

Flexion Therapeutics (FLXN - \$28.24)

Zilretta Approved with Strong Label, Raising PT to \$38

FLXN recently announced the FDA approval of Zilretta making it the first and only extended-release, intra-articular injection for osteoarthritis (OA) knee pain. While the successful PDUFA was in-line with expectations, we are especially encouraged by the product's label as it includes the positive results from their blood glucose trial in patients with type 2 diabetes (~20% of OA patients). We believe this data could help Zilretta become first line therapy as blood glucose spikes can be seen with immediate-release (IR) TCA in diabetic patients. We also believe the label's inclusion of allowance for 6 weeks of room temperature storage and no post-marketing commitments are real positives for FLXN as this should benefit their commercial efforts. Additionally, FLXN has now enrolled >200 patients for their repeat-dose study and ~140 patients have already received a second dose following consultation with their physician, which we view as a testament to Zilretta's safety/efficacy profile (full data set 3Q18). In terms of label expansion, FLXN still intends to initiate hip and shoulder trials before YE17. While they recently announced the development of FX-101 (2x Zilretta's extended release profile in pre-clinical trials), FLXN is still focused on in-licensing candidates to complement their internal discovery efforts in locally applied therapies for musculoskeletal disease (low back pain, post-op pain or bursitis and tendinitis). We view Zilretta's positive PDUFA with a strong label as de-risking the story and are reiterating our BUY rating and raising our price target from \$35 to \$38.

- **Zilretta is approved with impressive label.** While Zilretta's approval was in line with expectations. We see the inclusion of the glucose data in diabetics as a real positive since they represent ~20% of the OA population.
- **Label expansion trials and in-licensing in the near future.** FLXN still expects to initiate OA trials in hip and knee by YE17 and are constantly looking to in-license new candidates to add to their organic growth.
- **Maintain BUY rating, raising price target to \$38.** Our \$38 price target is based on a sum-of-the-parts analysis, with Zilretta valued at \$32/share and cash (end '18) and technology at \$6/share.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY18E	NA	NA	NA	NA	(\$2.78)	NA
FY17E	(0.75)A	(0.91)A	(0.67)	(0.87)	(\$3.20)	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: ↑	\$38

Trading Data:

Last Price (10/09/2017)	\$28.24
52-Week High (10/06/2017)	\$32.25
52-Week Low (11/08/2016)	\$15.92
Market Cap. (MM)	\$901.0
Shares Out. (MM)	31.9

Analyst

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Source: Company data and Laidlaw & Company estimates

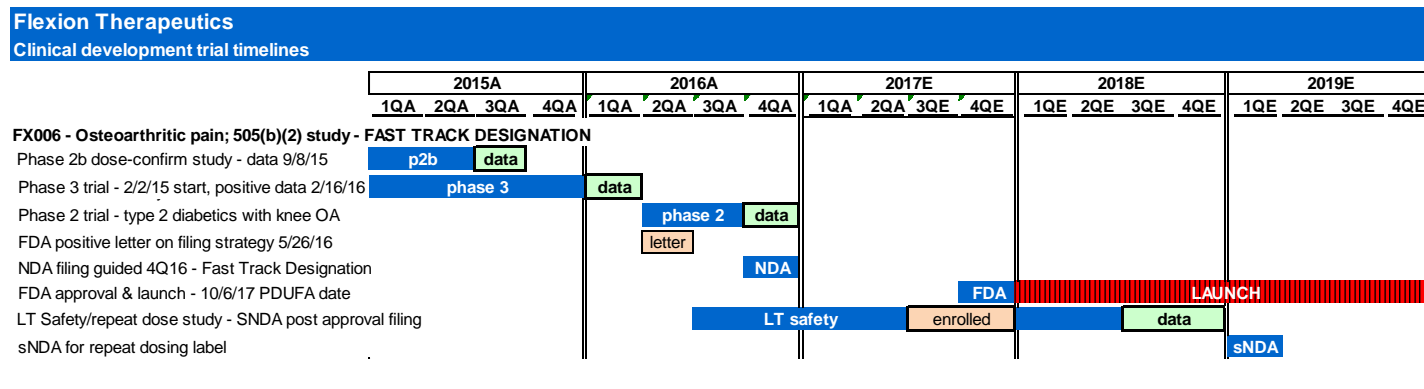
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Figure 1: Valuation

