

Flexion Therapeutics (FLXN - \$12.48)

Healthcare / Biotechnology

SHIP Study Looks Solid, Phase 3 for Hip OA Underway

FLXN recently announced that they had enrolled their first patient in their Phase 3 trial for hip OA on 12/26/18. Additionally, they announced that their Phase 2 open-label SHIP study was safe with a PK profile consistent with previous knee studies. The study showed 6X lower peak plasma and systemic exposure vs. IR TA. FLXN expects final Phase 3 (n=440) hip data readout in 2020, which could add significant value as ~25% of the US population could develop symptomatic hip OA. FLXN also plans on initiating additional Phase 2 studies in shoulder by YE19 for OA and adhesive capsulitis. With only a quarter left to report in 2018, which we continue to consider a foundation year, we were impressed with certain key metrics of their launch. For instance, as of their 3Q18 conference call, 79% of their target accounts had purchased samples and 64% of ordering accounts had re-ordered Zilretta. Additionally, FLXN's market access team had engaged with 48 key commercial insurers, which represents 75% of all commercially covered US lives. We also want to remind investors that FLXN mentioned feeling comfortable with topline consensus numbers thus far for 4Q18. With J-code effective as of 1/1/19, we are looking forward to additional guidance from the company related to 2019's topline. Although FLXN's share price has been declining, we continue to view the stock as undervalued. We believe FLXN's extensive commercial preparation should help create shareholder value. We are reiterating our Buy rating and \$38 price target.

- **Phase 2 SHIP successful, on to Phase 3 for hip OA.** With SHIP showing solid safety and PK consistent with knee OA, we see as positive FLXN's decision to move on to a placebo-controlled Phase 3 study in hip OA (~25% of US population). The first patient was enrolled on 12/26/18.
- **Only 4Q18 left to report, foundation launch year wrapping up.** With strong key metrics in their foundation year of launch, we believe their extensive commercial preparations are bearing fruit. We look forward to FLXN announcing additional topline color for 2019 in the near future.
- **Maintain BUY rating and \$38 price target.** Our \$38 price target is based on a sum-of-the-parts analysis, with Zilretta valued at \$35/share and cash (end '19) and technology at \$3/share.

Ticker: **FLXN**
Rating: **Buy**
Price Target: **\$38**

Trading Data:

Last Price (01/02/2019)/	\$12.48
52-Week High (06/20/2018)	\$29.10
52-Week Low (12/24/2018)	\$11014
Market Cap. (MM)	\$471.7
Shares Out. (MM)	37.9

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY18E	(\$1.10)A	(\$1.16)A	(\$1.15)A	(\$1.23)	(\$5.24)	NA
FY17A	(\$0.75)	(\$0.91)	(\$1.07)	(\$1.35)	(\$4.16)	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

Analyst

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

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	\$1,467,668	\$35
Cash (end '19) & tech value	\$143,767	\$3
	SUM \$1,611,436	\$38
Shares out '19E (000)		41,744

Source: Company Reports; Laidlaw & Company estimates

Figure 2: Quarterly Income Statement

Flexion Therapeutics						
Quarterly income statement						
(\$000 except per share)	2018E				2018E	2019E
	1QA	2QA	3QA	4QE	Year	Year
Revenues						
Total Revenue	\$2,194	\$3,797	\$6,990	\$8,866	\$21,847	\$103,256
Expenses:						
Cost of Revenue (COGS)	2,698	946	1,619	1,551	6,814	12,907
Gross Margin	(504)	2,851	5,371	7,314	15,032	90,349
R&D	11,551	13,094	13,578	16,000	54,223	70,000
SG&A	26,899	31,036	32,804	35,150	125,889	130,600
Total op. exp.	38,450	44,130	46,382	51,150	180,112	200,600
Inc (loss) from Ops	(38,954)	(41,279)	(41,011)	(43,836)	(165,080)	(110,251)
Int inc (exp), net	(2,758)	(2,672)	(2,773)	(2,750)	(10,953)	(10,000)
Other income (exp)	143	76	144	(100)	263	(500)
Inc (loss) before taxes	(41,569)	(43,875)	(43,640)	(46,686)	(175,770)	(120,751)
Income tax exp (benefit)						
NI as reported	(41,569)	(43,875)	(43,640)	(46,686)	(175,770)	(120,751)
EPS as reported	(\$1.10)	(\$1.16)	(\$1.15)			
Adj-NI ex-1x items	(\$1.10)	(\$1.16)	(\$1.15)	(\$1.23)	(\$5.24)	(\$3.08)
Weighted avg. shares (000)	37,620	37,697	37,818	37,938	33,568	39,244
Fully diluted shares (000)	40,120	40,197	40,318	40,438	36,068	41,744

