

Flexion Therapeutics (FLXN - \$29.00)

Phase 2b Only Misses On 1 Week...But It's the 12th Week

Last night after the close FLXN announced the Phase 2b dose confirmatory data for FX006 and FX006 positively separated from placebo in all weeks...except the 12th week (p=0.0821) - which was the primary endpoint of the study. Management commented in preliminary discussions that the placebo response in week 12 was anomalous, possibly due to the higher than anticipated drop-out rate (8% placebo, 3% active). On a BOCF/LOCF analysis to account for dropouts it seems that week 12 does hit statistical significance (p=0.042), but it remains to be seen if this analysis holds water with the FDA. Management plans to meet with the FDA post the upcoming Phase 3 data (expected 1Q16) to determine if another trial is necessary or if this Phase 2b is sufficient. Typically we hold little hope for a failed trial passing muster at the FDA but given the flexibility the FDA has already shown and the fact this is a Phase 2b trial, it doesn't seem entirely out of the question. Worst case in our opinion the FDA requires one more Phase 3 trial and the NDA filing is delayed from 2H16 to 2H17/1H18 - assuming the Phase 3 data we are awaiting in 1Q16 looks good. A 12-18 month delay would likely impact our PT by \$8-\$10/share to account for the additional time & uncertainty in the program, which would still be well above where the stock seems likely to open this AM, and we would reiterate our Buy rating. Additional comments post-tomorrow's 9am ET conference call (details below).

- **Placebo appears to be the culprit yet again.** FLXN notes that there was an unexpected placebo response in week 12 well above where the historical placebo response would indicate. The relatively small size (n~300) and the high drop-out likely impacted the week 12 data, in our opinion.
- **Much will depend on the Phase 3 data in 1Q16 - as it always has.** We continue to anticipate positive Phase 3 results in 1Q16, given the larger size (n=462) and the primary endpoint (vs. placebo at 12 weeks). The FX00s IR TCA is a secondary supportive endpoint.
- **Maintain BUY rating, \$35 price target, conference call at 9AM today.** Our \$35 price target is based on a sum-of-the-parts, FX006: \$30/share & cash (end 2016) and tech: \$5/share. Conference call US dial-in: (908) 982-4677, code: 33691273.

Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
FY16E	(\$0.55)	(\$0.58)	(\$0.58)	(\$0.58)	(\$2.30)	NA
FY15E	(\$0.43)A	(\$0.58)A	(\$0.60)	(\$0.59)	(\$2.20)	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

Healthcare / Biotechnology

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

Trading Data:

Last Price (09/08/2015)	\$29.00
52-Week High (03/20/2015)	\$30.37
52-Week Low (09/08/2014)	\$14.09
Market Cap. (MM)	\$623.5
Shares Out. (MM)	21.5

Analyst

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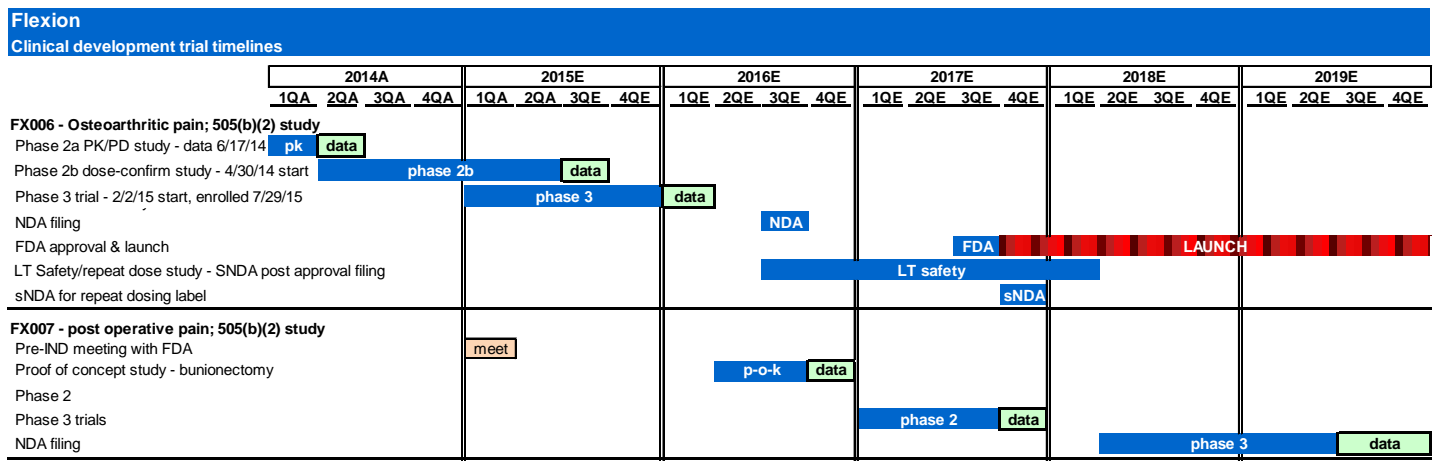
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Figure 1. Valuation

