

## Flexion Therapeutics (FLXN - \$27.50)

Healthcare / Biotechnology

### FLXN Take-Out Chatter Remains a Key Driver Near-Term

We recently had the chance to spend time with FLXN management on the tail of widespread market comments of a take-out by Sanofi (SNY) that sent the stock soaring more than 30% on 3/23/17. As expected, FLXN did not comment on the market activity and reiterated their focus on the upcoming Zilretta launch following their 10/6/17 PDUFA. CEO Clayman noted that he does not expect an AdCom for Zilretta since it is a 505-b2 long-acting formulation of a known steroid triamcinolone acetonide (TCA). Although we believe FLXN is taking every precaution to ensure a good launch, we do think an acquisition by SNY would make sense and be a huge positive, as small company single product launches are usually challenging. As a reminder, the hyaluronic acid (HA) market is currently > \$1B and Zilretta will be priced at parity to HA with a greater efficacy. When compared to IR steroids, Zilretta shows greater efficacy in WOMAC A, B, and C scores, which is highly valued by the medical community. With a very strong FDA package of Phase 2b, 3, and type 2 diabetes data (presentation at a major conference in 2H17), we come away incrementally more positive of Zilretta's chance of approval on their 10/16 PDUFA date. Finally, FLXN reiterated their confidence that can add 1 or 2 assets to their pipeline by end of 2017, with a focus on local therapy for musculoskeletal disease. Reiterate Buy rating, \$35 PT.

Ticker: FLXN  
Rating: **Buy**  
Price Target: **\$35.00**

#### Trading Data:

Last Price (04/04/2017)	\$27.50
52-Week High (03/27/2017)	\$29.41
52-Week Low (05/13/2016)	\$8.46
Market Cap. (MM)	\$872.6
Shares Out. (MM)	31.73

- **SNY acquisition would make sense to us.** FLXN declined to comment on the market activity, but small company single-product launches are challenging and Zilretta could complement SNY's strong presence in the HA space. SNY should know FLXN, given the former SNY folks at FLXN.
- **FLXN "laser-focused" on Zilretta launch.** We still see Zilretta having a strong submission package, and we are encouraged by FLXN's senior sales hires. We project Zilretta sales of \$54M, \$147M, \$287M, and \$517M from 2018E-2021E, respectively.
- **More shots on goal in near future.** FLXN reiterated their confidence in adding 1 or 2 assets to their pipeline by YE17 in musculoskeletal pain.
- **Maintain BUY rating, \$35 price target.** Our \$35 price target is based on a sum-of-the-parts analysis, with Zilretta valued at \$34/share and cash (end '17) and technology at \$1/share.

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY18E</b>	NA	NA	NA	NA	(\$2.10)	NA
<b>FY17E</b>	(0.74)	(0.80)	(0.80)	(0.81)	(\$3.15)	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

Jim Molloy/Spec Pharma & Biotech  
(857) 317-5061  
jmolloy@laidlawltd.com

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

Source: Company data and Laidlaw & Company estimates

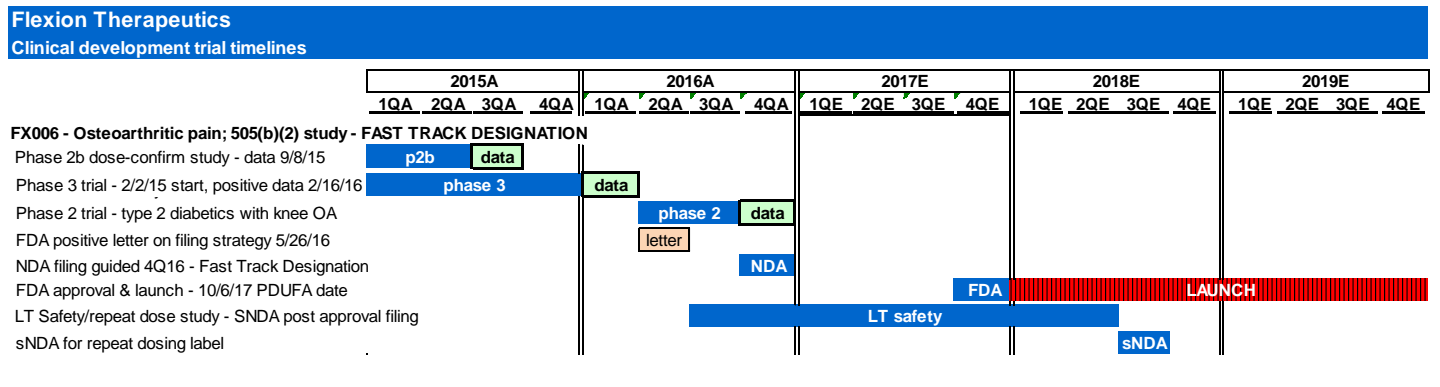
FOR ANALYST CERTIFICATION AND DISCLOSURES, PLEASE SEE DISCLOSURES SECTION AT THE END OF THIS REPORT. This report has been prepared by Laidlaw & Co (UK), Ltd. Investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider 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: Valuation

