

Flexion Therapeutics (FLXN - \$19.43)

With Plenty of Cash, all Eyes on 10/6/17 Zilretta PDUFA

FLXN reported their 1Q17 last night after the close and while still not an earnings story; they came roughly in-line on bottom line with (\$0.75) vs. our estimated (\$0.74). Zilretta's PDUFA day (10/6/17) is now less than 6 months away and we still are positive on FLXN's chances of approval. FLXN has a strong cash position as they finished 1Q17 with ~\$187.5M in cash and recently (5/2/17) added ~\$201M gross through a convertible senior note expected to provide cash runway well into 2019. FLXN's IP position got stronger as they recently received two additional patents ('048 and '047) providing protection into 2031. Additionally, FLXN released data at OARSI last week. The data demonstrated clinically meaningful pain relief and functional improvement in an analysis of pooled Phase 2/3 data, as well as a Phase 2 study demonstrating prolonged synovial localization exposure of corticosteroid with Zilretta vs. traditional steroid injections. This could be especially interesting for diabetics who are susceptible to increase in blood-glucose levels with IR steroids. FLXN also indicated that they expect their repeat dose study to be fully enrolled by 2H17 followed by data read-out in 2H18, which could be useful for safety as well as real-world efficacy data. The stock has pulled back since the widespread market comments of a take-out by SNY slowed down and the convertible debt was announced, but we do think an acquisition by SNY could make sense as single-product launches are usually challenging. We still expect FLXN to add 1 or 2 assets to their pipeline by YE17 in musculoskeletal pain (OA, lower back, bursitis or post-operative pain). Reiterate Buy rating, \$35 PT.

- **Recent stock pullback with plenty of cash, we see opportunity.** As small company single-product launches can be challenging, we don't believe acquisitions are off the table and still like Zilretta's chances of approval with more encouraging data presented at OARSI.
- **Commercial efforts ramping up.** With most sales directors hired, strategic planning is intensifying at FLXN and we still project Zilretta sales of \$54M, \$147M, and \$287 M from 2018E-2020E, respectively.
- **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
FY18E	NA	NA	NA	NA	(\$2.02)	NA
FY17E	(0.75)A	(0.77)	(0.75)	(0.78)	(\$3.06)	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 (05/04/2017)	\$19.43
52-Week High (03/27/2017)	\$29.41
52-Week Low (05/13/2016)	\$8.16
Market Cap. (MM)	\$617.1
Shares Out. (MM)	31.76

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)	1Q16A	1Q17A	1Q17E	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	8,981	10,756	12,500	(1,744)	20%
SG&A Expense	4,692	13,026	9,250	3,776	178%
Operating Inc (loss)	(13,673)	(23,782)	(21,750)	(2,032)	74%
Int. inc. (expense), net	60	(75)	50	(125)	-225%
Other (exp) gain, net	(202)	(22)	(200)	178	-89%
Pretax Income (loss)	(13,815)	(23,879)	(21,900)	(1,979)	73%
Income Tax exp (benefit)	0	0	0	0	NA
NI as reported	(13,815)	(23,879)	(21,900)	(1,979)	73%
1x items & non-cash exp	3,000	0	0	0	NA
Adj-NI ex-1X items	(16,815)	(23,879)	(21,900)	(1,979)	NA
Weighted avg. shares (000)	21,570	31,704	29,754	1,950	47%
Fully diluted shares (000)	23,948	34,204	32,254	1,950	43%
Adj EPS ex-1x items	(\$0.78)	(\$0.75)	(\$0.74)	(\$0.02)	-3%

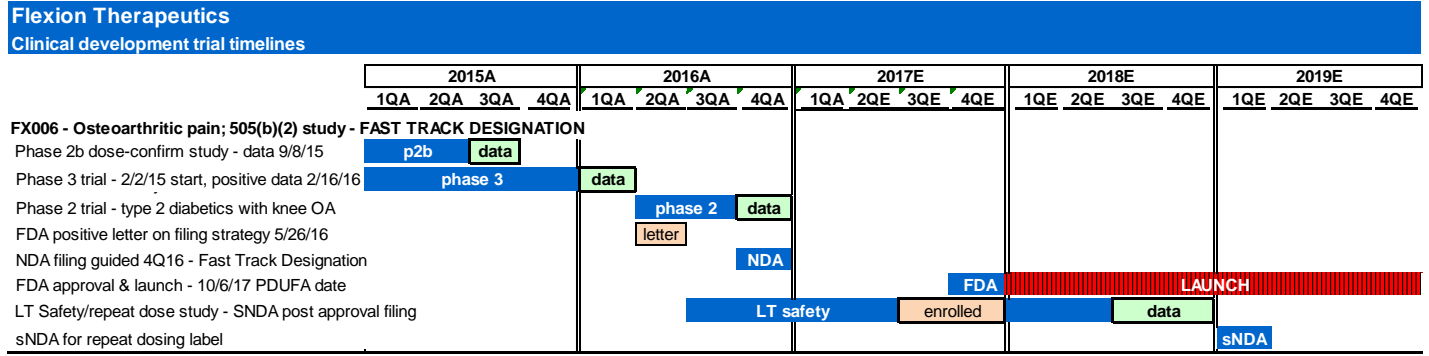
Source: Company reports; Laidlaw & Company estimates.

