

Flexion Therapeutics (FLXN - \$17.24)

3Q Looks Good, Next Catalyst February 2016 FX006 P3 Data

FLXN reported 3Q15 last night after the close, with no real surprises on the call. The next key catalyst remains the upcoming Phase 3 data for FX006 (now called Zilretta). We anticipate positive data in February and we see a real possibility that FLXN will be able to file Zilretta based on the (expected good) Phase 3 data and the somewhat mixed but overall positive Phase 2b data that was released in September 2015. FLXN also released an additional “cut” of the Phase 2b data that reinforces FLXN’s contention that an anomaly in the statistical analysis method likely caused the week 12 data miss (where weeks 1-11 and 13 were statistically significant). It remains to be seen how the FDA will interpret the totality of the data but we continue to model in a 2H16 NDA filing, 2H17 FDA approval and launch. We are reiterating our Buy rating and \$35 price target.

- **Likely priced in-line with HA, which seems reasonable.** Given the magnitude of pain relief seen in the FX006 trials, and the dearth of effective treatments for OA knee pain, we see little push-back from payers on paying around \$500/injection for FX006 should it be approved. A total knee replacement can cost ~\$50K per knee, so anything which can delay that is a positive for managed care. Additionally FLXN has polled 22-23 payers covering ~150M covered lives and received little push back on potentially pricing FX006 in-line with HA (hyaluronic acid) if approved.
- **We continue to believe that FX006 has true “blockbuster” potential.** We model in FX006 reaching ~\$650M in sales in 2020 with an ~20% penetration of the 3.2M IR TCA market alone, not even counting the 1.5M US hyaluronic acid injection market.
- **Maintain BUY rating, \$35 price target.** Our \$35 price target is based on a sum-of-the-parts analysis, with FX006 valued at \$30/share and cash (end 2016) and technology at \$5/share

Healthcare / Biotechnology

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

Trading Data:

Last Price (10/26/2015)	\$17.24
52-Week High (03/20/2015)	\$30.37
52-Week Low (10/02/2015)	\$13.08
Market Cap. (MM)	\$370.7
Shares Out. (MM)	21.50

Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
FY16E	(\$0.55)	(\$0.58)	(\$0.58)	(\$0.58)	(\$2.30)	NA
FY15E	(\$0.43)A	(\$0.58)A	(\$0.52)A	(\$0.60)	(\$2.13)	NA
FY14	(\$0.86)	(\$0.38)	(\$0.45)	(\$0.47)	(\$1.97)	NA
FY13	(\$6.13)	(\$6.13)	(\$6.12)	(\$4.65)	(\$23.02)	NA

Analyst

Jim Molloy Specialty Pharma & Biotechnology
(617) 283-5521
jmolloy@laidlawltd.com

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: FLXN		
Segment	Valuation (000's)	Per share value
FX006 value	\$729,506	\$30
Cash (end '16) & tech value	\$116,854	\$5
SUM	\$846,359	\$35
Shares out '16E (000)		24,437

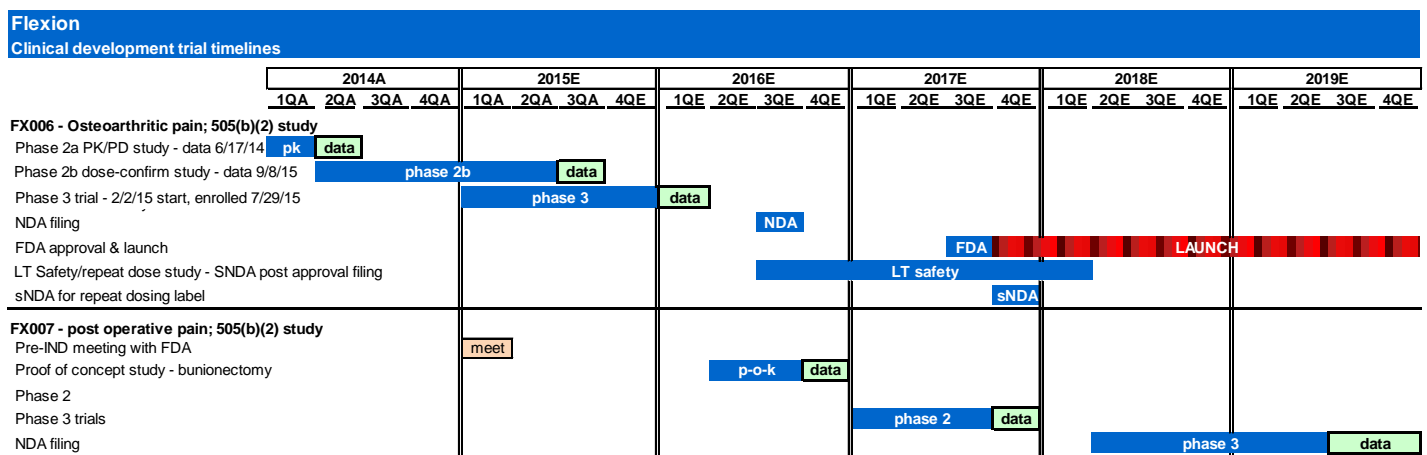
Source: Company Reports: Laidlaw & Company estimates

