Flexion Therapeutics (FLXN - $25.74)

Healthcare / Biotechnology

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

First Full Quarter of Launch, Early Stages of a Foundation Year

FLXN reported their 1Q18 results last night after the close, missing on topline as Zilretta remains in its very first steps of launch, and beating on bottom line due to much lower than anticipated operating expenses. Although Zilretta sales came in at $2.2M vs. consensus $2.7M, we continue to consider 2018 a foundation year and aren't concerned with slight misses especially in 1H18. In the first 5 months of launch, they have called on 8,500 of ~10,500 target prescribers in 3,700 target accounts. Early launch metrics seem encouraging as ~40% of physicians have placed a reorder We were particularly encouraged by recent reimbursement developments as CMS issued a Q code for Zilretta (effective 7/1/18) and recommended a J code (effective 1/1/19). Additionally, we view the recent publication of their pivotal Phase 3 trial results in the highly regarded Journal of Bone and Joint surgery as a real positive. On top of the launch, FLXN expects a couple interesting data readouts in the near term. After having fully enrolled their concurrent administration of Zilretta in bilateral knee OA study in January, they still anticipate topline results in 2Q18. They also expect topline results from their Phase 3 repeat administration study in 3Q18. As of now, the magnitude and duration of pain relief in a "real world" setting seems similar to that seen in the Phase 3 trial as mean time to 2nd dose is > 16 weeks and 74% of subjects (n=179) were treated with a 2nd dose between weeks 16 and 24. While very early into launch, we see many positive signs as a result of adequate preparations and reiterate our Buy rating and $38 price target.

- **Slight topline miss, too early to judge.** Even though topline came in at $2.2M vs. consensus $2.7M in Zilretta's first official full quarter of launch, we continue to consider 2018 as a foundation year and are encouraged by the commercial metrics so far (40% reorder rate).
- **Near term catalysts could ultimately help launch.** FLXN still expects their PK/safety data in bilateral knee OA as well as their repeat dose trial to read out in 2Q18 and 3Q18, respectively.
- **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.

Trading Data:

Last Price (05/08/2018)	$25.74
52–Week High (10/06/2017)	$32.25
52–Week Low (06/15/2017)	$16.51
Market Cap. (MM)	$968.7
Shares Out. (MM)	37.6

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Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY18E	($1.10)A	($1.22)	($1.07)	($1.01)	($4.63)	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

Source: Company data and Laidlaw & Company estimates

Figure 1: Variance Analysis

Flexion Therapeutics
Quarterly variance analysis

(000's except per share)	1Q17A	1Q18A	1Q18E	Variance	% Y/Y
Total Revenue	**$0**	**$2,194**	**$4,092**	**($1,898)**	**NA**
COGS	0	2,698	409	2,289	NA
Gross Profit	**0**	**(504)**	**3,683**	**(4,187)**	**NA**
R&D Expense	10,756	11,551	17,500	(5,949)	7%
SG&A Expense	13,026	26,899	30,150	(3,251)	107%
Operating Inc (loss)	**(23,782)**	**(38,954)**	**(43,967)**	**5,013**	**64%**
Int. inc. (expense), net	(75)	(2,758)	(2,750)	(8)	3577%
Other (exp) gain, net	(22)	143	(100)	243	-750%
Pretax Income (loss)	**(23,879)**	**(41,569)**	**(46,817)**	**5,248**	**74%**
Income Tax exp (benefit)	0	0	0	0	NA
NI as reported	**(23,879)**	**(41,569)**	**(46,817)**	**5,248**	**74%**
1x items & non-cash exp	**0**	**0**	**0**	0	NA
Adj-NI ex-1X items	**(23,879)**	**(41,569)**	**(46,817)**	**5,248**	**NA**
Weighted avg. shares (000)	31,704	37,620	37,601	19	19%
Fully diluted shares (000)	35,208	40,120	40,101	19	14%
Adj EPS ex-1x items	**($0.75)**	**($1.10)**	**($1.25)**	**$0.14**	**47%**

Source: Company reports and 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	$184,717	$5
SUM	**$1,494,831**	**$38**
Shares out '18E (000)		39,977

Source: Company Reports: Laidlaw & Company estimates

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Figure 3: Quarterly Income Statement

