

February 2, 2015

FLXN-NASDAQ--Outperform (1) / V

Specialty Pharmaceuticals

FLXN: FX006 Phase 3 Is Initiated As Expected--Program Timeline Remains On Track

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Sector Rating: Specialty Pharmaceuticals, Overweight

Today (February 2), after market close, FLXN announced the initiation of the Phase 3 trial for the company's lead product candidate, FX006, for osteoarthritis (OA) of the knee with the first patient dosed as planned. The start of this trial is an expected but important step in the overall development program for FX006. Along with the confirmatory Phase 2b study currently underway, this trial is expected to form the data package for FDA approval.

Primary takeaway: program remains on track for H2 2016 FDA filing. Today's announcement validates that the FX006 clinical program is on track as previously believed. Key milestones expected by FLXN continue to include the following, consistent with past comments: (1) confirmatory Phase 2b data in H2 2015; (2) Phase 3 data in H1 2016; (3) NDA filing in H2 2016; (4) FDA approval in Q2-Q3 2017; and (5) a potential launch in H2 2017.

Key stock catalyst is confirmatory Phase 2b data in H2 2015. Data for FLXN's confirmatory Phase 2b study versus placebo is a critical development milestone and catalyst for the stock. The company is guiding to a H2 2015 release. We believe it could come in Q3 2015, as the timeline prior to the clinical hold could have resulted in Q2 2015 data, and the hold was about 2.5 months long. We look for more precise definition of the data timing if and when FLXN announces the completion of enrollment in the coming months.

Trial design details: The Phase 3 trial will occur in 60 centers worldwide in 450 patients and 3 arms treated with 40mg of FX006, IR TCA, or placebo. The primary objective is to assess pain relief at 12 weeks versus placebo with a 6 month follow-up. The Phase 2b study consists of 300 patients in 3 arms with 20mg and 40mg FX006 and placebo. FLXN reports that Phase 2b enrollment is progressing well and foresees no significant challenges recruiting for 2 concurrent studies.

Flexion Therapeutics, Inc. (FLXN-NASDAQ)

Price as of 2/2/2015: \$21.22

FY 14 EPS: \$-2.07

FY 15 EPS: \$-2.67

Shares Out.: 15.6 MM

Market Cap.: \$331.03 MM

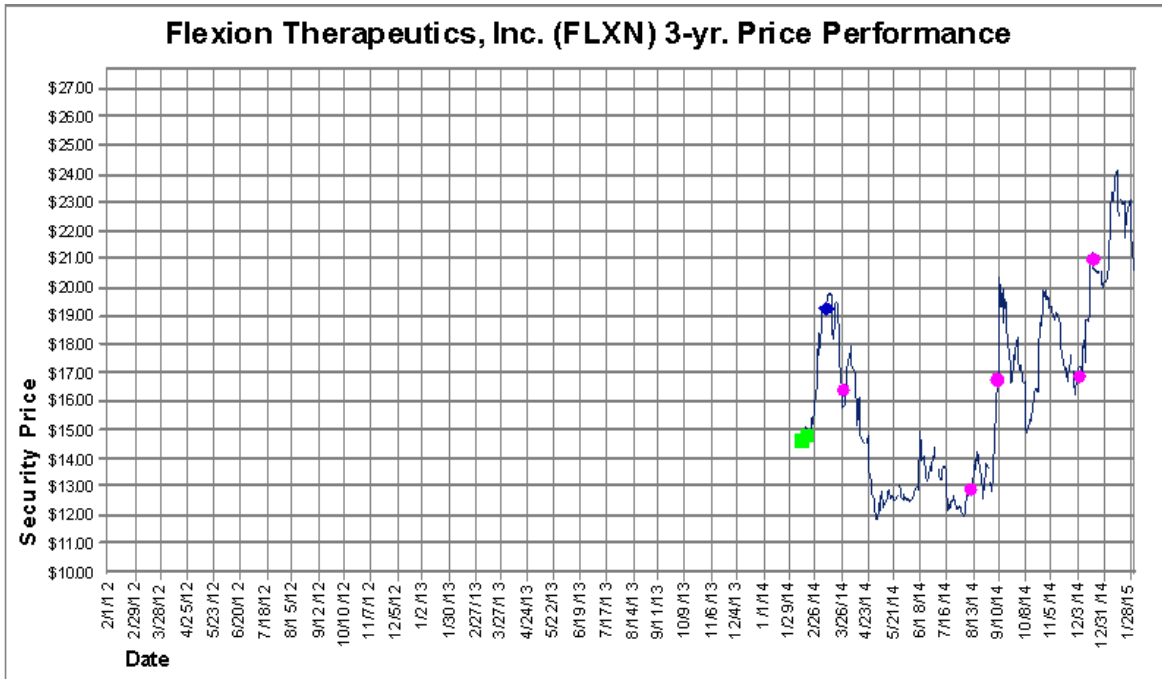
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Required Disclosures



	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
●	8/8/2014	12.93	1	24.00	26.00	12.95
●	9/8/2014	14.06	1	29.00	31.00	16.79
●	12/3/2014	16.85	1	28.00	30.00	16.89
●	12/18/2014	21.02	1	26.00	28.00	21.02

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

2 Market Perform/Hold

3 Underperform/Sell

SR Suspended

NR Not Rated

NE No Estimate

Additional Information Available Upon Request

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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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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

3 = Underperform: The stock appears overvalued, and we believe the stock's total return will be below the market over the next 12 months. SELL

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.

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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: February 2, 2015

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