

Flexion Therapeutics

(FLXN-NASDAQ)

Stock Rating: Outperform
Stock Price: US\$19.12
Target Price: US\$36.00

November 14, 2014
Specialty Pharmaceuticals

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3Q Results and FX006 Clinical Hold Response on Track

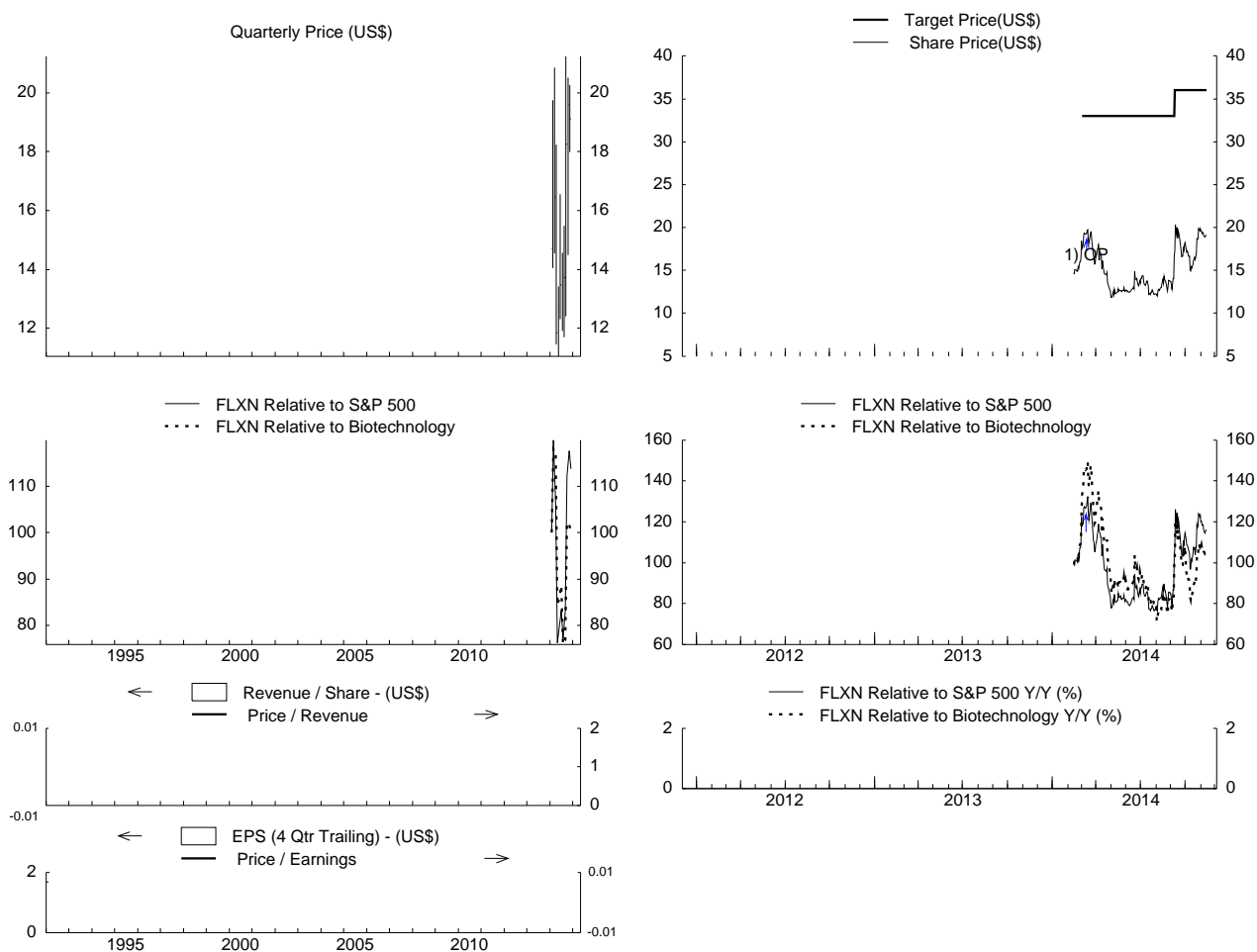
Flexion Therapeutics reported 3Q14 results with a net loss of \$7.0 million, compared with our estimate of \$11.4 million and consensus of \$7.98 million. Adjusted EPS were \$(0.45), beating our estimate of \$(0.73) due to lower spending, and consensus of \$(0.55).

Our View:

- As Flexion is a developmental company, clinical development remains the key focus over financial results. The company provided an update on its response to the clinical hold the FDA put on patient enrollment in Flexion's Phase IIb trial for FX006. The company's verbal discussion with the FDA and the agency's subsequent letter indicate the agency is concerned about sterility of the drug used in the procedure. Flexion is gathering the information the FDA asked for and will submit the data as soon as possible. The FDA should respond within 30 days of Flexion's submission and the company plans to provide an update after hearing from the FDA.
- On the conference call, Flexion noted the Phase III trial of FX006 is a global study and could begin outside the U.S. even if the clinical hold for the company's Phase IIb trial has not been lifted, but wherever it is studied it will likely begin in 1Q15. The global nature of the study has always been the company's plan and was not impacted by the clinical hold.
- FLXN's loss per share was lower than our expectation. On the spending, R&D was \$4.7 million below our estimate of \$9.8 million, and SG&A was \$2.4 million, versus our \$1.6 million forecast. Flexion had \$66.6 million in cash, cash equivalents, and marketable securities at September 30, 2014, compared with \$16.4 million as of December 31, 2013.
- We maintain our Outperform rating, given the potential upside to the shares; however, as we have said before regarding the FX006 clinical hold, 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 %	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	-4.7	na	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 (November 12, 2014): \$19.12
 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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