Sum-of-the-parts value		
Segment	Valuation (000's)	Per share value
FX006 value	\$1,091,413	\$34
Cash (end '17) & tech value	\$90,990	\$1
<b>SUM</b>	<b>\$1,182,403</b>	<b>\$35</b>
Shares out '17E (000)		32,354

Source: Company Reports; Laidlaw & Company estimates

Figure 2: Upcoming clinical trial timelines



Source: Company Reports; Laidlaw & Company estimates

Figure 3: Quarterly Income Statement

<b>Flexion Therapeutics</b>										
<b>Quarterly income statement</b>										
(\$000 except per share)	2016A				2016A Year	2017E				2017E Year
	1QA	2QA	3QA	4QA		1QE	2QE	3QE	4QE	
<b>Revenues</b>										
<b>Total Revenue</b>										
<b>Expenses:</b>										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
<b>Gross Margin</b>	-	-	-	-	-	-	-	-	-	-
R&D	8,981	8,905	9,047	14,381	41,314	12,500	12,500	11,250	10,000	46,250
SG&A	4,692	5,215	8,388	10,171	28,466	9,250	11,250	12,500	14,250	47,250
Total op. exp.	13,673	14,120	17,435	24,552	69,780	21,750	23,750	23,750	24,250	93,500
<b>Inc (loss) from Ops</b>	<b>(13,673)</b>	<b>(14,120)</b>	<b>(17,435)</b>	<b>(24,552)</b>	<b>(69,780)</b>	<b>(21,750)</b>	<b>(23,750)</b>	<b>(23,750)</b>	<b>(24,250)</b>	<b>(93,500)</b>
Int inc (exp), net	60	93	(140)	(239)	(226)	50	50	50	50	200
Other income (exp)	(202)	(158)	(207)	(1,320)	(1,887)	(200)	(200)	(200)	(200)	(800)
<b>Inc (loss) before taxes</b>	<b>(13,815)</b>	<b>(14,185)</b>	<b>(17,782)</b>	<b>(26,111)</b>	<b>(71,893)</b>	<b>(21,900)</b>	<b>(23,900)</b>	<b>(23,900)</b>	<b>(24,400)</b>	<b>(94,100)</b>
Income tax exp (benefit)										
<b>Adj-NI ex-1x items</b>	<b>(13,815)</b>	<b>(14,185)</b>	<b>(17,782)</b>	<b>(26,111)</b>	<b>(71,893)</b>	<b>(21,900)</b>	<b>(23,900)</b>	<b>(23,900)</b>	<b>(24,400)</b>	<b>(94,100)</b>
<b>Adj EPS ex-1x items</b>	<b>(\$0.64)</b>	<b>(\$0.63)</b>	<b>(\$0.65)</b>	<b>(\$0.89)</b>	<b>(\$2.84)</b>	<b>(\$0.74)</b>	<b>(\$0.80)</b>	<b>(\$0.80)</b>	<b>(\$0.81)</b>	<b>(\$3.15)</b>
<b>EPS as reported</b>	<b>(\$0.78)</b>				<b>(\$2.96)</b>					
Weighted avg. shares (000)	21,570	22,666	27,524	29,424	25,296	29,754	29,754	29,754	30,154	29,854
Fully diluted shares (000)	23,948	25,102	30,073	32,024	27,787	32,254	32,254	32,254	32,654	32,354

