November 13, 2015

OUTPERFORM

Reason for report:

EARNINGS

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LEERINK

FIBROGEN, INC.

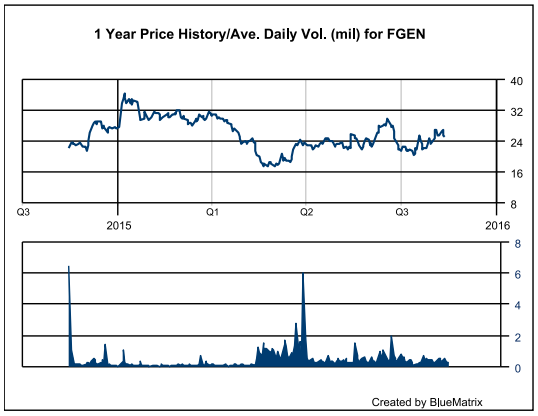
Roxadustat On Track; Intriguing Early Pancreatic Cancer for FG-3019

• **Bottom Line:** On its 3Q:15 earnings call, mgmt. discussed intriguing interim data from its Phase II study of FG-3019 (CTGF inhibitor) in inoperable pancreatic cancer. Of 7 pts who completed 6 months of follow-up, 3 of 4 randomized to receive FG-3019 + gemcitabine and Abraxane were able to undergo subsequent resection (the trial's goal) vs. none of 3 patients in the gemcitabine + Abraxane control arm. With the caveats of small pt numbers treated & evaluable from a single center in an open-label study, confirmation of a benefit w/ FG-3019 in this devastating disease would be a major upside surprise. Roxadustat Ph III enrollment remains on track and we expect investor interest to grow ahead of initial data in 2H:16 and final data in 2017. With projected cash of $295-300M at the end of 2016, >$1B in contingent development & regulatory milestones from partners AZN (MP) & Astellas for roxadustat, a potentially disruptive first in class anemia treatment, and little or no value attributed to FG-3019 in several high-value fibrotic conditions, we view FGEN as the most compelling risk-reward story in our coverage; our $52 price target is unchanged.

• **FGEN estimates only ~5-10% of previously inoperable non-metastatic pancreatic cancer patients are resectable post-treatment with chemotherapy.** Of the 4 pts randomized to receive FG-3019 + gemcitabine and Abraxane, 2 achieved an R0 resection, indicating clear margins, and 1 achieved an R1 resection. The remaining patient had stopped therapy due to a serious adverse event unrelated to FG-3019. Results with 2-3 add'l pts (2 control, 1 FG-3019) likely will be presented at the Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (ASCO GI) in January 2016, according to the company. The company plans to recruit up to 40 pts, including additional sites (Mayo Clinic and Georgetown added to date) with add'l interim looks before moving forward.

• **FG-3019 continues to advance in other fibrotic indications.** FGEN met with the FDA and now plans to file an IND for 1Q:16 for advanced liver fibrosis due to nonalcoholic steatohepatitis (NASH). In idiopathic pulmonary fibrosis (IPF), the enrollment in countries where Ofev (nintedanib) and Esbriet (pirfenidone) are commercially available remains challenging. As such, it is adding 23 sites in Canada, New Zealand, India, and South Africa, with 9 add'l sites pending in Australia, Bulgaria and Romania. Results are now expected in 1Q:17 (vs. late 2016). Enrollment of sites for a Phase II trial in non-ambulatory Duchenne muscular dystrophy (DMD) patients remains ongoing and the company continues to plan for an FDA meeting in 2016 to discuss a trial in ambulatory patients.

Key Stats:	**(NASDAQ :FGEN)**
Sector:	**Biotechnology**
S&P 600 Health Care Index:	**1,628.30**
Price :	**$25.26**
Price Target:	$52.00
Methodology:	DCF & sum-of-the-parts using probability-weighted revenues and 10% discount rate
52 Week High:	$40.59
52 Week Low:	$16.95
Shares Outstanding (mil):	60.1
Market Capitalization (mil):	1,518.1
Book Value/Share:	0.40
Cash Per Share:	$6.01
Net Debt to Total Capital:	0%
Dividend (ann):	$0.00
Dividend Yield:	0.0%



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2014A	$17.9	$90.0	$13.7	$16.1	$137.6	($1.23)	$1.36	($2.93)	($1.45)	($3.17)	NM
2015E - New	**$16.3A**	**$120.6A**	**$19.5A**	**$20.0**	**$176.4**	**($0.78)A**	**$0.83A**	**($0.74)A**	**($0.70)**	**($1.28)**	**NM**
2015E - Old	$16.3A	$120.6A	$25.0	$20.0	$181.8	($0.78)A	$0.83A	($0.82)	($0.59)	($1.23)	NM
2016E - New	**--**	**--**	**--**	**--**	**$175.0**	**--**	**--**	**--**	**--**	**($1.36)**	**NM**
2016E - Old	--	--	--	--	$175.0	--	--	--	--	($0.72)	NM