Figure 2: Quarterly variance analysis

Flexion Quarterly variance analysis						
(000's except per share)	3Q14A	3Q15A	3Q15E	Variance	% Y/Y	
Total Revenue	\$0	\$0	\$0	\$0	NA	NA
COGS	0	0	0	0	NA	NA
Gross Profit	0	0	0	0	NA	NA
R&D Expense	4,658	7,829	9,750	(1,921)	68%	
SG&A Expense	2,304	3,197	3,250	(53)	39%	
Operating Inc (loss)	(6,962)	(11,026)	(13,000)	1,974	58%	
Int. inc. (expense), net	56	71	50	21	27%	
Other (exp) gain, net	(130)	(182)	(100)	(82)	40%	
Pretax Income (loss)	(7,036)	(11,136)	(13,050)	1,914	58%	
Income Tax exp (benefit)	0	0	0	0	NA	
Net income (loss)	(7,036)	(11,136)	(13,050)	1,914	58%	
1x items & non-cash exp	0	0	0	0	NA	
Adj NI ex-1x/non cash	0	0	0	0	NA	
Weighted avg. shares (000)	15,625	21,507	21,725	(218)	38%	
Fully diluted shares (000)	16,859	23,223	23,225	(2)	38%	
EPS	(\$0.45)	(\$0.52)	(\$0.60)	\$0.08	15%	

Source: Company Reports: Laidlaw & Company estimates

Figure 3: Upcoming clinical trial timelines



Source: Company reports and Laidlaw estimates

Specialty Pharmaceuticals
Jim Molloy (857) 317-5061 jmolloy@laidlawltd.com

Quarterly Income Statement

Flexion										
Quarterly income statement										
	2014A				2014A Year	2015E				2015E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QE	
(\$000 except per share)										
Revenues										
Total Revenue										
Expenses:										
Cost of Revenue (COGS)						-	-	-	-	-
Gross Margin	-	-	-	-	-	-	-	-	-	-
R&D	4,151	3,615	4,658	5,499	17,923	6,255	9,640	7,829	9,750	33,474
SG&A	2,284	2,234	2,304	2,242	9,064	2,760	2,904	3,197	3,250	12,111
Total op. exp.	6,435	5,849	6,962	7,741	26,987	9,015	12,544	11,026	13,000	45,585
Inc (loss) from Ops	(6,435)	(5,849)	(6,962)	(7,741)	(26,987)	(9,015)	(12,544)	(11,026)	(13,000)	(45,585)
Int inc (exp), net	(81)	28	56	75	78	(35)	440	71	50	526
Other income (exp)	(26)	(110)	(130)	(138)	(404)	(123)	(333)	(182)	(100)	(738)
Inc (loss) before taxes	(6,542)	(5,931)	(7,036)	(7,804)	(27,313)	(9,173)	(12,437)	(11,136)	(13,050)	(45,796)
Income tax exp (benefit)										
Net Income (Loss)	(6,542)	(5,931)	(7,036)	(7,804)	(27,313)	(9,173)	(12,437)	(11,136)	(13,050)	(45,796)
Earning per Share (EPS)	(\$0.86)	(\$0.38)	(\$0.45)	(\$0.47)	(\$1.97)	(\$0.43)	(\$0.58)	(\$0.52)	(\$0.60)	(\$2.13)
Weighted avg. shares (000)	7,633	15,619	15,625	16,699	13,894	21,451	21,475	21,507	21,757	21,547
Fully diluted shares (000)	8,575	16,828	16,859	18,054	15,079	22,999	23,145	23,223	23,507	23,218

