

## Flexion Therapeutics (FLXN - \$14.27)

Healthcare / Biotechnology

### Zilretta Launch Keeps Trucking Along

FLXN reported their 3Q18 results last night after the close, with a very slight topline beat of \$6.99M vs. our anticipated \$6.82M and Street consensus of \$6.7M. While we continue to consider 2018 a foundation year, we are encouraged by their 84% topline growth. Additionally, we see as positive some key metrics FLXN shared on their call. For instance, 79% of their target accounts have purchased samples and 64% of ordering accounts have re-ordered Zilretta. On the reimbursement front, FLXN's market access team has engaged with 48 key commercial insurers, which represents 75% of all commercially covered US lives. We were encouraged to learn that FLXN intends to share topline guidance for 2019 during their 4Q18 conference call and that they feel comfortable with 4Q18 topline consensus numbers. We view their strong early execution as a testament to their commercial preparation. FLXN recently received a product-specific J-Code for Zilretta (effective 1/1/19), which should add to physicians' confidence in reimbursement. On a different note, we were particularly encouraged that their Phase 3b trial for repeat administration of Zilretta was safe/well tolerated and showed no deleterious effects on cartilage or joint structure at week 52 (sNDA submission expected in 4Q18). We view this as a significant positive since it could potentially enable them to alter their label (Limitation of Use or LOU), which states that Zilretta is not intended for repeat administration. FLXN continues to expect Phase 2 open-label SHIP (shoulder and hip) data to readout in 4Q18. We are encouraged by Zilretta's launch trajectory/metrics and are reiterating our Buy rating and \$38 price target.

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

#### Trading Data:

Last Price (11/07/2018)	\$14.27
52-Week High (06/20/2018)	\$29.10
52-Week Low (11/01/2018)	\$13.36
Market Cap. (MM)	\$539.6
Shares Out. (MM)	37.8

- **Topline slightly beats, encouraging launch metrics and reimbursement.** With Zilretta sales growing 84%, we are encouraged by topline beat of \$6.99M vs. our estimated \$6.82M and Street consensus \$6.7M. With J-Code in place and strong market penetration, we are optimistic going into 2019.
- **Positive repeat administration Phase 3b gives hope for label update.** With their current LOU label status, we view Zilretta's strong safety profile as clarifying and potentially changing their label for the better.
- **Maintain BUY rating and \$38 price target.** Our \$38 price target is based on a sum-of-the-parts analysis, with Zilretta valued at \$34/share and cash (end '19) and technology at \$4/share.

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY18E</b>	(\$1.10)A	(\$1.16)A	(\$1.15)A	(\$1.12)	(\$4.69)	NA
<b>FY17A</b>	(\$0.75)	(\$0.91)	(\$1.07)	(\$1.35)	(\$4.16)	NA
<b>FY16A</b>	(\$0.64)	(\$0.63)	(\$0.65)	(\$0.89)	(\$2.84)	NA
<b>FY15A</b>	(\$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

FOR ANALYST CERTIFICATION AND DISCLOSURES, PLEASE SEE DISCLOSURES SECTION AT THE END OF THIS REPORT. This report has been prepared by Laidlaw & Co (UK), Ltd. Investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decision. All prices are those current at the end of the previous trading session unless otherwise indicated. Prices and consensus estimates are sourced from a reliable market source

Figure 1: Variance Analysis

<b>Flexion Therapeutics</b>					
<b>Quarterly variance analysis</b>					
(000's except per share)	3Q17A	3Q18A	3Q18E	Variance	% Y/Y
<b>Total Revenue</b>	<b>\$0</b>	<b>\$6,990</b>	<b>\$6,820</b>	<b>\$170</b>	<b>NA</b>
COGS	0	1,619	1,000	619	NA
<b>Gross Profit</b>	<b>0</b>	<b>5,371</b>	<b>5,820</b>	<b>(449)</b>	<b>NA</b>
R&D Expense	12,846	13,578	15,000	(1,422)	6%
SG&A Expense	18,375	32,804	30,150	2,654	79%
<b>Operating Inc (loss)</b>	<b>(31,221)</b>	<b>(41,011)</b>	<b>(39,330)</b>	<b>(1,681)</b>	<b>31%</b>
Int. inc. (expense), net	(2,748)	(2,773)	(2,750)	(23)	1%
Other (exp) gain, net	(219)	144	(100)	244	-166%
<b>Pretax Income (loss)</b>	<b>(34,188)</b>	<b>(43,640)</b>	<b>(42,180)</b>	<b>(1,460)</b>	<b>28%</b>
Income Tax exp (benefit)	0	0	0	0	NA
<b>NI as reported</b>	<b>(34,188)</b>	<b>(43,640)</b>	<b>(42,180)</b>	<b>(1,460)</b>	<b>28%</b>
1x items & non-cash exp	0	0	0	0	NA
<b>Adj-NI ex-1X items</b>	<b>(34,188)</b>	<b>(43,640)</b>	<b>(42,180)</b>	<b>(1,460)</b>	<b>NA</b>
Weighted avg. shares (000)	31,931	37,818	41,697	(3,879)	18%
Fully diluted shares (000)	36,931	40,318	44,197	(3,879)	9%
<b>Adj EPS ex-1x items</b>	<b>(\$1.07)</b>	<b>(\$1.15)</b>	<b>(\$1.01)</b>	<b>(\$0.14)</b>	<b>8%</b>

Source: Laidlaw and Company estimates

Figure 2: Valuation

<b>Sum-of-the-parts value</b>		
Segment	Valuation (000's)	Per share value
FX006 value	\$1,467,668	\$34
Cash (end '18) & tech value	\$162,567	\$4
<b>SUM</b>	<b>\$1,630,236</b>	<b>\$38</b>
Shares out '19E (000)		42,921

Source: Company Reports: Laidlaw &amp; 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	3QA	4QE	
<b>Revenues</b>										
<b>Total Revenue</b>				\$355	\$355	\$2,194	\$3,797	\$6,990	\$8,866	\$21,847
<b>Expenses:</b>										
Cost of Revenue (COGS)	-	-	-	4	4	2,698	946	1,619	1,551	6,814
<b>Gross Margin</b>	-	-	-	351	351	(504)	2,851	5,371	7,314	15,032
R&D	10,756	11,769	12,846	15,860	51,231	11,551	13,094	13,578	16,000	54,223
SG&A	13,026	15,133	18,375	32,267	78,801	26,899	31,036	32,804	35,150	125,889
Total op. exp.	23,782	26,902	31,221	48,127	130,032	38,450	44,130	46,382	51,150	180,112
<b>Inc (loss) from Ops</b>	<b>(23,782)</b>	<b>(26,902)</b>	<b>(31,221)</b>	<b>(47,776)</b>	<b>(129,681)</b>	<b>(38,954)</b>	<b>(41,279)</b>	<b>(41,011)</b>	<b>(43,836)</b>	<b>(165,080)</b>
Int inc (exp), net	(75)	(2,090)	(2,748)	(2,637)	(7,550)	(2,758)	(2,672)	(2,773)	(2,750)	(10,953)
Other income (exp)	(22)	112	(219)	(121)	(250)	143	76	144	(100)	263
<b>Inc (loss) before taxes</b>	<b>(23,879)</b>	<b>(28,880)</b>	<b>(34,188)</b>	<b>(50,534)</b>	<b>(137,481)</b>	<b>(41,569)</b>	<b>(43,875)</b>	<b>(43,640)</b>	<b>(46,686)</b>	<b>(175,770)</b>
Income tax exp (benefit)										
<b>NI as reported</b>	<b>(23,879)</b>	<b>(28,880)</b>	<b>(34,188)</b>	<b>(50,534)</b>	<b>(137,481)</b>	<b>(41,569)</b>	<b>(43,875)</b>	<b>(43,640)</b>	<b>(46,686)</b>	<b>(175,770)</b>
<b>EPS as reported</b>	<b>(\$0.75)</b>	<b>(\$0.91)</b>	<b>(\$1.07)</b>	<b>(\$1.35)</b>	<b>(\$4.16)</b>	<b>(\$1.10)</b>	<b>(\$1.16)</b>	<b>(\$1.15)</b>	<b>(\$1.12)</b>	<b>(\$4.69)</b>
<b>Adj-NI ex-1x items</b>	<b>(\$0.75)</b>	<b>(\$0.91)</b>	<b>(\$1.07)</b>	<b>(\$1.35)</b>	<b>(\$4.16)</b>	<b>(\$1.10)</b>	<b>(\$1.16)</b>	<b>(\$1.15)</b>	<b>(\$1.12)</b>	<b>(\$4.69)</b>
Weighted avg. shares (000)	31,704	31,826	31,931	37,451	33,027	37,620	37,697	37,818	41,818	37,448
Fully diluted shares (000)	35,208	40,421	36,931	42,451	38,753	40,120	40,197	40,318	44,318	39,948

