

Flexion Therapeutics (FLXN - \$18.24)

Zilretta NDA Filing Locked and Loaded for December 2016

FLXN reported their 3Q16 last night missing on bottom line with and EPS of (\$0.65) vs. our estimated (\$0.52) due to higher than anticipated SG&A related to the costs associated with building commercial infrastructure for commercialization of Zilretta. Having completed the transfer of Zilretta manufacturing technology to Patheon, management reiterated their confidence in filing an NDA this December. On top of the fact that the FDA didn't deem it necessary to meet with FLXN with the Phase 2b and 3 data in hand, we believe the recent positive data from their Zilretta Phase 2 trial in patients with OA and type 2 diabetes only strengthens FLXN's already extensive NDA filing package. Management also mentioned their continued focus on expanding their pipeline through organic growth or acquisitions with focus in the pain and musculoskeletal spaces. With several senior level executives hired in anticipation for the Zilretta launch we continue to see Zilretta as a de-risked asset at these levels, and we maintain our Buy rating and our \$35 price target.

- **Not an earnings story just yet, Zilretta NDA filing December 2016.** While FLXN missed on bottom line with EPS (\$0.65) vs. our estimated (\$0.52) because of higher than anticipated SG&A associated with commercial infrastructure building, FLXN isn't quite an earnings story as management is confident they will be filing their NDA this December. With strong Phase 2b and 3 data as well as the recent (11/1/16) diabetic OA data, we believe FLXN has a strong filing package and should receive approval in 2H17.
- **Commercial preparations underway, near-term pipeline expansion.** FLXN has hired key senior level executives in preparation for the Zilretta launch and the company is still aggressively looking to expand their somewhat thin pipeline. Of special interest are locally acting therapies that avoid systemic exposure in the pain and musculoskeletal space. A 505(b)2 pathway to market is preferred. FLXN also plans to explore expanded indications for Zilretta post knee OA approval.
- **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.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY17E	(0.67)	(0.68)	(0.67)	(0.73)	(\$2.75)	NA
FY16E	(\$0.64)A	(\$0.63)A	(\$0.65)A	(\$0.73)	(\$2.66)	NA
FY15	(\$0.43)	(\$0.58)	(\$0.52)	(\$0.63)	(\$2.15)	NA
FY14	(\$0.86)	(\$0.38)	(\$0.45)	(\$0.47)	(\$1.97)	NA

Healthcare / Biotechnology

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

Trading Data:

Last Price (11/08/2016)	\$18.24
52-Week High (12/17/2015)	\$21.71
52-Week Low (03/17/2016)	\$7.56
Market Cap. (MM)	\$502.0
Shares Out. (MM)	27.52

Analyst

Jim Molloy/Spec Pharma &
Biotech
(857) 317-5061
jmolloy@laidlawltd.com

Francois Brisebois,
MSc/Associate (857) 317-5362
fbrisebois@laidlawltd.com

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)	3Q15A	3Q16A	3Q16E	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	7,829	9,047	9,250	(203)	16%
SG&A Expense	3,197	8,388	5,250	3,138	162%
Operating Inc (loss)	(11,026)	(17,435)	(14,500)	(2,935)	58%
Int. inc. (expense), net	71	(140)	50	(190)	-296%
Other (exp) gain, net	(182)	(207)	(200)	(7)	14%
Pretax Income (loss)	(11,136)	(17,782)	(14,650)	(3,132)	60%
Income Tax exp (benefit)	0	0	0	0	NA
Adj NI ex-1x/non cash	(11,136)	(17,782)	(14,650)	(3,132)	60%
1x items & non-cash exp	0	0	0	0	NA
NI as reported	0	0	0	0	NA
Weighted avg. shares (000)	21,507	27,524	28,241	(717)	28%
Fully diluted shares (000)	23,223	30,024	30,741	(717)	29%
Adj EPS ex-1x items	(\$0.52)	(\$0.65)	(\$0.52)	(\$0.13)	25%

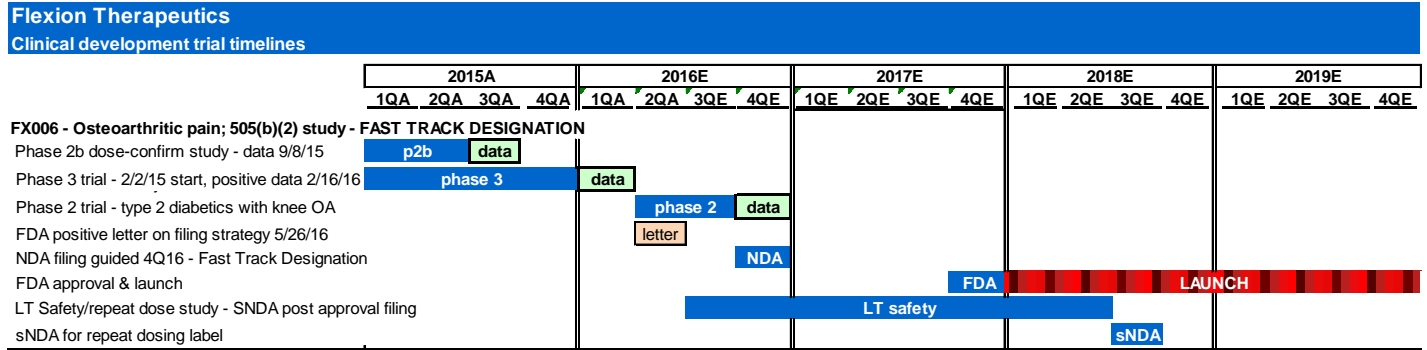
Source: Company reports; Laidlaw & Company estimates.

