

Chiara Russo crusso@janney.com

617-557-2984

Flexion Therapeutics, Inc.

FLXN - BUY

August 8, 2014

#### **Specialty Pharmaceuticals**

# Flexion Therapeutics, Inc. (FLXN) - BUY

Price:	\$12.65
Fair Value Estimate:	\$22.00
52-Week Range:	\$11.06-\$20.85
Market Cap (MM):	\$197
Shr.O/S-Diluted (mm):	15.6
Average Daily Volume:	38,830

FYE: Dec 2013A 2014E 2015E EPS: \$(2.69)A \$(2.03)E \$(3.28)E Prior EPS: \$(2.67) NC P/E: NA NA NA

#### Quarterly EPS:

Q1	\$(0.75)A \$(0.86)A	
Q2	\$(0.75)A \$(0.38)A	
Q1 Q2 Q3	\$(0.75)A \$(0.42)E	
Q4	\$(0.51)A \$(0.54)E	

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

#### Quarterly Revenue (M):

Q1	\$0.0A	\$0.0E	
Q2	\$0.0A	\$0.0E	
Q3	\$0.0A	\$0.0E	
Q4	\$0.0A	\$0.0E	



Equity Research Note

### FLXN: 2Q14 Lite on Spend, Strong Clinical Progress

#### INVESTMENT CONCLUSION:

FLXN reported after the close last night, reporting an EPS of (\$0.38), which was well above Janney estimates. On the call management focused on the progress of their lead candidate FX-006, a sustained-release corticosteroid for intra-articular injection for osteoarthritis of the knee with their positive read-out in June from the synovial fluid PK study and the clinical progress of the confirmatory Phase 2b trial expected to read-out in 1Q15. We continue to believe that FX-006 will deliver lasting clinical relief well past the 12 week FDA-required time frame into 16 weeks.. If approved, FX-006 would have a very compelling and competitive product profile compared to the current market. Maintain Buy rating, \$22 fair value.

#### **KEY POINTS:**

- Expect spending to increase in 2H14: FLXN reported 2Q14 earnings after the close of market yesterday with an EPS of (\$0.38), well above Janney estimate of (\$0.54) due to a QoQ decrease in R&D spend. We expect this spend to increase in 2H14 as several clinical trials should initiate. SG&A was in line with expectations. Cash at the end of the quarter was \$72M and should last until the end of 2015.
- Pipeline updates: The confirmatory Phase 2b dose ranging (20mg & 40mg) trial continues to enroll with top-line results expected in 1Q15. This trail is not measuring the aggregating and pre-releasing 60mg dose which threw off the previous Phase 2b results. With this trial 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. Another data point we expect to see is clinical effectiveness of FX-006 well beyond the FDA-required 12 weeks. We anticipate benefit at 16 weeks; however, 20 weeks seems to be pushing it given the PK read out.
- Slowly locking down IP: In late June, FLXN announced a exclusive worldwide licensing agreement with Southwest Research Institute to utilize the microsphere manufacturing process that is used to make FX-006. This move serves to shore up the IP around the manufacturing process. However, we are still waiting for the full composition of matter patent to be granted. Management has indicated an expectation of having the patent issued by the end of the year. Fingers crossed. This remains one of our overhangs on the name and if granted, solidifies some of the value proposition.
- Next Catalysts: Management highlighted several of the next catalysts for the name in the 2H14 and early 2015. First and foremost is the top-line data from the confirmatory Phase 2b for FX-006 which is expected to read out in 1H15. If positive, a Phase 3 would initiate shortly after. The repeat dose/safety trial should initiate in 4Q14. Lastly, a Proof-of-Concept trial for FX-007 (for post-operative pain) is set to begin in late 2014
- Maintain Buy rating, \$22 fair value: We value FLXN at \$22/share based on a sumof-the-parts with FX-006 sales of \$17/share based on 3.5x multiple of 2019 US sales discounted 5 years at 45% to account for the risks remaining in the program. 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

#### **EXHIBIT 1:**

Sum-of-the-parts value: Flexion		
Segment	Valuation	Per share
	(000's)	value
FX006 value	\$249,292	\$17.0
Cash (end '14) & tech value	\$70,869	\$5.0
SUM	\$320,161	\$22
Shares out '14E (000)		14,746

Source: Janney estimates

#### **EXHIBIT 2:**

Flexion

**Quarterly Financial Statements** 

FYE December			Mar	Jun	Sept	Dec	
	F12A	F13A	1Q14A	2Q14A	3Q14E	4Q14E	F14E
INCOME STATEMENT (\$000's except per share)							
Product Revenue							
Other Revenue							
Total Revenues	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	6,300	18,266
Selling, General and Administration	3,947	6,704	2,284	2,234	2,400	2,400	9,318
% of Sales						L	
Total Operating Expenses	15,012	17,765	6,435	5,849	6,600	8,700	27,584
% of Sales							
Operating Income (Loss)	(15,012)	(17,765)	(6,435)	(5,849)	(6,600)	(8,700)	(27,584)
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)
B 4 1	(44.000)	(40.400)	(0.540)	/E 0041	(0.075)	(0.775)	(07.000)
Pretax Income	(14,982)	(18,188) <b>N/A</b>	(6,542)	(5,931)	(6,675)	(8,775)	(27,923)
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)	(8,775)	(27,923)
Net Margin							
GAAP EPS	(3.39)	(2.51)	(0.86)	(0.38)	(0.42)	(0.54)	(2.03)
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.

#### Janney Montgomery Scott LLC ("Janney") Equity Research Disclosure Legend

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.

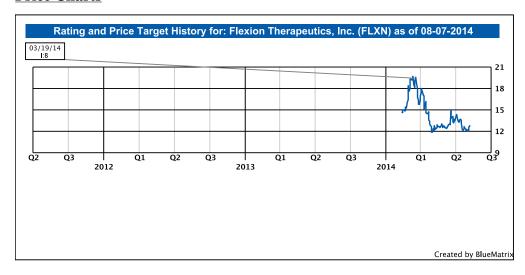
#### **Definition of Ratings**

**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

IB Serv./Past 12 Mos.

Rating	Count	Percent	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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