

Flexion Therapeutics (FLXN - \$23.11)

2Q15 in-line, clinical trials progressing ahead of schedule

FLXN 2Q15 EPS was 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 1Q16. With \$127MM in cash as of 2Q15 we anticipate that FLXN is capitalized through the FDA approval for FX006 in 2017 (FDA approval anticipated 3Q17). With a target market of over 3MM steroid injections in the US annually and an additional ~1.5MM hyaluronic acid injections, we believe FX006 can reach \$340MM by 2019. We are reiterating our Buy rating, \$35 price target.

- **Clinical trials should report data ahead of expectations, now 3Q15/1Q16 data.** The key second Phase 3 pivotal trial for FX006 has completed enrollment early and top line data is now expected in 1Q16, ~1Q ahead of our expectations. We estimate a 3Q16 NDA filing (see page 2 of this report for our detailed trial timeline).
- **Manufacturing agreement with Patheon.** In July 2015, FLXN entered into a strategic manufacturing and supply agreement with Patheon creating additional supply for FX006.
- **\$30MM loan facility to finance manufacturing build.** FLXN has drawn down \$15MM under the facility from with Midcap Financial and Silicon Valley Bank and may take the remaining \$15MM if the Phase 3 FX006 data is positive.
- **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.
- **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 (08/07/2015)	\$23.11
52-Week High (03/20/2015)	\$30.37
52-Week Low (09/03/2014)	\$12.41
Market Cap. (MM)	\$496.0
Shares Out. (MM)	21.46

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

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)	2Q14A	2Q15A	2Q15E	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	3,615	9,640	8,150	1,490	167%
SG&A Expense	2,234	2,904	3,000	(96)	30%
Operating Inc (loss)	(5,849)	(12,544)	(11,150)	(1,394)	114%
Int. inc. (expense), net	28	440	50	390	1471%
Other (exp) gain, net	(110)	(333)	(100)	(233)	203%
Pretax Income (loss)	(5,931)	(12,437)	(11,200)	(1,237)	110%
Income Tax exp (benefit)	0	0	0	0	NA
Net income (loss)	(5,931)	(12,437)	(11,200)	(1,237)	110%
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)	15,619	21,475	21,701	(226)	37%
Fully diluted shares (000)	16,828	22,975	22,701	274	37%
EPS	(\$0.38)	(\$0.58)	(\$0.52)	(\$0.06)	53%

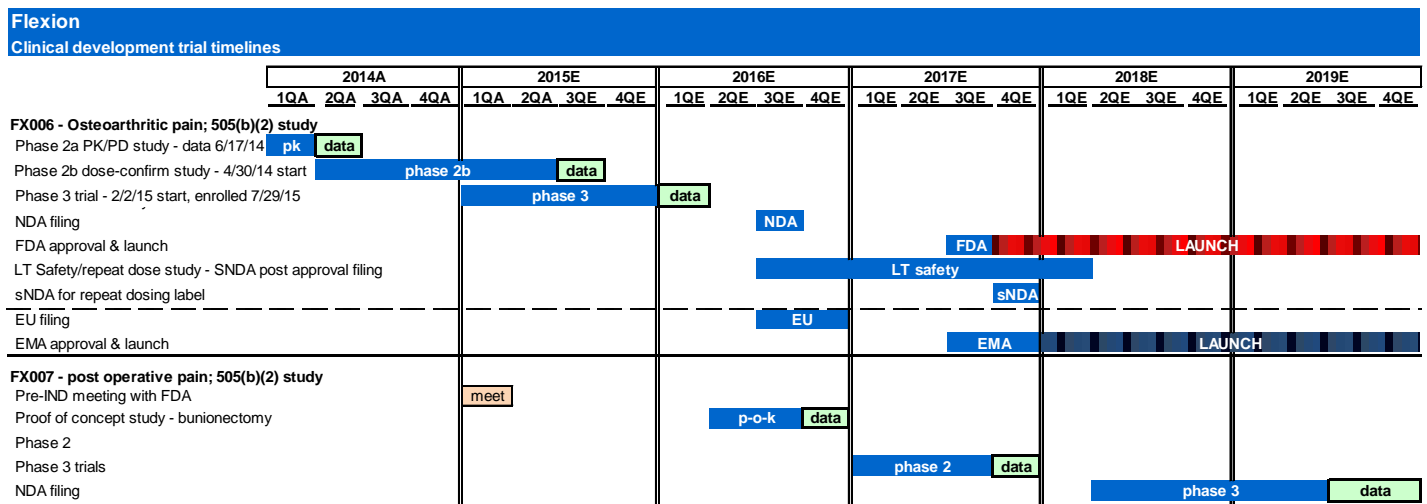
Source: Company Reports: Laidlaw & Company estimates

Figure 2. Valuation

Sum-of-the-parts value: FLXN		
Segment	Valuation (000's)	Per share value
FX006 value	\$713,621	\$30
Cash (end '16) & tech value	\$114,440	\$5
SUM	\$828,061	\$35
Shares out '15E (000)		23,169

Source: Company Reports: Laidlaw & Company estimates

Figure 3. 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	\$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	35,395	38,000	40,750	44,750	40,000	
G&A	9,064	12,164	14,750	16,750	44,000	86,000	Self-launch FX006 in US
Total op exp	26,987	47,559	52,750	57,500	88,750	126,000	
Inc/(loss) from Ops	(26,987)	(47,559)	(52,750)	(56,093)	95,421	185,937	
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)	95,521	186,188	
Income tax exp (benefit)	-	-	-	-	-	27,928	Sig. tax loss carryforwards
Net Income (Loss)	(\$27,313)	(\$47,710)	(\$52,750)	(\$56,043)	\$95,521	\$158,260	
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	\$154,143	\$314,553	cash into 2017

Source: Company reports and Laidlaw estimates

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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.

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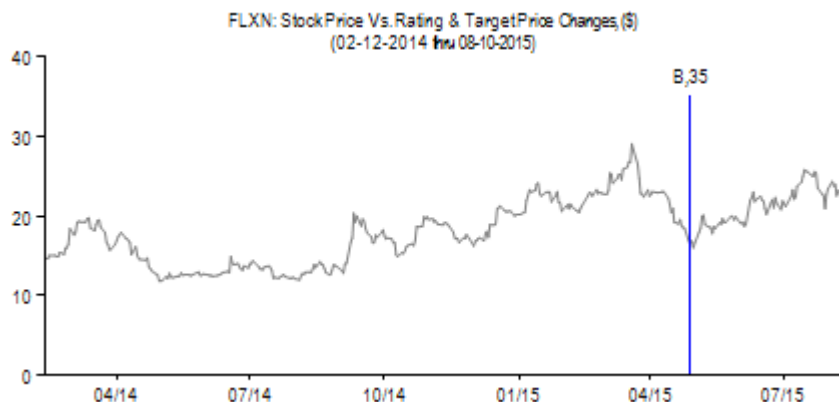
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Rating and Price Target Change History



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.	75.00%	32.14%	7.14%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.57%	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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