

Flexion Therapeutics (FLXN - \$24.39)

Healthcare / Biotechnology

KOL call highlights the pressing need for additional OA treatments like FX006

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

We recently held a Key Opinion Leader (KOL) call with a leading osteoarthritis specialist discussing the potential of FLXN's lead product FX006, a novel extended-release formulation of triamcinolone acetonide (TCA) for osteoarthritic (OA) pain. What jumped out of the call first & foremost is the dearth of options for physicians at present to effectively treat OA in the knee and the need for new options like FX006. Our KOL highlighted that should FX006 simply replicate the Phase 2b dose-ranging trial results (much less beat them) he anticipates FDA approval and widespread adoption in practice. Our KOL notes the relative ineffectiveness of hyaluronic acid (HA) therapy but that much of the HA usage is – frankly – given for the potential placebo effect since the side effect profile is so clean. We continue to anticipate positive data from the ongoing Phase 2b dose-confirmatory study in 3Q15, followed by Phase 3 data in 1Q16. We are reiterating our Buy rating, \$35 price target.

Trading Data:

Last Price (08/21/2015)	\$24.39
52-Week High (03/20/2015)	\$30.37
52-Week Low (09/03/2014)	\$12.41
Market Cap. (MM)	\$524.4
Shares Out. (MM)	21.5

- **Pressing need for additional treatments for OA.** Our KOL was very definite about the pressing need for additional treatments for OA, given the limited armamentarium physicians currently have for treating this incurable, progressive disease. Greater pain relief and persistence of effect are seen as the keys to differentiating FX006 from the IR TCA.
- **Clinical trial design should differentiate FX006.** Our KOL believes the design of the two ongoing Phase 2b and Phase 3 trials should show clear differentiation of FX006 from IR TCA, and placebo. Our KOL was positive on the published Phase 2b dose-ranging study data as well, where 40mg FX006 showed significant differentiation from IR TCA through week 10 (p=0.023). The lack of significant differentiation from IR TCA seen in weeks 11 & 12 was seen as less concerning, and likely due to an unusual persistence of effect in the IR version more than a problem with the long acting FX006 TCA.
- **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 2016) and technology at \$5/share.

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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Pain relief will drive pricing. Our KOL sees the need for a real differentiation from IR TCA in order to command premium pricing to HAs. A 20%-25% difference would be clinically relevant and allow for premium pricing.

Off label usage a real possibility as well. While we expect that FLXN will market to their label, physicians are of course free to prescribe as they see fit. Our KOL believes that there's a real possibility for off-label usage in shoulder or other joint OA if approved for OA of the knee.

Promising other treatments remain a long way to go. The emerging cartilage building FGF-18 and BMP-7 disease modifying treatments look interesting, as current options just treat the symptoms (pain) and not the cause (cartilage degradation) of OA. It remains an open question if the MRI imaging or X-ray measurements of cartilage thickness will be an approvable endpoint at the FDA. Our KOL was less favorable on the potential for stem cell treatment or platelet rich plasma (PRP) injections for OA. There is very little clinical data to date on these treatments, and our KOL is unconvinced that these options will prove viable. That said, currently many of his patients who can afford it seek stem cell treatment ex-US, speaking to the need for additional treatment options for OA.

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.

Figure 1. Pain change from baseline in Phase 2b trial

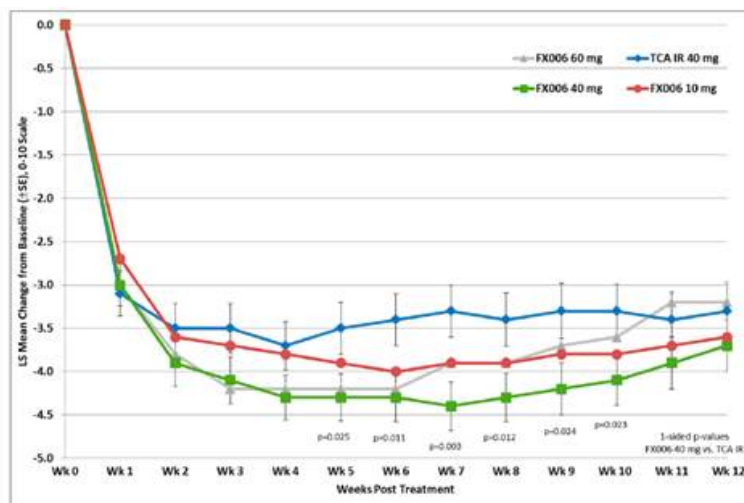


Fig. 1 Change from baseline in the weekly mean of the mean daily pain intensity scores are shown for 10, 40, and 60 mg of FX006 compared with 40 mg of immediate-release triamcinolone acetonide (TCA IR). LS = least square.

