

## Specialty Pharmaceuticals

### Flexion Therapeutics, Inc.

#### (FLXN) - BUY

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

Fair Value Estimate: \$24.50

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

Market Cap (MM): \$302

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

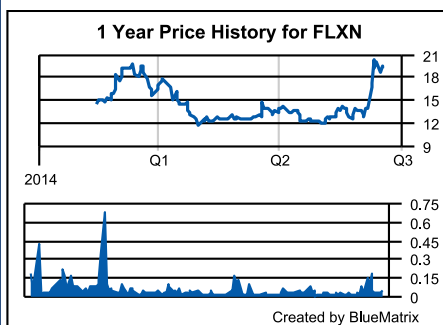
#### Quarterly EPS:

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**  
**Note**

## FLXN: FX006 Program Will See Delay, Most Likely Less Than 6 Months

### INVESTMENT CONCLUSION:

After the close on Wednesday, FLXN announced that the FDA had placed a clinical hold on patient enrollment and dosing of its Phase 2b clinical trial of FX006, FLXN's lead product candidate for osteoarthritis of the knee. FX006 is an intra-articular injection of a sustained-release corticosteroid and the hold was due to a single serious adverse event of a patient developing an infection in the injected knee that required hospitalization and antibiotics. Management believes that the main concern of the FDA for the hold is the potential of batch contamination. However, with ~100 patients already dosed from the same single batch of drug and the pristine pedigree of the manufacturing facility, we believe that FLXN will be able to provide data to the FDA that supports product and batch sterility. Though this will delay the FX006 program, we do not believe that it will be longer than 6 months if not shorter, based on other clinical halt outcomes. We are adjusting our FV to support a 4.5 month delay to the program. Maintain Buy rating, \$24.50 FV down from \$31.

### KEY POINTS:

- **Most Likely Not Batch Contamination: - 1) Patients:** The most immediate concern of the FDA is most likely batch contamination. Management stated on the follow up conference call that all patients in the trial are being dosed from the same single batch produced by Evonik. With ~100 patients already dosed from that batch with only mild to moderate musculoskeletal side effects seen, it seems unlikely that the batch as a whole is contaminated. **2) Facility:** The single batch of drug was manufactured by Evonik in their Birmingham, AL plant. Evonik is a German based global specialty chemical manufacturer and is one of the largest manufacturers of PLGA products in the world. As mentioned in the call, the facility operates in an aseptic environment with the FX006 product dosed with gamma radiation in final packaging for "terminal sterility". The facility manufactures other PGLA drugs and components and as far as we are aware has never had any issues with product sterility testing.
- **Multiple Points of Origin for Infection:** There are many points other than batch contamination in which the infection could have come from. There is an inherent risk in injection from needle and skin sterility as well as the patients themselves with the possibility of septic arthritis; a condition that occurs in 1/1000 patients and is an escalation of an already existing infection such as UTI. We feel that one of these more minor scenarios is most likely the cause and would not warrant additional clinical delay.
- **Resolution Timeframe of Less than 6 Months:** 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 will be in constant contact with the FDA throughout this process.

- **Maintain Buy rating, \$24.50 FV:** Our \$24.50 FV is based on a delay of 4.5 months taken as an average between a 3- and 6-month delay FV. We value FLXN with a 6-month delay at \$22 with \$17/share on WW sales of FX006 with remaining \$5/share in **Research Analyst Certifications and Important Disclosures are on pages 4 - 5 of this report**

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cash & tech and with a 3-month delay at \$27 with \$22/share on WW sales of FX006 with remaining \$5/share in cash & tech.

**EXHIBIT 1:**

Company	Background	Initial Hold	Hold Lifted	TIME ELAPSED
Insmmed (INSM)	Phase 3 in NTM, potential cancer signal, 9-month canine tox study required	August 2011	May 2012	9 months
Geron (GERN)	Phase 2 for ET and PV, potential liver function	March 2014	Partial lift June 2014	3 months
Achillion Pharma (ACHN)	Phase 1 in Hep C, potential liver function	Sept 2013	June 2014	9 months
Concert Pharma (CNCE)	Phase 1 for spasticity, pretoxicity required	Nov 2013	July 2014	8 months
Araid Pharma (ARIA)	Phase 2 for cancer, potential for blood clots and liver tox, partial clinical hold	Oct 2013	June 2014	8 months
Halozyne Therapeutics (HALO)	Phase 2 in pancreatic cancer, potential of thromboembolic events	April 2014	June 2014	2 months
Helix Biopharma (HPB)	Phase 2/3 in cervical lesions, durability issues	Nov 2010	Nov 2011	12 months
Idenix (IDIX)	Phase 1 - IDX184 for Hep C, potential drug-drug interactions with liver tox	Sept 2010	Full lifted, put on partial Feb 2011	5 months
	IDX320	Sept 2010	Discontinued Feb 2011	N/A
	IDX184	Partial Feb 2011	Discontinued Feb 2012	N/A
	IDX20963	June 2013	Meredck bought company June 2014	N/A
Oncomed (OMED)	Phase 1 in solid tumors, partial clinical hold due to bone adverse events	June 2014	Sept 2014	3 months
Source: Janney estimates		<b>AVERAGE:</b>		<b>6.56</b>

**EXHIBIT 2:**

Sum-of-the-parts value: THREE MONTH DELAY		
Segment	Valuation (000's)	Per share value
FX006 value	\$298,875	\$22.0
Cash (end '14) & tech value	\$70,069	\$5.0
<b>SUM</b>	<b>\$368,944</b>	<b>\$27</b>
Shares out '14E (000)		13,755

Source: Janney estimates

Sum-of-the-parts value: SIX MONTH DELAY		
Segment	Valuation (000's)	Per share value
FX006 value	\$228,752	\$17.0
Cash (end '14) & tech value	\$70,069	\$5.0
<b>SUM</b>	<b>\$298,821</b>	<b>\$22</b>
Shares out '14E (000)		13,755

Source: Janney estimates

## **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.

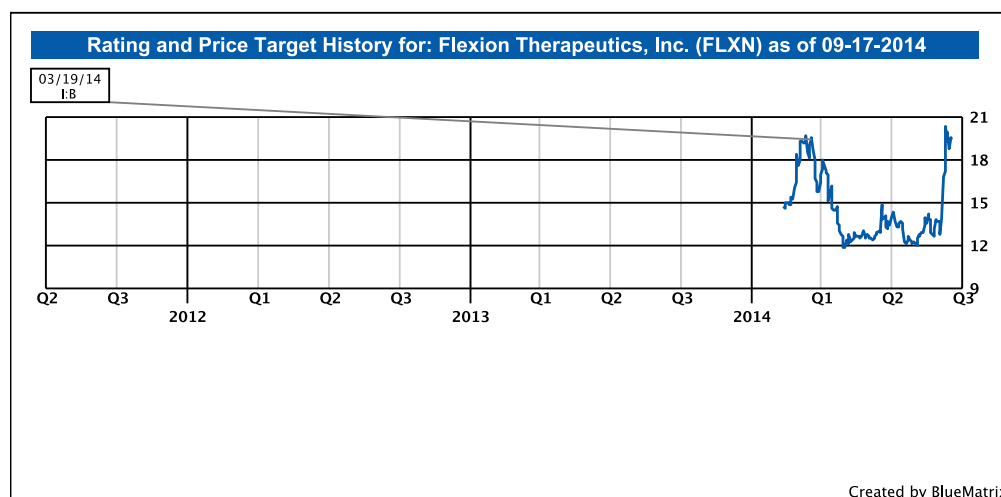
### **Definition of Ratings**

**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**



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### **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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