

## Flexion Therapeutics (FLXN - \$21.23)

### With 10/6/17 Zilretta PDUFA Around the Corner, Launch Preparations Well Underway

Yesterday, FLXN hosted an investor/analyst day in NYC during which data, launch preparations as well as pipeline expansion were discussed extensively. From a clinical perspective, we were encouraged by the first KOL's conviction in Zilretta's superior and differentiated profile. He emphasized the current unmet medical need (early onset and duration) and the clinical relevance of Zilretta's statistically significant WOMAC scores A (pain), B (stiffness) and C (physical function) as well as KOOS quality of life improvements vs. both placebo and TCA IR through 12 weeks. Additionally, as there are currently ~4.5M (rapidly growing market) Diabetes Mellitus (DM) patients in the US with knee OA, we see real value in Zilretta's ability to prevent blood-glucose elevations vs. TCA IR due to lower systemic exposure. In fact, the second KOL acknowledged that many of his patients are reluctant to receiving further injections due to this very reason. While FLXN is well financed, with ~\$187.5M in cash at the end of 1Q17 and another ~\$201M gross raised in a convertible senior note issued in May, we still view single product launches as challenging and believe a potential take-out could make sense. Additionally, their buy and bill model (multiple steps vs. prescription model) could add layers of complications to the launch. Finally, we are encouraged to see FLXN's pipeline grow as they announced the introduction of FX101, Fluticasone Extended Release (ER), which doubled Zilretta's extended release profile in animal studies (up to 6 months). We remain positive and reiterate our Buy rating and \$35 price target.

- **Zilretta statistically and clinically significant, launch preparations continue.** While IR TCA seems to last longer than expected and average daily pain scores (ADP) aren't always the most reliable testing tools, both KOLs emphasized Zilretta's statistically and clinically significant superiority to standard of care.
- **FLXN begins pipeline expansion with FX101, Fluticasone ER.** While very few details were shared, we see FX101 as potentially providing additional support to Zilretta sales as it may present a very attractive cost saving profile.
- **Maintain BUY rating, \$35 price target.** Our \$35 price target is based on a sum-of-the-parts analysis, with Zilretta valued at \$27/share and cash (end '17) and technology at \$8/share.

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY18E</b>	NA	NA	NA	NA	(\$2.02)	NA
<b>FY17E</b>	(0.75)A	(0.73)	(0.67)	(0.78)	(\$2.94)	NA
<b>FY16A</b>	(\$0.64)	(\$0.63)	(\$0.65)	(\$0.89)	(\$2.84)	NA
<b>FY15A</b>	(\$0.43)	(\$0.58)	(\$0.52)	(\$0.63)	(\$2.15)	NA

Healthcare / Biotechnology

Ticker:	FLXN
Rating:	<b>Buy</b>
Price Target:	<b>\$35</b>

#### Trading Data:

Last Price (07/10/2017)	\$21.23
52-Week High (03/27/2017)	\$29.41
52-Week Low (04/14/2016)	\$15.00
Market Cap. (MM)	\$677.3
Shares Out. (MM)	31.9

#### Analyst

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Source: Company data and Laidlaw & Company estimates

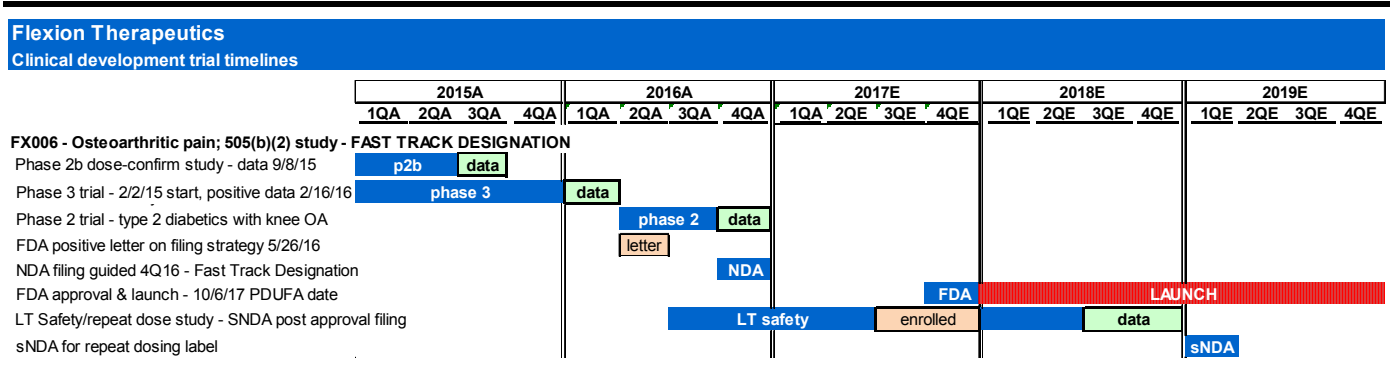
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Figure 1: Valuation

