Flexion Therapeutics

(FLXN-NASDAQ)

Stock Rating: **Outperform**
Stock Price: **US$19.38**
Target Price: **US$36.00**

September 18, 2014
Specialty Pharmaceuticals

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Phase IIb Clinical Trial On Hold

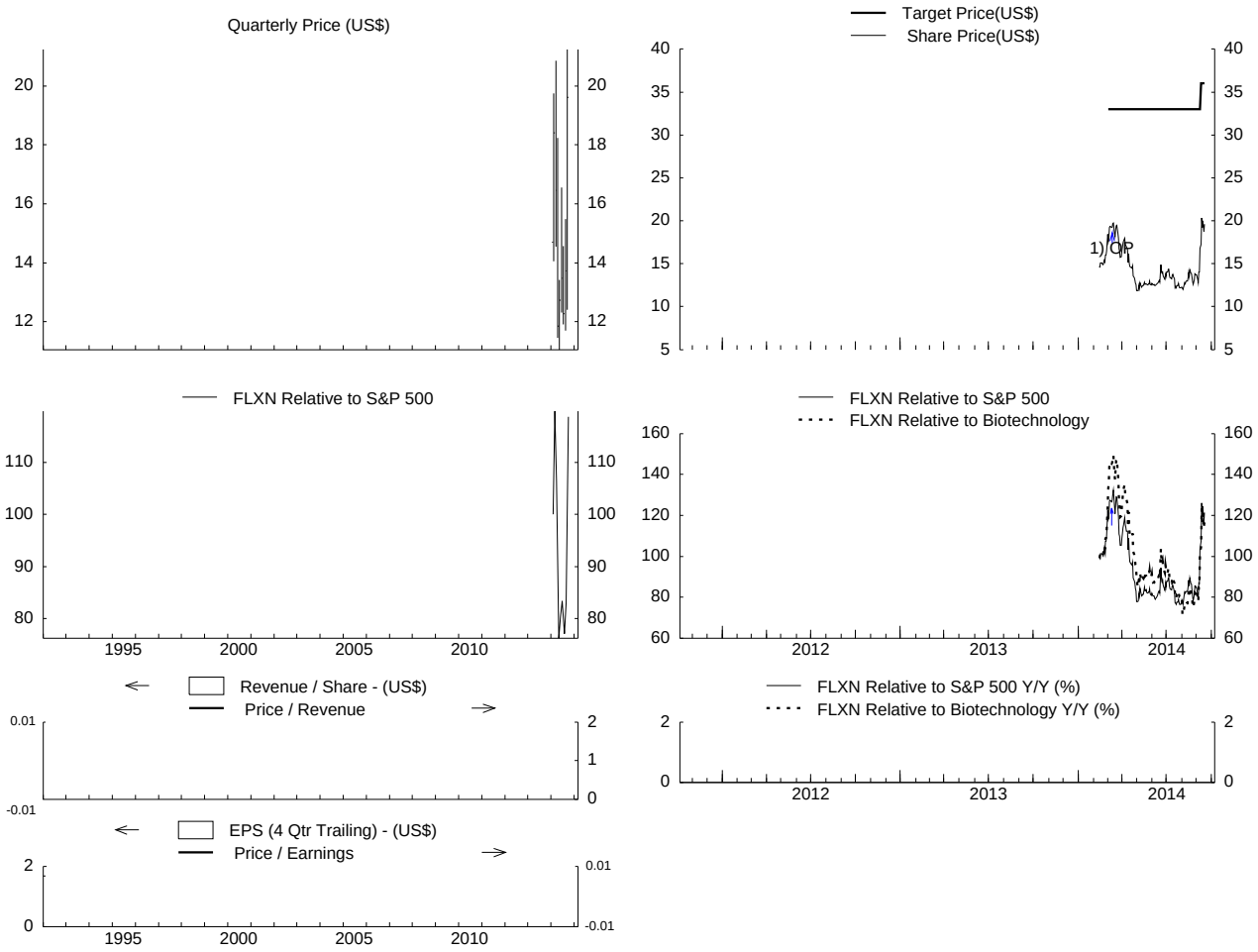
Flexion has announced that the FDA put a clinical hold on patient enrollment in Flexion's Phase IIb trial for FX006. FLXN has yet to receive a written notice, but the FDA verbally indicated the hold is due to a single occurrence of an infection in the injected knee joint of a patient. The FDA needs to be certain that the infection was not caused by clinical drug supplies before it will allow the study to continue.

Our View:

- We spoke to the company and got some additional color. Infection hasn't been seen in previous or ongoing FX006 studies until this point, and while there is no assurance it's not a manufacturing issue, it seems to us that it's unlikely at first glance as this was an isolated incident. FLXN notes its use of gamma radiation for terminal sterility and USP sterility testing of each batch to ensure the highest level safeguards. In addition, the vial is made from a known contract manufacturer with PLGA experience and the site at which this infection occurred has a long history of experience with clinical trials and intra-articular (IA) injections. Septic arthritis, which is what happened in this case, is a known but rare side effect for all IA injections and occurs in less than roughly 1% treated. FLXN is collecting data for the FDA now, and based on our discussion, this is existing data and no further test or analyses are expected - thus the turnaround of information should be relatively short (we estimate a few weeks). However, the amount of time the FDA could take to investigate, once Flexion has provided the necessary data, is unknown. According to Flexion, the FDA will make its analyses a high priority given the agency is aware this is part of a blinded study. We believe investors should recognize that it seems very unlikely that this is drug-compound related (that is the drug causing an infection), but rather external contamination perhaps by the injection. This is an important distinction, for we believe a worst-case scenario would not result in a discontinuation of development, but rather a delay while new clinical materials are validated.
- Whether this is a serious setback (needing new clinical supplies) or short few weeks' delay (if determined this was a one-off occurrence) is to be seen after the FDA has time to review things. At this time, we are not changing our timelines or forecasts and will wait to see the FDA's and FLXN's findings.
- While disappointing and concerning, we have solace that this has not been seen before in any FLXN studies, including any of the other 150 enrolled patients, roughly 100 patients in the active group, and 230+ patients exposed in prior studies. This setback comes on the heels of some recent positives: a patent issued that takes IP protection out to 2031 and the development timeline for FLXN's FX006 was fast-tracked, but this positive news takes a back seat while we wait for the outcome of the FDA's clinical hold review. We maintain our Outperform rating given the potential upside to the shares; however, anything more than a several month delay will have a negative outcome on our timeline, and as a result, our valuation.

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*	ND	na	0.00	0.0	na	-4.2	-3.3	na

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 Q2/2014.
* Valuation metrics are based on high and low for the fiscal year.
* Range indicates the valuation range for the period presented above.

Last Price (September 16, 2014): $19.61
Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

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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 (June 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	50.9%	8.4%	31.3%	51.2%	39.9%	39.5%
Sell	Underperform	5.0%	3.4%	1.3%	5.5%	1.5%	5.1%

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