Source: Company Information and Leerink Partners LLC Research
Revenues in $M; GAAP EPS presented; IPO 11.13.14

INVESTMENT THESIS

FGEN is a leader in developing novel agents targeting fibrosis and hypoxia pathways for the treatment of anemia and fibrotic diseases. Roxadustat, a first-in-class prolyl-hydroxylase (PHD) inhibitor, mimics the body's natural response to hypoxia (low oxygen) conditions and has been shown in a large Phase II program involving nearly 1,300 patients to be safe and effective in treating both dialysis-dependent (DD) and non-dialysis dependent (NDD) chronic kidney disease (CKD). Erythropoietin-stimulating agents (ESAs), the current mainstay for the anemia market still generate sales of ~$8-9B despite significant limitations including cardiovascular (CV) safety concerns. Unlike ESAs, roxadustat is an oral agent that 1) raises hemoglobin (Hb) without causing supraphysiologic elevations in endogenous erythropoietin, 2) reduces the need for IV iron by through the suppression of hepcidin, 3) is effective in incident dialysis patients and hypo-responders to ESAs without requiring a high dose, 4) lowers LDL and total cholesterol, and 5) does not raise blood pressure. Consistent with MEDACorp key opinion leader (KOLs) feedback, we think roxadustat has the potential to be a "game changer" in the large anemia market. The key investor concerns appear to be whether roxadustat is safe and whether there are safety liabilities associated with PHD inhibition and stabilizing hypoxia-inducible factor HIF as a result. While it is impossible to exclude cancer or CV risks associated with PHD (prolyl hydroxylase) inhibition, we believe the preponderance of scientific and clinical evidence suggests that the risk is not high. Additionally, we believe available data also strongly suggest that high levels of ESAs, rather than increased Hb levels are responsible for elevated CV risks from ESA use. We also believe roxadustat has a good chance to show reduced risks in cardiovascular outcomes relative to ESAs in its ongoing Phase III trials. Additionally, FGEN is taking a unique development approach in China using the "Green Channel", which could potentially allow the company to gain access to the country's rapidly expanding dialysis population. Finally, FG-3019, a CTGF inhibitor in Phase II development for a number of fibrotic indications, has shown a unique ability to reverse fibrosis and there is likely limited valuation associated with this asset in the stock.

FGEN's Phase III roxadustat trials remain on track; additional indications are being considered in China. Of the seven ongoing Phase III trials of roxadustat in chronic kidney disease (CKD), the company is responsible for conducting three: ANDES (non-dialysis), HIMALAYAS (incident dialysis), and SIERRAS (conversion in existing dialysis patients). FGEN has reached 80% of its cumulative enrollment in these trials (recruitment was reported to be two-thirds complete as of the 2Q:15 earnings call). At this pace, mgmt. continues to expect to meet its "base goal" of completing enrollment in all three studies by March or April of 2016 and to meet the "stretch goal" of enrollment completion by YE 2015 in one of the trials. In China, Phase III enrollment is expected to begin in mid-December and complete ~6 months after this. The company also plans to expand development of roxadustat in China to include trial in myelodysplastic syndrome (MDS) and chemotherapy-induced anemia (CIA).

Model update: For 3Q:15, FGEN reported a net loss of $45.1M and diluted EPS of ($0.74). R&D was $52.1M and G&A was $11.2M. The company noted that it had $11.8M in remaining R&D spending for roxadustat development as part of its AZN partnership (which it expects to use up before December 2015), after which it will only be responsible for 50% of development costs in China. The company expects to still incur a portion of roxadustat development costs outside of China as non-cash expenses in the P&L, and we have adjusted our model to reflect these changes. FGEN guided to ending 2015 and 2016 with $330-340M and $295-300M in cash, respectively.

