

Equity Research

Flexion Therapeutics, Inc.

FLXN:Financing On The Back Of Good News Of Clinical Hold Removal

Outperform / V

Sector: Specialty Pharmaceuticals

Overweight

Earnings Estimates Revised Up

	2013A	2014E	2015E		
EPS		Curr. Prior	Curr. Prior		
Q1 (Mar.)	(\$6.08)	(\$0.86) A NC	(\$0.60) (0.77)		
Q2 (June)	(5.83)	(0.38) A NC	(0.69) (0.88)		
Q3 (Sep.)	(6.38)	(0.45) A NC	(0.88) (0.89)		
Q4 (Dec.)	(4.66)	(0.55) (0.58)	(0.71) (0.86)		
FY	(\$23.02)	(\$2.06) (2.10)	(\$2.88) (3.41)		
CY	(\$23.02)	(\$2.06)	(\$2.88)		
FY P/EPS	NM	NM	NM		
Rev.(MM)	\$0	\$0	\$0		

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters
NA = Not Available, NC = No Change, NE = No Estimate, NM = Not Meaningful
V = Volatile, * = Company is on the Priority Stock List

Quarterly 2014 EPS do not add to FY2014 EPS due to change in share counts and February 2014 IPO

• **Summary:** Yesterday (December 2), FLXN held a conference call to discuss its December 1 announcement that the FDA has lifted the clinical hold on FX006 and, as a result, the company intends to immediately resume the FX006 clinical development program. Later in the morning FLXN filed an S-1 for a \$69MM follow on equity offering. The company provided more detail on the call into the efforts and outcome of the investigation into the adverse event (AE) that triggered the clinical hold and offered an update on its plans to immediately resume the ongoing pivotal Phase 2b and simultaneously proceed with the planned Phase 3 study. The information shared by management provided convincing evidence that the AE that drove the clinical hold was not related to FX006, in our view. We had expected a successful resolution to the hold, but the speed and thoroughness of the resolution are positives and should dispense with any lingering concerns about the AE. FLXN followed up on this good news with an S-1 filing for a \$69MM follow on offering. We had expected the company to raise about \$225MM in gross proceeds over 3 offerings between IPO and profitability, but this first financing comes a bit sooner than we expected (Q3 2015E, on the back of Phase 2b confirmatory data), and was timed to coincide with yesterday's good news about the hold removal. Our valuation range is reduced from \$29-31 to \$28-30 due to the additional shares from the offering, partly offset by the cash proceeds. Our EPS is revised as follows: 2014E from -\$2.10 to -\$2.06, and 2015E from -\$3.41 to -\$2.88.

• **Recall that on September 17, FLXN announced that the Phase 2b confirmatory trial and overall development program for FX006, FLXN's lead product, were placed on a clinical hold by the FDA.** This followed the report of a single adverse event in a single patient who had been administered FX006 during the Phase 2b trial. The FDA had general concerns about the adverse event, then thought to be septic arthritis, and made an information request of FLXN in order to understand the case in greater detail. In return, the company launched an investigation in order to ensure the sterility of the product and product administration and to verify that appropriate precautions are taken at the time of the study injection and that overall treatment techniques are properly administered through the course of its clinical studies.

• **Continued on the next page**

Valuation Range: \$28.00 to \$30.00 from \$29.00 to \$31.00

Our valuation range of \$28-\$30 is DCF-based and assumes WACC=15% and no terminal value. 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.

Investment Thesis:

We believe that FX006 can generate strong revenue and earnings growth due to 3 key positives: a large and growing market opportunity in OA; the potential to address an unmet medical need; and the opportunity for self-commercialization and strong revenue growth to drive operating margin expansion.

Ticker	FLXN
Price (12/02/2014)	\$16.85
52-Week Range:	\$11-22
Shares Outstanding: (MM)	15.6
Market Cap.: (MM)	\$262.9
S&P 500:	2,066.55
Avg. Daily Vol.:	22,724
Dividend/Yield:	\$0.00/0.0%
LT Debt: (MM)	\$4.0
LT Debt/Total Cap.:	27.0%
ROE:	NM
3-5 Yr. Est. Growth Rate:	NM
CY 2014 Est. P/EPS-to-Growth:	NM
Last Reporting Date:	11/13/2014

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters

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Please see page 9 for rating definitions, important disclosures and required analyst certifications

All estimates/forecasts are as of 12/03/14 unless otherwise stated.

