LAIDLAW & COMPANY
Est. 1842
London
New York
San Francisco
Boston

EQUITY RESEARCH
Company Report

February 17, 2016

Flexion Therapeutics (FLXN - $12.42)

Healthcare / Biotechnology

Make No Mistake – Positive P3 Data Is a Big Deal for FLXN

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

FLXN reported positive data from its recently completed Phase 3 trial for Zilretta (FX006) for the treatment of moderate-severe osteoarthritis (OA) knee pain. Zilretta met the primary endpoint of week 12 change from baseline vs. placebo ($p<0.0001$) and also hit statistical significance of pain relief vs. placebo over weeks 1-16, and a 50% greater pain reduction in pain vs. placebo over weeks 1-12. Zilretta also met a number of key secondary endpoints vs. immediate release steroid (IR TCA) including WOMAC A/B/C (pain/stiffness/function) and KOOS - key pain measures for determining efficacy of treatment. Zilretta did miss statistical significance on the secondary endpoint of daily pain score vs. IR TCA, but no safety issues arose in the trial. We view this as a huge positive for FLXN and believe them hitting on the primary endpoint at a highly statistically significant value in this trial greatly increases the odds that FLXN can file Zilretta with the FDA in 2H16 with this data and the previous Phase 2b data.

- **Hitting the primary endpoint the first derivative call.** The 50% decrease in pain vs. placebo weeks 1-12 is a real market differentiation, and also the greatest amount of pain relief ever seen in OA trials to date.
- **Secondary endpoints generally positive too.** While it would have been better to have seen statistically significant results vs. IR TCA on the daily pain score, hitting on all 3 WOMAC scores is real, and should allow for positioning vs. IR TCA in the marketplace. The lack of statistical significance vs. IR TCA is likely due to the persistence of pain relief in the IR TCA group, which appears to be common in clinical trials, also hitting FLXN's September 2015 P2b trial.
- **FDA meeting mid-2016 next.** FLXN will request an FDA meeting (likely 60-75 days) to discuss the filing strategy, with the transcript from that meeting available ~30 days post meeting to see if they will need to run another confirmatory P3 trial. We believe the prior P2b trial combined with this P3 data represents a strong submission package and should allow for an NDA in 2H16, with a 2H17 FDA approval and launch.
- **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

Trading Data:

Last Price (02/17/016)	$12.42
52–Week High (03/20/2015)	$30.37
52–Week Low (02/12/2016)	$1.46
Market Cap. (MM)	$267.4
Shares Out. (MM)	21.5

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

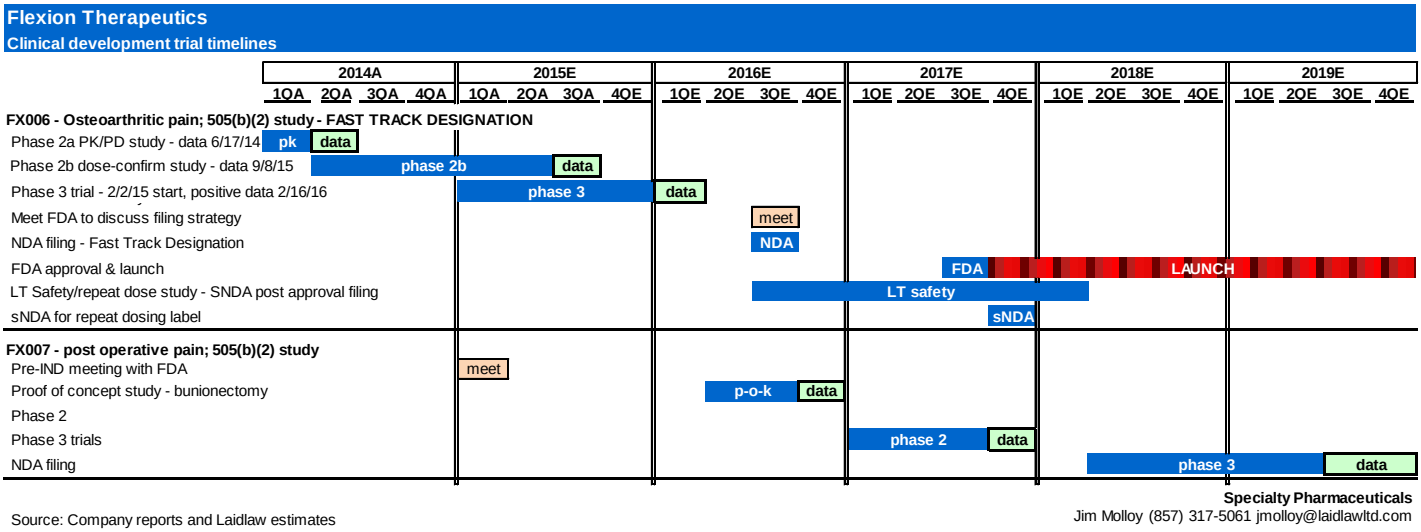
Analyst
Jim Molloy Specialty Pharma & Biotechnology
(617) 283-5521
jmolloy@laidlawltd.com

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: 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

($000 except per share)	2014A 1QA	2014A 2QA	2014A 3QA	2014A 4QA	2014A Year	2015E 1QA	2015E 2QA	2015E 3QA	2015E 4QE	2015E Year
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

Source: Company reports and Laidlaw estimates

Specialty Pharmaceuticals
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

Source: Company reports and Laidlaw estimates

Specialty Pharmaceuticals
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. 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.

Jim Molloy
jmolloy@laidlawltd.com

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

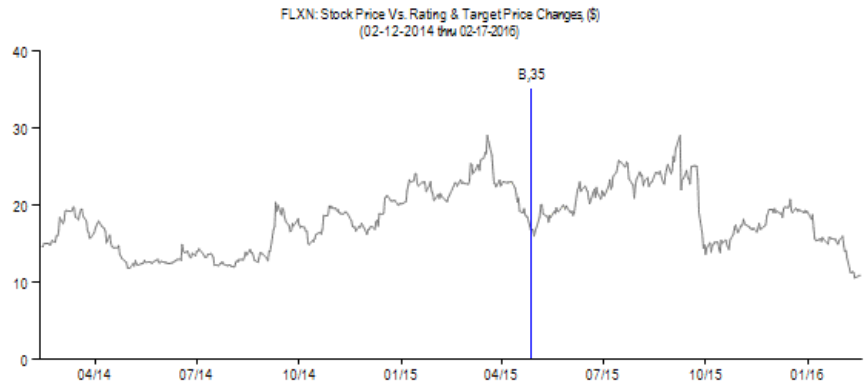
For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell 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.	64.71%	26.47%	2.94%
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%

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

Jim Molloy
jmolloy@laidlawltd.com

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.

Jim Molloy
jmolloy@laidlawltd.com

NOTES: