

Flexion Therapeutics (FLXN - \$25.81)

Healthcare / Biotechnology

Zilretta 10/6/17 PDUFA Approaching Very Quickly

We recently spent time with FLXN's senior management and come away incrementally more positive as we continue to believe Zilretta's PDUFA on 10/6/17 should have a positive outcome. We were especially encouraged by the extensive preparation work FLXN has done on a commercial front. As FLXN intends to hire all ~103 sales reps (contingent on PDUFA for optimal talent) at once, we have increased our SG&A expense estimates. In terms of launch expectations, we see 2018 as a foundational year and have consequently pulled back on topline revenue from \$54.6M to \$34.1M. Small company single product launches are always challenging and our more conservative early adoption outlook comes as a result of certain factors such as miscellaneous J-Code, feedback from the perspective of payments and patients as well as the slight learning curve related to reconstitution and refrigeration of the product. Due to the large market and the efficacy profile of Zilretta, we continue to feel confident in our sales of \$518M in 2021. We see the HA market getting pressured (Anthem to drop coverage) and the opioid epidemic as significant tailwinds that could help Zilretta. Regardless of pricing advantage of IR steroid vs. Zilretta, we continue to believe Zilretta's significantly greater WOMAC A, B and C scores, as well as the lack of hyperglycemia commonly seen in diabetic patients (~20% of OA patients) should encourage physicians to use Zilretta as first line therapy. While we don't expect sales reps to add much to their bag in the first couple years, FLXN reiterated their intent to in-license assets in the near term to complement their recently announced FX-101 product, which has shown 2X Zilretta's extended release profile in pre-clinical trials. FLXN is well-funded to launch Zilretta and has taken every precautionary step to be successful. We reiterate our Buy rating and \$35 price target.

- **Zilretta PDUFA, only 1 week away.** With PDUFA on 10/6/17, we continue to expect a positive outcome for Zilretta due to its strong filing package.
- **Commercial preparations, all boxes checked.** While single product launches are challenging, we believe FLXN's team is adequately experienced and equipped to be successful.
- **Maintain BUY rating, \$35 price target.** Our \$35 price target is based on a sum-of-the-parts analysis, with Zilretta valued at \$29/share and cash (end '18) and technology at \$6/share.

Ticker:	FLXN
Rating:	Buy
Price Target:	\$35

Trading Data:

Last Price (09/22/2017)	\$25.81
52-Week High (03/27/2017)	\$29.41
52-Week Low (11/08/2016)	\$15.93
Market Cap. (MM)	\$823.5
Shares Out. (MM)	31.9

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY18E	NA	NA	NA	NA	(\$2.78)	NA
FY17E	(0.75)A	(0.91)A	(0.67)	(0.87)	(\$3.20)	NA
FY16A	(\$0.64)	(\$0.63)	(\$0.65)	(\$0.89)	(\$2.84)	NA
FY15A	(\$0.43)	(\$0.58)	(\$0.52)	(\$0.63)	(\$2.15)	NA

Analyst

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Source: Company data and Laidlaw & Company estimates

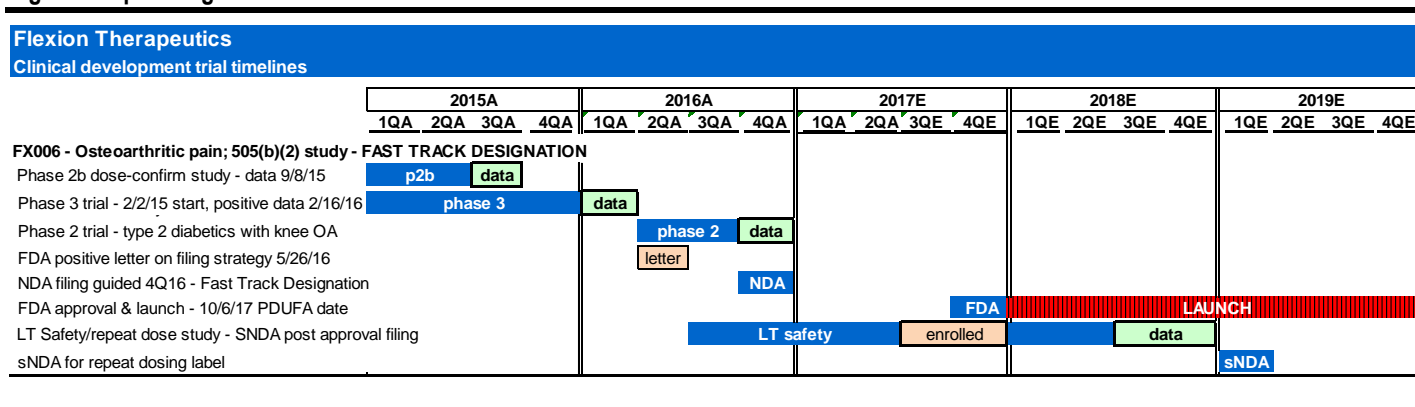
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Figure 1: Valuation

