

## Specialty Pharmaceuticals

### Flexion Therapeutics, Inc.

(FLXN) - BUY

**Price:** **\$19.38**

Fair Value Estimate: \$31.00

52-Week Range: \$11.06-\$21.23

Market Cap (MM): \$303

Shr.O/S-Diluted (mm): 15.6

Average Daily Volume: 41,037

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

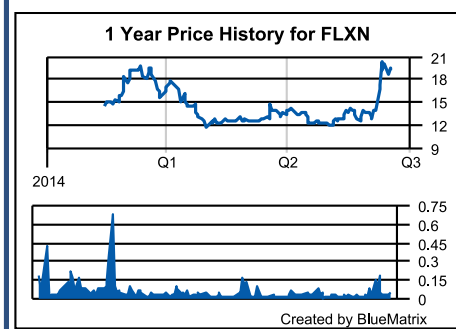
#### Quarterly EPS:

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):

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



Equity Research  
**FLASH** Note

## FLXN: Phase 2b of FX006 Halted over Single Infection

### KEY POINTS:

- **Clinical hold on Phase 2b trial of FX006:** After the close, FLXN announced that a clinical hold has been placed on their ongoing Phase 2b trial for FX006, a sustained-release corticosteroid intra-articular injection for osteoarthritis of the knee. The hold, as communicated verbally by the FDA is due to a single occurrence of an infection in the injected knee joint of a patient in the trial.
- **FDA being conservative, but understandable:** A single, yet serious infection did occur in the injected knee of a patient in the clinical trial with that patient having to go on IV antibiotics. Though the immediate concern centers around possible batch contamination, we feel this is unlikely considering that the drug is twice-sterilized via radiation, including the final container which is considered "terminally sterile". Though we understand the rationale of the FDA in halting the trial, we feel that this a conservative take on events.
- **Many other variables could cause infection:** As FX006 is administered via injection there are many possible points at which the infection could have originated, including an already underlying infection in the patient himself. We feel that it one of these more negligible issues at the root, considering FX006 has been dosed to more than 330 patients to date without such incidence.
- **Next steps - Wait and See:** With the clinical hold, FLXN now will need to provide documentation on manufacturing process, proper technique and procedure in the study sites as well as comprehensive and rigorous evaluation of the patient. No time line has been given as to when FLXN will have the necessary documentation submitted to the FDA, and there is no time line currently for a potential lift on the clinical halt.
- Conference call this morning at 9:00AM. Dial in: 855-770-0022

Research Analyst Certifications and Important Disclosures  
are on pages 2 - 3 of this report

## **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.

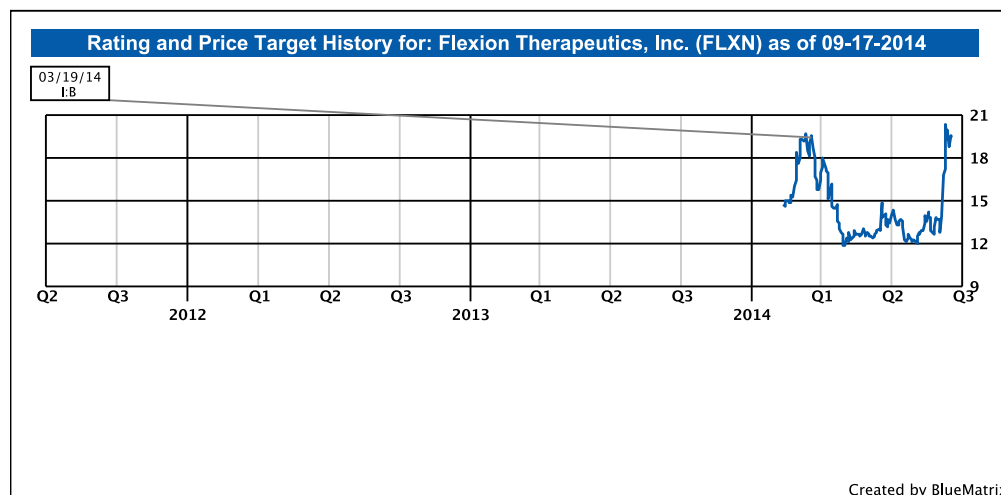
### **Definition of Ratings**

**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**

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**

Janney Montgomery Scott LLC, is a U.S. broker-dealer registered with the U.S. Securities and Exchange Commission and a member of the New York Stock Exchange, the Financial Industry Regulatory Authority and the Securities Investor Protection Corp.

This report is for your information only and is not an offer to sell or a solicitation of an offer to buy the securities or instruments named or described in this report. Interested parties are advised to contact the entity with which they deal or the entity that provided this report to them, should they desire further information. The information in this report has been obtained or derived from sources believed by Janney Montgomery Scott LLC, to be reliable. Janney Montgomery Scott LLC, however, does not represent that this information is accurate or complete. Any opinions or estimates contained in this report represent the judgment of Janney Montgomery Scott LLC at this time and are subject to change without notice.

Investment opinions are based on each stock's 6-12 month return potential. Our ratings are not based on formal price targets, however, our analysts will discuss fair value and/or target price ranges in research reports. Decisions to buy or sell a stock should be based on the investor's investment objectives and risk tolerance and should not rely solely on the rating. Investors should read carefully the entire research report, which provides a more complete discussion of the analyst's views. Supporting information related to the recommendation, if any, made in the research report is available upon request.