

Specialty Pharmaceuticals

Flexion Therapeutics, Inc.

(FLXN) - BUY

Price: **\$12.82**
Fair Value Estimate: \$31.00
52-Week Range: \$11.06-\$20.85
Market Cap (MM): \$200
Shr.O/S-Diluted (mm): 15.6
Average Daily Volume: 33,530

FYE: Dec	2013A	2014E	2015E
EPS:	\$(2.69)A	\$(2.09)E	\$(2.36)E
Prior EPS:		\$(2.03)	\$(3.28)
P/E:	NA	NA	NA

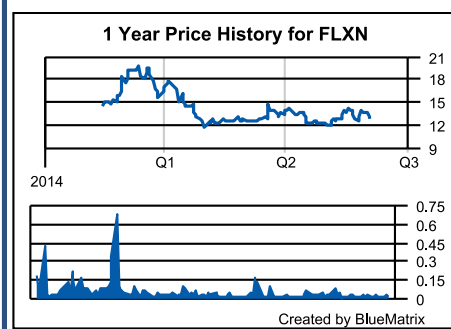
Quarterly EPS:

	2013A	2014E	
Q1	\$(0.75)A	\$(0.86)A	--
Q2	\$(0.75)A	\$(0.38)A	--
Q3	\$(0.75)A	\$(0.42)E	--
Q4	\$(0.51)A	\$(0.59)E	--

FYE: Dec	2013A	2014E	2015E
Revenue (M):	\$0.0A	\$0.0E	--

Quarterly Revenue (M):

	2013A	2014E	
Q1	\$0.0A	\$0.0E	--
Q2	\$0.0A	\$0.0E	--
Q3	\$0.0A	\$0.0E	--
Q4	\$0.0A	\$0.0E	--



Equity Research
Note

FLXN: FX006 Heading into Phase 3 a Year Early

INVESTMENT CONCLUSION:

After the close of the market last night, FLXN announced changes to its clinical development program for FX006 (a sustained-release corticosteroid injection for osteoarthritis of the knee) following a meeting with the FDA. First and foremost, FLXN now plans to initiate their pivotal Phase 3 trial in late 4Q14, almost a full year ahead of schedule. This is made possible by two other FDA decisions; that the approval of FX006 as a single-dose administration will not require data from the planned repeat dose/safety trial slated to begin in 4Q14 and that the current confirmatory Phase 2b trial will count as one of two key efficacy trials. If all goes to plan, this could potentially bring FX006 to the market in 2017, 12 months earlier than expected, which in such a large and growing patient population translates into a substantial revenue benefit. Maintain Buy rating, \$31 FV up from \$22.

KEY POINTS:

- **A full year? How is this really possible?** With the repeat dose/safety trial not necessary for registration as a single-dose injection, this frees up the time and money for FLXN to jump into the pivotal Phase 3. Let's recall that the repeat dose/safety trial was planned to initiate in 4Q14 and is about a 24 months long endeavor. The Phase 3 now will fill that space with the repeat dose/safety trial taking a back seat, now looking at a start date of 1H15 with the expectation of top-line data right after a potential FDA approval in 1H17.
- **A De-Risked Clinical Program:** One of reasons why we like FLXN is that we feel the inherent risk of their clinical program is very minimal. With the Phase 2b using a placebo comparator, we view this as a very de-risked trial and expect positive results due to the past performance in the previous Phase 2b of the 20mg and 40mg dose. In the planned pivotal Phase 3 trial, once again the primary endpoint is efficacy against placebo, and once again, we expect positive results. FLXN will also be running a comparator arm in the Phase 3 against the current standard of care, immediate-release corticosteroid which should benefit them in any discussions with the EMA.
- **Single-dose vs. Repeat-dose:** If FX006 is approved as a single-dose administration does this hinder it in the market place? FLXN management believes that it will not. Their data indicates that if the drug works the way they (we) believe that it will, physicians will use it regardless. Data from the repeat dose/safety trial should follow only a few short months after the potential approval which should take care of any naysayers.
- **Updated Pipeline Catalysts:** The confirmatory Phase 2b trial is still expected to read out in 1H15 with the Phase 3 expected to initiated in 4Q14. Top-line data from the Phase 3 is now expected by year end of 15 with an NDA filing in 1H16.
- **Maintain Buy Rating, \$31 FV up from \$22:** We value FLXN at \$31/share based on a sum-of-the-parts analysis with FX006 sales at \$26/share based on 3.5x multiple of 2019 US sales discounted 5 years at 35%. The remaining \$5/share value is based on cash (end 2014) and tech value.

