

FibroGen, Inc.

(FGEN – \$25.26)

HOLD

Price Target: \$25

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3Q Results Aligned w/ Estimates; Progression of Roxadustat and FG-3019 Remain On Course

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FibroGen Reports Q3 Results: The Company reported Q3 2015 results after the close Thursday, with results essentially aligned with EPS at (\$0.74) per share on a fully diluted basis, comparing to the LSCM and consensus estimates of (\$0.69) and (\$0.61), respectively.

Q3 2015	Q3 Est.	Q3 Act.
Revenue (in \$MM)	\$ 17.5	\$ 19.5
EPS	\$ (0.69)	\$ (0.74)

Q4 2015E	OLD	NEW
Revenue (in \$MM)	\$ 70.0	\$ 60.0
EPS	\$ 0.45	\$ 0.35

FY 2015E	OLD	NEW
Revenue (in \$MM)	\$ 224.4	\$ 216.4
EPS	\$ (0.08)	\$ (0.20)

Roxadustat: (CKD-Associated Anemia): Clinical progression of roxadustat remains intact. FGEN, which is conducting three of the seven Phase 3 trials, has achieved 80% enrollment. We expect its partners, AstraZeneca and Astellas, to complete enrollment in their respective trials in 2016. In China, two P3 trials are expected to begin enrollment by year-end 2015.

In October the roxadustat data safety monitoring board (DSMB) completed a scheduled review of active P3 studies and recommended the clinical programs continue with no change in protocol recommended.

FG-3019: (Fibrotic Disorders): The Phase 2 study evaluating FG-3019 in treating idiopathic pulmonary fibrosis (IPF) continues to expand in scope, with patient recruitment targeting Canada, New Zealand, Australia, India, South Africa, and other locations. FibroGen is expected to present data at ASCO-GI in January 2016 involving its Phase 2 study evaluating FG-3019 in patients with inoperable pancreatic cancer. Finally, the Company remains on track to initiate Phase 2 clinical studies evaluating FG-3019 for the treatment of Duchenne Muscular Dystrophy (DMD) by year-end 2015.

Conclusion: FGEN represents a very high risk, very high reward investment scenario, in our opinion. Their lead candidate, roxadustat, is a pioneering therapy involving the HIF pathway. This pathway is very complex and has not been fully elucidated. It is believed to be directly or indirectly involved in the regulation of numerous genes. For these reasons, we remain cautious on FGEN's shares as we view roxadustat as being highly speculative.

FGEN shares remain a HOLD rated with a 12-month price target of \$25.

Changes	Previous	Current
Rating:	–	Hold
Price Target:	–	\$25
FY15E Rev. (M):	\$224.4	\$216.4
FY16E Rev. (M):	–	\$155.0
FY15E EPS:	(\$0.08)	(\$0.20)
FY16E EPS:	–	(\$1.04)

Profile

Price:	\$25.26
Shares Out. (M):	60.8
Market Cap. (M):	\$1,535
Enterprise Value (M):	\$1,400
Avg. Daily Vol.:	485,771
Insiders Own:	19%
Short Int.(M) / % of Float:	3.4 / 6.5%
Tan. Book Val. / Sh.:	\$4.20
Net Cash / Sh.:	\$4.11
Div / Yield:	\$0/0.0%

Rev. (M)	2014E	2015E	2016E
Mar	NA	\$16.3A	NA
Jun	NA	\$120.6A	NA
Sep	NA	\$19.5A	NA
Dec	NA	\$60.0E	NA
FY	\$137.6	\$216.4E	\$155.0

EPS	2014E	2015E	2016E
Mar	NA	(\$0.78)A	NA
Jun	NA	\$0.83A	NA
Sep	NA	(\$0.74)A	NA
Dec	NA	\$0.35E	NA
FY	(\$3.17)	(\$0.20)	(\$1.04)
EBITDA	NM	NM	NM

* ex items

Valuation	2015E	2016E	2017E
P/E	NM	NM	NM
EV/EBITDA	NA	NA	NA

Management

Chrm/CEO	Thomas Neff
CFO	Pat Cotroneo

Company Description

FibroGen is a biopharmaceutical company, developing roxadustat for anemia; FG-3019 for various fibrotic disorders; and other candidates.

