

Flexion Therapeutics (FLXN - \$22.25)

10/6/17 Zilretta PDUFA Less than 60 Days Away

FLXN reported their 2Q17 last night after the close; and while still not quite an earnings story, they missed on bottom line with (\$0.91) vs. our estimated (\$0.73) and consensus (\$0.83) due mostly to higher than anticipated SG&A expenses related to increased headcount and the approaching potential launch of Zilretta. We still like FLXN's chances of approval and are encouraged by their strong balance sheet as they reported ~\$359.9M in cash, cash equivalents and marketable securities from their recent ~\$200M convertible senior note issuance. In line with our expectations, FLXN confirmed that their Phase 3 clinical trial for safety of repeat administration of Zilretta is fully enrolled and we still anticipate data in 2H18. In addition to thorough launch preparation discussions from their recent investor/analysts day on 7/10/17, FLXN also intends to begin clinical trials for OA of the hip and shoulder by YE17 with data sometime in 2018. While we see Zilretta as potentially fulfilling an unmet medical need through its early onset and longer duration, we continue to believe a potential take-out partner could still make sense as single product launches have their fair share of obstacles. We are looking forward to the future development of their recent addition to their pipeline, FX101, which has shown a doubling of Zilretta's extended release profile in animal models. We remain positive and reiterate our \$35 price target.

- **Zilretta's PDUFA approaching very quickly, positive on approval.** With FLXN adding on two members to their executive team (General Council & Corporate Secretary and VP Marketing) launch preparations are ramping. While no guidance on revenue and sales reps only hired post-approval, many changes are to expect in the short term.
- **After knee, hip and shoulder and pipeline expansion.** Management intends to begin clinical trials of Zilretta in OA of the hip and knee by YE17 with data in 2018. We see serious potential in FX-101 as animal studies have shown 2X Zilretta's effect.
- **Maintain BUY rating, \$35 price target.** Our \$35 price target is based on a sum-of-the-parts analysis, with Zilretta valued at \$30/share and cash (end '18) and technology at \$5/share.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY18E	NA	NA	NA	NA	(\$2.02)	NA
FY17E	(0.75)	(0.91)A	(0.67)	(0.77)	(\$3.11)	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

Healthcare / Biotechnology

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

Trading Data:

Last Price (08/08/2017)	\$22.25
52-Week High (03/27/2017)	\$29.41
52-Week Low (04/14/2016)	\$15.44
Market Cap. (MM)	\$709.9
Shares Out. (MM)	31.9

Analyst

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Source: Company data and Laidlaw & Company estimates

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Figure 1: Variance Analysis

Flexion Therapeutics					
Quarterly variance analysis					
(000's except per share)	2Q16A	2Q17A	2Q17E	Variance	% Y/Y
Total Revenue	\$0	\$0	\$0	\$0	NA
COGS	0	0	0	0	NA
Gross Profit	0	0	0	0	NA
R&D Expense	8,905	11,769	12,500	(731)	32%
SG&A Expense	5,215	15,133	10,000	5,133	190%
Operating Inc (loss)	(14,120)	(26,902)	(22,500)	(4,402)	91%
Int. inc. (expense), net	93	(2,090)	(500)	(1,590)	-2347%
Other (exp) gain, net	(158)	112	(200)	312	-171%
Pretax Income (loss)	(14,185)	(28,880)	(23,200)	(5,680)	104%
Income Tax exp (benefit)	0	0	0	0	NA
NI as reported	(14,185)	(28,880)	(23,200)	(5,680)	104%
1x items & non-cash exp	0	0	0	0	NA
Adj-NI ex-1X items	(14,185)	(28,880)	(23,200)	(5,680)	NA
Weighted avg. shares (000)	22,666	31,826	31,704	122	40%
Fully diluted shares (000)	25,102	34,326	34,204	122	37%
Adj EPS ex-1x items	(\$0.63)	(\$0.91)	(\$0.73)	(\$0.18)	45%

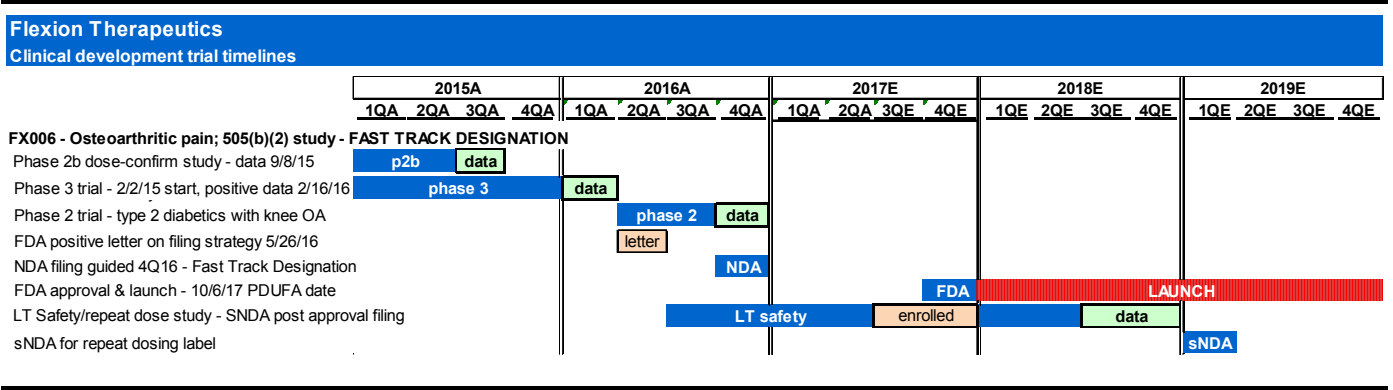
Source: Company Reports: Laidlaw & Company estimates

Figure 2: Valuation

Sum-of-the-parts value		
Segment	Valuation (000's)	Per share value
FX006 value	\$1,123,259	\$30
Cash (end '18) & tech value	\$172,774	\$5
SUM	\$1,296,033	\$35
Shares out '18E (000)		37,146

Source: Company Reports: Laidlaw & Company estimates

Figure 3: Upcoming clinical trial timelines



Source: Company Reports; Laidlaw & Company estimates

Figure 4: 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	14,250	52,409
Total op. exp.	13,673	14,120	17,435	24,552	69,780	23,782	26,902	21,250	24,250	96,184
Inc (loss) from Ops	(13,673)	(14,120)	(17,435)	(24,552)	(69,780)	(23,782)	(26,902)	(21,250)	(24,250)	(96,184)
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)	(24,950)	(99,109)
Income tax exp (benefit)										
NI as reported	(13,815)	(14,185)	(17,782)	(26,111)	(71,893)	(23,879)	(28,880)	(21,400)	(24,950)	(99,109)
EPS as reported	(\$0.64)	(\$0.63)	(\$0.65)	(\$0.89)	(\$2.84)	(\$0.75)	(\$0.91)	(\$0.67)	(\$0.77)	
Adj-NI ex-1x items	(\$0.78)	(\$0.63)	(\$0.65)	(\$0.89)	(\$2.96)	(\$0.75)	(\$0.91)			(\$3.11)
Weighted avg. shares (000)	21,570	22,666	27,524	29,424	25,296	31,704	31,826	31,826	32,226	31,896
Fully diluted shares (000)	23,948	25,102	30,073	32,024	27,787	34,204	34,326	34,326	34,726	34,396

Source: Company Reports: Laidlaw & Company estimates

Figure 5: Annual Income Statement

Flexion Therapeutics							
Annual income statement							
(\$000 except per share)	2015A	2016A	2017E	2018E	2019E	2020E	Comments
Revenues							
Zilretta - OA pain				\$54,557	\$147,509	\$287,155	US launch 1H18
Total Revenue	\$0	\$0	\$0	\$54,557	\$147,509	\$287,155	
Expenses:							
Cost of Revenue (COGS)	-	-	-	8,184	14,751	25,844	
Gross Margin	-	-	-	46,374	132,758	261,311	
R&D	32,691	41,314	43,775	52,000	49,000	47,500	
G&A	13,372	28,466	52,409	62,000	65,500	90,500	Self-launch Zilretta in US
Total op exp	46,063	69,780	96,184	114,000	114,500	138,000	
Inc/(loss) from Ops	(46,063)	(69,780)	(96,184)	(67,626)	18,258	123,311	
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)	(99,109)	(69,876)	15,758	120,811	
Income tax exp (benefit)	-	-	-	-	2,364	18,122	Sig. tax loss carryforwards
NI as reported	(\$46,315)	(\$71,893)	(\$99,109)	(\$69,876)	\$13,394	\$102,690	
EPS as reported	(\$2.15)	(\$2.84)					
Adj-EPS ex-1X items		(\$2.96)	(\$3.11)	(\$2.02)	\$0.34	\$2.44	
Weighted avg. shares (000)	21,497	25,296	31,896	34,646	37,146	39,646	
Fully diluted shares (000)	23,152	27,787	34,396	37,146	39,646	42,146	

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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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.	63.04%	30.43%	2.17%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.35%	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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