

Flexion Therapeutics (FLXN - \$27.01)

Zilretta Off to the Races!

FLXN reported 4Q17 results last night after the close, officially marking the very first steps toward becoming an earnings story. As a reminder, FLXN's full launch of Zilretta only started on 11/20/17, a very short period of time marked by holiday seasonality. With that in mind, Zilretta sales came in at \$0.355M vs. our estimated \$0.414M and consensus of \$0.6M. We were particularly encouraged by the speed of the patient and physician feedback loop, a key component of a successful launch in our opinion. Additionally, >95% of benefits verifications processed through their physician support hub, FlexForward, have received covered determination. We believe these early reimbursement successes result from their timely (years prior to launch) hiring of Dan Deardorf, their SVP, Commercial. After FLXN reported that 95% of patients in their repeat-dose trial (readout 3Q18) achieved clinical benefit after a single treatment, they reported that 92% of eligible patients elected to get a second treatment between weeks 12 and 24. This is an encouraging trend as 90% of patients had opted for the second injection as of 1/8/18. While the company remains laser focused on launch, they also expect their Phase 2 open-label PK/safety study in OA shoulder and hip to readout in 2H18. As a reminder, there are currently ~1.5M US patients injected for hip and shoulder combined. We are reiterating our Buy rating and \$38 price target.

- **Launched on 11/20/17, already positive feedback and reimbursement.** Only 3.5 months into launch of a 3 month injectable, we are happily surprised to hear positive patient and physician feedback. We also see the positive impact of launch preparation activities such as the FlexForward program as a real positive.
- **2018 laser focus on launch, other interesting data readouts.** Although the top priority at FLXN remains the Zilretta launch, we look forward to interesting catalysts such as PK/safety of bilateral knee OA readout in 2Q18, repeat dose in 3Q18 (potentially label expanding), and shoulder and hip in 2H18.
- **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.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY18E	(\$1.25)	(\$1.21)	(\$1.06)	(\$1.01)	(\$4.76)	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

Healthcare / Biotechnology

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

Trading Data:

Last Price (11/06/2017)	\$27.01
52-Week High (10/06/2017)	\$32.25
52-Week Low (06/15/2017)	\$16.51
Market Cap. (MM)	\$1,014
Shares Out. (MM)	37.5

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)	4Q16A	4Q17A	4Q17E	Variance	% Y/Y	FY16A	FY17A	FY17E	Variance	% Y/Y
Total Revenue	\$0	\$355	\$414	(\$59)	NA	\$0	\$355	\$414	(\$59)	NA
COGS	0	4	62	(58)	NA	0	4	62	(58)	NA
Gross Profit	0	351	352	(1)	NA	0	351	352	(1)	NA
R&D Expense	14,381	15,860	15,000	860	10%	41,314	51,231	50,371	860	24%
SG&A Expense	10,171	32,267	25,150	7,117	217%	28,466	78,801	71,684	7,117	177%
Operating Inc (loss)	(24,552)	(47,776)	(39,798)	(7,978)	95%	(69,780)	(129,681)	(121,703)	(7,978)	86%
Int. inc. (expense), net	(239)	(2,637)	(500)	(2,137)	1003%	(226)	(7,550)	(5,413)	(2,137)	3241%
Other (exp) gain, net	(1,320)	(121)	(200)	79	-91%	(1,887)	(250)	(329)	79	-87%
Pretax Income (loss)	(26,111)	(50,534)	(40,498)	(10,036)	94%	(71,893)	(137,481)	(108,328)	(10,036)	91%
Income Tax exp (benefit)	0	0	0	0	NA	0	0	(19,117)	19,117	NA
NI as reported	(26,111)	(50,534)	(40,498)	(10,036)	94%	(71,893)	(137,481)	(108,328)	(29,153)	91%
1x items & non-cash exp	0	0	0	0	NA	3,000	0	0	0	NA
Adj-NI ex-1X items	(26,111)	(50,534)	(40,498)	(10,036)	NA	(74,893)	(137,481)	(108,328)	(29,153)	NA
Weighted avg. shares (000)	29,424	37,451	37,451	0	27%	25,296	33,027	33,228	(201)	31%
Fully diluted shares (000)	32,024	42,451	42,451	0	33%	27,787	38,753	38,753	0	39%
Adj EPS ex-1x items	(\$0.89)	(\$1.35)	(\$1.08)	(\$0.27)	52%	(\$2.96)	(\$4.16)	(\$3.26)	(\$0.90)	41%