Sum-of-the-parts value		
Segment	Valuation (000's)	Per share value
FX006 value	\$926,432	\$27
Cash (end '17) & tech value	\$279,356	\$8
<b>SUM</b>	<b>\$1,205,788</b>	<b>\$35</b>
Shares out '17E (000)		32,354

Source: Company Reports; Laidlaw & Company estimates

Figure 2: Upcoming clinical trial timelines



Source: Company Reports; Laidlaw & Company estimates

## Quarterly Income Statement

Flexion Therapeutics										
Quarterly income statement										
(\$'000 except per share)	2016A				2016A Year	2017E				2017E Year
	1QA	2QA	3QA	4QA		1QA	2QE	3QE	4QE	
<b>Revenues</b>										
<b>Total Revenue</b>										
<b>Expenses:</b>										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
<b>Gross Margin</b>	-	-	-	-	-	-	-	-	-	-
R&D	8,981	8,905	9,047	14,381	41,314	10,756	12,500	11,250	10,000	44,506
SG&A	4,692	5,215	8,388	10,171	28,466	13,026	10,000	10,000	14,250	47,276
Total op. exp.	13,673	14,120	17,435	24,552	69,780	23,782	22,500	21,250	24,250	91,782
<b>Inc (loss) from Ops</b>	<b>(13,673)</b>	<b>(14,120)</b>	<b>(17,435)</b>	<b>(24,552)</b>	<b>(69,780)</b>	<b>(23,782)</b>	<b>(22,500)</b>	<b>(21,250)</b>	<b>(24,250)</b>	<b>(91,782)</b>
Int inc (exp), net	60	93	(140)	(239)	(226)	(75)	(500)	50	(500)	(1,025)
Other income (exp)	(202)	(158)	(207)	(1,320)	(1,887)	(22)	(200)	(200)	(200)	(622)
<b>Inc (loss) before taxes</b>	<b>(13,815)</b>	<b>(14,185)</b>	<b>(17,782)</b>	<b>(26,111)</b>	<b>(71,893)</b>	<b>(23,879)</b>	<b>(23,200)</b>	<b>(21,400)</b>	<b>(24,950)</b>	<b>(93,429)</b>
Income tax exp (benefit)										
<b>NI as reported</b>	<b>(13,815)</b>	<b>(14,185)</b>	<b>(17,782)</b>	<b>(26,111)</b>	<b>(71,893)</b>	<b>(23,879)</b>	<b>(23,200)</b>	<b>(21,400)</b>	<b>(24,950)</b>	<b>(93,429)</b>
<b>EPS as reported</b>	<b>(\$0.64)</b>	<b>(\$0.63)</b>	<b>(\$0.65)</b>	<b>(\$0.89)</b>	<b>(\$2.84)</b>	<b>(\$0.75)</b>	<b>(\$0.73)</b>	<b>(\$0.67)</b>	<b>(\$0.78)</b>	
<b>Adj-NI ex-1x items</b>	<b>(\$0.78)</b>	<b>(\$0.63)</b>	<b>(\$0.65)</b>	<b>(\$0.89)</b>	<b>(\$2.96)</b>	<b>(\$0.75)</b>				<b>(\$2.94)</b>
Weighted avg. shares (000)	21,570	22,666	27,524	29,424	25,296	31,704	31,704	31,704	32,104	31,804
Fully diluted shares (000)	23,948	25,102	30,073	32,024	27,787	34,204	34,204	34,204	34,604	34,304

