

Flexion Therapeutics (FLXN - \$15.67)

FDA deems existing data sufficient, NDA filing 4Q16

FLXN announced that they have received a written response from the FDA noting that the safety and efficacy data from the registration programs for Zilretta are acceptable for filing of an NDA submission (expected 4Q16). We view the fact that the FDA didn't deem it necessary to meet with FLXN as a strong positive, especially since the Phase 2b data was somewhat mixed (hit on almost every week except the 12 week primary endpoint). Management stated that this letter from the FDA appears to be unequivocal and the company expects to start hiring sales managers to prepare for launch, which we expect to begin 1H18. At our recent KOL dinner (see note from 05/24/2016), our KOL agreed that FLXN had a strong case to make to the FDA for filing with current data and could quickly see Zilretta used first line usage over an IR steroid. We maintain our Buy rating, \$35 PT.

- **Pre-NDA meeting, not necessary.** Although FLXN guided that they would meet with the FDA to discuss the questions the company had submitted in advance of a pre-NDA meeting, the fact that the FDA's response serves as the official meeting minutes is a testament to the strength of the Phase 2b and Phase 3 data accumulated so far.
- **Sales team hiring to commence in 3Q16.** As mentioned in their 1Q16 call, FLXN will now be able to focus on hiring sales managers to prepare for the launch that we now expect in 1H18. With ~\$98M in cash as of 1Q16, we have modelled in a \$40M raise in 2H16 to maintain launch preparations as we believe Zilretta has a very good chance of approval.
- **Maintain BUY rating, \$35 price target.** Our \$35 price target is based on a sum-of-the-parts analysis, with Zilretta valued at \$32/share and cash (end 2016) and technology at \$3/share.

Healthcare / Biotechnology

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

Trading Data:

Last Price (05/26/2016)	\$15.7
52-Week High (09/08/2015)	\$29.09
52-Week Low (03/17/2016)	\$7.56
Market Cap. (MM)	\$338.0
Shares Out. (MM)	21.57

Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
FY17E	(0.58)	(0.58)	(0.65)	(0.65)	(\$2.46)	NA
FY16E	(\$0.64)A	(\$0.64)	(\$0.57)	(\$0.57)	(\$2.40)	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

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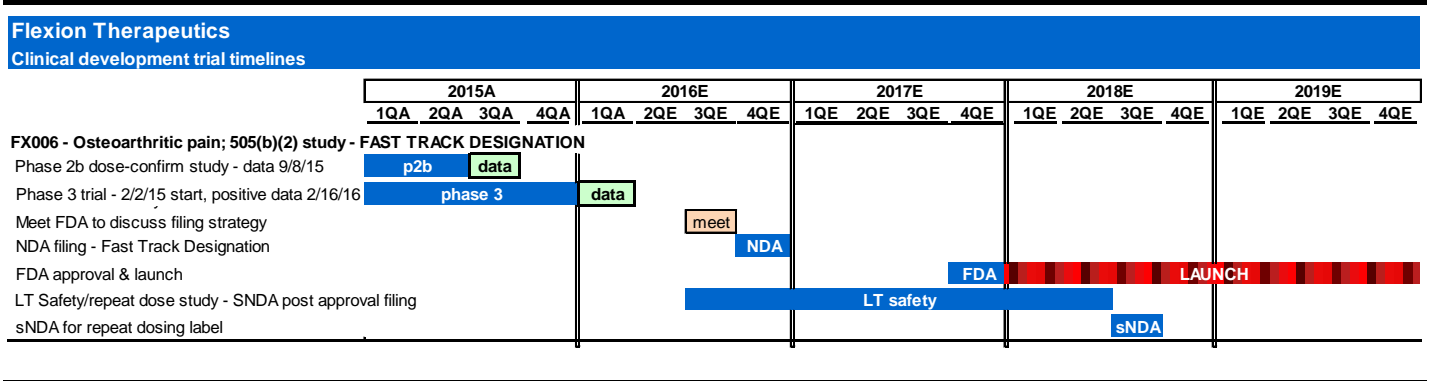
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Figure 1: Valuation

Sum-of-the-parts value: FLXN		
Segment	Valuation (000's)	Per share value
FX006 value	\$857,317	\$32
Cash (end '16) & tech value	\$80,466	\$3
SUM	\$937,783	\$35
Shares out '16E (000)		26,098

