

Flexion Therapeutics (FLXN - \$8.59)

Quarter In Line, Focus on Upcoming FDA Meeting

FLXN reported their 1Q16 last night after the close in-line with expectations. The call was focused on upcoming pre-NDA meeting with the FDA to discuss the potential of filing Zilretta with the somewhat mixed Phase 2b data and the very positive Phase 3 trial reported in February. We believe that with the combination of: a) the Phase 2b (hit on almost every week except the 12 week primary endpoint); b) the highly statistically significant Phase 3 ($p < 0.0001$); and c) the recently presented sub-group analysis of the Phase 3 data for unilateral knee OA at the Osteoarthritis Research Society International (OARSI) conference; FLXN has a strong case to make to the FDA this month for approval. Following the FDA meeting, if positive, FLXN anticipates filing Zilretta in 2H16. The company will also proceed to hire sales managers in 2H16 to prepare for the launch that we expect to begin 2H17. We maintain our Buy rating and \$35 price target.

- **Numbers roughly in line, pre-NDA meeting this month key.** This is after adjusting R&D for the one-time \$3M cost related to a manufacturing technology transfer; having moved all of the commercial manufacturing for Zilretta from Evonik to Patheon in the quarter. With the Zilretta pre-NDA meeting set for literally any day now, we anticipate a positive outcome and an NDA filing soon thereafter in 2H16. Management guided that the hiring of a head of sales would likely swiftly follow a positive FDA meeting and a near-term path for NDA filing.
- **Pipeline gets thinner, looking to rebuild.** FLXN has discontinued the FX007 (TrkA small molecule receptor antagonist) program for post-operative pain due to a lack of efficacy signals in early trials, which leaves their clinical development pipeline fairly bare. Management commented on the call their commitment to bringing in assets to re-stock their pipeline going forward.
- **Maintain BUY rating, \$35 price target.** Our \$35 price target is based on a sum-of-the-parts analysis, with Zilretta valued at \$32/share and cash net of debt (end '16) and tech value at \$3/share.

Healthcare / Biotechnology

Ticker:	FLXN
Rating:	Buy
Price Target:	\$35.00

Trading Data:

Last Price (05/12/2016)	\$8.59
52-Week High (09/08/2015)	\$29.09
52-Week Low (03/17/2016)	\$7.56
Market Cap. (MM)	\$185.3
Shares Out. (MM)	21.57

Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
FY17E	(\$0.58)	(\$0.58)	(\$0.66)	(\$0.67)	(\$2.48)	NA
FY16E	(\$0.64)A	(\$0.64)	(\$0.57)	(\$0.57)	(\$2.40)	NA
FY15	(\$0.43)	(\$0.58)	(\$0.52)	(\$0.63)	(\$2.15)	NA
FY14	(\$0.86)	(\$0.38)	(\$0.45)	(\$0.47)	(\$1.97)	NA

Analyst

Jim Molloy Specialty Pharma & Biotechnology
(617) 283-5521
jmolloy@laidlawltd.com

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Quarterly Income Statement

Flexion Therapeutics										
Quarterly income statement										
(\$000 except per share)	2015A				2015A Year	2016E				2016E Year
	1QA	2QA	3QA	4QA		1QA	2QE	3QE	4QE	
Revenues										
Total Revenue										
Expenses:										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
Gross Margin	-	-	-	-	-	-	-	-	-	-
R&D	6,255	9,640	7,829	8,967	32,691	8,981	9,250	9,250	9,500	36,981
SG&A	2,760	2,904	3,197	4,511	13,372	4,692	4,750	5,000	5,000	19,442
Total op. exp.	9,015	12,544	11,026	13,478	46,063	13,673	14,000	14,250	14,500	56,423
Inc (loss) from Ops	(9,015)	(12,544)	(11,026)	(13,478)	(46,063)	(13,673)	(14,000)	(14,250)	(14,500)	(56,423)
Int inc (exp), net	(35)	440	71	198.72	675	60	50	50	50	210
Other income (exp)	(123)	(333)	(182)	(289)	(927)	(202)	(200)	(200)	(200)	(802)
Inc (loss) before taxes	(9,173)	(12,437)	(11,136)	(13,569)	(46,315)	(13,815)	(14,150)	(14,400)	(14,650)	(57,015)
Income tax exp (benefit)										
Adj-NI ex-1x items	(9,173)	(12,437)	(11,136)	(13,569)	(46,315)	(13,815)	(14,150)	(14,400)	(14,650)	(57,015)
Adj EPS ex-1x items	(\$0.43)	(\$0.58)	(\$0.52)	(\$0.63)	(\$2.15)	(\$0.64)	(\$0.64)	(\$0.57)	(\$0.57)	(\$2.40)
Weighted avg. shares (000)	21,451	21,475	21,507	21,555	21,497	21,570	21,970	25,470	25,870	23,720
Fully diluted shares (000)	22,999	23,145	23,223	23,240	23,152	23,948	24,348	27,848	28,248	26,098

