EQUITY RESEARCH

RBC Capital Markets

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Sector: Biotechnology

November 13, 2015

FibroGen, Inc

New (+) surprise fibrosis data disclosed, adding whole new angle of upside - OP

Our view: FGEN remains a very attractive smid-cap with multiple shots-on-goal in blockbuster indications anemia, fibrosis, and cancer. Management reported surprising new positive preliminary Phase II pancreatic cancer data and the study could stop early for efficacy. Of course, lead Phase III anemia program continues to pass DSMB safety checks - which could lead to $1B+ in cash milestones over next 2+ years if FDA approved.

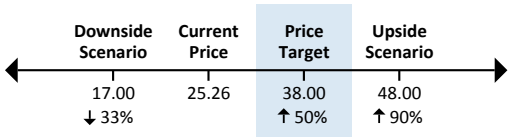
Key points:

- **We continue to like FGEN because: 1) they have multiple programs in Phase II/III and data has been very promising so far for blockbuster indications, 2) valuation is reasonable (25% of market cap is cash and the anemia program is fully funded and partnered with AZN and Astellas), and now...3) the other half of the company is starting to play out - Phase II fibrosis antibody FG-3019 that we have written about in prior notes is starting to report out positive data in pancreatic cancer.** Management guided to $330-340M cash at YE:15, and $295-300M cash at YE:16. Notably, this does not yet account for $1B+ in pre-commercial milestone payments FGEN could receive over the next 2-3 years....and would lead to one of the biggest balance sheets in smid-cap biotech.
- **New data from FG-3019 in pancreatic cancer disclosed.** FGEN has a fibrosis program, which is starting to develop into a multi-pronged asset. Management reported that in the ongoing Phase II study, 3/3 (100%) of patients who completed FG3019 treatment for unresectable pancreatic cancer all re-scored as resection-eligible vs 0% in the control. Getting to resection can double the survival of a pancreatic cancer patient. 1 patient discontinued due to an SAE unrelated to drug. 5 more patients are enrolled, and FGEN may enroll up to 40 pts - but if data continues to look positive, FGEN could stop the Phase II early and discuss next steps with FDA. More data is expected at the January ASCO GI meeting.
- **FG-3019 is an off-the-radar asset that's also being explored for other indications** - IPF with other recently approved IPF drugs; DMD Phase II now starting; and now NASH starting. FG3019 is FGEN's diamond-in-the-rough that Street doesn't give much credit to, but could become more interesting with more pancreatic data reading out. *See inside for details.*
- **Phase III oral roxadustat for anemia continues as expected.** Roxadustat passed another DSMB check looking for imbalances and none have occurred. The Phase III program is enrolling at or ahead of schedule, with pivotal US/EU data throughout 2017 and potential FDA filing in 2018. Bears suggest there will eventually be safety imbalances and the hurdle is very high - however every quarter that goes by there is thousands of patients safety that continues to add confidence and all the preclinical cancer studies have been clean and there has been massive diligence by AZN and Astellas and multiple companies are looking at this in Phase II (GSK and AKBA with different drugs) which further validates the HIF target.

Outperform
Speculative Risk
NASDAQ: FGEN; USD 25.26
Price Target USD 38.00

WHAT'S INSIDE	
☐ Rating/Risk Change	☐ Price Target Change
☐ In-Depth Report	☑ Est. Change
☐ Preview	☑ News Analysis

Scenario Analysis*



*Implied Total Returns

Key Statistics

Shares O/S (MM):	60.8	Market Cap (MM):	1,536
Dividend:	0.00	Yield:	0.0%
		Avg. Daily Volume:	384,012

RBC Estimates

FY Dec	2014A	2015E	2016E	2017E
Revenue	137.6	185.4	158.0	205.0
Prev.		193.8	157.9	
EPS, Adj Basic	(3.17)	(1.38)	(0.76)	(0.49)
Prev.			(1.75)	

Revenue	Q1	Q2	Q3	Q4
2014	17.9A	90.0A	13.7A	16.1A
2015	16.3A	120.6A	19.5A	29.0E
Prev.			28.0E	
2016	20.0E	73.0E	22.0E	43.0E
EPS, Adj Basic				
2014	(1.23)A	3.52A	(2.93)A	(1.45)A
2015	(0.78)A	0.95A	(0.74)A	(0.49)E
Prev.			(0.85)E	(0.71)E
2016	(0.47)E	0.39E	(0.49)E	(0.19)E

