

# Flexion Therapeutics

(FLXN-NASDAQ)

**Stock Rating:** Outperform  
**Stock Price:** US\$13.03  
**Target Price:** US\$33.00

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Specialty Pharmaceuticals

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## Positive Phase IIa Results Point to Three-Month Duration

Flexion Therapeutics reported results from its Phase IIa clinical trial of its lead program, FX006, an extended-release steroid injection for osteoarthritic knee pain. Current immediate-release steroid injections provide pain relief for only one to three weeks, and doctors inject patients only every three months due to safety concerns over injections of any greater frequency.

Flexion's Phase IIa study was designed to determine how long Flexion's FX006 remains in the knee joint and provides therapeutic pain relief. The study indicated Flexion's FX006 remains in the joint up to 12 weeks. The multi-center, open-label study included 50 patients with osteoarthritis of the knee. Patients received a single FX006 injection of either 10 or 40 mg or a 40 mg injection of immediate-release TCA. Each arm of the study included 10 patients. Synovial fluid was collected via aspiration on day one, just prior to the injection, and again at weeks 12, 16, or 20 depending on the group.

Flexion found both the 10 mg and the 40 mg injection of FX006 provided therapeutic concentrations of drug at 12 weeks, while the TCA injection left concentrations below the lower limit of quantification. The 40 mg FX006 injection also provided measurable concentrations of drug in the joint at 16 weeks, but fell below the limit of quantification at 20 weeks.

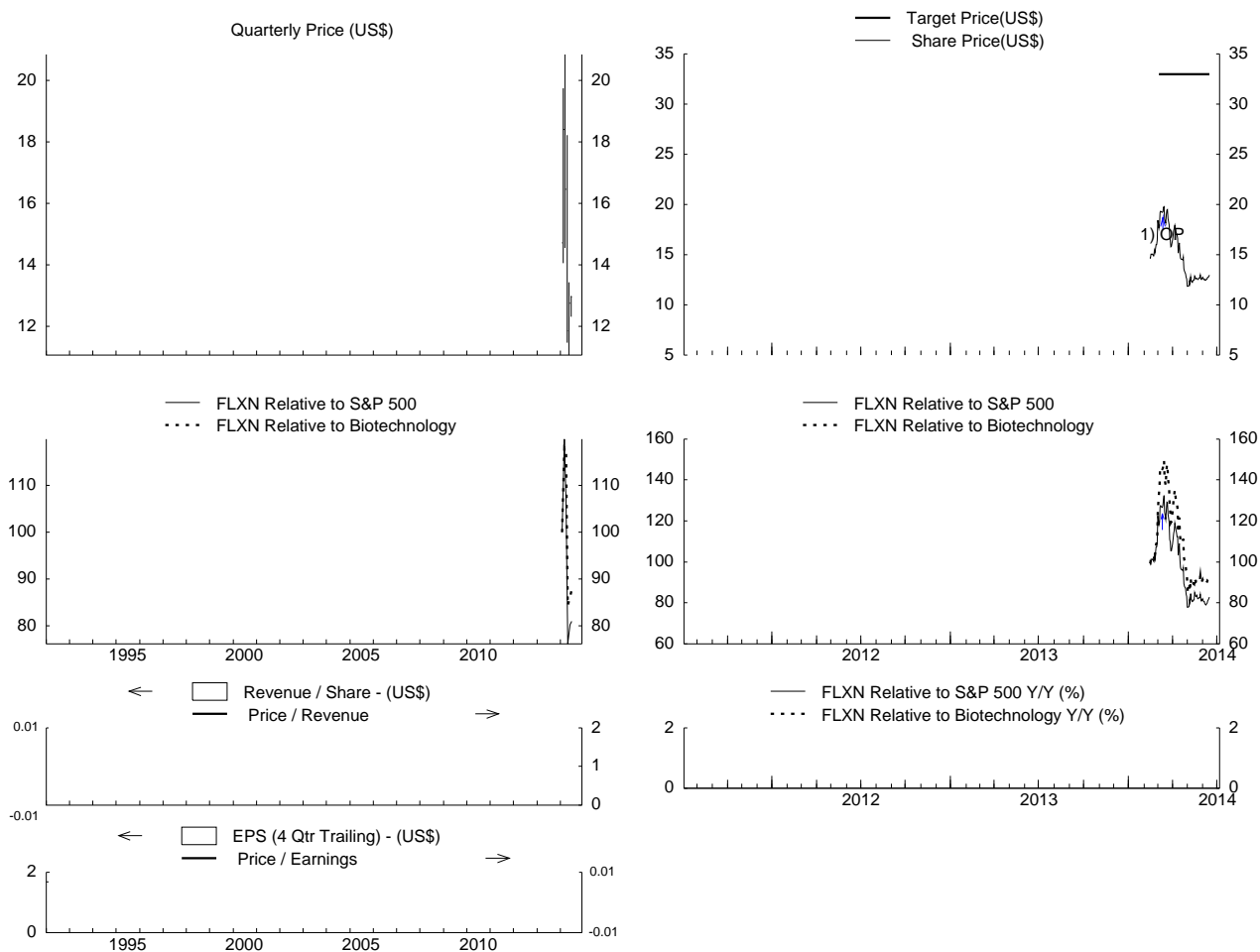
Based on the positive results of this study and previous findings from pre-clinical data, Flexion plans to continue studying FX006 in a confirmatory Phase IIb clinical trial to further identify a safe and well-tolerated dose of FX006 that demonstrates superior pain relief to placebo. Flexion expects data from the study in 1H15.

