

Flexion Therapeutics (FLXN - \$22.82)

Healthcare / Biotechnology

Although Early, Zilretta Launch on Track

FLXN reported their 2Q18 results last night after the close, slightly missing on topline as Zilretta remains in its launch foundation year. Although, topline came in at \$3.8M vs. our anticipated \$4.1M and Street consensus of \$4.2M, we see 2018 as a foundation year. R&D expenses of 13.1M vs. our anticipated \$15M led to the slight bottom line beat of (\$1.16) vs. our estimated (\$1.22), ultimately leading to a quarter very much in-line with expectations. We were particularly encouraged that 60% of target accounts have either purchased or received samples of Zilretta, and that >55% of ordering accounts have placed reorders. FLXN's market access team has engaged with 46 key commercial insurers; a real positive as these represent 225M covered lives. Although not yet accounted for, we remind investors that a product specific Q code for Zilretta became effective on 7/1/18. This should help speed up claims processing from 30-60 days to 2-3 weeks and could improve Zilretta's odds of ultimately getting their product specific J-Code, expected as of 1/1/19. Concerning potential label expansion, we were particularly encouraged that their Phase 2 for PK of Zilretta for bilateral knee OA vs. IR TA showed peak plasma concentrations of TA of 10X less in Zilretta arm (full data 4Q18). We also look forward to full data of their Phase 3b repeat administration trial in 4Q18. Finally, FLXN also anticipates Phase 2 open-label SHIP (shoulder and hip) data in 4Q18. We are reiterating our Buy rating and \$38 PT.

- **Top and bottom line mostly in-line, launch foundation year on track.** While topline line of \$3.8M missed our estimates by \$0.295M, we consider 2Q18 very much in-line with expectations as a 73% Q/Q revenue increase is a real positive, in our opinion.
- **Q code in effect and potentially label expanding readouts before YE18.** With strong chances of J-Code becoming effective as of 1/1/19, Phase 2 full data readout in bilateral knee and SHIP readout in 4Q18, many near term catalysts could add to Zilretta's first year of launch and potential label expansion.
- **Maintain BUY rating and \$38 price target.** Our \$38 price target is based on a sum-of-the-parts analysis, with Zilretta valued at \$33/share and cash (end '18) and technology at \$5/share.

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

Trading Data:

Last Price (08/07/2018)	\$22.82
52-Week High (10/06/2017)	\$32.25
52-Week Low (10/26/2017)	\$19.06
Market Cap. (MM)	\$858.9
Shares Out. (MM)	37.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY18E	(\$1.10)A	(\$1.16)A	(\$1.01)	(\$1.02)	(\$4.52)	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

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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)	2Q17A	2Q18A	2Q18E	Variance	% Y/Y
Total Revenue	\$0	\$3,797	\$4,092	(\$295)	NA
COGS	0	946	2,000	(1,054)	NA
Gross Profit	0	2,851	2,092	759	NA
R&D Expense	11,769	13,094	15,000	(1,906)	11%
SG&A Expense	15,133	31,036	30,150	886	105%
Operating Inc (loss)	(26,902)	(41,279)	(43,058)	1,779	53%
Int. inc. (expense), net	(2,090)	(2,672)	(2,750)	78	28%
Other (exp) gain, net	112	76	(100)	176	-32%
Pretax Income (loss)	(28,880)	(43,875)	(45,908)	2,033	52%
Income Tax exp (benefit)	0	0	0	0	NA
NI as reported	(28,880)	(43,875)	(45,908)	2,033	52%
1x items & non-cash exp	0	0	0	0	NA
Adj-NI ex-1X items	(28,880)	(43,875)	(45,908)	2,033	NA
Weighted avg. shares (000)	31,826	37,697	37,770	(73)	18%
Fully diluted shares (000)	40,421	40,197	40,270	(73)	-1%
Adj EPS ex-1x items	(\$0.91)	(\$1.16)	(\$1.22)	\$0.05	28%

Source: Laidlaw and Company estimates

Figure 2: Valuation

Sum-of-the-parts value		
Segment	Valuation (000's)	Per share value
FX006 value	\$1,310,114	\$33
Cash (end '18) & tech value	\$189,173	\$5
SUM	\$1,499,286	\$38
Shares out '18E (000)		39,977