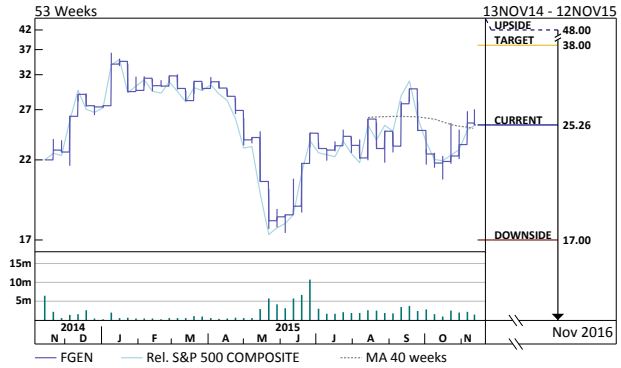
All values in USD unless otherwise noted.

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

For Required Conflicts Disclosures, see Page 8.

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; 2) FG-3019 is developed for IPF and becomes a $1.5B + WW drug by 2024 and applying 25-30% probability; 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, 2) higher prob. 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. 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 an attractive 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 significant 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

Advancement of pipeline in 2015-2016: FGEN is initiating Phase III 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), 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 a 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.

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.

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

FGEN's second drug candidate FG-3019 is a monoclonal antibody in Phase II development for treatment of fibrotic cancer and fibrotic diseases, including idiopathic pulmonary fibrosis (IPF) and Duchenne muscular dystrophy (DMD) and nonalcoholic steatohepatitis (NASH). The drug ties back to the original foundation of the company, which was to discover drugs targeting fibrotic diseases and hence the name "FibroGen". FG-3019 inhibits the activity of Connective Tissue Growth Factor (CTGF), shown to be a central mediator of fiborisis and a contributor of tumor growth and metastasis. 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.

FGEN is using FG-3019 to treat four main indications:

- **Pancreatic Cancer:** FGEN is running an open label, placebo-controlled Phase II trial of FG-3019/abraxane/gemcitabine combo in patients with inoperable pancreatic cancer**.** A published surgery review showed that treated patients had median survival of 21 months vs. 9 months for patients whose tumors could not be fully removed. 12 subjects are currently enrolled in the study, 7 of whom have finished. FGEN plans to enroll up to 40 subjects in the study, although management does not foresee enrolling all 40 subjects if data readouts continue to show efficacy. The company could theoretically elect to move forward before they finish enrolling all 40 patients, although management noted that the numbers are "still too small" to be convincing. Preliminary data will be presented at the ASCO GI Meeting in January 2016.

- **IPF:** FGEN has completed a dose-finding, single-arm open-label trial in subjects with moderate IPF. Results showed that 35% of subjects had stable or improved lung fibrosis after 48-week treatment. To management's knowledge, no IPF clinical trial has shown improvement in lung fibrosis – including trials of approved drugs Pirfenidone and nintedanib. FGEN is running Study 067, a randomized, double blind, placebo-controlled trial as a first-line therapy for patients with mild to moderate IPF. Accrual has slowed due to the US launch of pirfenidone and nintedanib. Ability to complete the trial depends on opening sites in countries where pirfenidone and nintedanib are not prevalent. FGEN is activating 23 new sites in Canada, New Zealand, India, and South Africa, and an additional 9 sites in Australia, Bulgaria and Romania. Management expects enrollment to complete in H1:16, with topline data slated for H1:17. FGEN is also evaluating a trial that combines FG-3019 with an approved therapy.

- **DMD:** FGEN views DMD as high-priority program, as FG-1303 could potentially treat all subjects with DMD, regardless of the underlying genetic defect. As such, FG-1303 appears to be differentiated from the current drugs in development that target specific genetic defects. The company received FDA clearance in July 2015 for IND to treat non-ambulatory patients with DMD. Endpoints include changes in lung function, arm function, and MRI assessment of cardiac and arm muscle fibrosis. The company is starting to screen subjects for enrollment in this trial. In 2016, the company intends to meet with the FDA to discuss plans for running trials in ambulatory patients.

- **Liver Fibrosis (NASH, Hepatitis C):** In October 2015, FGEN met with the FDA to discuss the treatment of liver fibrosis due to NASH or Hepatitis C. FGEN is working with an FDA reviewer to finalize plans for a Phase II trial for NASH, and the company plans to file an

IND in Q1:16. The NASH study will be a placebo-controlled trial, and management anticipates endpoints to include changes in fibrosis and liver function.