FGEN – Upcoming Catalysts

Catalyst	Expected Timing
Roxadustat	
Begin enrollment in Phase III trials in China	4Q:15
Complete enrolment in one Phase III US trial (stretch goal)	End of 2015
Complete enrolment in remaining Phase III US trials (base goal)	March/April 2016
Phase III China data	2H:16
Submit regulatory filings in China	2016
Data for US Phase III NDD-CKD studies	2017
China NDA review expected	2017
Submit regulatory filings in US	2018
FG-3019	
Interim Phase IIa data in neoadjuvant pancreatic cancer (in combo with gemcitabine and Abraxane) at ASCO GI	Jan-16
Initiate Phase II trial in DMD	4Q:15
Phase II data from HBV-associated liver fibrosis trial in Hong Kong and Thailand	2015
File IND for Phase II trial in liver fibrosis due to NASH	1Q:16
Discuss plans for ambulatory DMD trial with FDA	2016
Phase II data from Study 067 in mild-to-moderate IPF	1H:17
FG-5200 (Corneal implant)	
Start local production of material in China	1Q:16
Start chronic toxicology study	3Q:16

Source: Company reports

FGEN – Pipeline

Drug	MOA	Indication	Phase
Roxadustat	HIF-PH inhibitor	Anemia (DD- and NDD-CKD) - US/EU	III
		Anemia (DD- and NDD-CKD) - China	II
		Anemia (DD- and NDD-CKD)- Japan	II
FG-8205	Selective HIF-PH inhibitor	Heart failure after myocardial infarction	Preclinical
FG-6875	HIF-PH inhibitor	Stem cell mobilization	I
FG-3019	Anti-CTGF antibody	Pancreatic cancer	II
		IPF	II
		Duchenne muscular dystrophy (DMD)	II
		Liver fibrosis in NASH	Pre-IND
FG-5200	Corneal implant	Corneal blindness - China	Pilot

Source: Company reports

VALUATION

Our valuation for FGEN is $52 a share based on DCF and sum of the parts analysis. We include probability-weighted roxadustat royalties from Astellas (EU and Japan) and AZN (US and ROW) and the 50% roxadustat profit-share with AZN (MP) in China. For all territories, we assume a 70% probability of success for the dialysis-dependent chronic kidney disease (CKD) indication and a 60% probability of success for the non-dialysis dependent CKD indication. We assume a 10% discount rate, which believe is appropriate as given our probability-weighted sales. We currently assign $300M valuation to FGEN's pipeline programs beyond roxadustat.

RISKS TO VALUATION

- Clinical risks including ability for roxadustat to show a statistically significant improvement or clinically relevant trend towards improvement in cardiovascular (CV) outcomes versus erythropoietin-stimulating agents (ESAs) in its Phase III dialysis trials or placebo in its Phase III non-dialysis trials.
- Unknown safety issues associated with PHD inhibition or HIF stabilization.
- Clinical and regulatory risks associated with bringing a new class to the market in various territories, particularly in China.
- Uncertain size of the potential anemia market, particularly outside the dialysis setting.
- Unknown reimbursement landscape in the US regarding the inclusion of roxadustat in CMS's Prospective Payment System (aka, "The Bundle").
- Competition from other HIF-PH inhibitors