Source: Company Reports: Laidlaw &amp; Company estimates

**Annual Income Statement****Flexion Therapeutics****Annual income statement**

(\$000 except per share)	2015A	2016A	2017E	2018E	2019E	2020E	Comments
<b>Revenues</b>							
Ziretta - OA pain				\$54,557	\$147,509	\$287,155	US launch 1H18
<b>Total Revenue</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$54,557</b>	<b>\$147,509</b>	<b>\$287,155</b>	
<b>Expenses:</b>							
Cost of Revenue (COGS)	-	-	-	8,184	14,751	25,844	
<b>Gross Margin</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>46,374</b>	<b>132,758</b>	<b>261,311</b>	
R&D	32,691	41,314	44,506	52,000	49,000	47,500	
G&A	13,372	28,466	47,276	62,000	65,500	90,500	Self-launch Ziretta in US
Total op exp	46,063	69,780	91,782	114,000	114,500	138,000	
<b>Inc/(loss) from Ops</b>	<b>(46,063)</b>	<b>(69,780)</b>	<b>(91,782)</b>	<b>(67,626)</b>	<b>18,258</b>	<b>123,311</b>	
Int income (exp), net	675	(226)	(1,025)	(1,250)	(1,500)	(1,500)	
Other expenses, net	(927)	(1,887)	(622)	(1,000)	(1,000)	(1,000)	
<b>Inc/(loss) before taxes</b>	<b>(46,315)</b>	<b>(71,893)</b>	<b>(93,429)</b>	<b>(69,876)</b>	<b>15,758</b>	<b>120,811</b>	
Income tax exp (benefit)	-	-	-	-	2,364	18,122	Sig. tax loss carryforwards
<b>NI as reported</b>	<b>(\$46,315)</b>	<b>(\$71,893)</b>	<b>(\$93,429)</b>	<b>(\$69,876)</b>	<b>\$13,394</b>	<b>\$102,690</b>	
<b>EPS as reported</b>	<b>(\$2.15)</b>	<b>(\$2.84)</b>					
<b>Adj-EPS ex-1X items</b>		<b>(\$2.96)</b>	<b>(\$2.94)</b>	<b>(\$2.02)</b>	<b>\$0.34</b>	<b>\$2.44</b>	
Weighted avg. shares (000)	21,497	25,296	31,804	34,554	37,054	39,554	
Fully diluted shares (000)	23,152	27,787	34,304	37,054	39,554	42,054	

Source: Company Reports: Laidlaw &amp; Company 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. 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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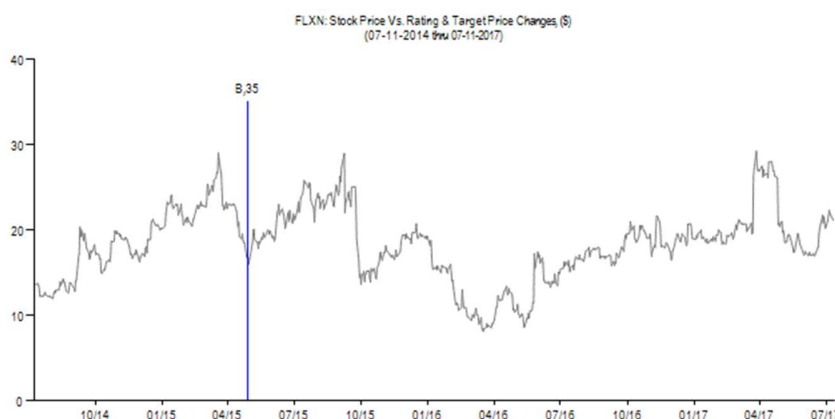
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#### Rating and Price Target Change History



#### 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
<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.	64.44%	31.11%	2.22%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	2.22%	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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