

Flexion Therapeutics (FLXN - \$20.09)

FX006 Clinical Trials Remain on-track for 4Q15/1H16 Data
FLXN reported 1Q15 EPS last night after the close in-line with expectations. FLXN remains a development and not an earnings story at this time. On the development front the company remains on-track to report phase 2B data in the FX006 first confirmatory trial by year end, with the phase 3 data expected to follow in 1H16. With \$137MM in cash as of 1Q15 following the 4Q14 ~\$100MM secondary we anticipate that FLXN is capitalized through the FDA approval for FX006 in 2017 (assuming the trials go well). With a target market of over 3MM steroid injections in the US annually (and an additional ~1.5MM hyaluronic acid injections too) with an improved longer acting version, we believe FX006 can reach \$340MM by 2019. We are reiterating our Buy rating, \$35 price target.

- **Clinical trials remain on track for 4Q15/1H16 data.** The rate-limiting second pivotal trial for FX006 appears to be enrolling on target for a 4Q15 completion, 1H16 data, keeping FX006 on track for our estimated 2H16 NDA filing (see page 2 of this report for our detailed trial timeline).
- **Hyaluronic acid (HA) & steroid combos questionable in our opinion.** We believe that the combination HA & steroid products like Anika's Cingal and Carbylan's Hydros-TA may find limited adoption relative to a long acting steroid alone, given the American Academy of Orthopedic Surgeons clinical practice guideline against using HA for OA pain.
- **OA of the knee represents 3MM US patients alone.** There are approximately 3MM US patients annually who receive IR TCA injections. A 10% penetration of this established patient group could equate to ~\$250MM in annual sales in the US alone. The ROW opportunity could be 4-5x as large as the US opportunity.
- **Significant pipeline catalysts over 2015-2016.** In 4Q15 we anticipate results from an ongoing confirmatory phase 2b dose-ranging trial, and we anticipate results from an ongoing phase 3 trial in 1H16.
- **Maintain BUY rating, \$35 price target.** Our \$35 price target is based on a sum-of-the-parts analysis, with FX006 valued at \$30/share and cash (end 2015) and technology at \$5/share.

Healthcare / Biotechnology

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

Trading Data:

Last Price (05/07/2015)	\$20.09
52-Week High (03/20/2015)	\$30.37
52-Week Low (05/01/2014)	\$11.06
Market Cap. (MM)	\$431.0
Shares Out. (MM)	21.45

Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
FY16E	NA	NA	NA	NA	(\$2.20)	NA
FY15E	(\$0.43)A	(\$0.52)	(\$0.52)	(\$0.52)	(\$1.98)	NA
FY14	(\$0.86)	(\$0.38)	(\$0.45)	(\$0.47)	(\$1.97)	NA
FY13	(\$6.13)	(\$6.13)	(\$6.12)	(\$4.65)	(\$23.02)	NA

Analyst

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Source: Laidlaw & Company estimates