INVESTMENT THESIS AND VALUATION

Our HOLD rating reflects our view that while the P2 clinical trials of roxadustat clearly support the global P3 program, the HIF system is highly complex, operating in most mammalian cells, and is not restricted to erythropoiesis synthesis. The HIF pathway is also believed to be involved in the expression of over 100 genes which significantly elevates our concerns relating to safety risks. Consequently, we caution investors to be cognizant of these risks as roxadustat enters into its global P3 program that is comprised of approximately 7,300 subjects. For these reasons, and considering the current valuation, we are HOLD rated on FGEN shares. Regarding FG-3019, we are cautiously optimistic considering its P2 status as a viable treatment for fibrotic diseases, namely idiopathic pulmonary fibrosis (IPF).

VALUATION

Our 12-month target price is \$25, which is derived by valuing each product franchise independently. We use an extrapolation of peak sales; FibroGen's royalty stream or ownership interest in that franchise; adjusted by a probability of success assumption; and adjusted by applying an appropriate multiple of royalties or sales. The implied valuations are then discounted to present value using a 15% discount factor. The implied per share valuation is quotient of the implied present value of all franchises divided by shares outstanding.

	Peak Sales	FGEN Interest	Probability Success	FGEN Interest x Prob. Success	Multiple	Implied Valuation
Roxadustat, Global, ex-China, 22% Royalty	\$ 2,500,000,000	\$ 550,000,000	30%	\$ 165,000,000	15	\$2,475,000,000
Roxadustat, China, 50/50	\$ 1,000,000,000	\$ 500,000,000	30%	\$ 150,000,000	3	\$ 450,000,000
FG-3019, Wholly-Owned	\$ 2,000,000,000	\$2,000,000,000	30%	\$ 600,000,000	3	\$1,800,000,000

Program	Implied Valuation	Discount Factor	Years	Present Value
Roxadustat, Global, ex-China, 22% Royalty	\$ 2,475,000,000	15%	7	\$ 930,444,174
Roxadustat, China, 50/50	\$ 450,000,000	15%	5	\$ 223,729,531
FG-3019, Wholly-Owned	\$ 1,800,000,000	15%	8	\$ 588,423,193
Total Implied Present Value				\$1,742,596,898
Implied Present Value Per Share				\$ 25.35

RISKS

An investment in FibroGen, Inc., involves risk.

- **Clinical and Regulatory Hurdles** – The Company’s success is predicated upon its ability to advance its lead compounds through human clinical trials that demonstrate safety and efficacy such that the Company attains the necessary marketing clearances from regulating agencies in multiple jurisdictions.
- **Reimbursement and Payor Risk** – The Company must garner funding from various entitlement programs, insurance carriers, private payors, and other funding sources.
- **Safety Risk** – Any safety risks associated with any of its products that arise at any time represent a risk to performance.
- **Sales, Marketing, and Distribution** – Impairment of the Company’s or its license partners’ ability to sell, market, or distribute its products represent risk to performance.
- **Manufacturing and Supply Chain** – Impairment of the Company’s or its license partners to procure or produce compliant finished products represent a risk to performance.
- **Competition, Generics and Biosimilars, and Pricing** – Competition from existing therapies, generics, biosimilars, and/or low adoption of its branded products represent a risk to performance. The Company’s success is predicated on broad commercial acceptance of its products.
- **Future Capital Needs** – The Company may need to raise capital to support development and commercialization of its products; its ability to raise sufficient funding represents a risk.
- **Intellectual Property** – The Company’s success also depends on its ability to enforce its intellectual property. Litigation and defense expenses associated with enforcing its intellectual property also represent a risk to the Company’s performance.

FINANCIAL MODEL

FibroGen, Inc.