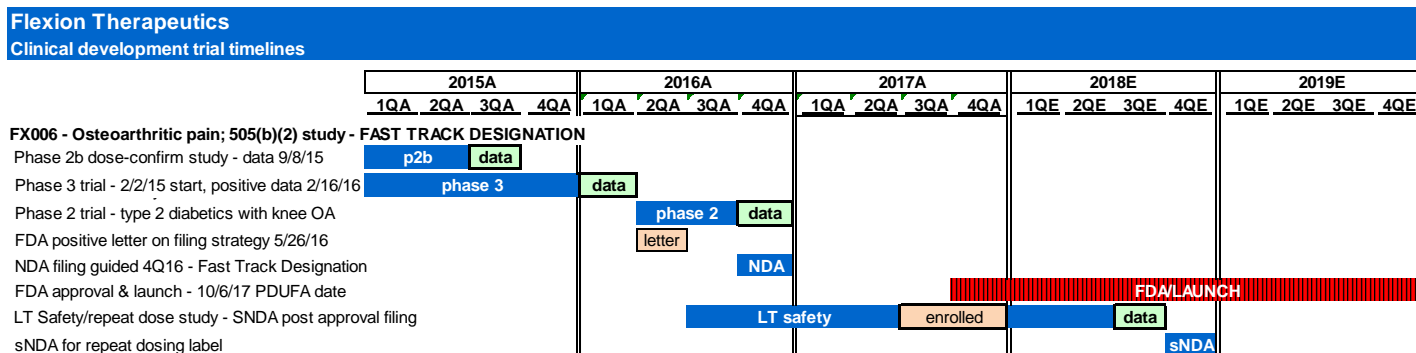
Source: Laidlaw Estimates

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	\$180,097	\$5
SUM	\$1,490,211	\$38
Shares out '18E (000)		39,977

Source: Company Reports: Laidlaw & Company estimates

Figure 3: Upcoming clinical trial timelines



Source: Company Reports; Laidlaw & Company estimates

Figure 4: Quarterly Income Statement

Flexion Therapeutics										
Quarterly income statement										
(\$000 except per share)	2016A				2016A Year	2017A				2017A Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QA	
Revenues										
Total Revenue										\$355
Expenses:										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	4	4
Gross Margin	-	-	-	-	-	-	-	-	351	351
R&D	8,981	8,905	9,047	14,381	41,314	10,756	11,769	12,846	15,860	51,231
SG&A	4,692	5,215	8,388	10,171	28,466	13,026	15,133	18,375	32,267	78,801
Total op. exp.	13,673	14,120	17,435	24,552	69,780	23,782	26,902	31,221	48,127	130,032
Inc (loss) from Ops	(13,673)	(14,120)	(17,435)	(24,552)	(69,780)	(23,782)	(26,902)	(31,221)	(47,776)	(129,681)
Int inc (exp), net	60	93	(140)	(239)	(226)	(75)	(2,090)	(2,748)	(2,637)	(7,550)
Other income (exp)	(202)	(158)	(207)	(1,320)	(1,887)	(22)	112	(219)	(121)	(250)
Inc (loss) before taxes	(13,815)	(14,185)	(17,782)	(26,111)	(71,893)	(23,879)	(28,880)	(34,188)	(50,534)	(137,481)
Income tax exp (benefit)										
NI as reported	(13,815)	(14,185)	(17,782)	(26,111)	(71,893)	(23,879)	(28,880)	(34,188)	(50,534)	(137,481)
EPS as reported	(\$0.64)	(\$0.63)	(\$0.65)	(\$0.89)	(\$2.84)	(\$0.75)	(\$0.91)	(\$1.07)	(\$1.35)	(\$4.16)
Adj-NI ex-1x items	(\$0.78)	(\$0.63)	(\$0.65)	(\$0.89)	(\$2.96)	(\$0.75)	(\$0.91)	(\$1.07)	(\$1.35)	(\$4.16)
Weighted avg. shares (000)	21,570	22,666	27,524	29,424	25,296	31,704	31,826	31,931	37,451	33,027
Fully diluted shares (000)	23,948	25,102	30,073	32,024	27,787	35,208	40,421	36,931	42,451	38,753

