Summer Street RESEARCH PARTNERS

# Flexion Therapeutics, Inc. (FLXN)

## FDA Letter Confirms "Best-Case" Scenario for Flexion

**October 28, 2014**

Biopharmaceuticals — Company Update

### SUMMARY

We understand that FLXN has recently received its clinical hold letter from the FDA, and per our conversations with management we believe that letter confirms a "best case" scenario for FLXN. In agreement with FLXN's comments back in September after receiving verbal notification of the clinical hold, the FDA is simply requiring FLXN to determine that the infection in the trial was not related to FX006, rather than the more challenging task of determining the ultimate root cause of the infection. We believe that proving FX006 was not the cause of infection ought to be a lower bar to resolve, involving a 30-day culture of a sample from the trial batch, which is currently ongoing, with results likely in early November. At this point, assuming the culture comes back negative, FLXN will look to have a meeting with the FDA to discuss lifting the clinical hold. This will likely be the biggest source of delay, in our opinion, given the upcoming year-end holidays and the relative challenges of getting the FDA to prioritize what FLXN wants prioritized, as opposed to what the FDA wants to prioritize. We continue to expect the FX006 clinical hold will be resolved in 1H15 to mid-15, and we reiterate our BUY rating $28 price target.

### INTERPRETATION

**Compounding pharmacy fiasco likely drove excess caution.** The 2012 fiasco involving the New England Compounding Center (among others), where a fungal contamination in epidural steroid injections led to multiple deaths, is likely the main reason for the FDA's abundance of caution with FLXN.

**FX006 culture results potentially in early November.** FLXN is currently culturing samples from the batch used in the clinical trial, with results expected after ~30 days (early November in our estimate). Assuming the cultures show no contamination in November, as all the post-manufacturing samples from the same batch have already shown, we expect FLXN to seek a meeting with the FDA in the November-December timeframe to resolve the clinical hold.

**Awaiting the FDA now the biggest hurdle.** While resolving the clinical hold is a top priority for FLXN, it is likely not as big a priority at the FDA, where smaller companies can be put "at the back of the line." We believe that waiting on the FDA to lift the clinical hold will ultimately end up being the biggest delay in resolving FX006's clinical hold.

**Trial should be able to restart quickly.** While not enrolling or injecting any new patients while on hold, FLXN is still collecting 20-week follow-up data on patients who have already received their initial dose of FX006. Once the clinical hold is lifted it should be a quick process to restart injecting patients with drug.

### ACTION

**Reiterate BUY rating, $28 price target.** Our $28 price target is based on a sum-of-the-parts analysis, with FX006 valued at $22/share, FX007 at $0.50/share, and cash (end 2015) and technology at $5.50/share.

**FLXN**
**Rating: BUY**
**Price Target: $28.00**

| Market Data | |
|---|---|
| Price: | $19.90 |
| 52-week high: | $21.23 |
| 52-week low: | $11.06 |
| Shares out: | 15.62MM |
| Shares short: | 215.91K |
| Average volume (10-day): | 26,414 |

| Valuation Metrics | |
|---|---|
| Market cap: | $310.92MM |
| Enterprise value: | $223.35MM |

| Financial Highlights | |
|---|---|
| Cash/equivalents: | $71.99MM |
| Debt: | $4.57MM |

| REV ($MM) | 2013A | 2014E | 2015E |
|---|---|---|---|
| Q1 | 0.0 | 0.0A | 0.0 |
| Q2 | 0.0 | 0.0A | 0.0 |
| Q3 | 0.0 | 0.0 | 0.0 |
| Q4 | 0.0 | 0.0 | 0.0 |
| FY | 0.0 | 0.0 | 0.0 |

| EPS ($) | 2013A | 2014E | 2015E |
|---|---|---|---|
| Q1 | (6.13) | (0.86)A | (0.67) |
| Q2 | (6.13) | (0.38)A | (0.52) |
| Q3 | (6.12) | (0.43) | (0.52) |
| Q4 | (4.65) | (0.43) | (0.52) |
| FY | (23.02) | (1.90) | (2.20) |