Sum-of-the-parts value		
Segment	Valuation (000's)	Per share value
FX006 value	\$1,196,493	\$32
Cash (end '18) & tech value	\$213,134	\$6
SUM	\$1,409,627	\$38
Shares out '18E (000)		37,046

Source: Company Reports: Laidlaw & Company estimates

Figure 2: Upcoming clinical trial timelines



Source: Company Reports: Laidlaw & Company estimates

Figure 3: 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	17,650	55,809
Total op. exp.	13,673	14,120	17,435	24,552	69,780	23,782	26,902	21,250	27,650	99,584
Inc (loss) from Ops	(13,673)	(14,120)	(17,435)	(24,552)	(69,780)	(23,782)	(26,902)	(21,250)	(27,650)	(99,584)
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)	(28,350)	(102,509)
Income tax exp (benefit)										
NI as reported	(13,815)	(14,185)	(17,782)	(26,111)	(71,893)	(23,879)	(28,880)	(21,400)	(28,350)	(102,509)
EPS as reported	(\$0.64)	(\$0.63)	(\$0.65)	(\$0.89)	(\$2.84)	(\$0.75)	(\$0.91)			
Adj-NI ex-1x items	(\$0.78)	(\$0.63)	(\$0.65)	(\$0.89)	(\$2.96)	(\$0.75)	(\$0.91)	(\$0.67)	(\$0.87)	(\$3.20)
Weighted avg. shares (000)	21,570	22,666	27,524	29,424	25,296	31,704	31,826	32,126	32,526	32,046
Fully diluted shares (000)	23,948	25,102	30,073	32,024	27,787	34,204	34,326	34,626	35,026	34,546

Source: Company Reports: Laidlaw & Company estimates

Figure 4: Annual Income Statement

Flexion Therapeutics							
Annual income statement							
(\$000 except per share)	2015A	2016A	2017E	2018E	2019E	2020E	Comments
Revenues							
Zilretta - OA pain				\$34,098	\$103,256	\$223,343	
Total Revenue	\$0	\$0	\$0	\$34,098	\$103,256	\$223,343	
Expenses:							
Cost of Revenue (COGS)	-	-	-	5,115	10,326	20,101	
Gross Margin	-	-	-	28,983	92,931	203,242	
R&D	32,691	41,314	43,775	52,000	49,000	47,500	
G&A	13,372	28,466	55,809	70,600	75,600	87,100	Self-launch Zilretta in US
Total op exp	46,063	69,780	99,584	122,600	124,600	134,600	
Inc/(loss) from Ops	(46,063)	(69,780)	(99,584)	(93,617)	(31,669)	68,642	
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)	(102,509)	(95,867)	(34,169)	66,142	
Income tax exp (benefit)	-	-	-	-	(5,125)	9,921	Sig. tax loss carryforwards
NI as reported	(\$46,315)	(\$71,893)	(\$102,509)	(\$95,867)	(\$29,044)	\$56,221	
EPS as reported	(\$2.15)	(\$2.84)					
Adj-EPS ex-1X items		(\$2.96)	(\$3.20)	(\$2.78)	(\$0.83)	\$1.48	
Weighted avg. shares (000)	21,497	25,296	32,046	34,546	35,046	35,546	
Fully diluted shares (000)	23,152	27,787	34,546	37,046	37,546	38,046	

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



Date	Rating	Closing Price (\$)
04/28/2...	Buy (B)	16.87

Date	Target Price (\$)	Closing Price, (\$)
04/28/2...	35.00	16.87
10/10/2...	38.00	28.24*

* Previous Close 10/9/2017

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.	64.58%	31.25%	2.08%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.17%	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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