,
- Rapid heartbeat,
- Pale skin/gums,
- Impairment in walking (claudication),
- Palpitations (abnormal heartbeat) and symptoms of heart failure.



FibroGen, Inc
Annual and Quarterly Income Statement

Michael J. Yee (415)-633-8522

(\$ in millions, except per share) Fiscal Year Ends December	FYA 2012A	FYA 2013A	1QA Mar-14	2QA Jun-14	3QA Sep-14	4QE Dec-14	FYE 2014E	FYE 2015E	FYE 2016E	FYE 2017E	FYE 2018E	FYE 2019E
Revenues:												
Roxadustat Sales (China)											3.7	42.8
Roxadustat Royalties (US, ROW ex-China)											6.8	50.2
FG-3019 Sales											-	46.1
License and milestone revenue	62.8	95.0	48.6	48.6	9.0	10.0	116.2	125.0	150.0	150.0	100.0	50.0
Collaboration services and other revenue	3.1	7.2	5.3	5.3	4.6	5.0	20.3	30.0	40.5	40.0	30.0	20.0
Total Revenues, net	65.9	102.2	53.9	53.9	13.7	15.0	136.5	155.0	190.5	190.0	140.5	209.0
Costs and expenses:												
Cost of product sales											0.8	11.1
Research and development	74.2	85.7	23.6	35.4	40.6	45.0	144.5	225.0	270.0	250.0	200.0	220.0
Selling, general and administrative	18.9	24.4	5.6	8.4	10.1	15.0	39.1	76.0	87.4	109.3	136.6	150.2
Total operating costs and expenses	93.2	110.1	29.1	43.7	50.8	60.0	183.6	301.0	357.4	359.3	337.4	381.3
Income (loss) from operations	(27.2)	(7.9)	24.8	10.2	(37.1)	(45.0)	(47.1)	(146.0)	(166.9)	(169.3)	(196.9)	(172.3)
Total interest and other, net	(5.4)	(7.0)	(2.2)	(2.2)	(2.4)	(2.0)	(8.8)	(11.0)	(11.0)	(11.0)	(11.0)	(11.0)
Income (loss) before income taxes	(32.7)	(14.9)	22.6	8.0	(39.5)	(47.0)	(55.9)	(157.0)	(177.9)	(180.3)	(207.9)	(183.3)
Provision for Income Tax	0.1	-	-	-	-	-	-	-	-	-	-	-
Net income (loss)	(32.6)	(14.9)	22.6	8.0	(39.5)	(47.0)	(55.9)	(157.0)	(177.9)	(180.3)	(207.9)	(183.3)
EPS (basic)	(0.69)	(0.32)	0.48	0.17	(0.83)	(0.81)	(1.12)	(2.69)	(2.97)	(2.95)	(3.27)	(2.77)
EPS (diluted)	(0.69)	(0.32)	0.48	0.17	(0.83)	(0.81)	(1.12)	(2.69)	(2.97)	(2.95)	(3.27)	(2.77)
Shares outstanding:												
Basic	46.9	47.1	47.3	47.3	47.4	57.9	50.0	58.4	60.0	61.2	63.6	66.2
Diluted	46.9	47.1	47.3	47.3	47.4	57.9	50.0	58.4	60.0	61.2	63.6	66.2

Source: Company reports and RBC Capital Markets estimates.

*Basic shares used to calculate diluted EPS when earnings are negative.



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Ratings

Top Pick (TP): Represents analyst's best idea in the sector; expected to provide significant absolute total return over 12 months with a favorable risk-reward ratio.

Outperform (O): Expected to materially outperform sector average over 12 months.

Sector Perform (SP): Returns expected to be in line with sector average over 12 months.

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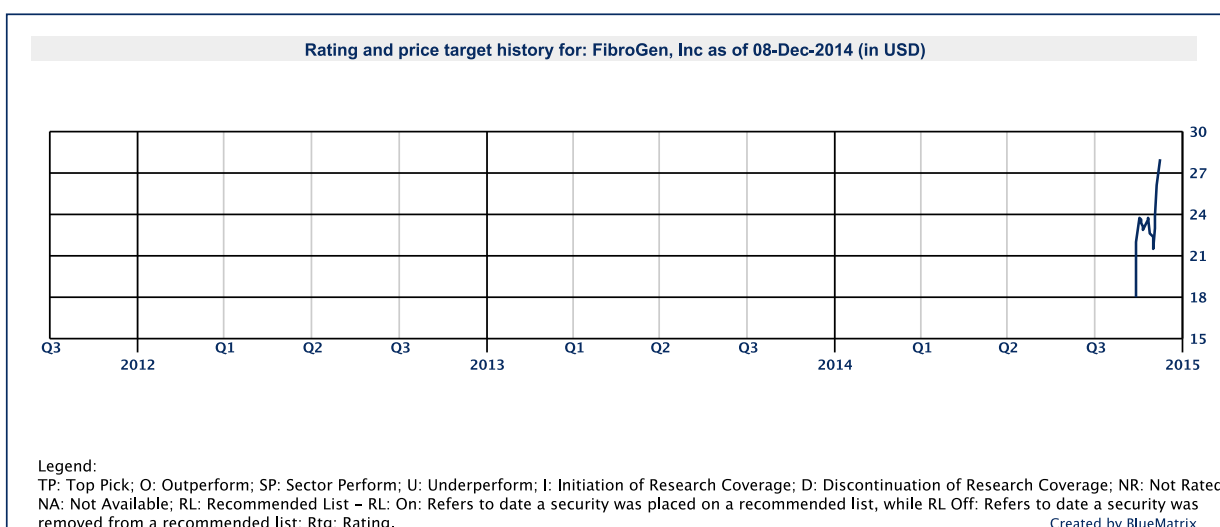
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Rating	Count	Percent	Investment Banking Serv./Past 12 Mos.	
			Count	Percent
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HOLD [Sector Perform]	683	41.67	151	22.11
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