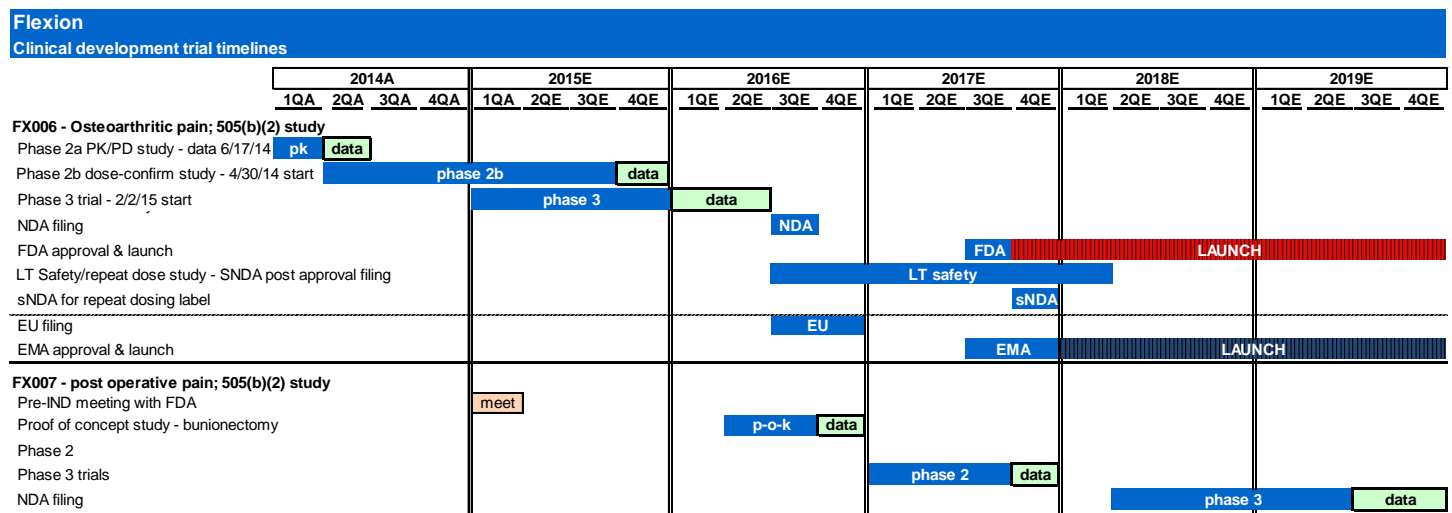
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Figure 1. Variance analysis

Flexion Quarterly variance analysis					
(000's except per share)	1Q14A	1Q15A	1Q15E	Variance	% Y/Y
Total Revenue	\$0	\$0	\$0	\$0	NA
COGS	0	0	0	\$0	NA
Gross Profit	0	0	0	\$0	NA
R&D Expense	4,151	6,255	8,000	(\$1,745)	51%
SG&A Expense	2,284	2,760	2,500	\$260	21%
Operating Inc (loss)	(6,435)	(9,015)	(10,500)	\$1,485	40%
Int. inc. (expense), net	(81)	(35)	50	(\$85)	-57%
Other (exp) gain, net	(26)	(123)	(100)	(\$23)	373%
Pretax Income (loss)	(6,542)	(9,173)	(10,550)	\$1,377	40%
Income Tax exp (benefit)	0	0	0	\$0	NA
Net income (loss)	(6,542)	(9,173)	(10,550)	\$1,377	40%
1x items & non-cash exp	0	0	0	\$0	NA
Adj NI ex-1x/non cash	0	0	0	\$0	NA
Weighted avg. shares (000)	7,633	21,451	22,495	(\$1,044)	181%
Fully diluted shares (000)	8,575	22,451	23,495	(\$1,044)	162%
EPS	(\$0.86)	(\$0.43)	(\$0.47)	\$0.04	-50%

Source: Company Reports: Laidlaw & Company estimates

Figure 2. Upcoming clinical trial timelines



Source::Laidlaw & Company estimates

Quarterly Income Statement

Flexion
Quarterly income statement

(\$000 except per share)	2014A				2014A Year	2015E				2015E Year
	1QA	2QA	3QA	4QA		1QA	2QE	3QE	4QE	
Revenues										
Total Revenue										
Expenses:										
Cost of Revenue (COGS)						-	-	-	-	-
Gross Margin	-	-	-	-	0	-	-	-	-	0
R&D	4,151	3,615	4,658	5,499	17,923	6,255	8,150	8,100	8,000	30,505
SG&A	2,284	2,234	2,304	2,242	9,064	2,760	3,000	3,250	3,500	12,510
Total op. exp.	6,435	5,849	6,962	7,741	26,987	9,015	11,150	11,350	11,500	43,015
Inc (loss) from Ops	(6,435)	(5,849)	(6,962)	(7,741)	(26,987)	(9,015)	(11,150)	(11,350)	(11,500)	(43,015)
Int inc (exp), net	(81)	28	56	75	78	(35)	50	50	50	115
Other income (exp)	(26)	(110)	(130)	(138)	(404)	(123)	(100)	(100)	(100)	(423)
Inc (loss) before taxes	(6,542)	(5,931)	(7,036)	(7,804)	(27,313)	(9,173)	(11,200)	(11,400)	(11,550)	(43,323)
Income tax exp (benefit)										
Net Income (Loss)	(6,542)	(5,931)	(7,036)	(7,804)	(27,313)	(9,173)	(11,200)	(11,400)	(11,550)	(43,323)
Earning per Share (EPS)	(\$0.86)	(\$0.38)	(\$0.45)	(\$0.47)	(\$1.97)	(\$0.43)	(\$0.52)	(\$0.52)	(\$0.52)	(\$1.98)
Weighted avg. shares	7,633	15,619	15,625	16,699	13,894	21,451	21,701	21,951	22,201	21,826
Fully diluted shares	8,575	16,828	16,859	18,054	15,079	22,451	22,701	22,951	23,201	22,826