Source: Company Reports: Laidlaw &amp; Company estimates

Figure 4: Annual Income Statement

<b>Flexion Therapeutics</b>						
<b>Annual income statement</b>						
(\$000 except per share)	<b>2015A</b>	<b>2016A</b>	<b>2017A</b>	<b>2018E</b>	<b>2019E</b>	<b>2020E</b>
<b>Revenues</b>						
Zilretta - OA pain			\$355	\$21,847	\$103,256	\$223,343
<b>Total Revenue</b>	<b>\$0</b>	<b>\$0</b>	<b>\$355</b>	<b>\$21,847</b>	<b>\$103,256</b>	<b>\$223,343</b>
<b>Expenses:</b>						
Cost of Revenue (COGS)	-	-	4	6,814	12,907	22,334
<b>Gross Margin</b>	<b>-</b>	<b>-</b>	<b>351</b>	<b>15,032</b>	<b>90,349</b>	<b>201,009</b>
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
<b>Inc/(loss) from Ops</b>	<b>(46,063)</b>	<b>(69,780)</b>	<b>(129,681)</b>	<b>(165,080)</b>	<b>(110,251)</b>	<b>(24,591)</b>
Int income (exp), net	675	(226)	(7,550)	(10,953)	(10,000)	(10,000)
Other expenses, net	(927)	(1,887)	(250)	263	(500)	(500)
<b>Inc/(loss) before taxes</b>	<b>(46,315)</b>	<b>(71,893)</b>	<b>(137,481)</b>	<b>(175,770)</b>	<b>(120,751)</b>	<b>(35,091)</b>
Income tax exp (benefit)	-	-	-	-	-	(5,264)
<b>NI as reported</b>	<b>(\$46,315)</b>	<b>(\$71,893)</b>	<b>(\$137,481)</b>	<b>(\$175,770)</b>	<b>(\$120,751)</b>	<b>(\$29,828)</b>
<b>EPS as reported</b>	<b>(\$2.15)</b>	<b>(\$2.84)</b>				
<b>Adj-EPS ex-1X items</b>		<b>(\$2.96)</b>	<b>(\$4.16)</b>	<b>(\$4.69)</b>	<b>(\$2.99)</b>	<b>(\$0.73)</b>
Weighted avg. shares (000)	21,497	25,296	33,027	37,448	40,421	40,921
Fully diluted shares (000)	23,152	27,787	38,753	39,948	42,921	43,421

Source: Company Reports: Laidlaw &amp; 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.

**DISCLOSURES:****ANALYST CERTIFICATION**

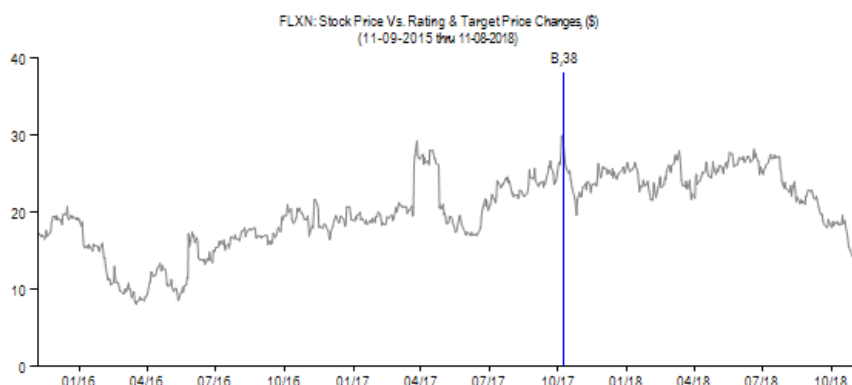
The analyst responsible for the content of this report hereby certifies that the views expressed regarding the company or companies and their securities accurately represent his personal views and that no direct or indirect compensation is to be received by the analyst for any specific recommendation or views contained in this report. Neither the author of this report nor any member of his immediate family or household maintains a position in the securities mentioned in this report.

