

December 1, 2014

FLXN-NASDAQ--Outperform (1) / V

Specialty Pharmaceuticals

FLXN: FX006 Clinical Hold Is Lifted Sooner Than Expected

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Sector Rating: Specialty Pharmaceuticals, Overweight

What happened: FLXN announced after market close on December 1, 2014 that FDA has removed the clinical hold on FX006, FLXN's lead drug candidate in studies for treatment of osteoarthritis knee pain. We are not surprised at this outcome, but it comes sooner than expected, and is good news in that it allows FLXN's clinical program to resume with modest impact to the overall timeline. FLXN will hold a conference call December 2 at 9:00am ET.

Good news comes sooner than expected: FLXN gave its last update on the clinical hold with Q3 earnings on November 13, when FLXN stated it was in progress with its investigation (per FDA) into the case of joint infection that caused the hold, and that next steps would be completing the investigation, submitting a complete response to FDA within 30 days, and receiving a response from FDA within 30 days. Now, FLXN has announced that the hold has been lifted. We had assumed that the hold would ultimately be lifted without material impact to FX006's development progress, but the speed of this resolution is encouraging, and provides further comfort that the single case of joint infection was likely an isolated incident, and that FLXN's injection procedures and clinical drug material are sterile and as they should be.

Impact on clinical timeline: FLXN will immediately resume recruitment and dosing in its Phase 2b confirmatory study, and will initiate its planned Phase 3 in early 2015. We expected Phase 2b confirmatory data to come in Q2 2015 when the study was initiated earlier this year; about 2.5 months has elapsed from the announcement of the clinical hold on September 17 until lifting, thus we'd expect data to come in Q3 2015, or possibly Q4. We hope to find out more on the conference call (details below). The Q1 2015E start of Phase 3 is in line with our expectations and consistent with FLXN's comments on the Q3 earnings call.

Flexion Therapeutics, Inc. (FLXN-NASDAQ)

Price as of 12/1/2014: \$16.25

FY 14 EPS: \$-2.10

FY 15 EPS: \$-3.41

Shares Out.: 15.6 MM

Market Cap.: \$253.5 MM

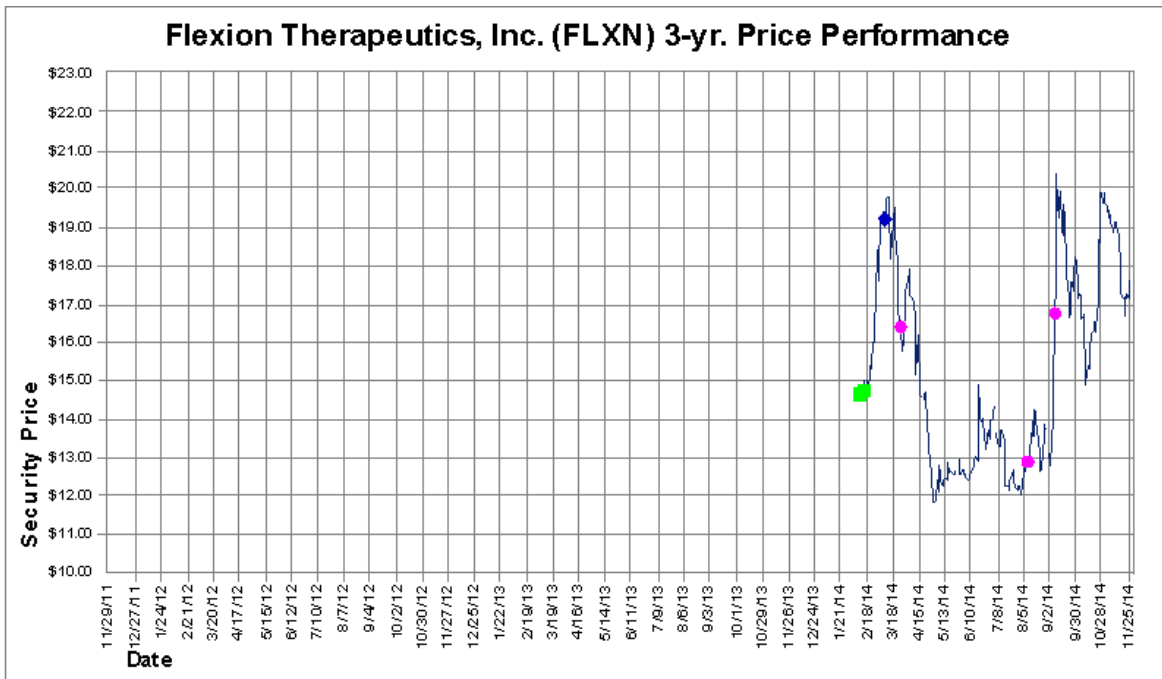
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| | Date | Publication Price (\$) | Rating Code | Val. Rng. Low | Val. Rng. High | Close Price (\$) |
|---|-----------|------------------------|----------------|---------------|----------------|------------------|
| □ | 2/12/2014 | | IPO at \$13.00 | | | |
| | 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 |

Source: Wells Fargo Securities, LLC estimates and Reuters data

Symbol Key

| | | | |
|---|------------------------|---|---|
| ▼ | Rating Downgrade | ◆ | Initiation, Resumption, Drop or Suspend |
| ▲ | Rating Upgrade | ■ | Analyst Change |
| ● | Valuation Range 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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SECTOR RATING

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M = Market Weight: Industry expected to perform in-line with the relevant broad market benchmark over the next 12 months.

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As of: December 1, 2014

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