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Together we'll go far



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- **Key takeaways from the investigation.** FLXN provided new details regarding the investigation and measures taken to assuage FDA concerns about the prospect of FX006 contamination and the potential for a compromise of sterile procedures at the trial site. By engaging a third-party sterility testing firm for product analysis, assessing its manufacturing sterility techniques, and deploying a quality assurance team to the clinical site, FLXN developed a data-driven response to the FDA request and reached the conclusion that the study drug was not contaminated and that sterile procedure was followed.
- **An important consequence of the investigation was the official change of the diagnosis on record associated with the adverse event.** Further examination of the patient's clinical presentation led the principal investigator to revise the initial diagnosis of septic arthritis to inflammatory arthritis effectively decoupling the complication described in the adverse event from the study product itself. Management provided a comprehensive review of each diagnosis and reiterated its confidence that no confirmed diagnoses of septic arthritis have emerged from its clinical trials to date and no adverse events attributed to FX006 have been described.
- **Potential FX006 timeline implications of the clinical hold removal.** With the clinical hold lifted, FLXN is free to continue with FX006 development without FDA restriction and intends to resume recruitment and dosing in the pivotal Phase 2b study immediately and will also move forward with plans to initiate a Phase 3 trial in Q1 2015. Key milestones are expected by FLXN as follows (with our commentary added): **(1) confirmatory Phase 2b data in H2 2015E** (could come in Q3 2015E in our view, as the timeline prior to the clinical hold could have resulted in Q2 2015E data, and the hold was about 2.5 months long); **(2) Phase 3 data in H1 2016E**; **(3) NDA filing in H2 2016E** (could come around mid 2016E in our view if trial is completed early in the year); **(4) FDA approval in Q2-Q3 2017E**; and **(5) launch in H2 2017E**.
- **FLXN files \$69MM follow-on offering, 6-9 months earlier than we expected.** On December 2 after the market open, FLXN filed an S-1 for a \$69MM follow-on offering, an amount which contemplates an approximately \$60MM offering plus a \$9MM (15%) overallotment option. We had anticipated that FLXN would need to raise substantial post-IPO capital (3 offerings of \$75MM each) to fund its phase 3 trial and get to profitability, however the timing of this filing comes earlier than expected, with FLXN currently possessing about one year's worth of cash and marketable securities (\$67MM balance as of September 30, 2014). After speaking with the company yesterday, our sense is that the offering timing was driven by a desire to mitigate a potential share price decline (that could result from an offering announcement) with the good news of the clinical hold removal--and this strategy clearly worked, with the stock up 3.7% on the day (S&P 500 up 1.1%, Nasdaq biotech index up 1.6%). The company also factored into its timing decision a desire to keep a cash cushion of a year or more, and a lack of catalysts before the Phase 2b confirmatory data. Before the clinical hold, we expected the Phase 2b data to read out in Q2 2015E, with an offering to follow in approximately early Q3 2015E. It's possible that the pushing back of this data to H2 2015E (by the clinical hold), and the resulting narrowed window to raise capital between that data and running out of cash, played some role in the decision to finance now, on the back of the catalyst of clinical hold removal rather than waiting for the Phase 2b data catalyst, in our view.
- **Financial model implications:** as a result of the announced financing, our valuation range is lowered from \$29-31 to \$28-30 (the clinical hold removal has no impact on our model as we had assumed its successful resolution). The decrease to our DCF-based valuation is the net impact of the share dilution (4.1MM shares added, based on \$69MM shares at \$16.85, the December 2 closing price), partly offset by the net cash raised (\$67MM, assuming approximately 3% for offering expenses). In addition, we have moved up our forecasted schedule of future capital raises. **Previously we assumed** \$75MM in Q3 2015E (after Phase 2b confirmatory data), \$75MM in Q4 2016E (after Phase 3 data) and \$75MM in 2017E (after FDA approval). **We have moved up the three assumed offerings** to \$69MM in December 2014 (per today's filing), \$75MM in Q4 2015E (after Phase 2b confirmatory data), and \$75MM in Q2 or Q3 2016E (after Phase 3 data).

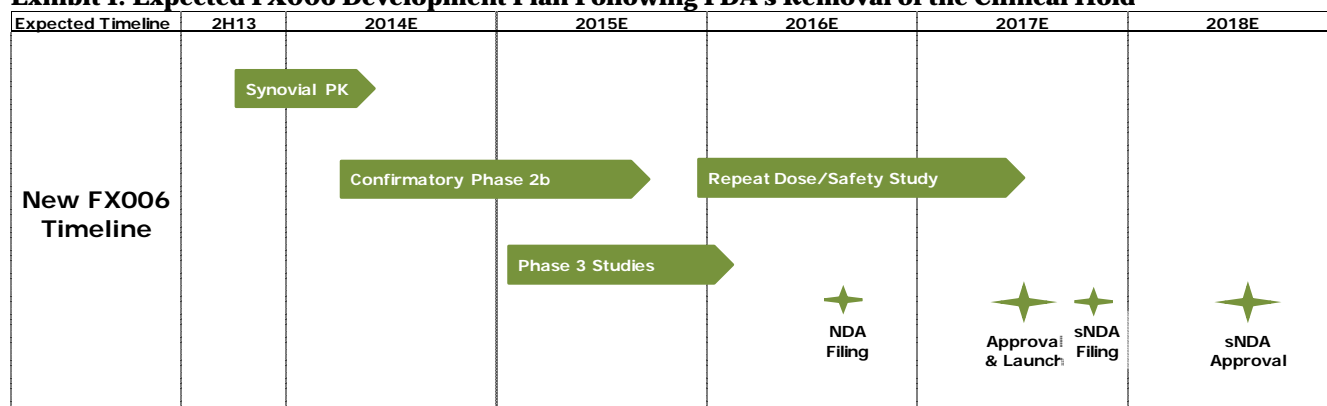
Additional detail on the FX006 clinical hold investigation and expected timeline of the FX006 clinical program

- **What we learned about the investigation:** on 12/2, FLXN elaborated on the investigation with previously undisclosed details on its progression and potential implications. Management confirmed that FDA had two objectives behind the clinical hold and its subsequent information request: 1) As the agency's principal concern, FDA wanted to ensure that this complication did not reflect the possibility of FX006 drug product contamination; 2) Secondly, FDA requested that FLXN explore other potential causes of infection including a compromise of sterile procedures during product administration and injection.
- **In regards to product contamination, FLXN synthesized and provided data from industry-standard sterility testing through a certified third-party sterility testing firm on the used drug vial assigned to the patient presenting with the AE.** In addition, FLXN stated that it took the investigation further by performing comparable testing on unused vials retained at both the clinical investigation site and the broader clinical distribution center to dispel any peripheral concerns about product contamination. The results from each of these tests showed that no microbial growth was present in any used or unused product vials. The conclusion reached was that there was no contamination and that the tested product met the requisite manufacturing sterility standards.
- **Management further reiterated the rigor to which FX006 is produced to further support its case.** It noted that FX006 microspheres are manufactured under septic conditions followed by a terminal sterilization that employs a maximum dose of gamma radiation that exceeds the dosage typically required to achieve standard product sterility. This entails a process subject to full-release testing including USP (U.S. Pharmacopeia Convention) sterility testing. To date, FLXN reported, no production batch has failed sterility testing and no infections have been described in patients in the same Phase 2b trial as the patient with the AE or any other completed clinical trials.
- **In regards to product administration protocol, FLXN deployed a team of quality assurance professionals to the clinical site to assess other potential causes of infection including contamination during the product preparation and administration.** After consulting with key personnel, the team found no indication of compromised procedure or protocol. Interestingly, the clinical injector was found to be a highly experienced professional who has performed over 15,000 knee injections without a single infection lending more reassurance that protocol was unlikely breached.
- **The diagnosis of septic arthritis may have been a false positive and was revised to inflammatory arthritis by the principal investigator on October 28.** Perhaps the most salient learning from FLXN's investigation is that the diagnosis of septic arthritis (associated with the patient's signs and symptoms of the adverse event) received a comprehensive review and was later changed to inflammatory arthritis by the principal investigator on October 28. The prevailing thinking is that the patient's initial diagnosis of septic arthritis may have been the result of a false positive workup. That is, despite the patient's atypical presentation for septic arthritis--the absence of the usual signs and symptoms of fever, elevate white blood cell (WBC) count, or pain upon knee flexion--this diagnosis was still made. Upon reexamination, the patient's synovial fluid analysis was also inconsistent with such an infection. Whereas a typical analysis of synovial fluid in septic arthritis shows a WBC count greater than 25,000 per cubic millimeter and a polymorphonuclear leukocytes (PML) percentage of above 90%, this patient's synovial fluid showed a WBC count of only 2,048 per cubic millimeter and a PML percentage of 65%. Such findings are suggestive of an etiology other than septic arthritis. Moreover, the patient's knee pain did not respond to the resultant course of antibiotics and, per report, extended to other joints beyond the initially affected knee. As the patient was readmitted to the hospital, markers were increasingly indicative of inflammatory arthritis and likely rheumatoid arthritis. As a result of this more holistic view of the patient's condition, the principal investigator concluded that the original diagnosis of septic arthritis was inaccurate and, thus, altered the diagnosis to the more likely explanation of inflammatory arthritis. The official record, including the MedWatch form, has been changed and was submitted to the FDA.
- **Management characterizes the emergence of inflammatory arthritis as a potential coincidence** given that rheumatoid arthritis (RA) is rarely known to be complication of osteoarthritis. Further, the company indicates that, given the high prevalence of osteoarthritis in the broader population, it would not be surprising that a patient in one of its study samples would also develop concomitant RA.
- **Management shared key insights on septic arthritis versus rheumatoid arthritis** to provide additional context into the presentation and treatment course of this patient and to validate the actions taken. Although initially, the presentation for both conditions may have overlapping symptoms such as knee pain and fluid accumulation, there are fundamental differences in etiology. Septic arthritis is an ongoing active infection that should respond to appropriate antibiotics and resolve completely thereafter while

rheumatoid arthritis is an autoimmune disease where the body systemically attacks its own tissues and is distinguished by serologic markers associated with inflammatory arthritis. As a result of this distinction, the principal investigator was convinced that the presentation was actually an inflammatory arthritis, likely RA. The patient was treated with a bolus of systemic steroids and experienced marked symptomatic improvement—an outcome consistent with the diagnosis of inflammatory arthritis rather than with septic arthritis. Of note, septic arthritis is a well-described complication of intra-articular injection and the label for the immediate-release form of TCA (triamcinolone acetonide) happens to include a precautionary mention of septic arthritis following TCA injection. Therefore, it is understandable that this condition would have initially been high on the differential diagnosis at the time of the adverse event. However, further examination into this patient's disease progression led to a more accurate understanding of the underlying inflammatory arthritis responsible for the presenting sign and symptoms and helped to revise the official trial record moving forward.

Below (Exhibit 1) is the updated FX006 clinical timeline. Key potential catalysts are listed below the exhibit. These catalysts follow from FLXN's plans to immediately resume Phase 2b recruitment and dosing, and initiate the Phase 3 in early 2015, following the lifting of the clinical hold. Management indicated that the investigation testing had no impact on available product supply and the company continues to manufacture product for use in the trials. To date, FLXN has just over 50% of patients enrolled in the Phase 2b and foresees no limitations on future enrollments or any adjustments required for enrollment criteria as a result of the clinical hold investigation.

Exhibit 1. Expected FX006 Development Plan Following FDA's Removal of the Clinical Hold



Source: Wells Fargo Securities, LLC estimates and Company reports

Key FX006 potential catalysts are as follows:

- Confirmatory Phase 2b data read out: **H2 2015E** per the company. We think it could come in **Q3 2015E**, as the timeline prior to the clinical hold could have resulted in Q2 2015E data, and the hold was about 2.5 months long.
- Phase 3 data in **H1 2016E**.
- NDA filing in **H2 2016E** per FLXN (could come around **mid 2016E** in our view if trial is completed early in the year)
- FDA approval in **Q2-Q3 2017E** (assuming a standard 10-month review).
- Launch in **H2 2017E**.

Financial Model

FLXN - Revenue Forecast

(In MM except price per injection)

	FY 2013A	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E	FY 2026E	FY 2027E	FY 2028E	FY 2029E	FY 2030E	FY 2031E	FY 2032E	FY 2033E
US Market																					
Overall Patient Pool																					
Number of patients with knee OA diagnosis	12.0	12.3	12.7	13.1	13.5	13.8	14.2	14.7	15.1	15.5	16.0	16.4	16.9	17.4	17.9	18.4	19.0	19.5	20.1	20.7	21.3
Growth, y/y		2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%
Number of patients with knee OA and IA steroid Rx	3.0	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	4.0	4.1	4.2	4.4	4.5	4.6	4.7	4.9	5.0	5.2	5.3
Growth, y/y		2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%
Avg No. of steroid injections/patient	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
Total number of steroid injections	3.3	3.4	3.5	3.6	3.7	3.8	3.9	4.0	4.1	4.3	4.4	4.5	4.7	4.8	4.9	5.1	5.2	5.4	5.5	5.7	5.8
Number of patients with knee OA and HA Rx	1.0	1.0	1.1	1.1	1.1	1.2	1.2	1.2	1.3	1.3	1.3	1.4	1.4	1.5	1.5	1.5	1.6	1.6	1.7	1.7	1.8
Growth, y/y		2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%
Avg No. of HA injections/patient	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Total number of HA injections	1.2	1.2	1.3	1.3	1.3	1.4	1.4	1.5	1.5	1.6	1.6	1.6	1.7	1.7	1.8	1.8	1.9	2.0	2.0	2.1	2.1
Total patients - steroid and HA	4.0	4.1	4.2	4.4	4.5	4.6	4.7	4.9	5.0	5.2	5.3	5.5	5.6	5.8	6.0	6.1	6.3	6.5	6.7	6.9	7.1
Growth, y/y		2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%
Total injections - steroid and HA	4.5	4.6	4.8	4.9	5.0	5.2	5.3	5.5	5.7	5.8	6.0	6.2	6.3	6.5	6.7	6.9	7.1	7.3	7.5	7.7	8.0
Growth, y/y		2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%
FX006 Market Opportunity																					
<i>Based on steroid injection volumes and FX006 pricing</i>																					
Total injections - steroid	3.3	3.4	3.5	3.6	3.7	3.8	3.9	4.0	4.1	4.3	4.4	4.5	4.7	4.8	4.9	5.1	5.2	5.4	5.5	5.7	5.8
FX006 price/injection	\$500	\$500	\$500	\$500	\$500	\$500	\$510	\$520	\$531	\$541	\$552	\$563	\$574	\$586	\$598	\$609	\$622	\$634	\$647	\$660	\$673
Market opportunity - FX006	\$1,650.0	\$1,697.9	\$1,747.1	\$1,797.8	\$1,849.9	\$1,903.5	\$1,997.9	\$2,097.0	\$2,200.9	\$2,310.1	\$2,424.6	\$2,544.8	\$2,671.0	\$2,803.4	\$2,942.4	\$3,088.3	\$3,241.4	\$3,402.1	\$3,570.8	\$3,747.8	\$3,933.6
Growth, y/y		2.9%	2.9%	2.9%	2.9%	2.9%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%
FX006 Penetration and Volumes																					
Number of patients receiving IA steroid	3.0	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	4.0	4.1	4.2	4.4	4.5	4.6	4.7	4.9	5.0	5.2	5.3
Est % penetration of FX006	0.0%	0.0%	0.0%	0.0%	1.3%	3.1%	6.9%	11.9%	16.3%	21.3%	25.0%	23.1%	20.6%	19.4%	18.1%	16.9%	15.6%	15.0%	6.3%	3.1%	1.3%
Est. no. of FX006 injections/patient	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Total no. FX006 inj. (steroid group)	-	-	-	-	0.1	0.2	0.4	0.7	0.9	1.2	1.5	1.4	1.3	1.3	1.2	1.2	1.1	1.1	0.5	0.2	0.1
Number of patients receiving HA	1.0	1.0	1.1	1.1	1.1	1.2	1.2	1.2	1.3	1.3	1.3	1.4	1.4	1.5	1.5	1.5	1.6	1.6	1.7	1.7	1.8
Est % penetration of FX006	0.0%	0.0%	0.0%	0.0%	1.3%	3.1%	6.9%	11.9%	16.3%	21.3%	25.0%	23.1%	20.6%	19.4%	18.1%	16.9%	15.6%	15.0%	6.3%	3.1%	1.3%
Est. no. of FX006 injections/patient	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Total no. FX006 inj. (HA group)	-	-	-	-	0.0	0.1	0.1	0.2	0.3	0.4	0.5	0.5	0.4	0.4	0.4	0.4	0.4	0.4	0.2	0.1	0.0
Total FX006 injections	-	-	-	-	0.1	0.2	0.5	0.9	1.2	1.6	2.0	1.9	1.7	1.7	1.6	1.6	1.5	1.5	0.6	0.3	0.1
Growth, y/y						157.3%	126.4%	77.7%	40.8%	34.6%	21.1%	(4.8%)	(8.2%)	(3.3%)	(3.7%)	(4.2%)	(4.7%)	(1.2%)	(57.1%)	(48.6%)	(58.8%)
FX006 Pricing and Revenues																					
FX006 price/injection	\$500	\$500	\$500	\$500	\$500	\$500	\$510	\$520	\$531	\$541	\$552	\$563	\$574	\$586	\$598	\$609	\$622	\$634	\$647	\$660	\$673
Price increase, y/y		0.0%	0.0%	0.0%	0.0%	0.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
FX006 revenues	\$0.0	\$0.0	\$0.0	\$0.0	\$42.0	\$108.2	\$249.7	\$452.8	\$650.3	\$892.5	\$1,102.1	\$1,070.0	\$1,001.6	\$987.6	\$969.7	\$947.5	\$920.9	\$927.8	\$405.8	\$212.9	\$89.4
Growth, y/y						157.3%	130.9%	81.3%	43.6%	37.3%	23.5%	(2.9%)	(6.4%)	(1.4%)	(1.8%)	(2.3%)	(2.8%)	0.8%	(56.3%)	(47.5%)	(58.0%)

Source: Wells Fargo Securities, LLC estimates and company reports

FLXN - INCOME STATEMENT (In MM except per share data)													
	2014				2014				2014				CAGR (E) '14E-'17E
	FY 2011A	FY 2012A	FY 2013A	Mar-14 1QA	Jun-14 2QA	Sep-14 3QA	Dec-14 4QE	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	
FX006 Revenues	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$42.0	\$108.2	NM
Total Revenues	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$42.0	\$108.2	NM
Cost of Products Sold	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$4.6	\$11.9	
Gross profit	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$37.4	\$96.3	NM
S&M	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$1.9	\$20.6	\$40.6	\$45.4	NM
G&A	\$3.0	\$3.9	\$6.7	\$2.3	\$2.2	\$2.3	\$2.5	\$9.4	\$11.2	\$12.3	\$13.6	\$14.9	13.2%
R&D	\$8.2	\$11.1	\$11.1	\$4.2	\$3.6	\$4.7	\$6.7	\$19.1	\$48.5	\$51.2	\$38.4	\$42.3	26.1%
EBITDA	(\$11.2)	(\$15.0)	(\$17.7)	(\$6.4)	(\$5.8)	(\$6.9)	(\$9.2)	(\$28.4)	(\$61.5)	(\$84.0)	(\$55.0)	(\$6.3)	NM
Amortization and Depreciation	\$0.1	\$0.0	\$0.1	\$0.0	\$0.0	\$0.0	\$0.0	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	
Operating Income	(\$11.3)	(\$15.0)	(\$17.8)	(\$6.4)	(\$5.8)	(\$7.0)	(\$9.2)	(\$28.5)	(\$61.6)	(\$84.1)	(\$55.1)	(\$6.4)	NM
Interest expense	\$0.0	\$0.0	(\$0.4)	(\$0.1)	(\$0.1)	(\$0.1)	\$0.0	(\$0.3)	\$0.0	\$0.0	\$0.0	\$0.0	
Interest income	\$0.2	\$0.2	\$0.2	\$0.0	\$0.1	\$0.2	\$0.1	\$0.4	\$1.0	\$1.3	\$1.2	\$0.6	
Net interest	\$0.2	\$0.2	(\$0.2)	(\$0.1)	\$0.0	\$0.1	\$0.1	\$0.1	\$1.0	\$1.3	\$1.2	\$0.6	
Other	(\$0.3)	(\$0.2)	(\$0.2)	(\$0.0)	(\$0.1)	(\$0.1)	\$0.0	(\$0.3)	\$0.0	\$0.0	\$0.0	\$0.0	
Total other income	(\$0.2)	\$0.0	(\$0.4)	(\$0.1)	(\$0.1)	(\$0.1)	\$0.1	(\$0.2)	\$1.0	\$1.3	\$1.2	\$0.6	NM
Pretax Income	(\$11.4)	(\$15.0)	(\$18.2)	(\$6.5)	(\$5.9)	(\$7.0)	(\$9.2)	(\$28.7)	(\$60.6)	(\$82.8)	(\$53.9)	(\$5.8)	NM
Income tax provision	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	NM
Net Income	(\$11.4)	(\$15.0)	(\$18.2)	(\$6.5)	(\$5.9)	(\$7.0)	(\$9.2)	(\$28.7)	(\$60.6)	(\$82.8)	(\$53.9)	(\$5.8)	NM
Shares outstanding (basic)		0.5	0.8	7.6	15.6	15.6	16.7	13.9	21.1	23.4	25.8	26.3	
Shares outstanding (diluted)		0.5	10.6	13.3	15.6	15.6	16.7	15.3	21.1	23.4	25.8	26.3	
Shares outstanding (for EPS)		0.5	0.8	7.6	15.6	15.6	16.7	13.9	21.1	23.4	25.8	26.3	
EPS		(\$27.59)	(\$23.02)	(\$0.86)	(\$0.38)	(\$0.45)	(\$0.55)	(\$2.06)	(\$2.88)	(\$3.54)	(\$2.09)	(\$0.22)	NM
Margin Analysis													
Gross Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	89.0%	89.0%	
S&M as % of sales	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	96.5%	42.0%	
G&A as % of sales	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	32.3%	13.8%	
R&D % sales	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	91.3%	39.1%	
EBITDA margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	(130.7%)	(5.8%)	
Operating margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	(131.0%)	(5.9%)	
Pre-tax margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	(128.1%)	(5.4%)	
Statutory tax rate	37.0%	37.0%	37.0%	37.0%	37.0%	37.0%	37.0%	37.0%	37.0%	37.0%	37.0%	37.0%	
AMT tax rate	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	
Tax rate, effective	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	
Net margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	(128.1%)	(5.4%)	
Year/Year Changes													
FX006 Revenues		NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	157.3%	
Total Revenues		NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	157.3%	
Gross profit		NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	157.3%	
S&M		NM	NM	NM	NM	NM	NM	NM	NM	983.1%	97.1%	12.0%	
G&A		29.5%	69.9%	50.2%	57.1%	(4.8%)	89.0%	39.6%	19.8%	10.0%	10.0%	10.0%	
R&D		34.3%	(0.0%)	30.3%	17.8%	81.2%	200.0%	73.0%	153.3%	5.6%	(25.0%)	10.2%	
EBITDA		33.9%	18.2%	36.4%	30.3%	39.5%	159.3%	60.4%	116.6%	36.6%	(34.6%)	(88.6%)	
Operating income		33.0%	18.3%	36.7%	30.3%	39.5%	158.4%	60.4%	116.2%	36.6%	(34.5%)	(88.4%)	
Net income		30.9%	21.4%	36.4%	29.0%	38.0%	148.2%	57.6%	111.2%	36.7%	(34.9%)	(89.2%)	
Earnings per share		NM	(16.6%)	(85.9%)	(93.5%)	(93.0%)	(88.3%)	(91.0%)	39.5%	23.1%	(40.9%)	(89.4%)	

Source: Wells Fargo Securities, LLC estimates and company reports

FLXN - BALANCE SHEET (In MM except per share data)				2014								
	FY 2011A	FY 2012A	FY 2013A	Mar-14 1QA	Jun-14 2QA	Sep-14 3QA	Dec-14 4QE	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E
Current Assets												
Cash and Equivalents	\$3.4	\$12.8	\$16.2	\$35.8	\$12.0	\$14.4	\$90.9	\$90.9	\$133.9	\$122.7	\$58.0	\$36.3
Restricted Cash and Restricted Cash Equivalents	\$0.0	\$0.0	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1
Marketable securities	\$7.2	\$16.5	\$0.3	\$42.7	\$60.0	\$52.2	\$32.2	\$32.2	\$0.0	\$0.0	\$0.0	\$0.0
Accounts Receivable			\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$6.9	\$17.8
Inventories, net			\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$3.8	\$9.8
Prepaid expenses and other assets	\$0.3	\$0.5	\$1.8	\$0.8	\$0.7	\$0.7	\$1.8	\$1.8	\$2.2	\$2.3	\$2.4	\$3.2
Total Current Assets	\$10.8	\$29.9	\$18.4	\$79.5	\$72.8	\$67.4	\$125.0	\$125.0	\$136.2	\$125.1	\$71.2	\$67.2
Long-term Assets												
Property and equipment, net	\$0.1	\$0.1	\$0.4	\$0.4	\$0.4	\$0.7	\$0.7	\$0.7	\$0.5	\$0.4	\$0.7	\$1.7
Other assets	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Total Assets	\$10.9	\$30.0	\$18.8	\$79.9	\$73.2	\$68.1	\$125.7	\$125.7	\$136.8	\$125.5	\$72.0	\$68.9
LIABILITIES AND SHAREHOLDERS' EQUITY												
Current Liabilities												
Accounts payable	\$0.7	\$0.5	\$1.3	\$1.8	\$1.0	\$1.5	\$1.8	\$1.8	\$2.2	\$2.3	\$2.5	\$3.9
Accrued expenses and other current liabilities	\$1.1	\$2.2	\$2.3	\$1.6	\$1.5	\$2.7	\$2.7	\$2.7	\$3.2	\$3.4	\$3.6	\$4.9
Current portion of long-term debt	\$0.0	\$0.0	\$1.5	\$2.0	\$2.0	\$2.0	\$2.0	\$2.0	\$1.5	\$0.0	\$0.0	\$0.0
Total Current Liabilities	\$1.8	\$2.7	\$5.0	\$5.4	\$4.4	\$6.2	\$6.5	\$6.5	\$7.0	\$5.7	\$6.0	\$8.8
Long-term Liabilities												
Long-term debt	\$0.0	\$0.0	\$3.5	\$3.1	\$2.6	\$2.1	\$1.6	\$1.6	\$0.0	\$0.0	\$0.0	\$0.0
Other Long-term Liabilities	\$0.0	\$0.0	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1
Total Long-term Liabilities	\$0.0	\$0.0	\$3.6	\$3.1	\$2.6	\$2.1	\$1.6	\$1.6	\$0.1	\$0.1	\$0.1	\$0.1
Shareholders' Equity												
Preferred Stock	\$41.8	\$74.8	\$74.8	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Common stock	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Additional paid-in capital	\$0.3	\$0.4	\$1.5	\$144.1	\$144.7	\$145.4	\$212.4	\$212.4	\$285.1	\$357.9	\$357.9	\$357.9
Accumulated other comprehensive income	\$0.0	\$0.0	(\$0.0)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Deficit accumulated during the development stage	(\$33.0)	(\$48.0)	(\$66.2)	(\$72.7)	(\$78.6)	(\$85.7)	(\$94.8)	(\$94.8)	(\$155.4)	(\$238.2)	(\$292.0)	(\$297.8)
Total Stockholders' Equity	\$9.2	\$27.3	\$10.1	\$71.4	\$66.1270	\$59.8	\$117.6	\$117.6	\$129.8	\$119.7	\$65.9	\$60.0
Total Liabilities & Stockholders' Equity	\$10.9	\$30.0	\$18.8	\$79.9	\$73.2	\$68.1	\$125.7	\$125.7	\$136.8	\$125.5	\$72.0	\$68.9

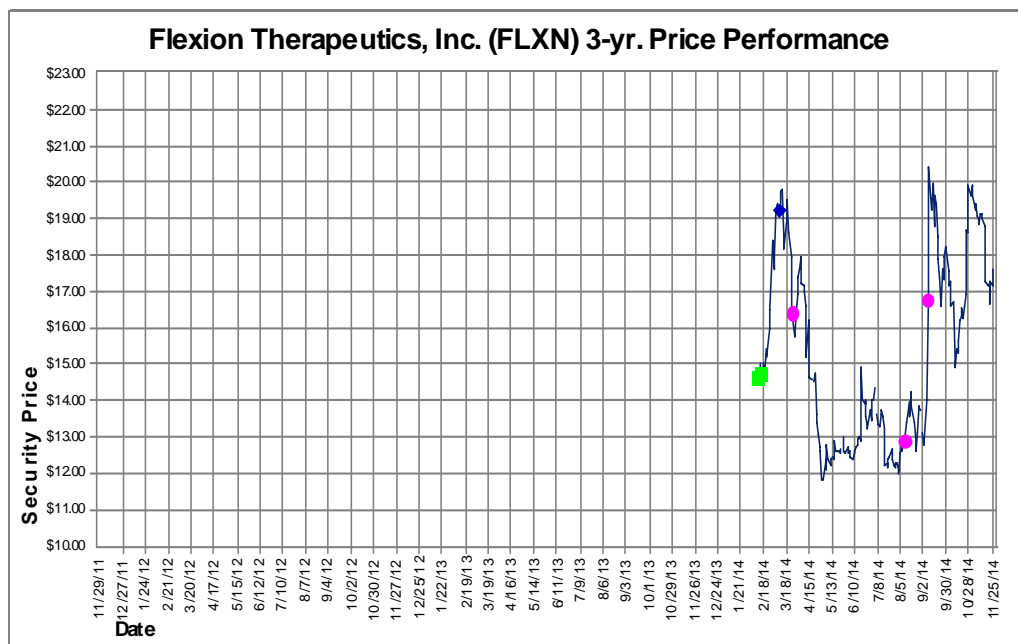
Source: Wells Fargo Securities, LLC estimates and company reports

FLXN - CASH FLOW STATEMENT (In MM except per share data)				2014								
	FY 2011A	FY 2012A	FY 2013A	Mar-14 1QA	Jun-14 2QA	Sep-14 3QA	Dec-14 4QE	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E
Net Income (Loss)	(\$11.4)	(\$15.0)	(\$18.2)	(\$6.5)	(\$5.9)	(\$7.0)	(\$9.2)	(\$28.7)	(\$60.6)	(\$82.8)	(\$53.9)	(\$5.8)
Adjustments to Net Income												
Depreciation	\$0.1	\$0.0	\$0.1	\$0.0	\$0.0	\$0.0	\$0.0	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1
Stock-based Compensation	\$0.1	\$0.1	\$0.9	\$0.4	\$0.7	\$0.7	\$0.0	\$1.8	\$0.0	\$0.0	\$0.0	\$0.0
Amortization of premium (discount) on marketable securities	\$0.1	\$0.1	\$0.3	\$0.0	\$0.1	\$0.1	\$0.0	\$0.2	\$0.0	\$0.0	\$0.0	\$0.0
Loss on disposal of property and equipment	\$0.2	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Other	\$0.0	\$0.0	\$0.0	\$0.0	\$0.7	(\$0.7)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<u>Changes in operating assets and liabilities</u>												
Prepaid Expenses and other assets	\$0.2	(\$0.2)	\$0.3	(\$0.7)	(\$0.5)	\$0.8	(\$1.1)	(\$1.4)	(\$0.4)	(\$0.1)	(\$0.1)	(\$0.8)
Accounts Payable, accr. Exps., and other curr. liab	\$0.4	\$0.9	(\$0.5)	\$0.2	(\$0.8)	\$1.5	\$0.3	\$1.3	\$1.0	\$0.3	\$0.3	\$2.8
Net Cash From Operations	(\$10.4)	(\$14.0)	(\$17.1)	(\$6.5)	(\$5.8)	(\$4.6)	(\$9.9)	(\$26.7)	(\$59.9)	(\$82.5)	(\$64.3)	(\$20.6)
Cash from Investing Activities												
Purchases of property and equipment	(\$0.0)	(\$0.0)	(\$0.7)	(\$0.0)	(\$0.0)	(\$0.3)	\$0.0	(\$0.3)	\$0.0	\$0.0	(\$0.4)	(\$1.1)
Change in restricted cash	\$0.0	\$0.0	(\$0.2)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Purchases of marketable securities	(\$16.8)	(\$28.5)	(\$25.6)	(\$42.7)	(\$19.5)	(\$10.2)	\$0.0	(\$72.4)	\$0.0	\$0.0	\$0.0	\$0.0
Redemption of marketable securities	\$12.8	\$19.0	\$45.4	\$0.3	\$2.1	\$17.8	\$20.0	\$40.2	\$32.2	\$0.0	\$0.0	\$0.0
Other	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Cash from Investing Activities	(\$4.1)	(\$9.5)	\$18.8	(\$42.5)	(\$17.4)	\$7.4	\$20.0	(\$32.5)	\$32.2	\$0.0	(\$0.4)	(\$1.1)
Cash from Financing Activities												
Proceeds from borrowings under term loan	\$0.0	\$0.0	\$10.0	\$0.0	\$0.0	\$0.0	(\$0.5)	(\$0.5)	(\$2.1)	(\$1.5)	\$0.0	\$0.0
Proceeds from issuance of Series A Cvt Pfd Stock, net	\$13.0	\$13.1	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Proceeds from issuance of Series B Cvt Pfd Stock, net	\$0.0	\$19.9	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Proceeds from common stock issuance	\$0.0	\$0.0	\$0.0	\$69.5	\$0.0	(\$1.3)	\$66.9	\$135.2	\$72.8	\$72.8	\$0.0	\$0.0
Proceeds from exercise of stock options	\$0.0	\$0.0	\$0.0	\$0.2	\$0.0	\$0.0	\$0.0	\$0.3	\$0.0	\$0.0	\$0.0	\$0.0
Other	\$0.0	(\$0.0)	(\$0.1)	(\$1.1)	(\$0.7)	\$0.8	\$0.0	(\$1.0)	\$0.0	\$0.0	\$0.0	\$0.0
Cash from financing	\$13.0	\$33.0	\$9.9	\$68.6	(\$0.6)	(\$0.5)	\$66.4	\$133.9	\$70.7	\$71.3	\$0.0	\$0.0
Increase/(decrease) in cash and cash equivalents	(\$1.5)	\$9.5	\$11.6	\$19.6	(\$23.8)	\$2.3	\$76.5	\$74.7	\$43.0	(\$11.2)	(\$64.7)	(\$21.7)
Beginning cash balance	\$4.8	\$3.4	\$12.8	\$16.2	\$35.8	\$12.0	\$14.4	\$16.2	\$90.9	\$133.9	\$122.7	\$58.0
Ending cash balance	\$3.4	\$12.8	\$24.4	\$35.8	\$12.0	\$14.4	\$90.9	\$90.9	\$133.9	\$122.7	\$58.0	\$36.3
Average cash balance	\$4.1	\$8.1	\$18.6	\$26.0	\$23.9	\$13.2	\$52.6	\$53.5	\$112.4	\$128.3	\$90.3	\$47.1

Source: Wells Fargo Securities, LLC estimates and company reports. Note: Quarterly cash flow statement historical figures for 1Q-3Q:2013 not available.

Company Description:

Flexion Therapeutics, Inc. is a development stage specialty pharmaceutical company, focused on osteoarthritis (OA) pain treatments. The lead product candidate, FX006, is a sustained-release intra-articular steroid injection in Phase 2b trials for the treatment of moderate to severe OA pain in the knee. FLXN is also developing FX007 for post-operative pain, and FX005 for end stage OA pain.

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

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

Additional Information Available Upon Request

I certify that:

- 1) All views expressed in this research report accurately reflect my personal views about any and all of the subject securities or issuers discussed; and
- 2) No part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed by me in this research report.

- Wells Fargo Securities, LLC maintains a market in the common stock of Flexion Therapeutics, Inc.

Specialty Pharmaceuticals

- Wells Fargo Securities, LLC or its affiliates managed or comanaged a public offering of securities for Flexion Therapeutics, Inc. within the past 12 months.
- Wells Fargo Securities, LLC or its affiliates intends to seek or expects to receive compensation for investment banking services in the next three months from Flexion Therapeutics, Inc.
- Wells Fargo Securities, LLC or its affiliates received compensation for investment banking services from Flexion Therapeutics, Inc. in the past 12 months.
- Flexion Therapeutics, Inc. currently is, or during the 12-month period preceding the date of distribution of the research report was, a client of Wells Fargo Securities, LLC. Wells Fargo Securities, LLC provided investment banking services to Flexion Therapeutics, Inc.
- Flexion Therapeutics, Inc. currently is, or during the 12-month period preceding the date of distribution of the research report was, a client of Wells Fargo Securities, LLC. Wells Fargo Securities, LLC provided noninvestment banking securities-related services to Flexion Therapeutics, Inc.
- Wells Fargo Securities, LLC received compensation for products or services other than investment banking services from Flexion Therapeutics, Inc. in the past 12 months.

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.

Wells Fargo Securities, LLC does not compensate its research analysts based on specific investment banking transactions. Wells Fargo Securities, LLC's research analysts receive compensation that is based upon and impacted by the overall profitability and revenue of the firm, which includes, but is not limited to investment banking revenue.

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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

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.

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: December 2, 2014

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51% of companies covered by Wells Fargo Securities, LLC Equity Research are rated Market Perform.

Wells Fargo Securities, LLC has provided investment banking services for 30% of its Equity Research Market Perform-rated companies.

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Wells Fargo Securities, LLC has provided investment banking services for 21% of its Equity Research Underperform-rated companies.

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