

#### Specialty Pharmaceuticals

\$16.25 Price: Fair Value Estimate: \$24.50 \$11.06 - \$21.23 52-Week Range: Market Cap (MM): \$254 Shr.O/S-Diluted (mm): 15.6 34,488 Average Daily Volume: Yield: 0.0% Cash/Share: \$(20.49) (12.9)% FCF Yield: Debt/Cap: 33%

FYE: Dec	2013A	2014E	2015E
EPS:	\$(2.69)A	\$(2.02)A	\$(2.36)E
Prior EPS:			NC
Consensus	NM	-2.06	-2.85
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):

December 2, 2014

# Flexion Therapeutics, Inc.

(FLXN) - BUY

# FLXN: Clinical Halt is Lifted

#### Flash Takeaways

FLXN announced after the close that the FDA has lifted the clinical halt from their pivotal Phase 2b trial of FX006 for osteoarthritis of the knee. Though our original prediction was 4.5 months or end of January until the lifting of the halt, FLXN has managed only a 2.5 month delay from the initial FDA notification in mid-Sept. Even more importantly, the offending infection appears to be a "false positive," meaning there was no infection in the first place. No SAEs related to the study drug will be recorded.

#### **Analysts Notes**

- A beat on timing: Our original assumption on resolution of the clinical halt was 4.5 months. FLXN management has proven cool and calm under pressure as they have bested our expectations, clearing themselves of the overhang in just 2.5 months. A job well done in our opinion.
- The false positive: As noted in the press release, the singular and only infection seen so far in the over 100 dosed patients appears to be a "false positive" which, per the literature, occurs in approximately 5% of cases. In other words, there was no infection to begin with. With that said....
- So what was it? The patient in question had a highly atypical presentation for septic arthritis, to the point where progress towards clinical resolution was not made until the patient received a large dose of steroids. This clinical course is more consistent with rheumatoid arthritis, not septic. The principal investigator has changed the initial SAE diagnosis from septic arthritis, possibly related to study drug to inflammatory arthritis, unrelated to treatment.
- <u>Conference call in the morning:</u> FLXN will be holding a conference call Tuesday morning at 9AM to provide further details.



#### 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.

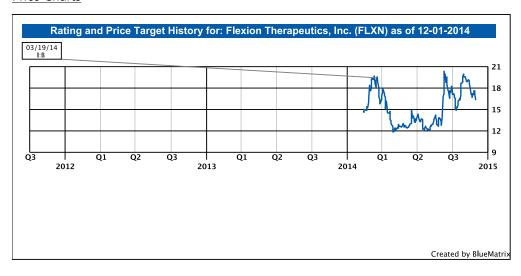
# Definition of Ratings

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

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Rating	Count	Percent	Count	Percent
BUY [B]	169	52.81	24	14.20
NEUTRAL [N]	150	46.88	18	12.00

0.31

0

IB Serv./Past 12 Mos.

SELL [S]

0

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

#### Other Disclosures

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