Sum-of-the-parts value		
Segment	Valuation (000's)	Per share value
FX006 value	\$1,068,917	\$29
Cash (end '18) & tech value	\$213,134	\$6
SUM	\$1,282,051	\$35
Shares out '18E (000)		37,046

Source: Company Reports: Laidlaw & Company estimates

Figure 2: Upcoming clinical trial timelines



Source: Company Reports: Laidlaw & Company estimates

Figure 3: Quarterly Income Statement

Flexion Therapeutics										
Quarterly income statement										
(\$000 except per share)	2016A				2016A Year	2017E				2017E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QE	4QE	
Revenues										
Total Revenue										
Expenses:										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
Gross Margin	-	-	-	-	-	-	-	-	-	-
R&D	8,981	8,905	9,047	14,381	41,314	10,756	11,769	11,250	10,000	43,775
SG&A	4,692	5,215	8,388	10,171	28,466	13,026	15,133	10,000	17,650	55,809
Total op. exp.	13,673	14,120	17,435	24,552	69,780	23,782	26,902	21,250	27,650	99,584
Inc (loss) from Ops	(13,673)	(14,120)	(17,435)	(24,552)	(69,780)	(23,782)	(26,902)	(21,250)	(27,650)	(99,584)
Int inc (exp), net	60	93	(140)	(239)	(226)	(75)	(2,090)	50	(500)	(2,615)
Other income (exp)	(202)	(158)	(207)	(1,320)	(1,887)	(22)	112	(200)	(200)	(310)
Inc (loss) before taxes	(13,815)	(14,185)	(17,782)	(26,111)	(71,893)	(23,879)	(28,880)	(21,400)	(28,350)	(102,509)
Income tax exp (benefit)										
NI as reported	(13,815)	(14,185)	(17,782)	(26,111)	(71,893)	(23,879)	(28,880)	(21,400)	(28,350)	(102,509)
EPS as reported	(\$0.64)	(\$0.63)	(\$0.65)	(\$0.89)	(\$2.84)	(\$0.75)	(\$0.91)			
Adj-NI ex-1x items	(\$0.78)	(\$0.63)	(\$0.65)	(\$0.89)	(\$2.96)	(\$0.75)	(\$0.91)	(\$0.67)	(\$0.87)	(\$3.20)
Weighted avg. shares (000)	21,570	22,666	27,524	29,424	25,296	31,704	31,826	32,126	32,526	32,046
Fully diluted shares (000)	23,948	25,102	30,073	32,024	27,787	34,204	34,326	34,626	35,026	34,546

Source: Company Reports: Laidlaw & Company estimates

Figure 4: Annual Income Statement

Flexion Therapeutics						
Annual income statement						
(\$000 except per share)	2015A	2016A	2017E	2018E	2019E	2020E
Revenues						
Zilretta - OA pain				\$34,098	\$103,256	\$223,343
Total Revenue	\$0	\$0	\$0	\$34,098	\$103,256	\$223,343
Expenses:						
Cost of Revenue (COGS)	-	-	-	5,115	10,326	20,101
Gross Margin	-	-	-	28,983	92,931	203,242
R&D	32,691	41,314	43,775	52,000	49,000	47,500
G&A	13,372	28,466	55,809	70,600	75,600	87,100
Total op exp	46,063	69,780	99,584	122,600	124,600	134,600
Inc/(loss) from Ops	(46,063)	(69,780)	(99,584)	(93,617)	(31,669)	68,642
Int income (exp), net	675	(226)	(2,615)	(1,250)	(1,500)	(1,500)
Other expenses, net	(927)	(1,887)	(310)	(1,000)	(1,000)	(1,000)
Inc/(loss) before taxes	(46,315)	(71,893)	(102,509)	(95,867)	(34,169)	66,142
Income tax exp (benefit)	-	-	-	-	(5,125)	9,921
NI as reported	(\$46,315)	(\$71,893)	(\$102,509)	(\$95,867)	(\$29,044)	\$56,221
EPS as reported	(\$2.15)	(\$2.84)				
Adj-EPS ex-1X items		(\$2.96)	(\$3.20)	(\$2.78)	(\$0.83)	\$1.48
Weighted avg. shares (000)	21,497	25,296	32,046	34,546	35,046	35,546
Fully diluted shares (000)	23,152	27,787	34,546	37,046	37,546	38,046

Source: Company Reports: Laidlaw & Company 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. 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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Additional information available upon request.

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Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price (\$)
04/28/2...	Buy (B)	16.87

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
04/28/2...	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.	64.58%	31.25%	2.08%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.17%	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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Anthem Inc. (ANTM – Not Rated)

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