(# in \$1,000s, except per share data)

	<u>Q1 2015A</u>	<u>Q2 2015A</u>	<u>Q3 2015A</u>	<u>Q4 2015E</u>	<u>FY 2014A</u>	<u>FY 2015E</u>	<u>FY 2016E</u>	<u>FY 2017E</u>	<u>FY 2018E</u>	<u>FY 2019E</u>	<u>FY 2020E</u>
License, Milestone Revenue	11,506	106,879	13,045	50,000	117,191	181,430	120,000	175,000	150,000	150,000	200,000
Collaboration and Other	4,792	13,671	6,493	10,000	20,410	34,956	35,000	35,000	35,000	30,000	30,000
Royalty Revenue	-	-	-	-	-	-	-	-	-	35,000	100,000
Sales Revenue, Roxadustat (China), FG-3019	-	-	-	-	-	-	-	-	2,500	50,000	125,000
Total Revenue	16,298	120,550	19,538	60,000	137,601	216,386	155,000	210,000	187,500	265,000	455,000
Cost of Goods Sold									500	10,000	18,750
Research & Development Exp.	50,539	51,555	52,071	25,000	150,794	179,165	135,000	150,000	185,000	220,000	255,000
General & Administrative Exp.	10,482	9,680	11,237	11,000	36,909	42,399	85,000	125,000	150,000	185,000	215,000
Total Operating Expense	61,021	61,235	63,308	36,000	187,703	221,564	220,000	275,000	335,000	405,000	470,000
Income from Operation (Loss)	(44,723)	59,315	(43,770)	24,000	(50,102)	(5,178)	(65,000)	(65,000)	(147,500)	(140,000)	(15,000)
Interest Expense	(2,758)	(2,762)	(2,758)	(2,750)	(11,108)	(11,028)	(12,500)	(12,500)	(12,500)	(12,500)	(12,500)
Interest and Other Income, Net	843	707	1,458	800	1,706	3,808	2,250	2,000	1,500	1,000	1,000
Income before Tax (Loss)	(46,638)	57,260	(45,070)	22,050	(59,504)	(12,398)	(75,250)	(75,500)	(158,500)	(151,500)	(26,500)
Income Tax Benefit, (Tax)	271	(205)	28	(150)		(56)	-	-	-	-	-
Net Income	(46,367)	57,055	(45,042)	21,900	(59,504)	(12,342)	(75,250)	(75,500)	(158,500)	(151,500)	(26,500)
EPS	\$ (0.78)	\$ 0.83	\$ (0.74)	\$ 0.35	\$ (3.17)	\$ (0.20)	\$ (1.04)	\$ (1.01)	\$ (2.07)	\$ (1.93)	\$ (0.33)
Average Shares Outstanding	59,197	68,752	60,767	62,267	18,775	62,746	72,500	74,500	76,500	78,500	80,500
Royalty Revenue	<u>Q1 2015A</u>	<u>Q2 2015A</u>	<u>Q3 2015A</u>	<u>Q4 2015E</u>	<u>FY 2014A</u>	<u>FY 2015E</u>	<u>FY 2016E</u>	<u>FY 2017E</u>	<u>FY 2018E</u>	<u>FY 2019E</u>	<u>FY 2020E</u>
Roxadustat (AZN, ex-China and Astellas licensing)	-	-	-	-	-	-	-	-	-	25,000	75,000
Roxadustat (Astellas)	-	-	-	-	-	-	-	-	-	10,000	25,000
Total Royalties	-	-	-	-	-	-	-	-	-	35,000	100,000
Roxadustat, China Sales									2,500	25,000	75,000
FG-3019 Sales									-	25,000	50,000
TTL Sales									2,500	50,000	125,000

IMPORTANT DISCLOSURES



Initiate: September 23, 2015 – Rating: HOLD - Price Target: \$25

Source: Thomson ONE

RATINGS DEFINITION

BUY rated stocks are expected to generate greater than 10% returns during the next 12 months. **HOLD** rated stocks are expected to generate returns of 0% to 10% during the next 12 months. **SELL** rated stocks are expected to generate negative returns over the next 12 months and generally do not have a price target.

Information on our valuation methodology and risks can be found in the “Valuation” and “Risks” sections.

RATINGS DISTRIBUTION

(as of October 6, 2015)

Rating	All Covered Companies (%)	Investment Banking Clients (%)
BUY	86.7%	10.3%
HOLD	13.3%	0.0%
SELL	0.0%	0.0%

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