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EQUITY RESEARCH
Company Report

May 24, 2016

Flexion Therapeutics (FLXN - $10.60)

Healthcare / Biotechnology

KOL dinner highlights Zilretta opportunity in knee OA

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

We recently hosted a KOL dinner in NYC with a leading orthopedic specialist from the NYU Langone Medical Center to get his thoughts on the pending FDA meeting between FLXN and the FDA on the file-ability of Zilretta based on the recent Phase 3 study and the prior Phase 2b study. Our KOL was not involved in any of the FLXN clinical trials and (obviously) isn't involved in the FDA decision on the Zilretta filing. With a practice that sees 5K-6K patients *per year*, our KOL is uniquely positioned, however, to opine on the merits of daily pain scores vs. WOMAC scores for clinical relevance to orthopedics; and on the pressing need for additional treatment options for treating knee OA. In short, our KOL agrees that FLXN has a strong case to make at the FDA for filing on the current data. Additionally our KOL believes the long-acting Zilretta could quickly see first line usage over an IR steroid, and not as a step-therapy after a course of IR steroid injections. We maintain our Buy rating, $35 PT.

Trading Data:

Last Price (05/23/2016)	$10.60
52–Week High (09/08/2015)	$29.09
52–Week Low (03/17/2016)	$7.56
Market Cap. (MM)	$228.7
Shares Out. (MM)	21.57

- **OARSI presentation a valid re-cut analysis.** A re-cut of Zilretta's Phase 3 data was presented at OARSI excluding bilateral knee pain patients showing statistically significant efficacy vs. IR TCA in unilateral knee pain. Our KOL agrees that excluding bilateral patients is a reasonable re-cut of the data, and bilateral patients should have been excluded from the study in the first place.

- **Will need to keep an eye on pre-TKA injection time.** Doctors would need to figure out how early before a total knee arthroplasty (replacement) operation they could safely inject Zilretta, given the longer duration of action. Injections of IR TCA too close to a TKA may result in an infection.

- **An additional trial – if needed – could improve clinical uptake.** Our KOL notes that a solid well replicated Phase 3 trial with a bilateral knee pain exclusion could be a significant help to post approval marketing of Zilretta. Ultimately FLXN could be better served running a 2nd Phase 3 trial and getting significantly better unilateral knee results vs. IR TCA and getting statistically significant results on the 12-week daily pain score.

- **Maintain BUY rating, $35 price target**. Our $35 price target is based on a sum-of-the-parts analysis, with Zilretta valued at $32/share and cash (end 2016) and technology at $3/share.

Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
FY17E	(0.58)	(0.58)	(0.66)	(0.67)	($2.48)	NA
FY16E	($0.64)A	($0.64)	($0.57)	($0.57)	($2.40)	NA
FY15	($0.43)	($0.58)	($0.52)	($0.63)	($2.15)	NA
FY14	($0.86)	($0.38)	($0.45)	($0.47)	($1.97)	NA

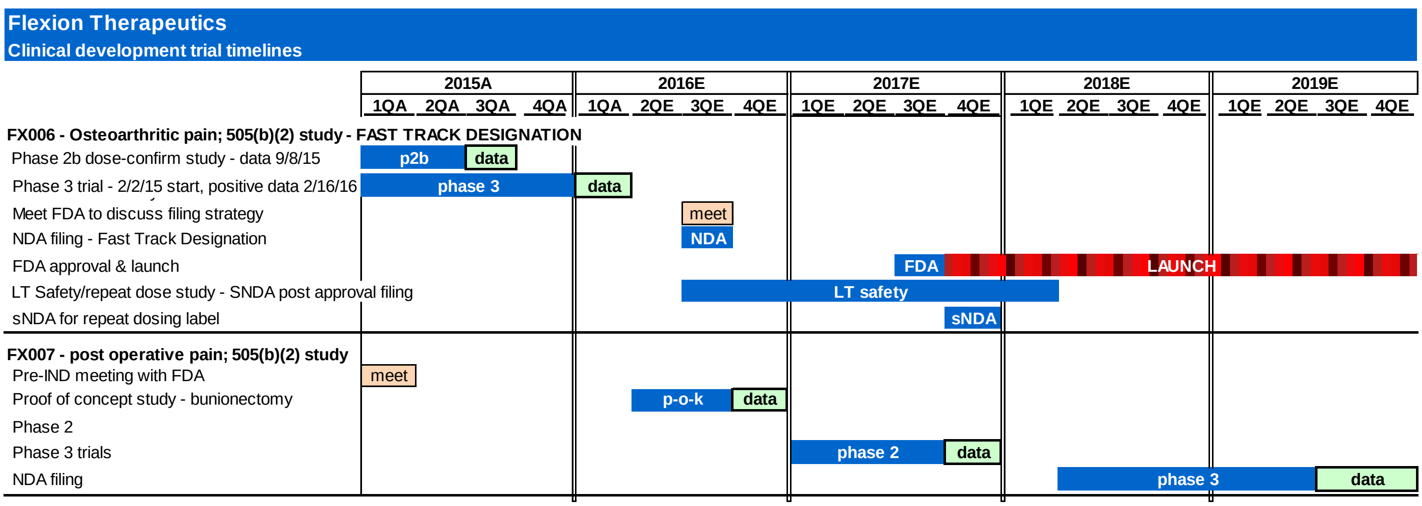
Analyst
Jim Molloy Specialty Pharma & Biotechnology
(617) 283-5521
jmolloy@laidlawltd.com