FGEN P&L Model, $M except per share data	2011A	2012A	2013A	1Q:14A	2Q:14A	3Q:14A	4Q:14A	2014A	1Q:15A	2Q:15A	3Q:15A	4Q:15E	2015E	2016E	2017E	2018E	2019E	2020E
AZN partnership																		
US Sales (POS-adj.)	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*144.2*	*329.6*
ROW Sales (POS-adj.)	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*43.3*	*98.9*
Total AZN royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	44.0	100.7
China Sales (POS-adj.)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	56.9	124.2	212.4
Astellas partnership																		
EU Sales (POS-adj.)	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*115.3*	*263.6*
Japan Sales (POS-adj.)	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*57.7*	*131.8*
Total Astellas Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	34.6	79.1
Total roxadustat sales/royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	56.9	202.9	392.2
License/milestone revenues	1.2	62.8	95.0	12.8	84.9	8.6	11.0	117.2	11.5	106.9	13.0	15.0	146.4	155.0	0.0	63.7	259.9	259.9
Collaboration services and other revenue	12.6	3.1	7.2	5.1	5.1	5.1	5.1	20.4	4.8	13.7	6.5	5.0	30.0	20.0	20.0	20.0	20.0	20.0
Total revenue	13.8	65.9	102.2	17.9	90.0	13.7	16.1	137.6	16.3	120.6	19.5	20.0	176.4	175.0	20.0	140.6	482.8	672.1
R&D	65.4	74.2	85.7	25.1	33.8	40.6	51.3	150.8	50.5	51.6	52.1	47.0	201.2	190.0	200.0	170.0	180.0	190.0
SG&A	23.8	18.9	24.4	7.0	7.0	10.2	12.8	36.91	10.5	9.7	11.2	13.0	44.4	60.0	62.0	64.0	66.0	68.0
Profit share payment to AZN	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	28.5	62.1	106.2
Total operating expense	89.2	93.2	110.1	32.1	40.8	50.8	64.1	187.7	61.0	61.2	63.3	60.0	245.6	250.0	262.0	262.5	308.1	364.2
Operating income	**(75.4)**	**(27.2)**	**(7.9)**	**(14.2)**	**49.2**	**(37.1)**	**(48.0)**	**(50.1)**	**(44.7)**	**59.3**	**(43.8)**	**(40.0)**	**(69.2)**	**(75.0)**	**(242.0)**	**(121.9)**	**174.7**	**307.9**
Interest expense and other, net																		
Interest expense		(10.0)	(10.7)	(3.0)	(3.3)	(1.8)	(2.9)	(11.1)	(2.8)	(2.8)	(2.8)	(2.8)	(11.1)	(11.1)	(11.1)	(11.1)	(11.1)	(11.1)
Interest income		4.4	3.6	0.9	0.9	(0.5)	0.3	1.7	0.8	0.7	1.5	0.4	3.4	3.4	3.4	3.4	3.4	3.4
Other income (expense), net		0.2	0.2	0.1	0.1	(0.2)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total interest and other, net		(5.4)	(7.0)	(2.0)	(2.3)	(2.4)	(2.6)	(9.4)	(1.9)	(2.1)	(1.3)	(2.4)	(7.6)	(7.6)	(7.6)	(7.6)	(7.6)	(7.6)
Income (loss) before income taxes		(32.7)	(14.9)	(16.2)	46.8	(39.5)	(50.6)	(59.5)	(46.6)	57.3	(45.1)	(42.4)	(76.8)	(82.6)	(249.6)	(129.5)	167.1	300.3
Benefit from income taxes	0.4	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.3	(0.2)	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0
Net income (loss)		**(32.6)**	**(14.9)**	**(16.2)**	**18.1**	**(39.5)**	**(50.6)**	**(59.5)**	**(46.4)**	**57.1**	**(45.1)**	**(42.4)**	**(76.7)**	**(82.6)**	**(249.6)**	**(129.5)**	**167.1**	**300.3**
GAAP EPS (basic)		**($2.48)**	**($1.13)**	**($1.23)**	**$1.36**	**($2.93)**	**($1.45)**	**($3.17)**	**($0.78)**	**$0.95**	**($0.74)**	**($0.70)**	**($1.28)**	**($1.36)**	**($4.07)**	**($2.09)**	**$2.67**	**$4.75**
GAAP EPS (diluted)		**($2.48)**	**($1.13)**	**($1.23)**	**$0.58**	**($2.93)**	**($1.45)**	**($3.17)**	**($0.78)**	**$0.83**	**($0.74)**	**($0.70)**	**($1.28)**	**($1.36)**	**($4.07)**	**($2.09)**	**$2.11**	**$3.76**
Shares - basic (pro-forma)	13.128	13.128	13.186	13.203	13.326	13.493	34.869	18.775	59.197	59.798	60.767	60.828	60.147	60.749	61.356	61.970	62.590	63.216
Shares - diluted (pro-forma)	13.128	13.128	13.186	13.203	13.326	13.493	34.869	18.775	75.749	68.752	75.927	75.988	74.104	76.748	77.515	78.290	79.073	79.864

Source: Company filings, Leerink estimates

Disclosures Appendix

Analyst Certification

I, Seamus Fernandez, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Valuation

Our valuation for FGEN is $52 a share based on DCF and sum of the parts analysis. We include probability-weighted roxadustat royalties from Astellas (EU and Japan) and AZN (US and ROW) and the 50% roxadustat profit-share with AZN (MP) in China. For all territories, we assume a 70% probability of success for the dialysis-dependent chronic kidney disease (CKD) indication and a 60% probability of success for the non-dialysis dependent CKD indication. We assume a 10% discount rate, which believe is appropriate as given our probability-weighted sales. We currently assign $300M valuation to FGEN's pipeline programs beyond roxadustat.

Risks to Valuation

· Clinical risks including ability for roxadustat to show a statistically significant improvement or clinically relevant trend towards improvement in cardiovascular (CV) outcomes versus erythropoetin-stimulating agents (ESAs) in its Phase III dialysis trials or placebo in its Phase III non-dialysis trials.

· Unknown safety issues associated with PHD inhibition or HIF stabilization.