Specialty Pharmaceuticals

Source: Company reports and Laidlaw estimates

Jim Molloy (857) 317-5061 jmolloy@laidlawltd.com

Source: Company reports and Laidlaw & Company estimates

Annual Income Statement

Flexion Therapeutics

Annual income statement

(\$000 except per share)	2015A	2016E	2017E	2018E	2019E	Comments
Revenues						
FX006 - OA pain			\$1,655	\$214,246	\$363,049	US launch 2H17
Total Revenue	\$0	\$0	\$1,655	\$214,246	\$363,049	
Expenses:						
Cost of Revenue (COGS)	-	-	248	32,137	54,457	
Gross Margin	-	-	1,407	182,109	308,591	
R&D	32,691	36,981	40,750	35,000	40,000	
G&A	13,372	19,442	26,650	74,750	108,750	Self-launch FX006 in US
Total op exp	46,063	56,423	67,400	109,750	148,750	
Inc/(loss) from Ops	(46,063)	(56,423)	(65,993)	72,359	159,841	
Int income (exp), net	675	210	210	300	450	
Other expenses, net	(927)	(802)	(800)	(1,000)	(1,000)	
Inc/(loss) before taxes	(46,315)	(57,015)	(66,583)	71,659	159,291	
Income tax exp (benefit)	-	-	-	-	23,894	Sig. tax loss carryforwards
Adj-NI ex-1x items	(46,315)	(57,015)	(66,583)	\$71,659	\$135,398	
Adj EPS ex-1x items	(\$2.15)	(\$2.40)	(\$2.48)	\$2.25	\$3.95	
Weighted avg. shares (000)	21,497	23,720	26,800	29,300	31,800	
Fully diluted shares (000)	23,152	26,098	29,300	31,800	34,300	
Cash balance	\$111,327	\$87,015	\$13,496	\$81,698	\$215,016	Assume funding 2H16

Source::Company reports and Laidlaw & Company estimates

Major Risks

Exogenous events could impact our outlook. We believe pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies.

Actual clinical results and the FDA's conclusions may deviate from expectations. Many of our assumptions are based on a review of incomplete clinical trial data available in the public domain. Often, our conclusions are drawn from early stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations. Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

Legal risks could lead to additional liabilities and revenue loss. In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

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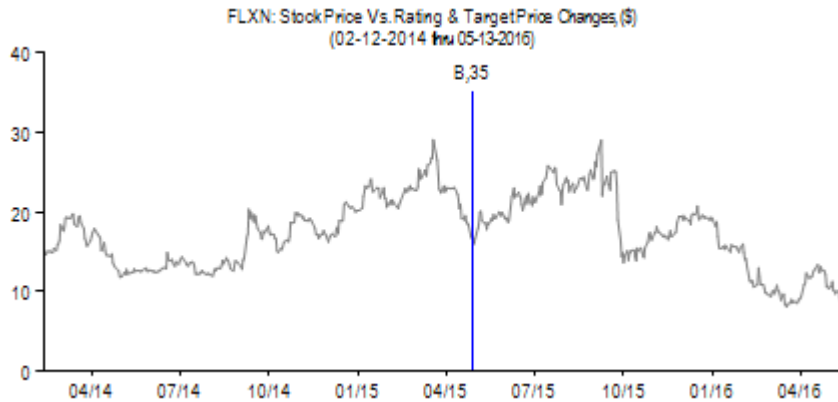
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Additional information available upon request.

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RATINGS INFORMATION

Rating and Price Target Change History



Date	Rating	Closing Price (\$)
04/28/2015	Buy (B)	16.87

Date	Target Price (\$)	Closing Price, (\$)
04/28/2015	35.00	16.87

Source: Laidlaw & Company

Created by: Blue-Compass.net

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	66.67%	27.78%	2.78%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Evonik (EVK.DE – Not Rated)

ADDITIONAL DISCLOSURES

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