

#### Specialty Pharmaceuticals

\$23.30 Price: Fair Value Estimate: \$30.00 \$11.06 - \$24.48 52-Week Range: Market Cap (MM): \$482 Shr.O/S-Diluted (mm): 20.7 106,415 Average Daily Volume: Yield: 0.0% Cash/Share: \$(20.49) FCF Yield: (9.0)% Debt/Cap: 33%

FYE: Dec	2013A	2014E	2015E
EPS:	\$(2.69)A	\$(1.82)E	\$(1.75)E
Prior EPS:		NC	NC
Consensus	NM	NM	-2.05
P/E Ratio:	NA	NA	NA

#### Quarterly EPS:

Q1	\$(0.75)A	\$(0.86)A	\$(0.54)E
Q2	\$(0.75)A	\$(0.38)A	\$(0.40)E
Q3	\$(0.75)A	\$(0.45)A	\$(0.41)E
Q4	\$(0.51)A	\$(0.37)E	\$(0.41)E

#### Quarterly Revenue (M):

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



February 24, 2015

# Flexion Therapeutics, Inc.

(FLXN) - BUY

# InFLEXION Point in 4Q15 as Phase 2b Completes Enrollment

#### Flash Takeaways

FLXN announced this morning that it has completed the enrollment of its Phase 2b clinical study of lead product candidate FX006 (extended-release corticosteroid for osteoarthritis of the knee). This trial will count as a pivotal trial for FDA approval with data expected in 4Q15. If positive, which we have a high degree of confidence for this outcome, it should be predictive of the ongoing Phase 3 trial set to read out in 1H16. FLXN remains one of our top picks for 2015. Maintain Buy rating, \$30 FV.

#### **Analysts Notes**

- <u>Details of the Phase 2b:</u> FLXN's Phase 2b trial is powered to be a pivotal confirmatory clinical trial with 310 enrolled patients. Patients were treated with either 20mg or 40mg of FX006 or placebo. The primary endpoint is weekly mean change of average daily pain measured by an 11 point scale. Though measured over a 24-week period, the primary endpoint is 12 weeks. Secondary endpoints include WOMAC pain, stiffness and function, and patient feedback.
- Phase 2b should be highly predictive of Phase 3: The ongoing Phase 3 trial is slightly larger with ~450 patients with three treatment arms, 40mg of FX006, 40mg or triamcinolone acetonide (TCA) or placebo. Here again, the primary endpoint is magnitude and pain relief over 12 weeks of FX006 compared to placebo. The use of immediate release TCA is more for generating head-to-head data for commercial and marketing purposes. Data for the Phase 3 is expected in 1H16.
- <u>Catalysts Going Forward:</u> We believe that the read out of the Phase 2 will be a meaningful value driver for FLXN, namely for the read-through into the Phase 3. Again, Phase 2b data in 4Q15 with Phase 3 in 1H16. If both trials are positive, the NDA should file in 2H16 with approval in 2H17.
- Maintain Buy rating, \$30 FV: We value FLXN at \$30/share based on a sum-of-the-parts analysis with FX006 sales at \$25/share based on a 3.5x sales multiple of 2020 US sales discounted 5 years at 32%. The remaining \$5/share is based on cash (end 2015) and tech value.

#### 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.

# <u>Definition of Ratings</u>

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 12/31/14

			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [B]	138	51.30	15	10.87
NEUTRAL [N]	131	48.70	5	3.82
SELL [S]	0	0.00	0	0.00

<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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