

## Flexion Therapeutics (FLXN - \$24.56)

### Fast Track from Left Field Helps De-Risk the Story

Last night after the close FLXN announced that the FDA has granted FX006 a Fast Track designation. This is a surprising – and positive – development for FX006 as it grants FLXN the ability to submit a rolling review, and automatically puts FX006 into consideration for both Priority Review and Accelerated Approval designation. If also granted a Priority Review FX006 could be on the market in 1H17 rather than 2H17 as we currently model. There are still many rivers to cross for FX006, we are still awaiting the Phase 2b dose confirmatory data (expected this month) and the Phase 3 data (expected 1Q16), and both of those need to look good too. But that said, it's a nice positive to have, and this is a tangible demonstration of the seriousness that the FDA places on osteoarthritis of the knee disease and the potential for FX006 to be a dramatic improvement in treating the disease.

- **Earlier approval is always a better than a delay.** While we are not changing our model at this point we note that a 1H17 approval & launch (as opposed to our current 2H17 approval & launch) could add as much as \$20M in sales for FX006 in 2017. Our model would still have FLXN generating an EPS loss in 2017, so no dramatic change, but still it would be a positive to be earlier.
- **Priority Review shows how seriously the FDA is taking knee OA.** FLXN hadn't even publicly disclosed that they were seeking Fast Track status, possibly because of the long odds (in our opinion) that FX006 would get it anyway.
- **Doctors remain anxious for any new treatments for OA too.** On our recent call our KOL was very definitive about the pressing need for additional treatments for OA, given the limited options 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.
- **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
<b>FY16E</b>	(\$0.55)	(\$0.58)	(\$0.58)	(\$0.58)	(\$2.30)	NA
<b>FY15E</b>	(\$0.43)A	(\$0.58)A	(\$0.60)	(\$0.59)	(\$2.20)	NA
<b>FY14</b>	(\$0.86)	(\$0.38)	(\$0.45)	(\$0.47)	(\$1.97)	NA
<b>FY13</b>	(\$6.13)	(\$6.13)	(\$6.12)	(\$4.65)	(\$23.02)	NA

Healthcare / Biotechnology

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

#### Trading Data:

Last Price (08/21/2015)	\$24.56
52-Week High (03/20/2015)	\$30.37
52-Week Low (09/03/2014)	\$12.41
Market Cap. (MM)	\$528.1
Shares Out. (MM)	21.5

#### Analyst

Jim Molloy Specialty Pharma & Biotechnology  
(617) 283-5521  
jmolloy@laidlawltd.com

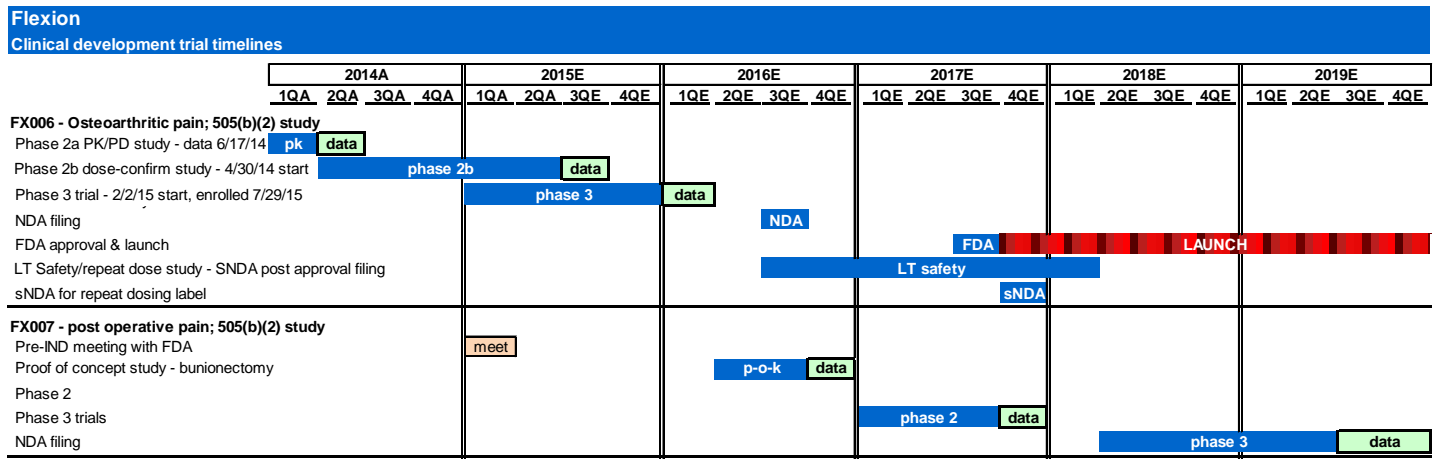
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Figure 1. Valuation

