

Specialty Pharmaceuticals

Price:	\$19.00
Fair Value Estimate:	\$24.50
52-Week Range:	\$11.06 - \$21.23
Market Cap (MM):	\$296
Shr.O/S-Diluted (mm):	15.6
Average Daily Volume:	34,260
Yield:	0.0%
Cash/Share:	\$(20.49)
FCF Yield:	NA
Debt/Cap:	33%

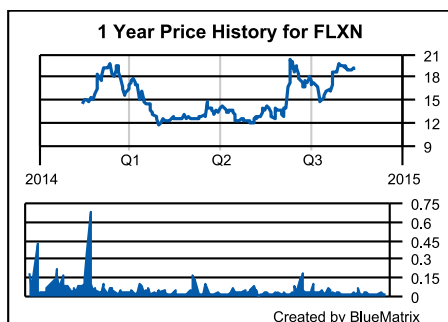
FYE: Dec	2013A	2014E	2015E
EPS:	\$(2.69)A	\$(2.02)A	\$(2.36)E
Prior EPS:		\$(2.09)	NC
Consensus	NM	-2.23	-2.71
P/E Ratio:	NA	NA	NA

Quarterly EPS:

Q1	\$(0.75)A	\$(0.86)A	--
Q2	\$(0.75)A	\$(0.38)A	--
Q3	\$(0.75)A	\$(0.45)A	--
Q4	\$(0.51)A	\$(0.51)A	--

Quarterly Revenue (M):

Q1	\$0A	\$0E	--
Q2	\$0A	\$0E	--
Q3	\$0A	\$0E	--
Q4	\$0A	\$0E	--
Year:	\$0A	\$0E	--



November 14, 2014

## Flexion Therapeutics, Inc.

(FLXN) - BUY

### FLXN: 3Q14 - It was the best of times, it was the worst of times

#### PORTFOLIO MANAGER BRIEF

FLXN reported earnings last night after the close with an EPS of (\$0.45), in-line with Janney estimates of (\$0.42). The clinical halt of the Phase 2b trial for FX006 remains front and center; however, we remain confident that our 4.5 month time-frame for resolution is achievable based on the areas of concern for the FDA and the time required to investigate and gather the needed materials in order for FLXN to submit the complete response. Maintain Buy rating, \$24.50 FV.

#### ANALYST NOTES

- It was the age of wisdom: There were several positive highlights to the quarter. The big positives were two FDA decisions that accelerated the FX006 clinical program by ~12 month: 1) a repeat dose trial for FX006 would not be necessary for approval, and 2) the current Phase 2b trial would count as one of two pivotal trials. Another was the issuance of a composition of matter patent for FX006 in early September. This patent allows for protection out to 2031.

It was the age of foolishness: In mid-September, FLXN announced that the FDA had issued a clinical hold on their Phase 2b trial for FX006 due to a single serious infection at the injection site. From the conference call FLXN management noted the specific FDA concerns around three issues involving product sterility and that FLXN would have to address:

- Recover and test the used drug vial that was used to treat the infected patient
- Recover and test unused drug vials from the study site that the infection occurred
- Explore other potential causes for the infection.
- It was the spring of hope: We come away from the 3Q14 conference call incrementally more positive that our initial estimate of a 4.5 month time until the clinical hold lift is correct. FLXN had study protocols in place that recovered and stored the used vile. Culturing from the used and unused viles takes ~30 days. We believe that FLXN management has been working hard to do a thorough and rigorous evaluation and has either submitted or is close to submitting their complete response to the FDA. Once filed, the FDA has 30 days to respond.
- 3Q14 Financial Review: FLXN reported 3Q14 earnings of (\$0.45) which was in-line with Janney estimates of (\$0.42). R&D spend was \$4.7M incorporating nearly all of

the 3Q Phase 2b expenses and G&A was \$2.3M. The company ended 3Q14 with \$66.6M in cash and cash equivalents.

- Maintain Buy rating, \$24.50 FV: Our \$24.50 FV is based on a delay of 4.5 months. We value FX006 at \$19.50/share on WW sales with \$5/share in cash and technology.

## INVESTMENT THESIS

FLXN is a specialty pharmaceutical company with lead product candidate is FX006, an injectable, sustained-release, intra-articular (IA) steroid treatment for osteoarthritis (OA) pain. FX006 has successfully completed a clinical Phase 2b dose-ranging trial in which it demonstrated clinically meaningful and significantly better pain relief compared to the current injectable standard of care which we believe de-risks the pivotal Phase 2b and future Phase 3. In Sept, the confirmatory Phase 2b trial was halted due to a single patient infection. We believe that the halt will be lifted within 4.5 months, offering upside to the name.

