

## Flexion Therapeutics (FLXN - \$10.95)

### OARSI presentation highlights Zilretta benefit

Yesterday FLXN highlighted their presentation from this past weekend at the Osteoarthritis Research Society International (OARSI) in Amsterdam, where they presented the most complete data set to date from their Phase 2b and Phase 3 trials. While much of the data were already known, FLXN did present an interesting sub-group analysis of the Phase 3 data for unilateral knee OA, which is pain in only one knee instead of bilateral pain in both knees. In this analysis Zilretta did show a statistically significant differentiation from placebo ( $p < 0.05$ ) and IR TCA ( $p < 0.05$ ) in not only all 3 WOMAC endpoints but also in the NRS Daily Pain score (where it missed in the overall group). This could be significant as the bilateral patients are treated in only one knee in the trial, and the continued pain in the untreated knee could be skewing the pain scores which could have been the reason Zilretta missed the NRS Daily Pain endpoint in the overall group. Much still depends on the FDA pre-NDA meeting in May, but we continue to believe that FLXN has a strong case to make to the FDA for approval on the basis of the Phase 2b and Phase 3 trial data. Maintain Buy rating and \$35 price target.

- **Unilateral OA data interesting, but not definitive.** One of the few “knocks” on the highly significant p3 data ( $p < 0.0001$ ) was that the secondary endpoint of daily pain compared to IR TCA did not show a statistically significant benefit for Zilretta. This could present challenges when counter-detailing vs. IR TCA (or commanding a premium price). The sub-group analysis presented at OARSI suggests that the bilateral results could have skewed the comparison. It is a post-hoc analysis; so not definitive but certainly interesting, and the unilateral patient population (N=170, 35% of patients) was a sizeable subset of the overall patient population. See Figure 1 on page 2 for the unilateral OA chart.
- **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

Healthcare / Biotechnology

Ticker:	FLXN
Rating:	<b>Buy</b>
Price Target:	<b>\$35.00</b>

#### Trading Data:

Last Price (04/04/2016)	\$10.95
52-Week High (09/08/2015)	\$29.09
52-Week Low (03/17/2016)	\$7.56
Market Cap. (MM)	\$236.2
Shares Out. (MM)	23.15

#### Earnings Estimates: (per share)

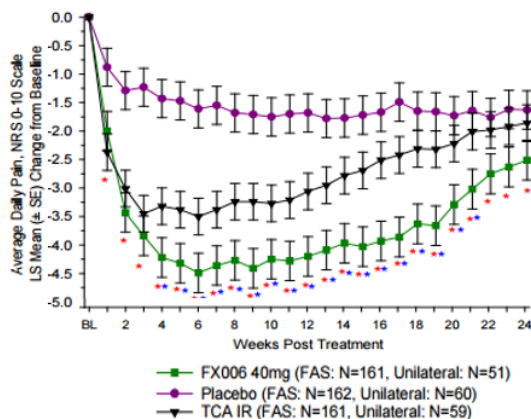
(Sep)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY17E</b>	-	-	-	-	(\$2.30)	NA
<b>FY16E</b>	(\$0.55)	(\$0.58)	(\$0.58)	(\$0.58)	(\$2.30)	NA
<b>FY15</b>	(\$0.43)	(\$0.58)	(\$0.52)	(\$0.63)	(\$2.15)	NA
<b>FY14</b>	(\$0.86)	(\$0.38)	(\$0.45)	(\$0.47)	(\$1.97)	NA

#### Analyst

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Figure 1: Unilateral Knee Daily Pain Relief