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
<b>SUM</b>	<b>\$840,080</b>	<b>\$35</b>
Shares out '16E (000)		24,405

Source: Company Reports; Laidlaw & Company estimates

Figure 2. Upcoming clinical trial timelines



Source: Company reports and Laidlaw estimates

Specialty Pharmaceuticals  
Jim Molloy (857) 317-5061 jmolloy@laidlawltd.com

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	
<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	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
<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>(13,000)</b>	<b>(13,000)</b>	<b>(47,559)</b>
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)
<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>(13,050)</b>	<b>(13,050)</b>	<b>(47,710)</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>(13,050)</b>	<b>(13,050)</b>	<b>(47,710)</b>
<b>Earning per Share (EPS)</b>	<b>(\$0.86)</b>	<b>(\$0.38)</b>	<b>(\$0.45)</b>	<b>(\$0.47)</b>	<b>(\$1.97)</b>	<b>(\$0.43)</b>	<b>(\$0.58)</b>	<b>(\$0.60)</b>	<b>(\$0.59)</b>	<b>(\$2.20)</b>
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

Specialty Pharmaceuticals  
Jim Molloy (857) 317-5061 jmolloy@laidlawltd.com

Source::Laidlaw &amp; Company estimates

## Annual Income Statement

Flexion							
Annual income statement							
(\$000 except per share)	2014A	2015E	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	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	
<b>Inc/(loss) from Ops</b>	<b>(26,987)</b>	<b>(47,559)</b>	<b>(52,750)</b>	<b>(56,093)</b>	<b>95,359</b>	<b>185,841</b>	
Int income (exp), net	78	505	200	250	300	450	
Other expenses, net	(404)	(656)	(200)	(200)	(200)	(199)	
<b>Inc/(loss) before taxes</b>	<b>(27,313)</b>	<b>(47,710)</b>	<b>(52,750)</b>	<b>(56,043)</b>	<b>95,459</b>	<b>186,092</b>	
Income tax exp (benefit)	-	-	-	-	-	27,914	Sig. tax loss carryforwards
<b>Net Income (Loss)</b>	<b>(\$27,313)</b>	<b>(\$47,710)</b>	<b>(\$52,750)</b>	<b>(\$56,043)</b>	<b>\$95,459</b>	<b>\$158,179</b>	
<b>Earning per Share</b>	<b>(\$1.97)</b>	<b>(\$2.20)</b>	<b>(\$2.30)</b>	<b>(\$2.30)</b>	<b>\$3.30</b>	<b>\$5.00</b>	
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

Source: Company reports and Laidlaw estimates

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Source: Company reports and Laidlaw estimates.

## 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. 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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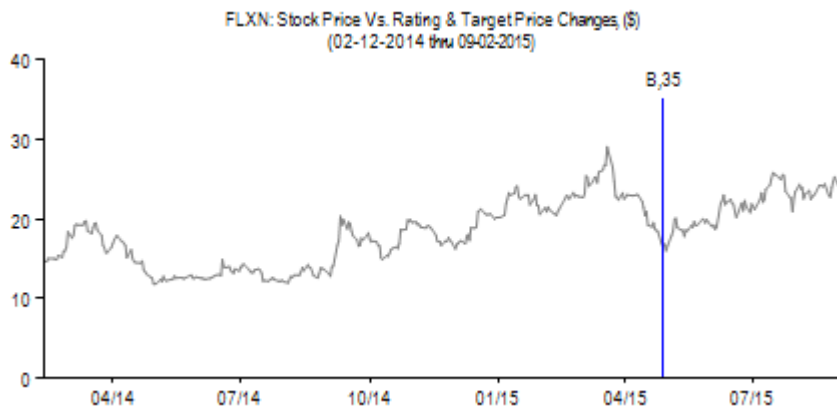
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#### Additional information available upon request.

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