Source: Company reports and Laidlaw estimates

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Annual Income Statement

Flexion

Annual income statement

(\$000 except per share)	2014A	2015E	2016E	2017E	2018E	2019E	Comments
Revenues							
FX006 - OA pain				\$1,655	\$200,497	\$340,745	US launch late 2017
FX006 ex-US royalties					13,748	22,303	Partner ex-US
Total Revenue	\$0	\$0	\$0	\$1,655	\$214,246	\$363,049	
Expenses:							
Cost of Revenue (COGS)	-	-	-	248	30,075	51,112	
Gross Margin	-	-	-	1,407	184,171	311,937	
R&D	17,923	30,505	35,500	36,000	38,000	45,250	
G&A	9,064	12,510	15,250	16,750	43,750	73,750	Self-launch FX006 in US
Total op exp	26,987	43,015	50,750	52,750	81,750	119,000	
Inc/(loss) from Ops	(26,987)	(43,015)	(50,750)	(51,343)	102,421	192,937	
Int income (exp), net	78	115	200	250	300	450	
Other expenses, net	(404)	(423)	(200)	(200)	(200)	(199)	
Inc/(loss) before taxes	(27,313)	(43,323)	(50,750)	(51,293)	102,521	193,188	
Income tax exp (benefit)	-	-	-	-	-	28,978	Sig. tax loss carryforwards
Net Income (Loss)	(\$27,313)	(\$43,323)	(\$50,750)	(\$51,293)	\$102,521	\$164,210	
Earning per Share	(\$1.97)	(\$1.98)	(\$2.20)	(\$2.09)	\$3.53	\$5.16	
Weighted avg. shares (000)	13,894	21,826	23,076	24,576	27,076	29,576	
Fully diluted shares (000)	15,079	22,826	24,076	25,826	29,076	31,826	
Cash balance	\$151,753	\$110,719	\$62,819	\$14,876	\$121,772	\$288,132	cash into 2017

Source: Company reports and Laidlaw 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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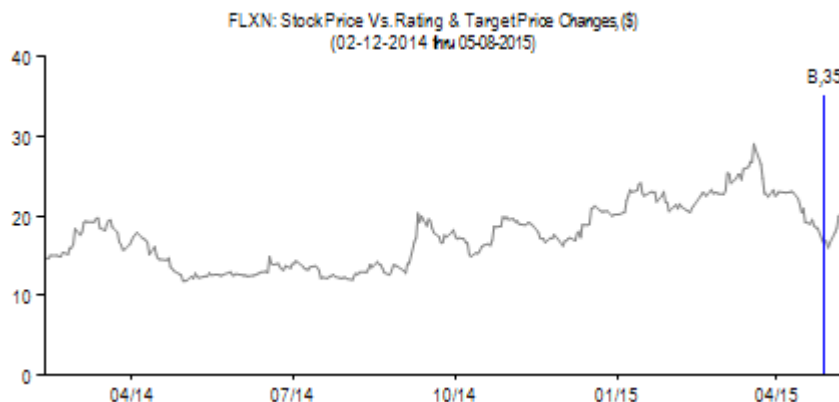
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Rating and Price Target Change History



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.	72.00%	32.00%	8.00%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.00%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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