## **Equity Research**

### Flash Comment



June~18,~2014 FLXN-NASDAQ--Outperform (1) / V

**Specialty Pharmaceuticals** 

# FLXN: FX006 Development Remains On Track with Positive Phase 2a PK Results

Michael Faerm, Senior Analyst (212) 214-8026

### Sector Rating: Specialty Pharmaceuticals, Overweight

- Summary. On June 17 after market close, FLXN announced top-line results from the Phase 2a synovial fluid pharmacokinetic (PK) trial for FX006. More discussion of the data is expected at the 2014 Wells Fargo Healthcare Conference on June 18 at 3:00pm ET. The Phase 2a data were positive and in line with our expectations, and FX006 remains on track toward FLXN's target of releasing data from the Phase 2b confirmatory study in H1 2015.
- Key takeaways. Therapeutic concentration levels of FX006 were found to be maintained in the synovial fluid through at least 12 weeks following a single intra-articular (IA) injection. The results are consistent with the previously completed Phase 2b dose-ranging efficacy trial demonstrating meaningful pain relief over 12 weeks compared to standard of care, and could point toward use of a 3-4 month interval in FLXN's repeat dose safety study expected to start in late 2014.
- Study results. The study consisted of 50 patients with OA of the knee in one of five arms one arm receiving a single IA injection of FX006 at 10mg, three arms each receiving a 40mg dose, and another arm receiving a dose of immediate release triamcinolone acetonide (TCA). The 10mg dose arm and one of the 40mg dose arms were each sampled at 12 weeks revealing therapeutic concentrations of FX006 in the synovial fluid. Another 40mg arm was sampled at 16 weeks showing measurable but lower drug concentrations than those of the 12 week sampling while a third 40mg arm, sampled at 20 weeks, showed unmeasurable drug concentrations. The TCA arm sampled at 20 weeks demonstrated unmeasurable quantities.
- What's next? FLXN expects to share more details of the study at an upcoming scientific meeting and anticipates topline data from the Phase 2b confirmatory study in H1 2015 and the initiation of Phase 3 development thereafter.

Flexion Therapeutics, Inc. (FLXN-NASDAQ)

Price as of 6/17/2014: \$12.88

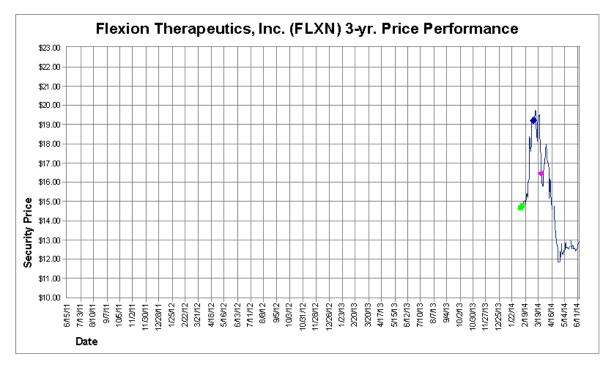
FY 14 EPS: \$-2.79 FY 15 EPS: \$-3.41 Shares Out.: 15.6 MM Market Cap.: \$200.93 MM

Please see Disclosure Appendix for rating definitions, important disclosures, and required analyst certifications.

All estimates/forecasts are as of 06/18/14 unless otherwise stated.

### DISCLOSURE APPENDIX

### **Required Disclosures**



	Date	Publication Price (\$)	Rating Code	Val. Rng. Low	Val. Rng. High	Close Price (\$)
•	2/12/2014		IPO at \$13.00			
	3/10/2014		Faerm			
•	3/10/2014	19.26	1	24.00	26.00	19.22
•	3/26/2014	15.76	1	23.00	25.00	16.43

Source: Wells Fargo Securities, LLC estimates and Reuters data

### Symbol Key

- Rating Downgrade
- Rating Upgrade
- Valuation Range Change

### Initiation, Resumption, Drop or Suspend

- Analyst Change
- Split Adjustment

### Rating Code Key

1 Outperform/Buy SR Suspended 2 Market Perform/Hold NR Not Rated 3 Underperform/Sell NE No Estimate

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**FLXN:** Risks to our valuation pertain to FLXN's ability to successfully develop and commercialize FX006, including product concentration, clinical, regulatory, commercial, intellectual property, and future financing risk.

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- **1 = Outperform:** The stock appears attractively valued, and we believe the stock's total return will exceed that of the market over the next 12 months, BUY
- **2** = **Market Perform:** The stock appears appropriately valued, and we believe the stock's total return will be in line with the market over the next 12 months. HOLD
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#### SECTOR RATING

- **O** = **Overweight:** Industry expected to outperform the relevant broad market benchmark over the next 12 months.
- **M** = **Market Weight:** Industry expected to perform in-line with the relevant broad market benchmark over the next 12 months.
- **U** = **Underweight:** Industry expected to underperform the relevant broad market benchmark over the next 12 months.

### **VOLATILITY RATING**

V = A stock is defined as volatile if the stock price has fluctuated by +/-20% or greater in at least 8 of the past 24 months or if the analyst expects significant volatility. All IPO stocks are automatically rated volatile within the first 24 months of trading.

#### As of: June 18, 2014

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