Source: Company Reports: Laidlaw & Company estimates

Figure 3: Annual Income Statement

Flexion Therapeutics						
Annual income statement						
(\$000 except per share)	2015A	2016A	2017A	2018E	2019E	2020E
Revenues						
Zilretta - OA pain			\$355	\$21,847	\$103,256	\$223,343
Total Revenue	\$0	\$0	\$355	\$21,847	\$103,256	\$223,343
Expenses:						
Cost of Revenue (COGS)	-	-	4	6,814	12,907	22,334
Gross Margin	-	-	351	15,032	90,349	201,009
R&D	32,691	41,314	51,231	54,223	70,000	80,000
G&A	13,372	28,466	78,801	125,889	130,600	145,600
Total op exp	46,063	69,780	130,032	180,112	200,600	225,600
Inc/(loss) from Ops	(46,063)	(69,780)	(129,681)	(165,080)	(110,251)	(24,591)
Int income (exp), net	675	(226)	(7,550)	(10,953)	(10,000)	(10,000)
Other expenses, net	(927)	(1,887)	(250)	263	(500)	(500)
Inc/(loss) before taxes	(46,315)	(71,893)	(137,481)	(175,770)	(120,751)	(35,091)
Income tax exp (benefit)	-	-	-	-	-	(5,264)
NI as reported	(\$46,315)	(\$71,893)	(\$137,481)	(\$175,770)	(\$120,751)	(\$29,828)
EPS as reported	(\$2.15)	(\$2.84)				
Adj-EPS ex-1X items		(\$2.96)	(\$4.16)	(\$5.24)	(\$3.08)	(\$0.75)
Weighted avg. shares (000)	21,497	25,296	33,027	33,568	39,244	39,744
Fully diluted shares (000)	23,152	27,787	38,753	36,068	41,744	42,244

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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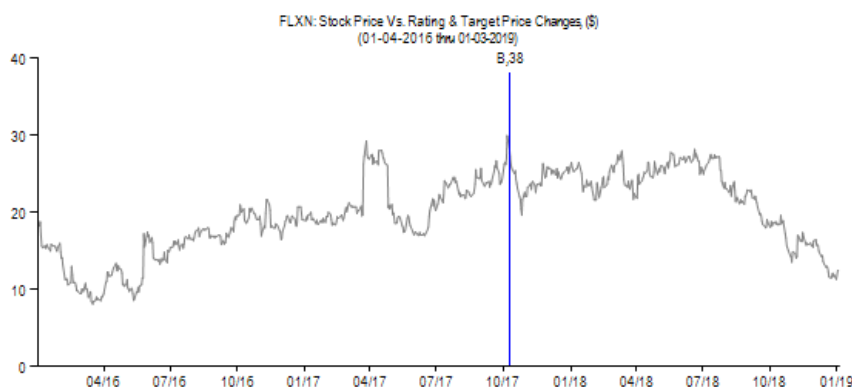
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RATINGS INFORMATION

Rating and Price Target Change History



Date	Rating	Closing Price (\$)
10/10/2017	Buy (B)	27.17

Date	Target Price (\$)	Closing Price, (\$)
10/10/2017	38.00	27.17

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.	61.67%	25.00%	3.33%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	6.67%	1.67%	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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