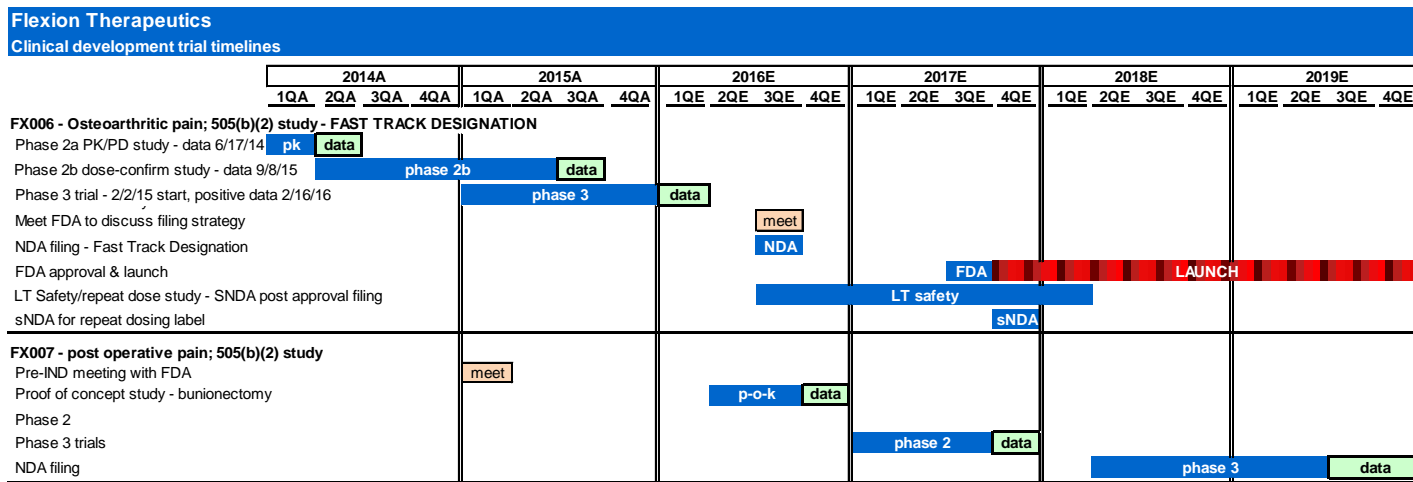
Source: Company Reports

Figure 2: Valuation

Sum-of-the-parts value: FLXN		
Segment	Valuation (000's)	Per share value
FX006 value	\$729,506	\$30
Cash (end '16) & tech value	\$116,835	\$5
<b>SUM</b>	<b>\$846,341</b>	<b>\$35</b>
Shares out '16E (000)		24,437

Source: Company Reports; Laidlaw & Company estimates

Figure 3: Upcoming clinical trial timelines



Source: Company reports and Laidlaw estimates

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## Quarterly Income Statement

<b>Flexion Therapeutics</b>										
<b>Quarterly income statement</b>										
(\$000 except per share)	2014A				2014A Year	2015A				2015A Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QA	
<b>Revenues</b>										
<b>Total Revenue</b>										
<b>Expenses:</b>										
Cost of Revenue (COGS)						-	-	-	-	-
<b>Gross Margin</b>	-	-	-	-	-	-	-	-	-	-
R&D	4,151	3,615	4,658	5,499	17,923	6,255	9,640	7,829	8,967	32,691
SG&A	2,284	2,234	2,304	2,242	9,064	2,760	2,904	3,197	4,511	13,372
Total op. exp.	6,435	5,849	6,962	7,741	26,987	9,015	12,544	11,026	13,478	46,063
<b>Inc (loss) from Ops</b>	<b>(6,435)</b>	<b>(5,849)</b>	<b>(6,962)</b>	<b>(7,741)</b>	<b>(26,987)</b>	<b>(9,015)</b>	<b>(12,544)</b>	<b>(11,026)</b>	<b>(13,478)</b>	<b>(46,063)</b>
Int inc (exp), net	(81)	28	56	75	78	(35)	440	71	199	675
Other income (exp)	(26)	(110)	(130)	(138)	(404)	(123)	(333)	(182)	(289)	(927)
<b>Inc (loss) before taxes</b>	<b>(6,542)</b>	<b>(5,931)</b>	<b>(7,036)</b>	<b>(7,804)</b>	<b>(27,313)</b>	<b>(9,173)</b>	<b>(12,437)</b>	<b>(11,136)</b>	<b>(13,569)</b>	<b>(46,315)</b>
Income tax exp (benefit)										
<b>Net Income (Loss)</b>	<b>(6,542)</b>	<b>(5,931)</b>	<b>(7,036)</b>	<b>(7,804)</b>	<b>(27,313)</b>	<b>(9,173)</b>	<b>(12,437)</b>	<b>(11,136)</b>	<b>(13,569)</b>	<b>(46,315)</b>
<b>Earning per Share (EPS)</b>										
Weighted avg. shares (000)	7,633	15,619	15,625	16,699	13,894	21,451	21,475	21,507	21,555	21,497
Fully diluted shares (000)	8,575	16,828	16,859	18,054	15,079	22,999	23,145	23,223	23,305	23,168