Source: Company Reports: Laidlaw & Company estimates

Figure 5: Annual Income Statement

Flexion Therapeutics							
Annual income statement							
(\$000 except per share)	2015A	2016A	2017A	2018E	2019E	2020E	Comments
Revenues							
Zilretta - OA pain			\$355	\$25,233	\$103,256	\$223,343	
Total Revenue	\$0	\$0	\$355	\$25,233	\$103,256	\$223,343	
Expenses:							
Cost of Revenue (COGS)	-	-	4	2,523	10,326	20,101	
Gross Margin	-	-	351	22,709	92,931	203,242	
R&D	32,691	41,314	51,231	70,000	80,000	90,000	
G&A	13,372	28,466	78,801	120,600	130,600	145,600	Self-launch Zilretta in US
Total op exp	46,063	69,780	130,032	190,600	210,600	235,600	
Inc/(loss) from Ops	(46,063)	(69,780)	(129,681)	(167,891)	(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)	(400)	(500)	(500)	
Inc/(loss) before taxes	(46,315)	(71,893)	(137,481)	(178,291)	(128,169)	(42,858)	
Income tax exp (benefit)	-	-	-	-	-	(6,429)	
NI as reported	(\$46,315)	(\$71,893)	(\$137,481)	(\$178,291)	(\$128,169)	(\$36,429)	
EPS as reported	(\$2.15)	(\$2.84)					
Adj-EPS ex-1X items		(\$2.96)	(\$4.16)	(\$4.76)	(\$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.

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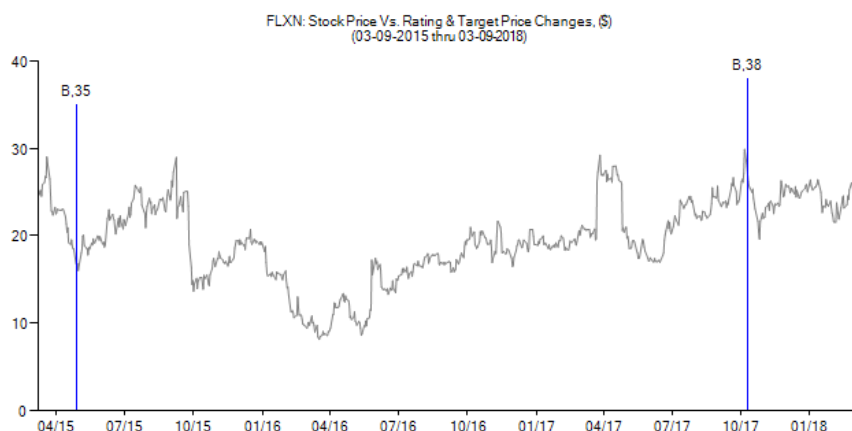
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Rating and Price Target Change History



3 Year Rating Change History

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

3 Year Price Change History

Date	Target Price (\$)	Closing Price. (\$)
04/28/...	35.00	16.87
10/10/...	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.	65.38%	26.92%	3.85%
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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