Exhibit 2: Anticipated news flow for FGEN

Time	Expected News Flow	Program
Roxadustat (Anemia, Cancer)		
YE:15/Q1:16	Complete enrollment in non-dialysis setting (ANDES)	Roxadustat (US/ ROW)
YE:15/Q1:16	Complete enrollment in global incident dialysis study (HIMALAYS)	Roxadustat (US/ ROW)
YE:15/Q1:16	Complete enrollment in FibroGen stable dialysis study (SIERRAS)	Roxadustat (US/ ROW)
H1:16	File clinical application trials in myelodysplastic syndromes (MDS) and chemo-induced anemia (CIA)	Roxadustat (China)
H2:16	Data readout from two Phase III studies in dialysis and non-dialysis settings in China	Roxadustat (China)
2016	Submit for regulatory approval in China	Roxadustat (China)
H1:17	Data readout from initial Phase III studies in non-dialysis setting	Roxadustat (US)
H2:17	NDA approval in China	Roxadustat (China)
2017	Final Phase III data from non-dialysis and dialysis setting	Roxadustat (US/EU)
2018	Submit for regulatory approval in EU and USA	Roxadustat (US/EU)
FG-3019 (IPF, Pancreatic cancer, other fibrotic diseases)		
Q4:15/early'16	Efficacy data from Phase II study in liver fibrosis associated with HBV in Hong Kong	FG-3019 (liver fibrosis)
YE:15	Initiate non-ambulatory patient enrollment in Phase II study of DMD	FG-3019 (DMD)
Jan 2016	Preliminary Phase II data on FG-3019/abraxane/gemcitabine combo at ASCO GI Meeting (Study 069)	FG-3019 (pancreatic)
H1:16	Complete enrollment of Phase IIb randomized controlled study in mild-moderate IPF (Study 067)	FG-3019 (IPF)
Q1:16	File IND for Phase II trial in subjects with liver fibrosis due to NASH	FG-3019 (liver fibrosis)
2016	Initiate stage 4 Phase II study in pancreatic cancer	FG-3019 (pancreatic)
2016	Discussions with FDA to extend to ambulatory patients with DMD	FG-3019 (DMD)
H1:17	Topline data from Phase IIb randomized controlled study in mild-moderate IPF	FG-3019 (IPF)
FG-5200 (Corneal Implant)		
Q1:16	Start local production of corneal implant materials in China	FG-5200 (China)
Q3:16	Start required chronic toxicity study in China	FG-5200 (China)

Source: Company reports, RBC Capital Markets estimates

Exhibit 3: FGEN product pipeline and expected launch dates

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 (HBV, HCV, NASH)		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 estimates

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Valuation

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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.

Company description

FibroGen is a San Francisco-based biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics to treat anemia and fibrosis. The company's lead anemia product candidate, FG-4592, is an oral small molecule inhibitor of HIF-PH. Its lead IPF drug candidate, FG-3019, is a monoclonal antibody under clinical development for treating IPF, pancreatic cancer, and liver fibrosis.