Source: Laidlaw &amp; Company estimates

## Annual Income Statement

Flexion Therapeutics  
Annual income statement

(\$000 except per share)	2014A	2015A	2016E	2017E	2018E	2019E	Comments
<b>Revenues</b>							
FX006 - OA pain				\$1,655	\$214,246	\$363,049	US launch late 2017
<b>Total Revenue</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$1,655</b>	<b>\$214,246</b>	<b>\$363,049</b>	
<b>Expenses:</b>							
Cost of Revenue (COGS)	-	-	-	248	32,137	54,457	
<b>Gross Margin</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>1,407</b>	<b>182,109</b>	<b>308,591</b>	
R&D	17,923	32,691	38,000	40,750	44,750	40,000	
G&A	9,064	13,372	13,750	15,850	42,500	85,250	Self-launch FX006 in US
Total op exp	26,987	46,063	51,750	56,600	87,250	125,250	
<b>Inc/(loss) from Ops</b>	<b>(26,987)</b>	<b>(46,063)</b>	<b>(51,750)</b>	<b>(55,193)</b>	<b>94,859</b>	<b>183,341</b>	
Int income (exp), net	78	675	200	250	300	450	
Other expenses, net	(404)	(927)	(200)	(200)	(200)	(199)	
<b>Inc/(loss) before taxes</b>	<b>(27,313)</b>	<b>(46,315)</b>	<b>(51,750)</b>	<b>(55,143)</b>	<b>94,959</b>	<b>183,592</b>	
Income tax exp (benefit)	-	-	-	-	-	27,539	Sig. tax loss carryforwards
<b>Net Income (Loss)</b>	<b>(\$27,313)</b>	<b>(\$46,315)</b>	<b>(\$51,750)</b>	<b>(\$55,143)</b>	<b>\$94,959</b>	<b>\$156,054</b>	
<b>Earning per Share</b>	<b>(\$1.97)</b>	<b>(\$2.15)</b>	<b>(\$2.30)</b>	<b>(\$2.30)</b>	<b>\$3.30</b>	<b>\$5.00</b>	
Weighted avg. shares (000)	13,894	21,497	22,485	23,985	26,485	28,985	
Fully diluted shares (000)	15,079	23,168	24,235	26,235	28,735	31,235	
Cash balance	\$151,753	\$158,235	\$109,335	\$57,542	\$156,876	\$315,079	cash into 2017

Source: Company reports and Laidlaw estimates

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## Major Risks

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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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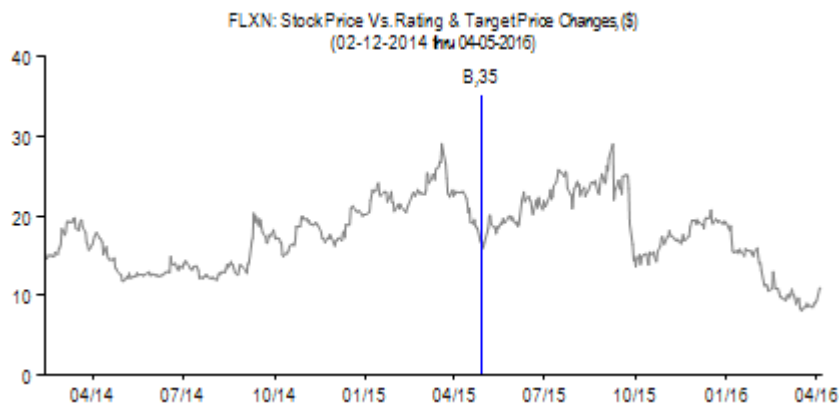
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### RATINGS INFORMATION

#### 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
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	65.71%	25.71%	2.86%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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