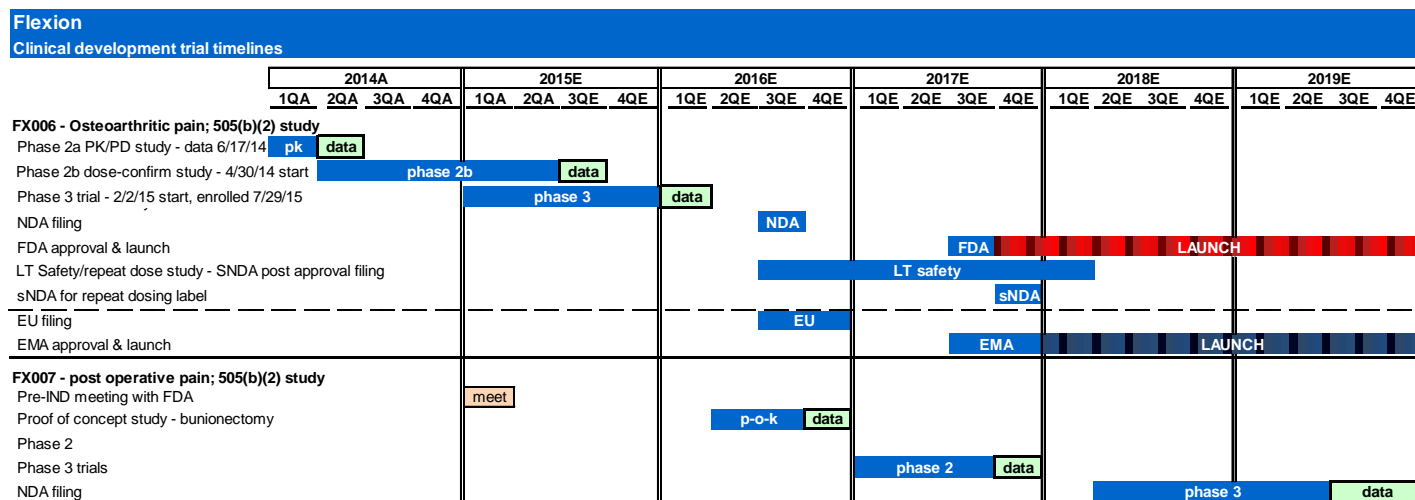
Source: The Journal of Bone and Joint Surgery

Figure 2. 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 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

Specialty Pharmaceuticals

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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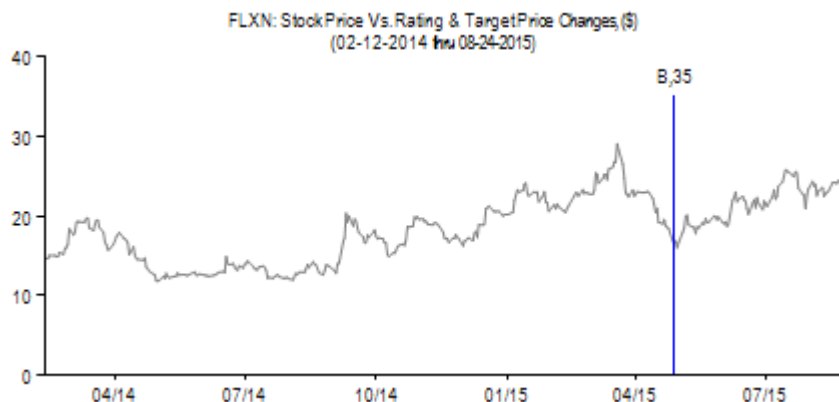
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Additional information available upon request.

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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

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			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.	75.86%	31.03%	6.90%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.45%	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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