Source: Company Reports: Laidlaw & Company estimates

Figure 3: Quarterly Income Statement

Flexion Therapeutics										
Quarterly income statement										
(\$000 except per share)	2017A				2017A Year	2018E				2018E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QE	4QE	
Revenues										
Total Revenue				\$355	\$355	\$2,194	\$3,797	\$6,820	\$8,866	\$21,676
Expenses:										
Cost of Revenue (COGS)	-	-	-	4	4	2,698	946	1,000	887	\$5,531
Gross Margin	-	-	-	351	351	(504)	2,851	5,820	7,979	16,146
R&D	10,756	11,769	12,846	15,860	51,231	11,551	13,094	15,000	17,500	57,145
SG&A	13,026	15,133	18,375	32,267	78,801	26,899	31,036	30,150	30,150	118,235
Total op. exp.	23,782	26,902	31,221	48,127	130,032	38,450	44,130	45,150	47,650	175,380
Inc (loss) from Ops	(23,782)	(26,902)	(31,221)	(47,776)	(129,681)	(38,954)	(41,279)	(39,330)	(39,671)	(159,234)
Int inc (exp), net	(75)	(2,090)	(2,748)	(2,637)	(7,550)	(2,758)	(2,672)	(2,750)	(2,750)	(10,000)
Other income (exp)	(22)	112	(219)	(121)	(250)	143	76	(100)	(100)	19
Inc (loss) before taxes	(23,879)	(28,880)	(34,188)	(50,534)	(137,481)	(41,569)	(43,875)	(42,180)	(42,521)	(169,215)
Income tax exp (benefit)										
NI as reported	(23,879)	(28,880)	(34,188)	(50,534)	(137,481)	(41,569)	(43,875)	(42,180)	(42,521)	(169,215)
EPS as reported	(\$0.75)	(\$0.91)	(\$1.07)	(\$1.35)	(\$4.16)	(\$1.10)	(\$1.16)			
Adj-NI ex-1x items	(\$0.75)	(\$0.91)	(\$1.07)	(\$1.35)	(\$4.16)	(\$1.10)	(\$1.16)	(\$1.01)	(\$1.02)	(\$4.52)
Weighted avg. shares (000)	31,704	31,826	31,931	37,451	33,027	37,620	37,697	41,697	41,847	37,477
Fully diluted shares (000)	35,208	40,421	36,931	42,451	38,753	40,120	40,197	44,197	44,347	39,977

Source: Company Reports: Laidlaw & Company estimates

Figure 4: Annual Income Statement

Flexion Therapeutics						
Annual income statement						
(\$000 except per share)	2015A	2016A	2017A	2018E	2019E	2020E
Revenues						
Zilretta - OA pain			\$355	\$21,676	\$103,256	\$223,343
Total Revenue	\$0	\$0	\$355	\$21,676	\$103,256	\$223,343
Expenses:						
Cost of Revenue (COGS)	-	-	4	5,531	10,326	20,101
Gross Margin	-	-	351	16,146	92,931	203,242
R&D	32,691	41,314	51,231	57,145	80,000	90,000
G&A	13,372	28,466	78,801	118,235	130,600	145,600
Total op exp	46,063	69,780	130,032	175,380	210,600	235,600
Inc/(loss) from Ops	(46,063)	(69,780)	(129,681)	(159,234)	(117,669)	(32,358)
Int income (exp), net	675	(226)	(7,550)	(10,000)	(10,000)	(10,000)
Other expenses, net	(927)	(1,887)	(250)	19	(500)	(500)
Inc/(loss) before taxes	(46,315)	(71,893)	(137,481)	(169,215)	(128,169)	(42,858)
Income tax exp (benefit)	-	-	-	-	-	(6,429)
NI as reported	(\$46,315)	(\$71,893)	(\$137,481)	(\$169,215)	(\$128,169)	(\$36,429)
EPS as reported	(\$2.15)	(\$2.84)				
Adj-EPS ex-1X items		(\$2.96)	(\$4.16)	(\$4.52)	(\$3.17)	(\$0.89)
Weighted avg. shares (000)	21,497	25,296	33,027	37,477	40,450	40,950
Fully diluted shares (000)	23,152	27,787	38,753	39,977	42,950	43,450

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 (\$)
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.	65.45%	25.45%	3.64%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	1.82%	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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