**EQUITY DISCLOSURES**

For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell most closely correspond to Buy, Hold and Sell, respectively, the meanings are not the same because our ratings are determined on a relative basis against the analyst sector universe of stocks. An analyst's coverage sector is comprised of companies that are engaged in similar business or share similar operating characteristics as the subject company. The analysis sector universe is a sub-sector to the analyst's coverage sector, and is compiled to assist the analyst in determining relative valuations of subject companies. The composition of an analyst's sector universe is subject to change over time as various factors, including changing market conditions occur. Accordingly, the rating assigned to a particular stock represents solely the analyst's view of how that stock will perform over the next 12-months relative to the analyst's sector universe.

**Additional information available upon request.**

‡ Laidlaw & Company has received compensation from the subject company for investment banking services in the past 12 months and expects to receive or intends to seek compensation for investment banking services from the company in the next three months.

**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 &amp; 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
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	61.40%	22.81%	3.51%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	5.26%	1.75%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

**ADDITIONAL COMPANIES MENTIONED****ADDITIONAL DISCLOSURES**

As of the date of this report, neither the author of this report nor any member of his immediate family or household maintains an ownership position in the securities of the company (ies) mentioned in this report.

This report does not provide individually tailored investment advice and has been prepared without regard to the individual financial circumstances and objectives of persons who receive it. Laidlaw & Co (UK), Ltd. recommends that investors independently evaluate particular investments and strategies, and encourages investors to seek the advice of a financial adviser. The appropriateness of a particular investment or strategy will depend on an investor's individual circumstances and objectives. The securities, instruments, or strategies discussed in this report may not be suitable for all investors, and certain investors may not be eligible to purchase or participate

in some or all of them. This report is not an offer to buy or sell or the solicitation of an offer to buy or sell any security/instrument or to participate in any particular trading strategy.

Associated persons of Laidlaw & Co (UK), Ltd not involved in the preparation of this report may have investments in securities/instruments or derivatives of securities/instruments of companies mentioned herein and may trade them in ways different from those discussed in this report. While Laidlaw & Co (UK), Ltd., prohibits analysts from receiving any compensation. Bonus or incentive based on specific recommendations for, or view of, a particular company, investors should be aware that any or all of the foregoing, among other things, may give rise to real or potential conflicts of interest.

With the exception of information regarding Laidlaw & Co (UK), Ltd. this report is based on public information. Laidlaw & Co (UK), Ltd makes every effort to use reliable, comprehensive information, but we make no representation that it is accurate or complete and it should not be relied upon as such. Any opinions expressed are subject to change and Laidlaw & Co (UK), Ltd disclaims any obligation to advise you of changes in opinions or information or any discontinuation of coverage of a subject company. Facts and views presented in this report have not been reviewed by, and may not reflect information known to, professionals in other Laidlaw & Co (UK), Ltd business areas. Laidlaw & Co (UK), Ltd associated persons conduct site visits from time to time but are prohibited from accepting payment or reimbursement by the company of travel expenses for such visits. The value of and income from your investments may vary because of changes in interest rates, foreign exchange rates, default rates, prepayment rates, securities/instruments prices, market indexes, operational or financial conditions of companies or other factors. There may be time limitations on the exercise of options or other rights in securities/instruments transactions. Past performance is not necessarily a guide to future performance. Estimates of future performance are based on assumptions that may not be realized. If provided, and unless otherwise stated, the closing price on the cover page is that of the primary exchange for the subject company's securities/instruments.

Any trademarks and service marks contained in this report are the property of their respective owners. Third-party data providers make no warranties or representations of any kind relating to the accuracy, completeness, or timeliness of the data they provide and shall not have liability for any damages of any kind relating to such data. This report or any portion thereof may not be reprinted, sold or redistributed without the written consent of Laidlaw & Co (UK), Ltd. This report is disseminated and available primarily electronically, and, in some cases, in printed form.

The information and opinions in this report were prepared by Laidlaw & Co (UK), Ltd. For important disclosures, please see Laidlaw & Co (UK), Ltd.'s disclosure website at [www.Laidlawltd.com](http://www.Laidlawltd.com), or contact your investment representative or Laidlaw & Co (UK), Ltd at 521 Fifth Ave, 12th Floor, New York, NY 10175 USA.

© 2018 Laidlaw & Co. (UK), Ltd.

**NOTES:**