Figure 1: Valuation

Sum-of-the-parts value: FLXN		
Segment	Valuation (000's)	Per share value
FX006 value	$845,226	$32
Cash (end '16) & tech value	$80,466	$3
SUM	**$925,692**	**$35**
Shares out '16E (000)		26,098

Source: Company Reports: Laidlaw & Company estimates

Figure 2: Upcoming clinical trial timelines



Source: Company Reports: Laidlaw & Company estimates

Quarterly Income Statement

Flexion Therapeutics
Quarterly income statement

	2015A				2015A	2016E				2016E
($000 except per share)	1QA	2QA	3QA	4QA	Year	1QA	2QE	3QE	4QE	Year
Revenues										
Total Revenue										
Expenses:										
Cost of Revenue (COGS)	-	-	-	-	-	-	-	-	-	-
Gross Margin	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
R&D	6,255	9,640	7,829	8,967	32,691	8,981	9,250	9,250	9,500	36,981
SG&A	2,760	2,904	3,197	4,511	13,372	4,692	4,750	5,000	5,000	19,442
Total op. exp.	9,015	12,544	11,026	13,478	46,063	13,673	14,000	14,250	14,500	56,423
Inc (loss) from Ops	**(9,015)**	**(12,544)**	**(11,026)**	**(13,478)**	**(46,063)**	**(13,673)**	**(14,000)**	**(14,250)**	**(14,500)**	**(56,423)**
Int inc (exp), net	(35)	440	71	198.72	675	60	50	50	50	210
Other income (exp)	(123)	(333)	(182)	(289)	(927)	(202)	(200)	(200)	(200)	(802)
Inc (loss) before taxes	**(9,173)**	**(12,437)**	**(11,136)**	**(13,569)**	**(46,315)**	**(13,815)**	**(14,150)**	**(14,400)**	**(14,650)**	**(57,015)**
Income tax exp (benefit)										
Adj-NI ex-1x items	**(9,173)**	**(12,437)**	**(11,136)**	**(13,569)**	**(46,315)**	**(13,815)**	**(14,150)**	**(14,400)**	**(14,650)**	**(57,015)**
Adj EPS ex-1x items	**($0.43)**	**($0.58)**	**($0.52)**	**($0.63)**	**($2.15)**	**($0.64)**	**($0.64)**	**($0.57)**	**($0.57)**	**($2.40)**
Weighted avg. shares (000)	21,451	21,475	21,507	21,555	21,497	21,570	21,970	25,470	25,870	23,720
Fully diluted shares (000)	22,999	23,145	23,223	23,240	23,152	23,948	24,348	27,848	28,248	26,098

Source: Company Reports: Laidlaw & Company estimates

jmolloy@laidlawltd.com

Annual Income Statement

Flexion Therapeutics
Annual income statement

($000 except per share)	2015A	2016E	2017E	2018E	2019E	Comments
Revenues						
Zilretta - OA pain			$1,655	$214,246	$363,049	US launch 2H17
Total Revenue	**$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	32,691	36,981	40,750	35,000	40,000	
G&A	13,372	19,442	26,650	74,750	108,750	Self-launch Zilretta in US
Total op exp	46,063	56,423	67,400	109,750	148,750	
Inc/(loss) from Ops	**(46,063)**	**(56,423)**	**(65,993)**	**72,359**	**159,841**	
Int income (exp), net	675	210	210	300	450	
Other expenses, net	(927)	(802)	(800)	(1,000)	(1,000)	
Inc/(loss) before taxes	**(46,315)**	**(57,015)**	**(66,583)**	**71,659**	**159,291**	
Income tax exp (benefit)	-	-	-	-	23,894	Sig. tax loss carryforwards
Adj-NI ex-1x items	**($46,315)**	**($57,015)**	**($66,583)**	**$71,659**	**$135,398**	
Adj EPS ex-1x items	**($2.15)**	**($2.40)**	**($2.48)**	**$2.25**	**$3.95**	
Weighted avg. shares (000)	21,497	23,720	26,800	29,300	31,800	
Fully diluted shares (000)	23,152	26,098	29,300	31,800	34,300	
Cash balance	$111,327	$87,015	$13,496	$81,698	$215,016	Assume funding 2H16

Source: Company Reports: Laidlaw & Company estimates

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

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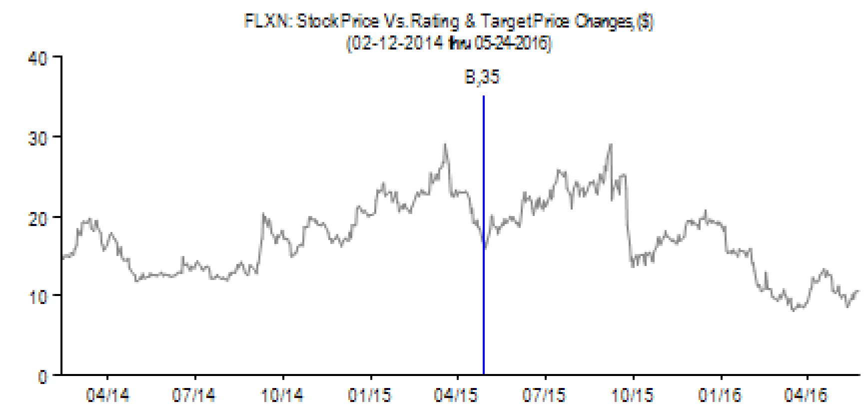
Additional information available upon request.

‡ 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.	66.67%	27.78%	2.78%
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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