March 10, 2014

WELLS FARGO SECURITIES

Equity Research

Flexion Therapeutics, Inc.

FLXN: Initiating Coverage With An Outperform Rating

Outperform / V

Sector: Specialty Drugs
Market Weight

Initiation of Coverage

- **Summary: We are initiating coverage of Flexion Therapeutics (FLXN) with an Outperform rating and a valuation range of $24-26.** We believe that FLXN is well positioned with its lead product FX006 to become a significant player in the large and growing market opportunity for intra-articular treatment of osteoarthritis (OA) pain. FX006 is a sustained-release injectable formulation of a common steroid currently administered in an immediate release (IR) formulation. In Phase 2b data, FX006 demonstrated significantly greater and more durable pain relief than IR steroid, in a head-to-head comparison. In our view, these data position FX006 to address an unmet medical need in OA pain treatment, for an efficacious, durable treatment with acceptable side effects. FX006 plans to begin a confirmatory Phase 2b study this year, with data expected in H1 2015 and estimated launch in 2017. We believe that the product can reach $1.1B in peak sales in 2024E. FLXN also has two pipeline products that are in earlier stages of development, which we treat as free options in our model. Our valuation range of $24-26 is DCF based.
- **FX006 can capitalize on a large and growing market opportunity in OA.** There are approximately 12 million OA knee patients in the United States, and the population is growing at about 2.9% per year. We believe that this will remain a large and growing market opportunity for years to come, due to demographic factors including aging of the population and obesity.
- **Potential for FX006 to address unmet medical need.** Currently available therapies to treat OA knee pain have significant shortcomings in either safety, or efficacy. There is an unmet medical need for a treatment that provides efficacious and durable pain relief, with minimal side effects. We believe that FX006 has the potential to address this need.
- **Self-commercialization and strong revenue growth could drive operating margin expansion.** FLXN plans to commercialize FX006 in the United States without a marketing partner, by establishing a sales force of approximately 60-100 representatives. The associated modest and relatively fixed selling expense, combined with strong revenue growth and high gross margin, could lead to rapid operating margin expansion.
- **FX007 and FX005 pipeline candidates represent free options in our model.** FLXN is developing two other pipeline candidates, FX007 for post-operative pain and FX005 for end-stage OA pain. We have excluded revenue for these products from our model, due to their earlier stages of development, and success of these programs could potentially provide upside to our model.

Valuation Range: $24.00 to $26.00 from NE to NE
Our valuation range of $24-$26 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.

	2012A	2013E		2014E	
EPS		**Curr.**	**Prior**	**Curr.**	**Prior**
Q1 (Mar.)	NE	(0.48) A	NC	(0.47)	NE
Q2 (June)	NE	(0.49) A	NC	(0.55)	NE
Q3 (Sep.)	NE	(0.52) A	NC	(0.67)	NE
Q4 (Dec.)	NE	(0.46)	NE	(0.81)	NE
FY	(2.04)	(1.94)	NE	(2.52)	NE
CY	($2.04)	($1.94)		($2.52)	
FY P/E	NM	NM		NM	
Rev.(MM)	NE	NE		NE	

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

Ticker	FLXN
Price (03/07/2014)	$19.26
52-Week Range:	$14-21
Shares Outstanding: (MM)	14.7
Market Cap.: (MM)	$283.1
S&P 500:	1,878.04
Avg. Daily Vol.:	0
Dividend/Yield:	$0.00/0.0%
LT Debt: (MM)	$5.0
LT Debt/Total Cap.:	27.0%
ROE:	NM
3-5 Yr. Est. Growth Rate:	NM
CY 2014 Est. P/E-to-Growth:	NM
Last Reporting Date:	09/30/2013

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

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Please see page 3 for rating definitions, important disclosures and required analyst certifications
All estimates/forecasts are as of 03/10/14 unless otherwise stated.

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.

FOR MORE DETAILS PLEASE SEE OUR FULL-LENGTH REPORT

Investment Risks

Product Concentration. FX006, which is currently in Phase 2 trials, is the company's lead product candidate. The other pipeline candidates, FX007 (preclinical) and FX005 (Phase 2a) are at earlier stages of development and farther away from potential commercialization. Therefore, the near-term success of the company is highly dependent on the success of FX006. As such, Flexion resources are concentrated on FX006. If FX006 is unable to reach the commercialization stage, Flexion may not be able to obtain the resources to further develop the remaining pipeline candidates.

Clinical Risk. Flexion still has multiple clinical trials remaining before new drug application (NDA) submission for FX006. These include the following: (1) Confirmatory Phase 2b; (2) Repeat dose and safety study; and (3) two pivotal Phase 3 trials. If FX006 does not meet primary efficacy endpoints or demonstrate an acceptable safety profile in any of these upcoming trials, that could be a material obstacle to eventual commercialization. Additionally, for the remaining trials, the Food and Drug Administration (FDA) has requested a placebo instead of active comparator, which could alter the statistical significance of the outcome compared to the Phase 2b trial, which was done with an active comparator.