FibroGen, Inc
Annual and Quarterly Income Statement

Michael J. Yee (415)-633-8522

($ in millions, except per share) Fiscal Year Ends December	FYA 2014A	1QA Mar-15	2QA Jun-15	3QE Sep-15	4QE Dec-15	FYE 2015E	1QE Mar-16	2QE Jun-16	3QE Sep-16	4QE Dec-16	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	117.2	11.5	106.9	13.0	20.0	151.4	10.0	62.0	10.0	30.0	112.0	150.0	100.0	50.0
Collaboration services and other revenue	20.4	4.8	13.7	6.5	9.0	34.0	10.0	11.0	12.0	13.0	46.0	55.0	56.1	57.2
Total Revenues, net	**137.6**	**16.3**	**120.6**	**19.5**	**29.0**	**185.4**	**20.0**	**73.0**	**22.0**	**43.0**	**158.0**	**205.0**	**166.6**	**246.2**
Costs and expenses:														
Cost of product sales													0.8	11.1
Research and development	150.8	50.5	51.6	52.1	45.0	199.2	37.0	39.0	41.0	43.0	160.0	184.0	202.4	212.5
Selling, general and administrative	36.9	10.5	9.7	11.2	12.0	43.4	10.0	8.0	9.0	10.0	37.0	40.7	44.8	56.0
Total operating costs and expenses	187.7	61.0	61.2	63.3	57.0	242.6	47.0	47.0	50.0	53.0	197.0	224.7	248.0	279.6
Income (loss) from operations	**(50.1)**	**(44.7)**	**59.3**	**(43.8)**	**(28.0)**	**(57.2)**	**(27.0)**	**26.0**	**(28.0)**	**(10.0)**	**(39.0)**	**(19.7)**	**(81.4)**	**(33.4)**
Toal interest and other, net	(9.4)	(1.9)	(2.1)	(1.3)	(2.0)	(7.3)	(2.0)	(2.0)	(2.0)	(2.0)	(11.0)	(11.0)	(11.0)	(11.0)
Income (loss) before income taxes	(59.5)	(46.6)	57.3	(45.1)	(30.0)	(64.4)	(29.0)	24.0	(30.0)	(12.0)	(47.0)	(30.7)	(92.4)	(44.4)
Provision for Income Tax	-	0.3	(0.2)	0.0	-	0.1	-	-	-	-	-	-	-	-
Net income (loss)	**(59.5)**	**(46.4)**	**57.1**	**(45.0)**	**(30.0)**	**(64.4)**	**(29.0)**	**24.0**	**(30.0)**	**(12.0)**	**(47.0)**	**(30.7)**	**(92.4)**	**(44.4)**
EPS (basic)	(3.17)	(0.78)	0.95	(0.74)	(0.49)	(1.07)	(0.47)	0.39	(0.49)	(0.19)	(0.76)	(0.49)	(1.41)	(0.65)
EPS (diluted)	(3.17)	(0.78)	0.83	(0.74)	(0.49)	(1.07)	(0.47)	0.39	(0.49)	(0.19)	(0.76)	(0.49)	(1.41)	(0.65)
Shares outstanding:														
Basic	18.8	59.2	59.8	60.8	61.0	60.2	61.3	61.5	61.7	62.0	61.6	62.9	65.4	68.0
Diluted	18.8	59.2	68.8	60.8	61.0	62.4	61.3	61.5	61.7	62.0	61.6	62.9	65.4	68.0

Source: Company reports and RBC Capital Markets estimates.
*Basic shares used to calculate diluted EPS when earnings are negative.

Required disclosures

Conflicts disclosures

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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.

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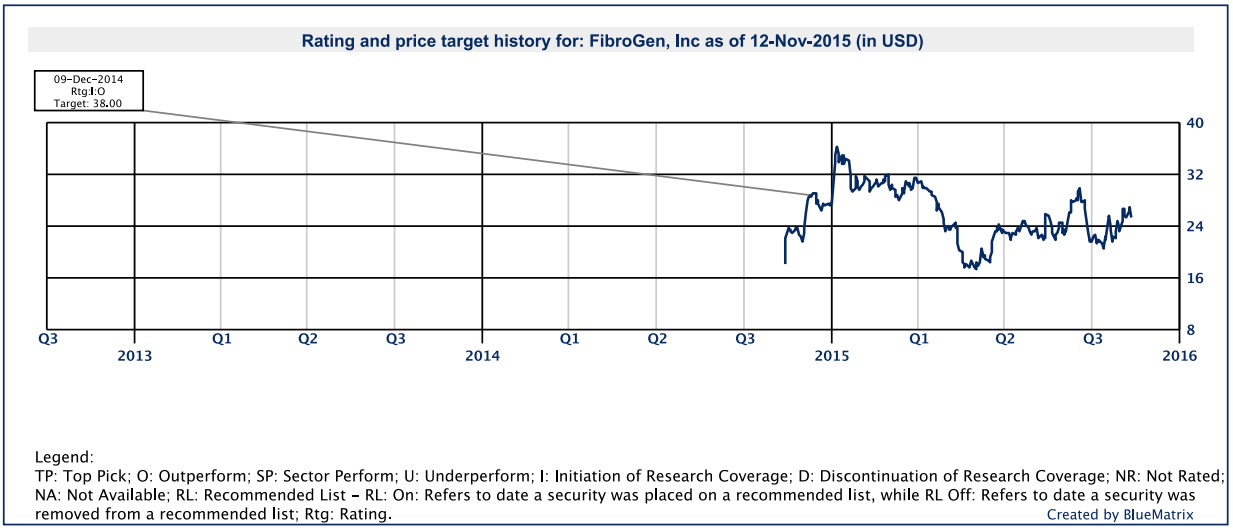
Distribution of ratings
RBC Capital Markets, Equity Research
As of 30-Sep-2015

			Investment Banking Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [Top Pick & Outperform]	958	54.40	281	29.33
HOLD [Sector Perform]	701	39.81	118	16.83
SELL [Underperform]	102	5.79	4	3.92



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