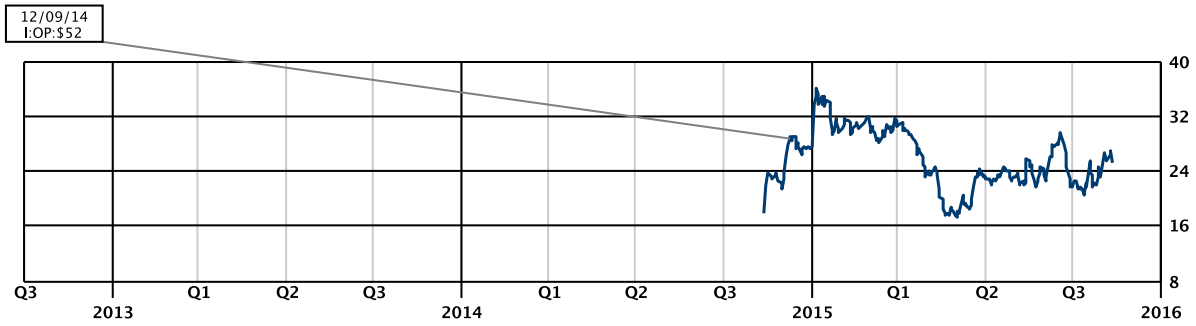
· Clinical and regulatory risks associated with bringing a new class to the market in various territories, particularly in China.

· Uncertain size of the potential anemia market, particularly outside the dialysis setting.

· Unknown reimbursement landscape in the US regarding the inclusion of roxadustat in CMS's Prospective Payment System (aka, "The Bundle").

· Competition from other HIF-PH inhibitors

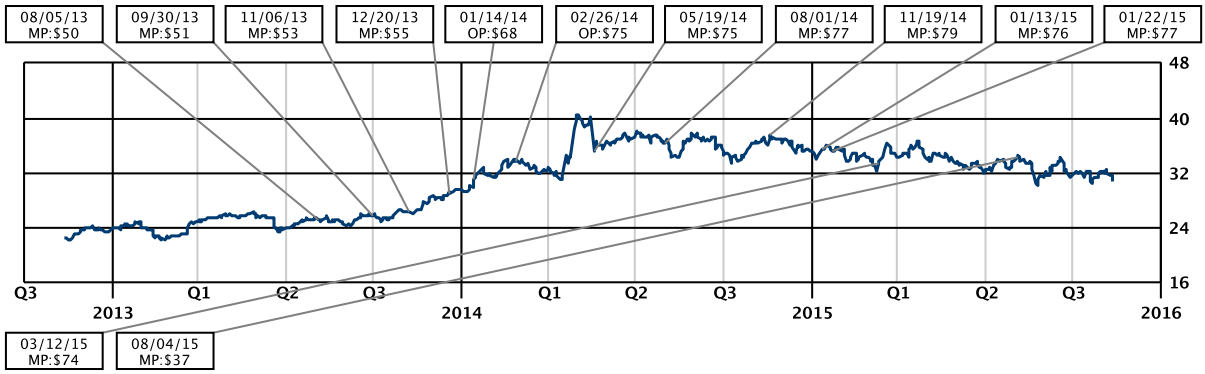
Rating and Price Target History for: FibroGen, Inc. (FGEN) as of 11-12-2015



OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage

Created by BlueMatrix

Rating and Price Target History for: AstraZeneca PLC (AZN) as of 11-12-2015



Leerink Swann initiated coverage of AZN with a Market Perform rating on Sept. 30, 2009. On June 11, 2013, Leerink Swann began a transition to specific price targets for the stocks under its coverage, replacing valuation ranges.

OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage

Created by BlueMatrix

Distribution of Ratings/Investment Banking Services (IB) as of 09/30/15				
			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	167	75.60	68	40.70
HOLD [MP]	54	24.40	2	3.70
SELL [UP]	0	0.00	0	0.00

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform in line with its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark over the next 12 months.The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over $2 billion.

Important Disclosures

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MEDACorp is a network of healthcare professionals, attorneys, physicians, key opinion leaders and other specialists accessed by Leerink and it provides information used by its analysts in preparing research.

In the past 12 months, the Firm has received compensation for providing investment banking services to FibroGen, Inc. .

Leerink Partners LLC makes a market in FibroGen, Inc.

Leerink Partners LLC is willing to sell to, or buy from, clients the common stock of AstraZeneca PLC on a principal basis.

Leerink Swann initiated coverage of AZN with a Market Perform rating on Sept. 30, 2009. On June 11, 2013, Leerink Swann began a transition to specific price targets for the stocks under its coverage, replacing valuation ranges.

Leerink Partners LLC has acted as the manager for a public offering of FibroGen, Inc. in the past 12 months.

LEERINK

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