## ISSUES TO CONSIDER

Key Issue	Our Position	Timing	Impact
When will the halt be lifted?	In pulling from past examples, we found that the average time from hold to lift was ~6.5 months. Obviously, this hinges on how quickly FLXN can deliver the requested data to the FDA, but we feel confident that FLXN has made this their highest priority and is already well on their way to submitting their response letter.	0-3 Months	<div><div>+</div><div>○</div><div>-</div></div>
Will the pivotal trials be successful?	The current confirmatory Phase 2b dose ranging (20mg & 40mg) trial 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 doses.	12-24 Months	<div><div>+</div><div>○</div><div>-</div></div>
Will the Phase 3 start on time?	We believe that this is a yes, though not in the way you are thinking. FLXN will most likely pursue the initial start of the Phase 3 abroad as the clinical halt in the US is most likely to remain through YE14 and into early 1Q15.	0-3 Months	<div><div>+</div><div>○</div><div>-</div></div>

## FIVE-YEAR VALUATION

Historical Multiples - Premium to Comps					
Current vs 5 yr Average Historical Premium		5 Yr Historical Premium Range		Implied @ Hist Avg	
Metric	Current	Low	High	Average	Multiple Price (USD)
Current Price					\$19.00
NTM/PE	N/A	N/A	N/A	N/A	N/A
NTM EV/EBITDA	-22.4x	N/A	N/A	N/A	N/A
NTM EV/FCF	N/A	N/A	N/A	N/A	N/A
NTM EV/REV	N/A	N/A	N/A	N/A	N/A
Price/Book	4.5x	2.6x	4.8x	3.2x	\$13.58

# EXHIBIT 1:

Flexion Therapeutics Quarterly variance analysis						
(\$000's except per share)	3Q13A	4Q14A	4Q14E	Variance	% Y/Y	
Product Revenue	\$0	\$0	\$0	\$0	NM	
				0	NM	
<b>Total Revenue</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>NM</b>	
COGS	-	-	-	-	NM	
<b>Gross Profit</b>				<b>0</b>	<b>NM</b>	
R&D Expense	2,942	4,658	4,200	458	58%	
SG&A Expense	1,788	2,304	2,400	(96)	29%	
<b>Operating Inc (loss)</b>	<b>(4,730)</b>	<b>(6,962)</b>	<b>(6,600)</b>	<b>(362)</b>	<b>47%</b>	
				0	NM	
Interest Income	(39)	56	(25)	81	-244%	
Interest expense	0			0	NM	
Other	(64)	(130)	(50)	(80)	103%	
<b>Pretax Inc (loss)</b>	<b>(4,833)</b>	<b>(7,036)</b>	<b>(6,675)</b>	<b>(361)</b>	<b>46%</b>	
Income Taxes	0	0	0	0	NM	
<b>Net Income - ex-1x items</b>	<b>(4,833)</b>	<b>(7,036)</b>	<b>(6,675)</b>	<b>(361)</b>	<b>46%</b>	
Average Shares (000)	6,416	15,625	15,793	(168)	144%	
<b>EPS ex-1x items</b>	<b>(\$0.75)</b>	<b>(\$0.45)</b>	<b>(\$0.42)</b>	<b>(\$0.03)</b>	<b>-40%</b>	