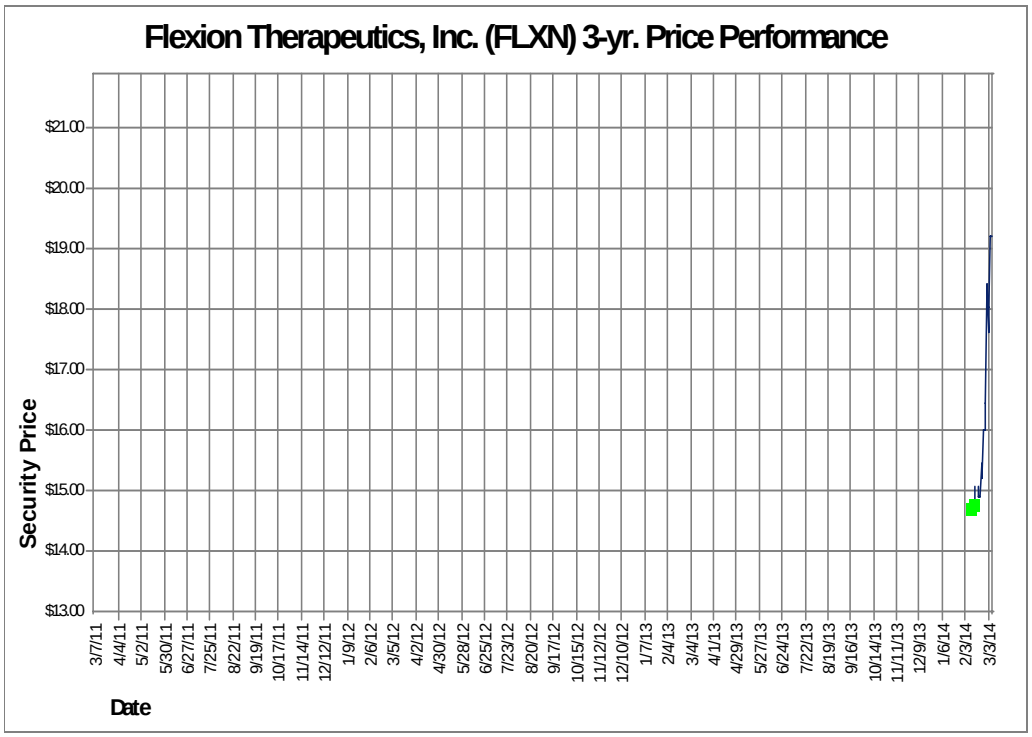
Regulatory Risk. As mentioned, there are still multiple clinical trials remaining for FX006 before NDA submission, and therefore, there is also regulatory risk remaining. If the FDA decides that there are issues with clinical trial design or with results from the clinical trials, the regulator can request additional studies prior to approval. Additionally, Flexion plans to pursue a 505(b)(2) filing, which allows the company to reference previously established data from the clinical studies of other companies. If at some point in the future the FDA decides that Flexion cannot use the 505(b)(2) pathway to approval for FX006, then that would likely result in additional clinical studies, material expenditure, and a delay in time to commercialization.

Commercial Risk. The eventual commercial success of FX006 is highly dependent on the product's pricing and reimbursement by payers such as managed care organizations. Given that the incumbent product, immediate release TCA, has been on the market for many years and is relatively inexpensive, FX006 would need to demonstrate clinical differentiation to enable premium pricing. At this time, it is difficult to determine whether the results from the completed Phase 2b clinical trial may readily translate into a clinically meaningful benefit for patients and encourage physicians to prescribe FX006 and payers to reimburse patient costs at premium pricing levels.

Future Financings Required. Flexion does not have enough cash to fund the development of FX006 through commercialization. The capital from the IPO should fund the company only until about mid-2015. It is anticipated that additional capital would be required to fund the two pivotal Phase 3 trials and the launch of FX006. We estimate that three more rounds of capital raises would be needed to fund FLXN through commercialization of FX006 and to cash flow positive status. If at any time Flexion is unable to obtain the capital needed to fund the operations of the company, that would pose a material risk to the advancement of FX006 to commercialization, and therefore, affect the valuation of FLXN stock.

Intellectual Property Not Yet Issued. While patent applications have been filed in both the United States and the European Union with potential patent coverage until 2031, there are currently no issued patents for FX006 in the United States or the European Union. If Flexion is unable to secure patents protecting the composition of matter, method of use, and method of manufacture around its lead product candidate FX006, then that would pose significant risk to its commercialization strategy. In the event that competition enters the market earlier than expected and prevents premium pricing of FX006 or prevents FX006 from achieving expected levels of market share, that could materially adversely affect the commercialization of FX006 and therefore, the valuation of the company. Separately, in the event that the patents are issued, the claims ultimately granted could still leave room for competing products to reach the market and reduce sales and profit of FX006.

Required Disclosures



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

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

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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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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

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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

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As of: March 10, 2014

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