### Our View:

- We believe these results are positive and will help investors feel more confident about the approach Flexion is taking. However, we believe data is positive but supplementary, as the efficacy data that the company has provided to date tells the real story and is the main reason investors are interested in FX006.
- We are encouraged that the data is in line with our and Flexion's expectations. Flexion expected to see at least three months of therapeutic concentration of drug in joint fluid following a single injection, as this duration is consistent with the length of time FX006 microspheres lasted in previous animal studies.
- We spoke with the Flexion management team after the data was released and heard the company's tentative plans for the planned repeat-dose safety clinical trial. While it will take some time for the company to digest this data and refine the appropriate study design, Flexion does believe the synovial PK data supports dosing in the three- to four-month range. The company is finalizing the details, and we suspect this study will begin in 2H14.
- Overall, today's data is another positive step in the right direction. We maintain our Outperform rating and \$33 price target.

Please refer to pages 2 to 5 for Important Disclosures, including the Analyst's Certification.

## Flexion Therapeutics (FLXN)



FYE (Dec.)	EPS US\$	P/E Hi - Lo	DPS US\$	Yield% Hi - Lo	Payout %	BV US\$	P/B Hi - Lo	ROE %	FLXN - Rating as of 11-Feb-14 = NR		
Range*:		na na		NC			>15 >15		Date	Rating Change	Share Price
Current*	ND	na	0.00	0.0	na	-4.2	-3.1	na	1 11-Mar-14	NR to OP	\$19.29

\* Current EPS is the 4 Quarter Trailing to Q1/2014.  
 \* Valuation metrics are based on high and low for the fiscal year.  
 \* Range indicates the valuation range for the period presented above.

Last Price ( June 13, 2014): \$12.95  
 Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

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**Methodology:** We arrive at our target price using a discounted cash flow analysis, as well as a sector multiple applied to discounted earnings.

**Risks:** In addition to the normal risks inherent in pharmaceutical companies, such as regulatory, reimbursement, and competitive risks, our valuation of FLXN carries several other risks. Among the risks to our valuation is FLXN's dependence on approval of their lead product and anticipated sales and profitability to drive the value of FLXN.

Unseen side effects, safety issues, and competitive threats have not been taken into account in our valuation and if any of these were to emerge, it is likely FLXN shares would be significantly and negatively impacted. FLXN is currently running at a substantial loss, and with this fact comes several other risks, including the potential need for financing. One cannot be certain that FLXN would be able to secure additional financing and at what cost. Our valuation includes a value for the current pipeline of additional products FLXN is investigating. We have estimated a public market value for these assets based on what a similar company might be valued in a public market. Less is known about these programs relative to FLXN's lead program and given their early nature, they carry substantial development risk.

**Distribution of Ratings (March 31, 2014)**

Rating Category	BMO Rating	BMOCM US Universe*	BMOCM US IB Clients**	BMOCM US IB Clients***	BMOCM Universe****	BMOCM IB Clients*****	Starmine Universe
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Hold	Market Perform	52.8%	10.8%	38.2%	52.8%	43.8%	40.8%
Sell	Underperform	5.2%	3.2%	1.1%	6.3%	2.7%	5.6%

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(S) = speculative investment;

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