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)	2015A				2015A Year	2016E				2016E Year
	1QA	2QA	3QA	4QA		1QA	2QE	3QE	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	9,250	9,250	9,500	36,981
SG&A	2,760	2,904	3,197	4,511	13,372	4,692	4,750	5,000	5,000	19,442
Total op. exp.	9,015	12,544	11,026	13,478	46,063	13,673	14,000	14,250	14,500	56,423
Inc (loss) from Ops	(9,015)	(12,544)	(11,026)	(13,478)	(46,063)	(13,673)	(14,000)	(14,250)	(14,500)	(56,423)
Int inc (exp), net	(35)	440	71	198.72	675	60	50	50	50	210
Other income (exp)	(123)	(333)	(182)	(289)	(927)	(202)	(200)	(200)	(200)	(802)
Inc (loss) before taxes	(9,173)	(12,437)	(11,136)	(13,569)	(46,315)	(13,815)	(14,150)	(14,400)	(14,650)	(57,015)
Income tax exp (benefit)										
Adj-NI ex-1x items	(9,173)	(12,437)	(11,136)	(13,569)	(46,315)	(13,815)	(14,150)	(14,400)	(14,650)	(57,015)
Adj EPS ex-1x items	(\$0.43)	(\$0.58)	(\$0.52)	(\$0.63)	(\$2.15)	(\$0.64)	(\$0.64)	(\$0.57)	(\$0.57)	(\$2.40)
Weighted avg. shares (000)	21,451	21,475	21,507	21,555	21,497	21,570	21,970	25,470	25,870	23,720
Fully diluted shares (000)	22,999	23,145	23,223	23,240	23,152	23,948	24,348	27,848	28,248	26,098

Source: Company Reports: Laidlaw & Company estimates

Annual Income Statement

Flexion Therapeutics
 Annual income statement

(\$000 except per share)	2015A	2016E	2017E	2018E	2019E	Comments
Revenues						
Zilretta - OA pain				\$204,044	\$345,761	US launch 1H18
Total Revenue	\$0	\$0	\$0	\$204,044	\$345,761	
Expenses:						
Cost of Revenue (COGS)	-	-	-	30,607	51,864	
Gross Margin	-	-	-	173,437	293,897	
R&D	32,691	36,981	40,750	34,500	37,500	
G&A	13,372	19,442	24,200	74,750	108,750	Self-launch Zilretta in US
Total op exp	46,063	56,423	64,950	109,250	146,250	
Inc/(loss) from Ops	(46,063)	(56,423)	(64,950)	64,187	147,647	
Int income (exp), net	675	210	210	300	450	
Other expenses, net	(927)	(802)	(800)	(1,000)	(1,000)	
Inc/(loss) before taxes	(46,315)	(57,015)	(65,540)	63,487	147,097	
Income tax exp (benefit)	-	-	-	-	22,064	Sig. tax loss carryforwards
Adj-NI ex-1x items	(\$46,315)	(\$57,015)	(\$65,540)	\$63,487	\$125,032	
Adj EPS ex-1x items	(\$2.15)	(\$2.40)	(\$2.45)	\$2.00	\$3.65	
Weighted avg. shares (000)	21,497	23,720	26,800	29,300	31,800	
Fully diluted shares (000)	23,152	26,098	29,300	31,800	34,300	
Cash balance	\$111,327	\$87,015	\$14,539	\$74,569	\$197,521	Assume funding 2H16

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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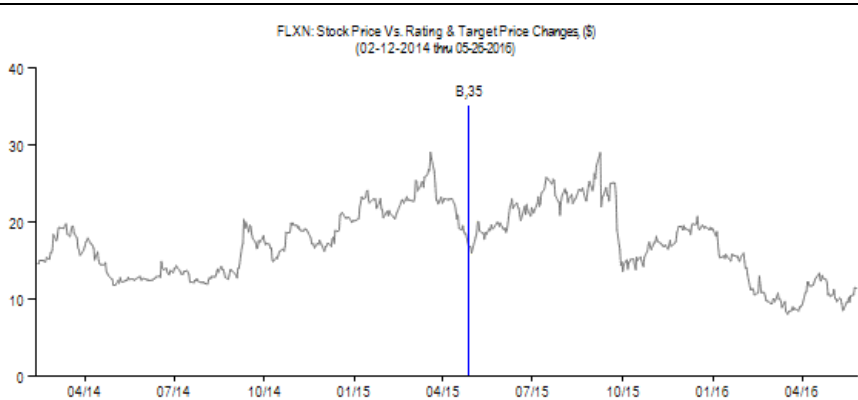
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Additional information available upon request.

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Rating and Price Target Change History



3 Year Rating Change History

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

3 Year Price Change History

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.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	66.67%	27.78%	2.78%
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.	0.00%	0.00%	0.00%

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