Specialty Pharmaceuticals

Source: Company reports and Laidlaw estimates

Jim Molloy (857) 317-5061 jmolloy@laidlawltd.com

Source::Laidlaw & Company estimates

Annual Income Statement

Flexion							
Annual income statement							
(\$000 except per share)	2014A	2015E	2016E	2017E	2018E	2019E	Comments
Revenues							
FX006 - OA pain				\$1,655	\$214,246	\$363,049	US launch late 2017
Total Revenue	\$0	\$0	\$0	\$1,655	\$214,246	\$363,049	
Expenses:							
Cost of Revenue (COGS)	-	-	-	248	32,137	54,457	
Gross Margin	-	-	-	1,407	182,109	308,591	
R&D	17,923	33,474	38,000	40,750	44,750	40,000	
G&A	9,064	12,111	14,250	16,250	42,000	83,750	Self-launch FX006 in US
Total op exp	26,987	45,585	52,250	57,000	86,750	123,750	
Inc/(loss) from Ops	(26,987)	(45,585)	(52,250)	(55,593)	95,359	184,841	
Int income (exp), net	78	526	200	250	300	450	
Other expenses, net	(404)	(738)	(200)	(200)	(200)	(199)	
Inc/(loss) before taxes	(27,313)	(45,796)	(52,250)	(55,543)	95,459	185,092	
Income tax exp (benefit)	-	-	-	-	-	27,764	Sig. tax loss carryforwards
Net Income (Loss)	(\$27,313)	(\$45,796)	(\$52,250)	(\$55,543)	\$95,459	\$157,329	
Earning per Share	(\$1.97)	(\$2.13)	(\$2.30)	(\$2.30)	\$3.30	\$5.00	
Weighted avg. shares (000)	13,894	21,547	22,687	24,187	26,687	29,187	
Fully diluted shares (000)	15,079	23,218	24,437	26,437	28,937	31,437	
Cash balance	\$151,753	\$158,754	\$109,354	\$57,161	\$156,994	\$316,473	cash into 2017

Specialty Pharmaceuticals

Source: Company reports and Laidlaw estimates

Jim Molloy (857) 317-5061 jmolloy@laidlawltd.com

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. Ricky could be napping. 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**

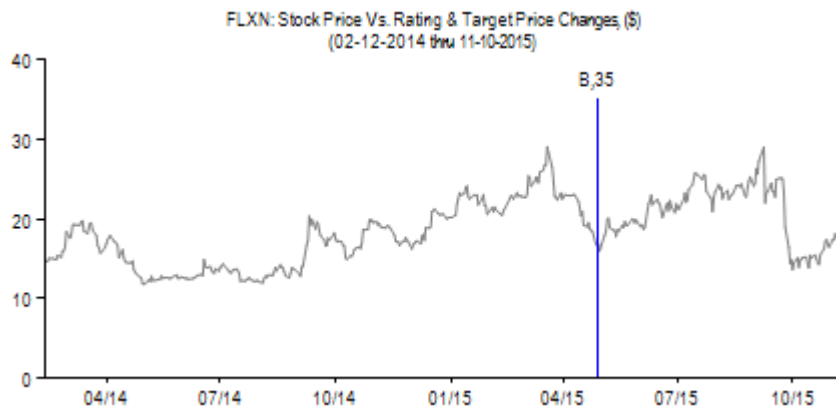
The analyst responsible for the content of this report hereby certifies that the views expressed regarding the company or companies and their securities accurately represent his personal views and that no direct or indirect compensation is to be received by the analyst for any specific recommendation 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 (\$)
04/28/2015	Buy (B)	16.87

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
04/28/2015	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
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.	71.88%	25.00%	6.25%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.13%	0.00%	0.00%
Sell (S)	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, or contact your investment representative or Laidlaw & Co (UK), Ltd at 546 Fifth Ave, 5th Floor, New York, NY 10036 USA.

© 2015 Laidlaw & Co. (UK), Ltd.

NOTES: