

Flexion Therapeutics

(FLXN-NASDAQ)

Stock Rating: Outperform
Stock Price: US\$16.25
Target Price: US\$36.00

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Specialty Pharmaceuticals

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Infection Unrelated to FX006; Clinical Hold Removed

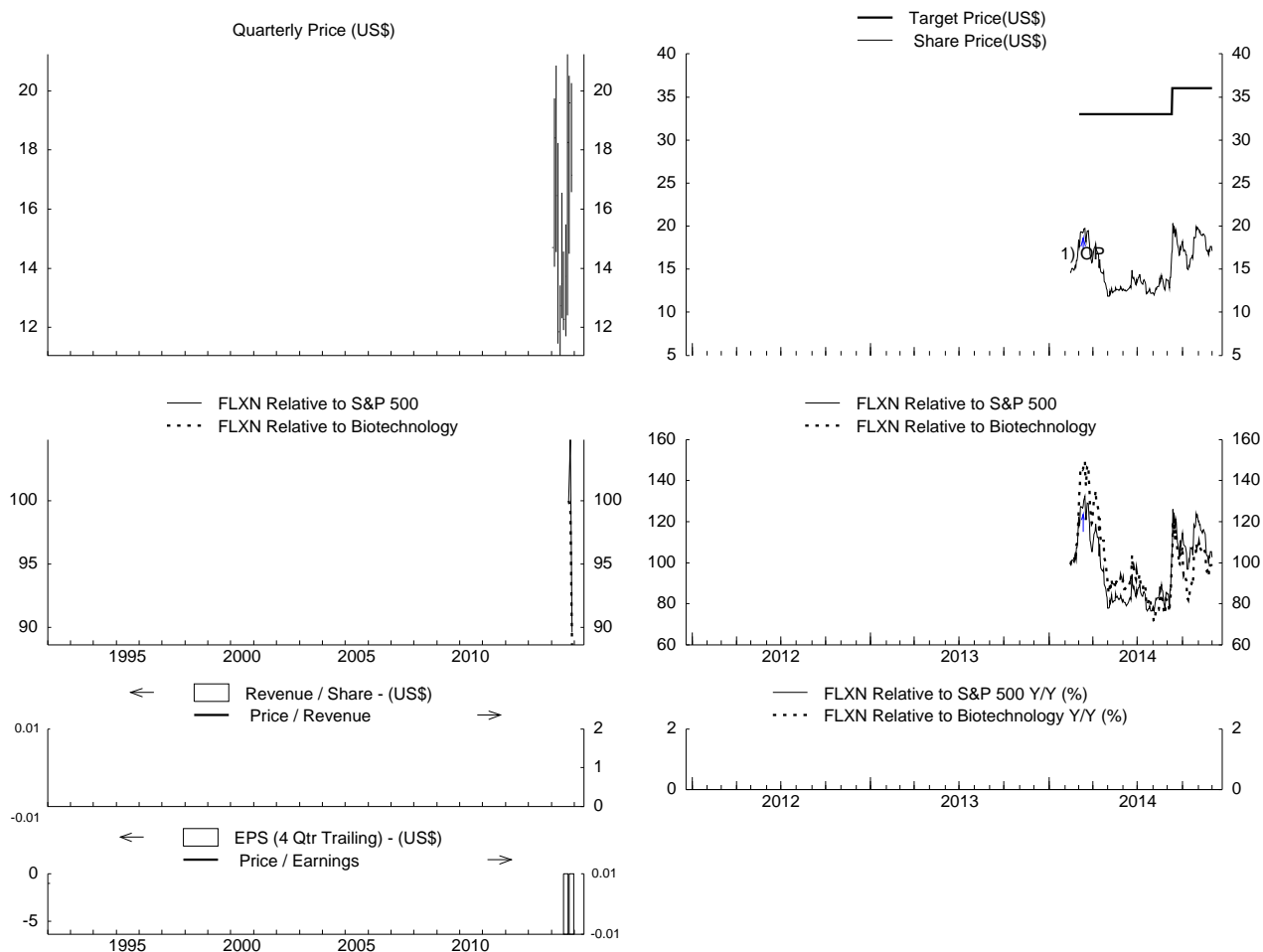
Today Flexion has announced it has been notified by the FDA that the clinical hold on FX006 has been lifted following the company's successful completion of the FDA's requested testing and investigation related to what was originally reported as a single case of septic arthritis of the knee.

Our View:

- **Recruitment and dosing to resume immediately.** Flexion plans to immediately resume recruitment and dosing of its Phase IIb trial of FX006 and will initiate the Phase III trial in early 2015 – in line with the company's prior guidance.
- **The study drug was not contaminated.** We now know that the FDA had requested that Flexion complete industry standard contamination tests through a certified third party, which showed that no microbial growth could be found in any of the used or unused vials.
- **No indication that sterile procedures were compromised during the injection.** The company consulted with the principal investigator, study coordinator, and healthcare professional who administered the injection and examined other potential causes of the possible infection including contamination during the preparation or administration of FX006 - no indication that sterile procedures were compromised during the injection.
- **There have been no other infections in the other patients dosed with FX006 in this trial.** Approximately 100 other patients were dosed as part of the trial, and, as we mentioned previously, when the clinical trial was placed on hold we had solace that infection had not been seen before in any Flexion studies.
- **Infection unrelated to the study drug treatment.** The principal investigator has changed the initial diagnosis of serious adverse event from septic arthritis to inflammatory arthritis, unrelated to study drug treatment. The company reported that the only positive synovial fluid culture obtained from this patient was presumed to be a false positive, which ensues in about 5% of such cases. Further, in all clinical trials to date, there have been no confirmed diagnoses of septic arthritis among greater than 300 patients treated with FX006 and no serious adverse events that have been attributed to the study drug.
- The company will be hosting a conference call tomorrow at 9:00am EST at (855) 770-0022.

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 %
Range*		na na		NC			>15 >15	
Current*	-6.33	na	0.00	0.0	0	-4.2	-4.1	>50

FLXN - Rating as of 11-Feb-14 = NR

Date	Rating Change	Share Price
1 11-Mar-14	NR to OP	\$19.29

* Current EPS is the 4 Quarter Trailing to Q3/2014.
 * Valuation metrics are based on high and low for the fiscal year.
 * Range indicates the valuation range for the period presented above.

Last Price (November 28, 2014): \$ND
 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 (September 30, 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	52.5%	9.7%	38.5%	51.6%	42.1%	39.1%
Sell	Underperform	3.2%	5.3%	1.3%	4.5%	1.4%	4.9%

* Reflects rating distribution of all companies covered by BMO Capital Markets Corp. equity research analysts.

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(S) = speculative investment;

NR = No rating at this time;

R = Restricted – Dissemination of research is currently restricted.

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