Research Analyst Certifications and Important Disclosures are on pages 3 - 4 of this report

EXHIBIT1:

Sum-of-the-parts value: Flexion		
Segment	Valuation (000's)	Per share value
FX006 value	\$356,353	\$26.0
Cash (end '14) & tech value	\$70,069	\$5.0
SUM	\$426,422	\$31
Shares out '14E (000)		13,755

Source: Janney estimates

EXHIBIT 2:

Flexion																												
Clinical development trial timelines																												
	2013E				2014E				2015E				2016E				2017E				2018E				2019E			
	1QA	2QA	3QA	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE
FX006 - Osteoarthritic pain; 505(b)(2) study																												
PK study - Phase 2a					pk		data																					
Confirmatory phase 2b study							phase 2				data																	
LT Safety/repeat dose study																												
Phase 3																												
NDA filing																												
FDA approval & launch																												
EU comparatory trial																												
EU filing																												
EMA approval & launch																												
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Source: Company reports and Janney estimates

EXHIBIT 3:
Flexion
Quarterly Financial Statements

FYE December

	F12A	F13A	1Q14A	Jun	Sept	Dec	F14E
INCOME STATEMENT (\$000's except per share)							
Product Revenue							
Other Revenue							
Total Revenues	0	0	0	0	0	0	0
Cost of Sales		0	0	0	0	0	0
Operating Expenses:							
Research & Development	11,065	11,061	4,151	3,615	4,200	6,500	18,466
Selling, General and Administration	3,947	6,704	2,284	2,234	2,400	3,000	9,918
% of Sales							
Total Operating Expenses	15,012	17,765	6,435	5,849	6,600	9,500	28,384
% of Sales							
Operating Income (Loss)	(15,012)	(17,765)	(6,435)	(5,849)	(6,600)	(9,500)	(28,384)
Operating Margin	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Interest Income	194	234	(81)	28	(25)	(25)	(103)
Interest Expense		(449)					0
Other income (expense)	(164)	(207)	(26)	(110)	(50)	(50)	(236)
Pretax Income	(14,982)	(18,188)	(6,542)	(5,931)	(6,675)	(9,575)	(28,723)
Pretax Margin	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Income Tax	0	0	0	0	0	0	0
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
GAAP Net Income	(14,982)	(18,188)	(6,542)	(5,931)	(6,675)	(9,575)	(28,723)
Net Margin							
GAAP EPS	(3.39)	(2.51)	(0.86)	(0.38)	(0.42)	(0.59)	(2.09)
Weighted Avg Shares (000)	4,417	7,247	7,633	15,483	15,793	16,109	13,755
Diluted Shares (000)			9,383	17,233	17,543	17,859	15,505

IMPORTANT DISCLOSURES

Research Analyst Certification

I, Chiara Russo, the Primarily Responsible Analyst for this research report, hereby certify that all of the views expressed in this research report accurately reflect my personal views about any and all of the subject securities or issuers. No part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views I expressed in this research report.

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Flexion Therapeutics, Inc. currently is, or during the past 12 months was, a Janney Montgomery Scott LLC client. Janney Montgomery Scott LLC, provided investment banking related services.

Janney Montgomery Scott LLC managed or co-managed a public offering of securities for Flexion Therapeutics, Inc. in the past 12 months.

Janney Montgomery Scott LLC received compensation for investment banking services from Flexion Therapeutics, Inc. in the past 12 months.

Janney Montgomery Scott LLC intends to seek or expects to receive compensation for investment banking services from Flexion Therapeutics, Inc. in the next three months.

The research analyst is compensated based on, in part, Janney Montgomery Scott's profitability, which includes its investment banking revenues.

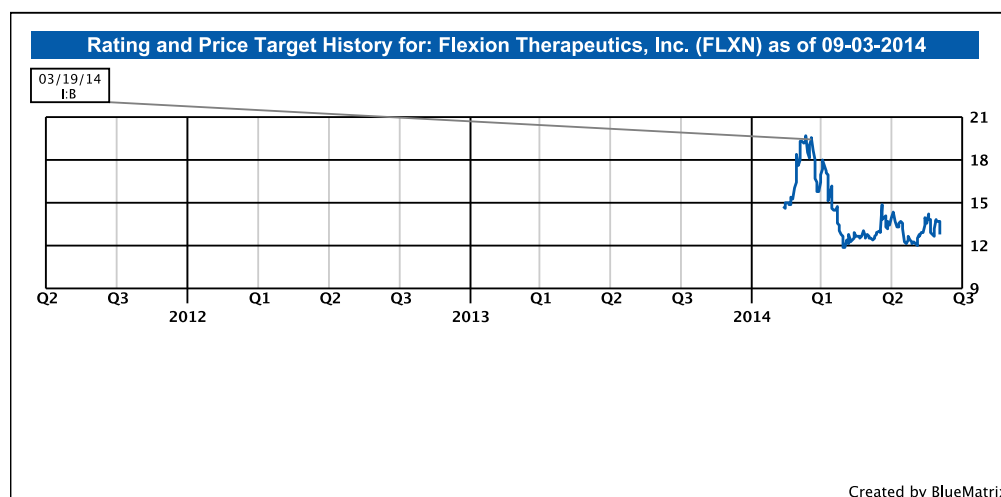
Definition of Ratings

BUY: Janney expects that the subject company will appreciate in value. Additionally, we expect that the subject company will outperform comparable companies within its sector.

NEUTRAL: Janney believes that the subject company is fairly valued and will perform in line with comparable companies within its sector. Investors may add to current positions on short-term weakness and sell on strength as the valuations or fundamentals become more or less attractive.

SELL: Janney expects that the subject company will likely decline in value and will underperform comparable companies within its sector.

Price Charts



Janney Montgomery Scott Ratings Distribution as of 6/30/14

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [B]	207	53.80	53	25.60
NEUTRAL [N]	176	45.70	28	15.90
SELL [S]	2	0.50	0	0.00

***Percentages of each rating category where Janney has performed Investment Banking services over the past 12 months.**

Other Disclosures

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