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)	2015A	2016A	2017E	2018E	2019E	2020E	Comments
<b>Revenues</b>							
Zilretta - OA pain				\$54,557	\$147,509	\$287,155	US launch 1H18
<b>Total Revenue</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$54,557</b>	<b>\$147,509</b>	<b>\$287,155</b>	
<b>Expenses:</b>							
Cost of Revenue (COGS)	-	-	-	8,184	14,751	25,844	
<b>Gross Margin</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>46,374</b>	<b>132,758</b>	<b>261,311</b>	
R&D	32,691	41,314	46,250	52,000	49,000	47,500	
G&A	13,372	28,466	47,250	62,000	65,500	90,500	Self-launch Zilretta in US
Total op exp	46,063	69,780	93,500	114,000	114,500	138,000	
<b>Inc/(loss) from Ops</b>	<b>(46,063)</b>	<b>(69,780)</b>	<b>(93,500)</b>	<b>(67,626)</b>	<b>18,258</b>	<b>123,311</b>	
Int income (exp), net	675	(226)	200	300	450	450	
Other expenses, net	(927)	(1,887)	(800)	(1,000)	(1,000)	(1,000)	
<b>Inc/(loss) before taxes</b>	<b>(46,315)</b>	<b>(71,893)</b>	<b>(94,100)</b>	<b>(68,326)</b>	<b>17,708</b>	<b>122,761</b>	
Income tax exp (benefit)	-	-	-	-	2,656	18,414	Sig. tax loss carryforwards
<b>Adj-NI ex-1x items</b>	<b>(\$46,315)</b>	<b>(\$71,893)</b>	<b>(\$94,100)</b>	<b>(\$68,326)</b>	<b>\$15,052</b>	<b>\$104,347</b>	
<b>Adj EPS ex-1x items</b>	<b>(\$2.15)</b>	<b>(\$2.84)</b>	<b>(\$3.15)</b>	<b>(\$2.10)</b>	<b>\$0.40</b>	<b>\$2.60</b>	
<b>EPS as reported</b>		<b>(\$2.96)</b>					
Weighted avg. shares (000)	21,497	25,296	29,854	32,604	35,104	37,604	
Fully diluted shares (000)	23,152	27,787	32,354	35,104	37,604	40,104	
Cash balance	\$111,327	\$199,307	\$95,021	\$19,988	\$29,460	\$141,232	Fund raise 2017

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

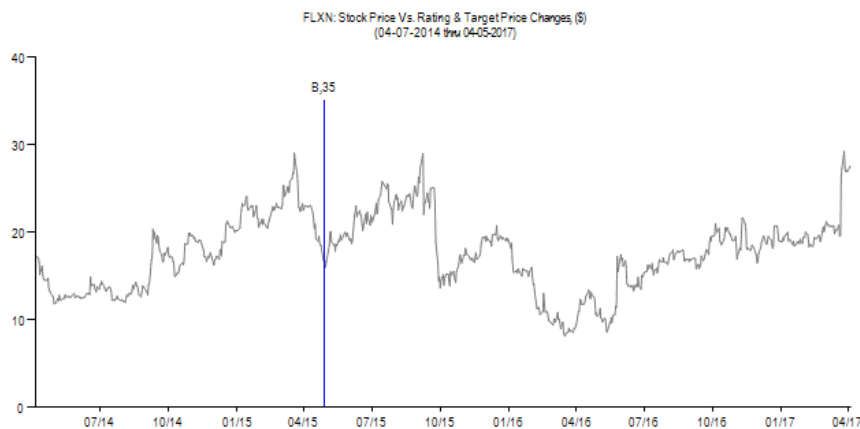
For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell 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



#### 3 Year Rating Change History

Date	Rating	Closing Price (\$)
04/28/2...	Buy (B)	16.87

#### 3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
04/28/2...	35.00	16.87

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
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	2.33%	2.33%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	65.12%	30.23%	2.33%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	2.33%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	4.65%	0.00%	0.00%

### ADDITIONAL COMPANIES MENTIONED

Sanofi (SNY – Not Rated)

### 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 546 Fifth Ave, 5th Floor, New York, NY 10036 USA.

© 2017 Laidlaw & Co. (UK), Ltd.

**NOTES:**