Flexion Therapeutics **Quarterly income statement**	2017A				2017A	2018E				2018E
($000 except per share)	1QA	2QA	3QA	4QA	Year	1QA	2QE	3QE	4QE	Year
Revenues										
Total Revenue				**$355**	**$355**	**$2,194**	**$4,092**	**$6,820**	**$8,866**	**$21,971**
Expenses:										
Cost of Revenue (COGS)	-	-	-	4	4	2,698	2,000	1,000	887	$6,585
Gross Margin	**-**	**-**	**-**	**351**	**351**	**(504)**	**2,092**	**5,820**	**7,979**	**15,386**
R&D	10,756	11,769	12,846	15,860	51,231	11,551	15,000	17,500	17,500	61,551
SG&A	13,026	15,133	18,375	32,267	78,801	26,899	30,150	30,150	30,150	117,349
Total op. exp.	23,782	26,902	31,221	48,127	130,032	38,450	45,150	47,650	47,650	178,900
Inc (loss) from Ops	**(23,782)**	**(26,902)**	**(31,221)**	**(47,776)**	**(129,681)**	**(38,954)**	**(43,058)**	**(41,830)**	**(39,671)**	**(163,514)**
Int inc (exp), net	(75)	(2,090)	(2,748)	(2,637)	(7,550)	(2,758)	(2,750)	(2,750)	(2,750)	(10,000)
Other income (exp)	(22)	112	(219)	(121)	(250)	143	(100)	(100)	(100)	(157)
Inc (loss) before taxes	**(23,879)**	**(28,880)**	**(34,188)**	**(50,534)**	**(137,481)**	**(41,569)**	**(45,908)**	**(44,680)**	**(42,521)**	**(173,671)**
Income tax exp (benefit)										
NI as reported	**(23,879)**	**(28,880)**	**(34,188)**	**(50,534)**	**(137,481)**	**(41,569)**	**(45,908)**	**(44,680)**	**(42,521)**	**(173,671)**
EPS as reported	**($0.75)**	**($0.91)**	**($1.07)**	**($1.35)**	**($4.16)**	**($1.10)**				
Adj-NI ex-1x items	**($0.75)**	**($0.91)**	**($1.07)**	**($1.35)**	**($4.16)**	**($1.10)**	**($1.22)**	**($1.07)**	**($1.01)**	**($4.63)**
Weighted avg. shares (000)	31,704	31,826	31,931	37,451	33,027	37,620	37,770	41,770	41,920	37,477
Fully diluted shares (000)	35,208	40,421	36,931	42,451	38,753	40,120	40,270	44,270	44,420	39,977

Source: Company Reports: Laidlaw & Company estimates

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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	$21,971	$103,256	$223,343
Total Revenue	**$0**	**$0**	**$355**	**$21,971**	**$103,256**	**$223,343**
Expenses:						
Cost of Revenue (COGS)	-	-	4	6,585	10,326	20,101
Gross Margin	**-**	**-**	**351**	**15,386**	**92,931**	**203,242**
R&D	32,691	41,314	51,231	61,551	80,000	90,000
G&A	13,372	28,466	78,801	117,349	130,600	145,600
Total op exp	46,063	69,780	130,032	178,900	210,600	235,600
Inc/(loss) from Ops	**(46,063)**	**(69,780)**	**(129,681)**	**(163,514)**	**(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)	(157)	(500)	(500)
Inc/(loss) before taxes	**(46,315)**	**(71,893)**	**(137,481)**	**(173,671)**	**(128,169)**	**(42,858)**
Income tax exp (benefit)	-	-	-	-	-	(6,429)
NI as reported	**($46,315)**	**($71,893)**	**($137,481)**	**($173,671)**	**($128,169)**	**($36,429)**
EPS as reported	**($2.15)**	**($2.84)**				
Adj-EPS ex-1X items		**($2.96)**	**($4.16)**	**($4.63)**	**($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

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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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Additional information available upon request.

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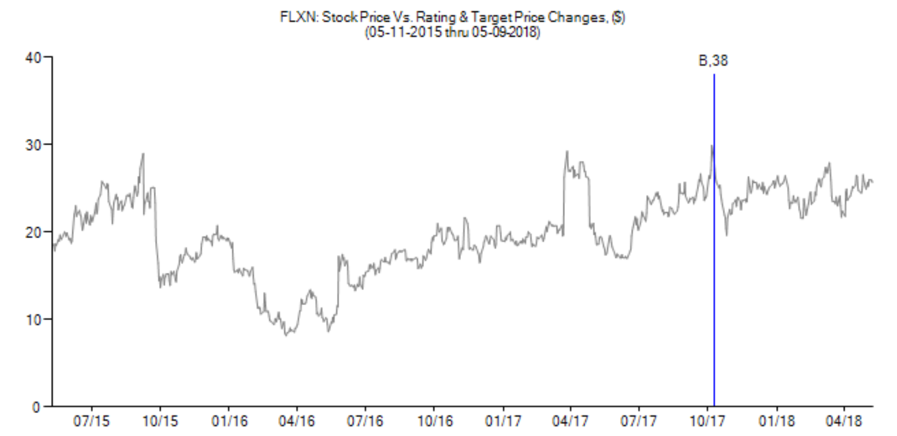
RATINGS INFORMATION

Rating and Price Target Change History



3 Year Rating Change History

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

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
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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