Source: Company reports and Janney estimates

# EXHIBIT 2:

Flexion Quarterly Financial Statements FYE December												
	F12A	Mar	Jun	Sept	Dec		Mar	Jun	Sept	Dec		
		1Q13A	2Q13A	3Q13A	4Q13A	F13A	1Q14A	2Q14A	3Q14A	4Q14E	F14E	
<b>INCOME STATEMENT (\$000's except per share)</b>												
Product Revenue												
Other Revenue												
<b>Total Revenues</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Cost of Sales		0	0	0	0	0	0	0	0	0	0	0
<b>Operating Expenses:</b>												
Research & Development	11,065	3,187	2,950	2,942	1,982	11,061	4,151	3,615	4,658	5,500	17,924	
Selling, General and Administration	3,947	1,521	1,788	1,788	1,607	6,704	2,284	2,234	2,304	2,500	9,322	
% of Sales												
Total Operating Expenses	15,012	4,708	4,738	4,730	3,589	17,765	6,435	5,849	6,962	8,000	27,246	
% of Sales												
<b>Operating Income (Loss)</b>	<b>(15,012)</b>	<b>(4,708)</b>	<b>(4,738)</b>	<b>(4,730)</b>	<b>(3,589)</b>	<b>(17,765)</b>	<b>(6,435)</b>	<b>(5,849)</b>	<b>(6,962)</b>	<b>(8,000)</b>	<b>(27,246)</b>	
<b>Operating Margin</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	
Interest Income	194	(11)	(39)	(39)	323	234	(81)	28	56	(25)	(22)	
Interest Expense					(450)	(449)					0	
Other income (expense)	(164)	(101)	(64)	(64)	22	(207)	(26)	(110)	(130)	(50)	(316)	
<b>Pretax Income</b>	<b>(14,982)</b>	<b>(4,820)</b>	<b>(4,841)</b>	<b>(4,833)</b>	<b>(3,694)</b>	<b>(18,188)</b>	<b>(6,542)</b>	<b>(5,931)</b>	<b>(7,036)</b>	<b>(8,075)</b>	<b>(27,584)</b>	
<b>Pretax Margin</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	
Income Tax	0	0	0	0	0	0	0	0	0	0	0	
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	
<b>GAAP Net Income</b>	<b>(14,982)</b>	<b>(4,820)</b>	<b>(4,841)</b>	<b>(4,833)</b>	<b>(3,694)</b>	<b>(18,188)</b>	<b>(6,542)</b>	<b>(5,931)</b>	<b>(7,036)</b>	<b>(8,075)</b>	<b>(27,584)</b>	
Net Margin												
<b>GAAP EPS</b>	<b>(3.39)</b>	<b>(0.75)</b>	<b>(0.75)</b>	<b>(0.75)</b>	<b>(0.38)</b>	<b>(2.51)</b>	<b>(0.86)</b>	<b>(0.38)</b>	<b>(0.45)</b>	<b>(0.51)</b>	<b>(2.02)</b>	
Weighted Avg Shares (000)	4,417	6,416	6,416	6,416	9,741	7,247	7,633	15,483	15,625	15,938	13,670	
Diluted Shares (000)							9,383	17,233	17,375	17,688	15,420	
<b>Non-GAAP Net Income</b>	<b>(14,982)</b>	<b>(4,820)</b>	<b>(4,841)</b>	<b>(4,833)</b>	<b>(3,694)</b>	<b>(18,188)</b>	<b>(6,542)</b>	<b>(5,931)</b>	<b>(7,036)</b>	<b>(8,075)</b>	<b>(27,584)</b>	
Net Margin												
<b>Non-GAAP EPS</b>	<b>\$ (3.39)</b>	<b>\$ (0.75)</b>	<b>\$ (0.75)</b>	<b>\$ (0.75)</b>	<b>\$ (0.38)</b>	<b>\$ (2.51)</b>	<b>\$ (0.86)</b>	<b>\$ (0.38)</b>	<b>\$ (0.45)</b>	<b>\$ (0.51)</b>	<b>\$ (2.02)</b>	
Weighted Avg Shares (000)	4,417	6,416	6,416	6,416	9,741	7,247	7,633	15,483	15,625	15,938	13,670	
Diluted Shares (000)							9,383	17,233	17,375	17,688	15,420	

## 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.

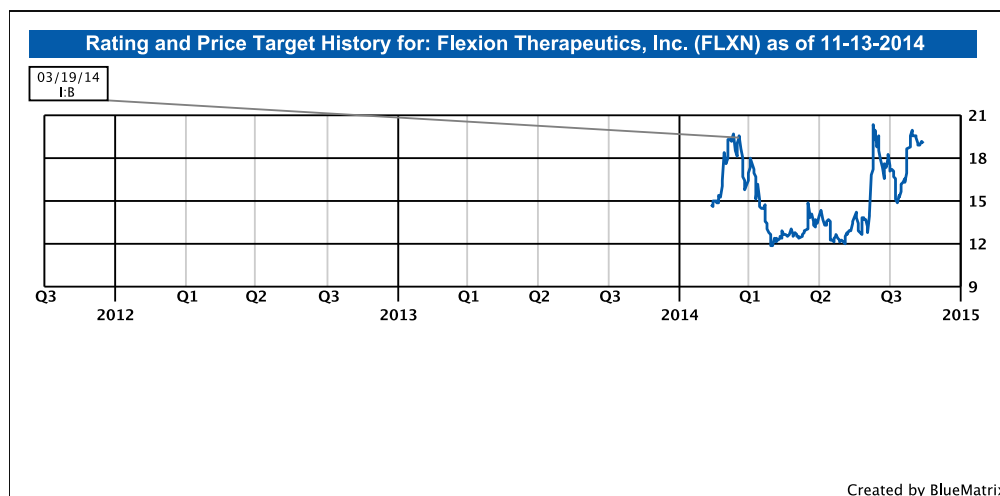
### Definition of Ratings

**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 9/30/14

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
<b>BUY [B]</b>	169	52.81	24	14.20
<b>NEUTRAL [N]</b>	150	46.88	18	12.00
<b>SELL [S]</b>	1	0.31	0	0

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

## Other Disclosures

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