Sum-of-the-parts value: FLXN		
Segment	Valuation (000's)	Per share value
FX006 value	\$725,640	\$30
Cash (end '16) & tech value	\$114,440	\$5
SUM	\$840,080	\$35
Shares out '16E (000)		24,405

Source: Company Reports; Laidlaw & Company estimates

Figure 2. Upcoming clinical trial timelines



Source: Company reports and Laidlaw estimates

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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	2QA	3QE	4QE	
Revenues										
Total Revenue										
Expenses:										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
Gross Margin	-	-	-	-	-	-	-	-	-	-
R&D	4,151	3,615	4,658	5,499	17,923	6,255	9,640	9,750	9,750	35,395
SG&A	2,284	2,234	2,304	2,242	9,064	2,760	2,904	3,250	3,250	12,164
Total op. exp.	6,435	5,849	6,962	7,741	26,987	9,015	12,544	13,000	13,000	47,559
Inc (loss) from Ops	(6,435)	(5,849)	(6,962)	(7,741)	(26,987)	(9,015)	(12,544)	(13,000)	(13,000)	(47,559)
Int inc (exp), net	(81)	28	56	75	78	(35)	440	50	50	505
Other income (exp)	(26)	(110)	(130)	(138)	(404)	(123)	(333)	(100)	(100)	(656)
Inc (loss) before taxes	(6,542)	(5,931)	(7,036)	(7,804)	(27,313)	(9,173)	(12,437)	(13,050)	(13,050)	(47,710)
Income tax exp (benefit)										
Net Income (Loss)	(6,542)	(5,931)	(7,036)	(7,804)	(27,313)	(9,173)	(12,437)	(13,050)	(13,050)	(47,710)
Earning per Share (EPS)	(\$0.86)	(\$0.38)	(\$0.45)	(\$0.47)	(\$1.97)	(\$0.43)	(\$0.58)	(\$0.60)	(\$0.59)	(\$2.20)
Weighted avg. shares (000)	7,633	15,619	15,625	16,699	13,894	21,451	21,475	21,725	21,975	21,657
Fully diluted shares (000)	8,575	16,828	16,859	18,054	15,079	22,999	22,975	23,225	23,475	23,169

Source: Company reports and Laidlaw estimates

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Source::Laidlaw & Company estimates

Annual Income Statement

Flexion							
Annual income statement							
(\$000 except per share)	2014A	2015E	2016E	2017E	2018E	2019E	Comments
Revenues							
FX006 - OA pain				\$1,655	\$214,246	\$363,049	US launch late 2017
Total Revenue	\$0	\$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	17,923	35,395	38,000	40,750	44,750	40,000	
G&A	9,064	12,164	14,750	16,750	42,000	82,750	Self-launch FX006 in US
Total op exp	26,987	47,559	52,750	57,500	86,750	122,750	
Inc/(loss) from Ops	(26,987)	(47,559)	(52,750)	(56,093)	95,359	185,841	
Int income (exp), net	78	505	200	250	300	450	
Other expenses, net	(404)	(656)	(200)	(200)	(200)	(199)	
Inc/(loss) before taxes	(27,313)	(47,710)	(52,750)	(56,043)	95,459	186,092	
Income tax exp (benefit)	-	-	-	-	-	27,914	Sig. tax loss carryforwards
Net Income (Loss)	(\$27,313)	(\$47,710)	(\$52,750)	(\$56,043)	\$95,459	\$158,179	
Earning per Share	(\$1.97)	(\$2.20)	(\$2.30)	(\$2.30)	\$3.30	\$5.00	
Weighted avg. shares (000)	13,894	21,657	22,905	24,405	26,905	29,405	
Fully diluted shares (000)	15,079	23,169	24,405	26,155	28,905	31,655	
Cash balance	\$151,753	\$156,840	\$106,940	\$54,247	\$154,081	\$314,409	cash into 2017

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Source: Company reports and Laidlaw estimates

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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. Codzilla could throw up a huge wake. 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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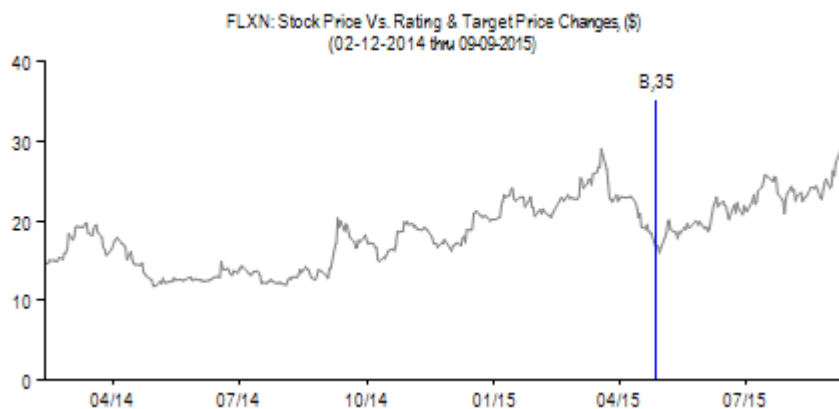
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Additional information available upon request.

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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.	77.42%	29.03%	6.45%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.23%	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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