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	\$4,922	\$1
SUM	\$1,078,258	\$35
Shares out '17E (000)		31,354

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)	2015A				2015A Year	2016E				2016E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QE	
Revenues										
Total Revenue										
Expenses:										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
Gross Margin	-	-	-	-	-	-	-	-	-	-
R&D	6,255	9,640	7,829	8,967	32,691	8,981	8,905	9,047	9,750	36,683
SG&A	2,760	2,904	3,197	4,511	13,372	4,692	5,215	8,388	10,500	28,795
Total op. exp.	9,015	12,544	11,026	13,478	46,063	13,673	14,120	17,435	20,250	65,478
Inc (loss) from Ops	(9,015)	(12,544)	(11,026)	(13,478)	(46,063)	(13,673)	(14,120)	(17,435)	(20,250)	(65,478)
Int inc (exp), net	(35)	440	71	198.72	675	60	93	(140)	50	63
Other income (exp)	(123)	(333)	(182)	(289)	(927)	(202)	(158)	(207)	(200)	(767)
Inc (loss) before taxes	(9,173)	(12,437)	(11,136)	(13,569)	(46,315)	(13,815)	(14,185)	(17,782)	(20,400)	(66,182)
Income tax exp (benefit)										
Adj-NI ex-1x items	(9,173)	(12,437)	(11,136)	(13,569)	(46,315)	(13,815)	(14,185)	(17,782)	(20,400)	(66,182)
1x items & non-cash exp						3,000				3,000
NI as reported						(16,815)				(69,182)
Adj EPS ex-1x items	(\$0.43)	(\$0.58)	(\$0.52)	(\$0.63)	(\$2.15)	(\$0.64)	(\$0.63)	(\$0.65)	(\$0.73)	(\$2.66)
EPS as reported						(\$0.78)				(\$2.78)
Weighted avg. shares (000)	21,451	21,475	21,507	21,555	21,497	21,570	22,666	27,524	27,924	24,921
Fully diluted shares (000)	22,999	23,145	23,223	23,240	23,152	23,948	25,102	30,073	30,524	27,412

Source: Company Reports: Laidlaw & Company estimates

Annual Income Statement

Flexion Therapeutics

Annual income statement

(\$000 except per share)	2015A	2016E	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	36,683	38,750	38,500	39,000	40,000	
G&A	13,372	28,795	47,250	62,000	65,500	90,500	Self-launch Zilretta in US
Total op exp	46,063	65,478	86,000	100,500	104,500	130,500	
Inc/(loss) from Ops	(46,063)	(65,478)	(86,000)	(54,126)	28,258	130,811	
Int income (exp), net	675	63	210	300	450	450	
Other expenses, net	(927)	(767)	(800)	(1,000)	(1,000)	(1,000)	
Inc/(loss) before taxes	(46,315)	(66,182)	(86,590)	(54,826)	27,708	130,261	
Income tax exp (benefit)	-	-	-	-	4,156	19,539	Sig. tax loss carryforwards
Adj-NI ex-1x items	(\$46,315)	(\$66,182)	(\$86,590)	(\$54,826)	\$23,552	\$110,722	
1x items & non-cash exp	0	3,000	0	0	0	0	
NI as reported	\$0	(\$69,182)	\$0	\$0	\$0	\$0	
Adj EPS ex-1x items	(\$2.15)	(\$2.66)	(\$2.75)	(\$1.60)	\$0.60	\$2.65	
EPS as reported		(\$2.78)					
Weighted avg. shares (000)	21,497	24,921	31,479	34,229	36,729	39,229	
Fully diluted shares (000)	23,152	27,412	33,979	36,729	39,229	41,729	
Cash balance	\$111,327	\$95,729	\$83,553	\$22,020	\$39,991	\$158,139	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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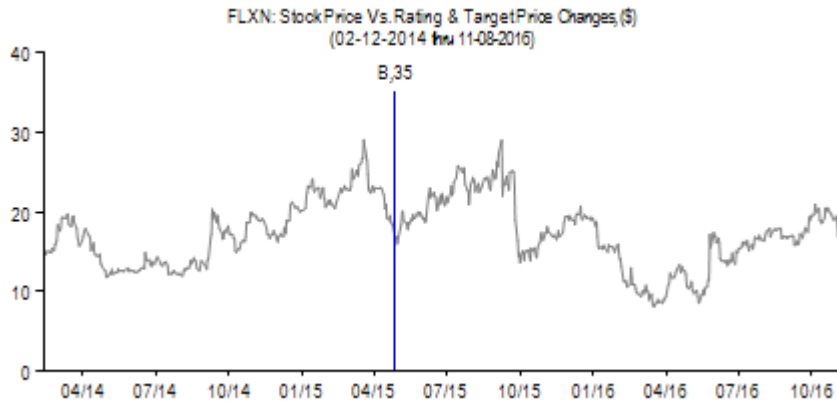
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Additional information available upon request.

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Rating and Price Target Change History



Date	Rating	Closing Price (\$)
04/28/2015	Buy (B)	16.87

Date	Target Price (\$)	Closing Price, (\$)
04/28/2015	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.	2.56%	2.56%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	58.97%	28.21%	2.56%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.13%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.56%	0.00%	0.00%

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Patheon (PTHN – Not Rated)

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