Figure 2: Valuation

Sum-of-the-parts value		
Segment	Valuation (000's)	Per share value
FX006 value	\$926,432	\$27
Cash (end '17) & tech value	\$275,606	\$8
	SUM \$1,202,038	\$35
Shares out '17E (000)		32,354

Source: Company Reports; Laidlaw & Company estimates

Figure 3: 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	
Revenues										
Total Revenue										
Expenses:										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
Gross Margin	-	-	-	-	-	-	-	-	-	-
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	11,250	12,500	14,250	51,026
Total op. exp.	13,673	14,120	17,435	24,552	69,780	23,782	23,750	23,750	24,250	95,532
Inc (loss) from Ops	(13,673)	(14,120)	(17,435)	(24,552)	(69,780)	(23,782)	(23,750)	(23,750)	(24,250)	(95,532)
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)
Inc (loss) before taxes	(13,815)	(14,185)	(17,782)	(26,111)	(71,893)	(23,879)	(24,450)	(23,900)	(24,950)	(97,179)
Income tax exp (benefit)										
NI as reported	(13,815)	(14,185)	(17,782)	(26,111)	(71,893)	(23,879)	(24,450)	(23,900)	(24,950)	(97,179)
EPS as reported	(\$0.64)	(\$0.63)	(\$0.65)	(\$0.89)	(\$2.84)	(\$0.75)	(\$0.77)	(\$0.75)	(\$0.78)	
Adj-NI ex-1x items	(\$0.78)	(\$0.63)	(\$0.65)	(\$0.89)	(\$2.96)	(\$0.75)				(\$3.06)
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 & Company estimates

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	44,506	52,000	49,000	47,500	
G&A	13,372	28,466	51,026	62,000	65,500	90,500	Self-launch Zilretta in US
Total op exp	46,063	69,780	95,532	114,000	114,500	138,000	
Inc/(loss) from Ops	(46,063)	(69,780)	(95,532)	(67,626)	18,258	123,311	
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)	
Inc/(loss) before taxes	(46,315)	(71,893)	(97,179)	(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)	(\$97,179)	(\$69,876)	\$13,394	\$102,690	
EPS as reported	(\$2.15)	(\$2.84)					
Adj-EPS ex-1X items		(\$2.96)	(\$3.06)	(\$2.02)	\$0.34	\$2.44	
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	
Cash balance	\$111,327	\$206,084	\$286,987	\$180,544	\$151,649	\$212,263	\$195M net convert

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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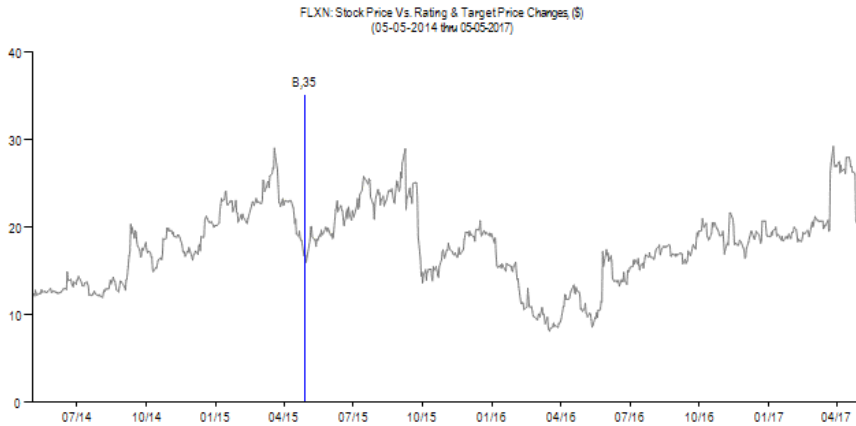
Rating and Price Target Change History

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

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	2.27%	2.27%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	61.36%	29.55%	2.27%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.27%	0.00%	0.00%

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Sanofi (SNY – Not Rated)

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