

Flexion Therapeutics (FLXN - \$20.63)

Additional Acquisitions and a Zilretta PDUFA in 2017

FLXN reported their 4Q16 last night and while still not an earnings story, they missed on bottom line with (\$0.89) vs our estimated (\$0.73) due to higher than expected R&D related to the costs associated with the clinical development program for Zilretta and for the NDA filing back in December (PDUFA date 10/6/17). With the addition of a positive Zilretta Phase 2 trial in patients with OA and type 2 diabetes (publication expected 2H17) to an already strong FDA filing package, we like FLXN's chances of approval come October. FLXN has retained their contingent sales reps (as opposed to at risk hiring prior to approval) in order to attract what they believe is the best talent. The company projects a 4Q17 launch for Zilretta (we conservatively model in 1Q18). While FLXN is primarily focused on the upcoming launch, they reiterated their intent to add shots on goal for sustainability and believe they will have 1-2 additional assets in their pipeline for either lower back pain, wound healing, or post-operative pain by 2H17. As FLXN's PDUFA quickly approaches, we still view Zilretta as a de-risked asset for FDA approval at these levels, and we reiterate our Buy rating, \$35 PT.

- **All hands on deck for Zilretta's 2017 PDUFA.** We believe Zilretta has a strong submission package for approval and are encouraged by their ongoing extensive strategic launch preparations such as key senior level executive hires. We model in sales of \$54M, \$147M, \$287M, and \$517M from 2018E-2021E, respectively.
- **Growing the pipeline a priority at FLXN.** While FLXN's main focus is centered on Zilretta commercialization efforts, management once again reaffirmed their desire to broaden their pipeline in locally acting therapies in the pain and musculoskeletal space. More specifically, they are targeting lower back pain, wound healing and post-operative pain and foresee one or two additional assets by 2H17.
- **Maintain BUY rating, \$35 price target.** Our \$35 price target is based on a sum-of-the-parts analysis, with Zilretta valued at \$34/share and cash (end '17) and technology at \$1/share.

Healthcare / Biotechnology

Ticker: FLXN
Rating: **Buy**
Price Target: **\$35.00**

Trading Data:

Last Price (03/09/2017)	\$20.63
52-Week High (11/11/2016)	\$23.57
52-Week Low (03/17/2016)	\$7.56
Market Cap. (MM)	\$642.2
Shares Out. (MM)	31.13

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY18E	NA	NA	NA	NA	(\$2.10)	NA
FY17E	(0.74)	(0.80)	(0.80)	(0.81)	(\$3.15)	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

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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)	4Q16A	4Q16E	Variance	% Y/Y	FY15A	FY16A	FY16E	Variance	% Y/Y
Total Revenue	\$0	\$0	\$0	NA	\$0	\$0	\$0	\$0	NA
COGS	0	0	0	NA	0	0	0	0	NA
Gross Profit	0	0	0	NA	0	0	0	0	NA
R&D Expense	14,381	9,750	4,631	60%	32,691	41,314	36,683	4,631	26%
SG&A Expense	10,171	10,500	(329)	125%	13,372	28,466	28,795	(329)	113%
Operating Inc (loss)	(24,552)	(20,250)	(4,302)	82%	(46,063)	(69,780)	(65,478)	(4,302)	51%
Int. inc. (expense), net	(239)	50	(289)	-220%	675	(226)	63	(289)	-133%
Other (exp) gain, net	(1,320)	(200)	(1,120)	357%	(927)	(1,887)	(767)	(1,120)	104%
Pretax Income (loss)	(26,111)	(20,400)	(5,711)	92%	(46,315)	(71,893)	(66,182)	(5,711)	55%
Income Tax exp (benefit)	0	0	0	NA	0	0	0	0	NA
Adj NI ex-1x/non cash	(26,111)	(20,400)	(5,711)	92%	(46,315)	(71,893)	(66,182)	(5,711)	55%
1x items & non-cash exp	0	0	0	NA	0	3,000	3,000	0	NA
NI as reported	0	0	0	NA	0	(74,893)	(69,182)	(5,711)	NA
Weighted avg. shares (000)	29,424	27,924	1,500	37%	21,497	25,296	24,921	375	18%
Fully diluted shares (000)	32,024	30,524	1,500	38%	23,152	27,787	27,412	375	20%
Adj EPS ex-1x items	(\$0.89)	(\$0.73)	(\$0.16)	41%	(\$2.15)	(\$2.84)	(\$2.66)	(\$0.19)	32%

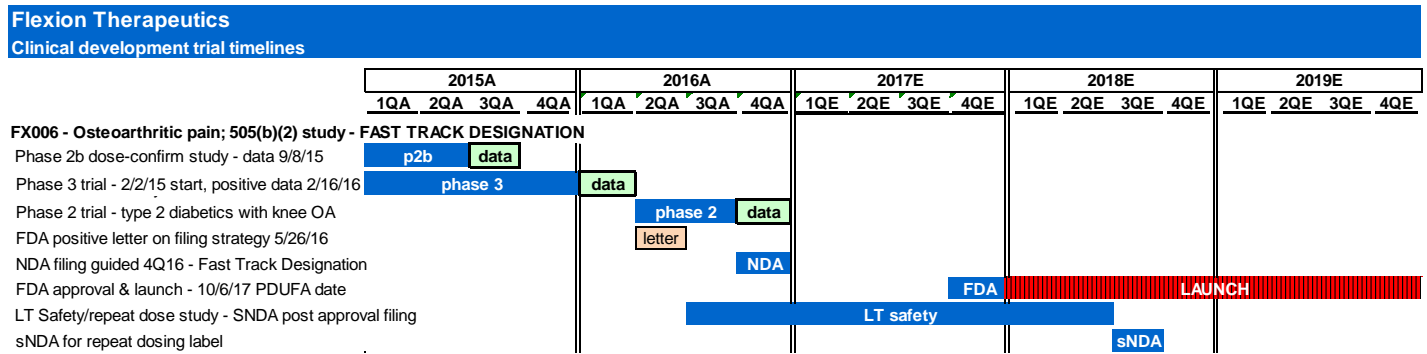
Source: Company reports; Laidlaw & Company estimates.