One-Year History


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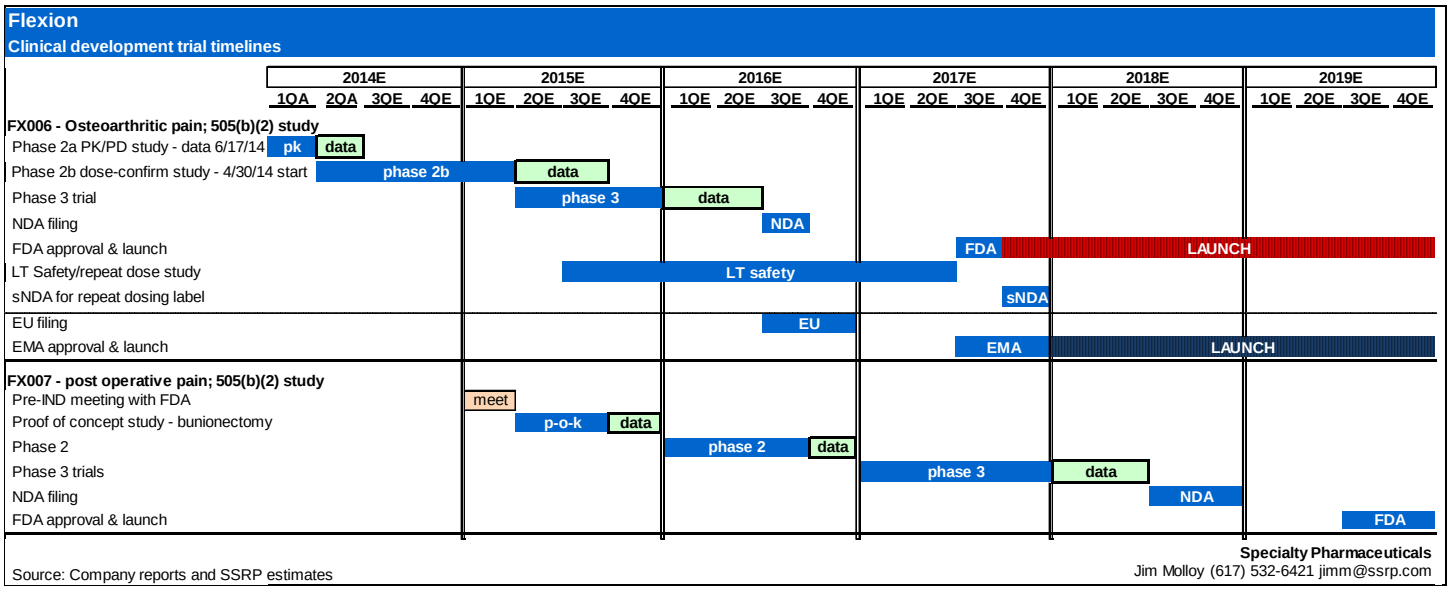
## Figure 1. Sum-of-the-Parts Analysis

| Sum-of-the-parts value: Flexion | | |
|---|---|---|
| Segment | Valuation (000's) | Per share value |
| FX006 value | $471,253 | $22 |
| FX007 | $11,156 | $0.5 |
| Cash (end '15) & tech value | $112,963 | $5.5 |
| **SUM** | **$595,371** | **$28** |
| Shares out '15E (000) | | 21,432 |

*Source: SSRP Estimates*

## Figure 2. Potential Clinical Trial Timelines



## Figure 3. Quarterly Income Statement

**Flexion**
**Quarterly income statement**

| ($000 except per share) | 2013A 1QA | 2013A 2QA | 2013A 3QA | 2013A 4QA | 2013A Year | 2014E 1QA | 2014E 2QA | 2014E 3QE | 2014E 4QE | 2014E Year |
|---|---|---|---|---|---|---|---|---|---|---|
| **Revenues** | | | | | | | | | | |
| **Total Revenue** | | | | | | | | | | |
| **Expenses:** | | | | | | | | | | |
| Cost of Revenue (COGS) | | | | | | | | | | |
| **Gross Margin** | - | - | - | - | | - | - | - | - | **0** |
| Research and development | 2,950 | 2,950 | 2,942 | 2,219 | 11,061 | 4,151 | 3,615 | 4,250 | 4,250 | 16,266 |
| General and administrative | 1,788 | 1,788 | 1,788 | 1,340 | 6,704 | 2,284 | 2,234 | 2,500 | 2,500 | 9,518 |
| Total operating expenses | 4,738 | 4,738 | 4,729 | 3,560 | 17,765 | 6,435 | 5,849 | 6,750 | 6,750 | 25,784 |
| **Income (loss) from Operations** | **(4,738)** | **(4,738)** | **(4,729)** | **(3,560)** | **(17,765)** | **(6,435)** | **(5,849)** | **(6,750)** | **(6,750)** | **(25,784)** |
| Interest income (expense), net | (39) | (39) | (39) | (98) | (215) | (81) | 28 | (25) | (25) | (103) |
| Other income (exp) | (64) | (64) | (64) | (15) | (207) | (26) | (110) | (50) | (50) | (236) |
| **Income (loss) before taxes** | **(4,841)** | **(4,841)** | **(4,832)** | **(3,673)** | **(18,187)** | **(6,542)** | **(5,931)** | **(6,825)** | **(6,825)** | **(26,123)** |
| Income tax exp (benefit) | - | - | - | - | | | | | | |
| **Net Income (Loss)** | **(4,841)** | **(4,841)** | **(4,832)** | **(3,673)** | **(18,187)** | **(6,542)** | **(5,931)** | **(6,825)** | **(6,825)** | **(26,123)** |
| **Earning per Share (EPS)** | **($6.13)** | **($6.13)** | **($6.12)** | **($4.65)** | **($23.02)** | **($0.86)** | **($0.38)** | **($0.43)** | **($0.43)** | **($1.90)** |
| Weighted avg. shares (000) | 789 | 790 | 790 | 790 | 790 | 7,633 | 15,619 | 15,769 | 15,919 | 13,735 |

Source: Company reports and SSRP estimates

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## Figure 4. Annual Income Statement