Figure 2: Valuation

Sum-of-the-parts value		
Segment	Valuation (000's)	Per share value
FX006 value	\$1,073,336	\$34
Cash (end '17) & tech value	\$100,990	\$1
SUM	\$1,174,327	\$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	2017E				2017E
	1QA	2QA	3QA	4QA	Year	1QE	2QE	3QE	4QE	Year
Revenues										
Total Revenue										
Expenses:										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
Gross Margin	-	-	-	-	-	-	-	-	-	-
R&D	8,981	8,905	9,047	14,381	41,314	12,500	12,500	11,250	10,000	46,250
SG&A	4,692	5,215	8,388	10,171	28,466	9,250	11,250	12,500	14,250	47,250
Total op. exp.	13,673	14,120	17,435	24,552	69,780	21,750	23,750	23,750	24,250	93,500
Inc (loss) from Ops	(13,673)	(14,120)	(17,435)	(24,552)	(69,780)	(21,750)	(23,750)	(23,750)	(24,250)	(93,500)
Int inc (exp), net	60	93	(140)	(239)	(226)	50	50	50	50	200
Other income (exp)	(202)	(158)	(207)	(1,320)	(1,887)	(200)	(200)	(200)	(200)	(800)
Inc (loss) before taxes	(13,815)	(14,185)	(17,782)	(26,111)	(71,893)	(21,900)	(23,900)	(23,900)	(24,400)	(94,100)
Income tax exp (benefit)										
Adj-NI ex-1x items	(13,815)	(14,185)	(17,782)	(26,111)	(71,893)	(21,900)	(23,900)	(23,900)	(24,400)	(94,100)
Adj EPS ex-1x items	(\$0.64)	(\$0.63)	(\$0.65)	(\$0.89)	(\$2.84)	(\$0.74)	(\$0.80)	(\$0.80)	(\$0.81)	(\$3.15)
EPS as reported	(\$0.78)				(\$2.96)					
Weighted avg. shares (000)	21,570	22,666	27,524	29,424	25,296	29,754	29,754	29,754	30,154	29,854
Fully diluted shares (000)	23,948	25,102	30,073	32,024	27,787	32,254	32,254	32,254	32,654	32,354

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	46,250	52,000	49,000	47,500	
G&A	13,372	28,466	47,250	62,000	65,500	90,500	Self-launch Zilretta in US
Total op exp	46,063	69,780	93,500	114,000	114,500	138,000	
Inc/(loss) from Ops	(46,063)	(69,780)	(93,500)	(67,626)	18,258	123,311	
Int income (exp), net	675	(226)	200	300	450	450	
Other expenses, net	(927)	(1,887)	(800)	(1,000)	(1,000)	(1,000)	
Inc/(loss) before taxes	(46,315)	(71,893)	(94,100)	(68,326)	17,708	122,761	
Income tax exp (benefit)	-	-	-	-	2,656	18,414	Sig. tax loss carryforwards
Adj-NI ex-1x items	(\$46,315)	(\$71,893)	(\$94,100)	(\$68,326)	\$15,052	\$104,347	
1x items & non-cash exp	0	3,000	0	0	0	0	
NI as reported	\$0	(\$74,893)	\$0	\$0	\$0	\$0	
Adj EPS ex-1x items	(\$2.15)	(\$2.84)	(\$3.15)	(\$2.10)	\$0.40	\$2.60	
EPS as reported		(\$2.96)					
Weighted avg. shares (000)	21,497	25,296	29,854	32,604	35,104	37,604	
Fully diluted shares (000)	23,152	27,787	32,354	35,104	37,604	40,104	
Cash balance	\$111,327	\$199,307	\$95,021	\$19,988	\$29,460	\$141,232	Fund raise 2017

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.

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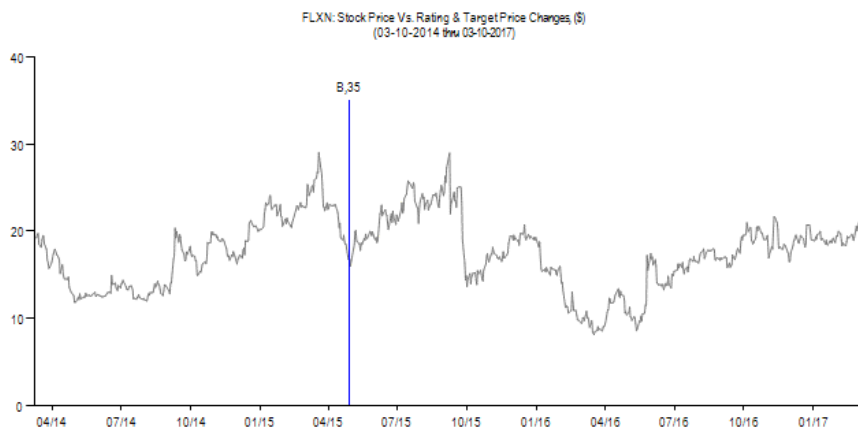
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3 Year Rating Change History

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

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	2.44%	2.44%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	60.98%	26.83%	2.44%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.44%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	4.88%	0.00%	0.00%

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