**Flexion**
**Annual income statement**

| ($000 except per share) | 2013A | 2014E | 2015E | 2016E | 2017E | 2018E | 2019E | Comments |
|---|---|---|---|---|---|---|---|---|
| **Revenues** | | | | | | | | |
| FX006 - OA pain | | | | | $1,655 | $200,497 | $340,745 | FDA 2H17 due to trial delay |
| FX007 - post operative pain | | | | | | | 0 | 2020 launch estimated |
| FX006 ex-US royalties | | | | | | 13,748 | 22,303 | Partner ex-US |
| **Total Revenue** | **$0** | **$0** | **$0** | **$0** | **$1,655** | **$214,246** | **$363,049** | |
| **Expenses:** | | | | | | | | |
| Cost of Revenue (COGS) | - | - | - | - | 248 | 30,075 | 51,112 | |
| **Gross Margin** | **-** | **-** | **-** | **-** | **1,407** | **184,171** | **311,937** | |
| R&D | 11,061 | 16,266 | 32,250 | 34,500 | 35,250 | 37,500 | 38,000 | |
| G&A | 6,704 | 9,518 | 12,550 | 15,250 | 17,000 | 49,250 | 72,500 | Self-launch FX006 in US |
| Total op exp | 17,765 | 25,784 | 44,800 | 49,750 | 52,250 | 86,750 | 110,500 | |
| **Inc/(loss) from Ops** | **(17,765)** | **(25,784)** | **(44,800)** | **(49,750)** | **(50,843)** | **97,421** | **201,437** | |
| Int income (exp), net | (215) | (103) | (100) | (100) | (100) | (100) | (99) | |
| Other expenses, net | (207) | (236) | (200) | (200) | (200) | (200) | (199) | |
| **Inc/(loss) before taxes** | **(18,187)** | **(26,123)** | **(45,100)** | **(50,050)** | **(51,143)** | **97,121** | **201,139** | |
| Income tax exp (benefit) | - | - | - | - | - | - | 50,285 | |
| **Net Income (Loss)** | **($18,187)** | **($26,123)** | **($45,100)** | **($50,050)** | **($51,143)** | **$97,121** | **$150,854** | |
| **Earning per Share** | **($23.02)** | **($1.90)** | **($2.20)** | **($2.30)** | **($2.20)** | **$3.50** | **$4.95** | |
| Weighted avg. shares (000) | 790 | 13,735 | 20,482 | 21,732 | 23,232 | 25,732 | 28,232 | |
| Fully diluted shares (000) | 1,439 | 14,748 | 21,432 | 22,732 | 24,482 | 27,732 | 30,482 | |
| Cash balance | $16,566 | $67,718 | $107,963 | $61,263 | $13,970 | $115,716 | $268,720 | IPO cash through 2H15 |

Source: Company reports and SSRP estimates

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## RISKS TO PRICE TARGET ESTIMATE

Exogenous events could impact our outlook. We believe pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies.

Actual clinical results and the FDA's conclusions may deviate from expectations. Many of our assumptions are based on a review of incomplete clinical trial data available in the public domain. Often, our conclusions are drawn from early stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations. Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

Legal risks could lead to additional liabilities and revenue loss. In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

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| Rating | Count | Percentage | Investment Banking Services (12 months) |
|---|---|---|---|
| BUY | 25 | 89% | 16% |
| NEUTRAL | 3 | 11% | 0% |
| SELL | 0 | 0% | 0% |
| **Companies under coverage at 9/30/14** | **28** | **100%** | **14%** |

**We have assigned an investment rating for the following subject companies mentioned in this report:**

**FLXN**

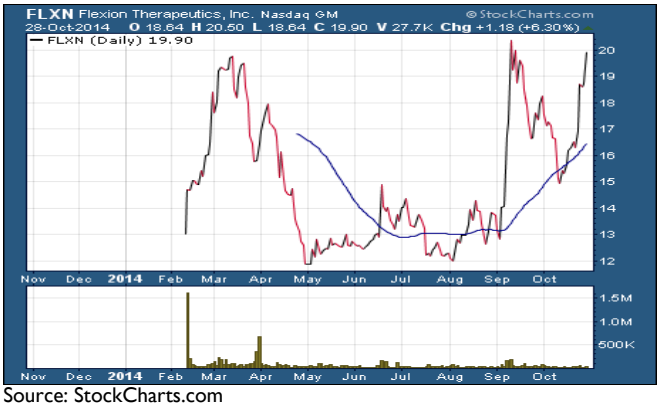
***Ratings History***

| Date | Rating | Share Price | Price Target |
|---|---|---|---|
| 8/14/14 | BUY | $13.37 | $25.00 |
| 9/5/14 | BUY | $14.02 | $28.00 |

***FLXN Investment Risks***

- Exogenous events could impact our outlook. Pharmaceutical companies have the least control over competitive, political, and regulatory risks.
- Actual clinical results and the FDA's conclusions may deviate from expectations.
- Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations.
- Legal risks could lead to additional liabilities and revenue loss.

***Valuation Method for Price Target:*** Sum of the parts



Source: StockCharts.com

