

Flexion Therapeutics

(FLXN-NASDAQ)

Stock Rating: Outperform
Stock Price: US\$21.22
Target Price: US\$36.00

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Specialty Pharmaceuticals

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Initiating Phase III Trial; In Line With Expectations

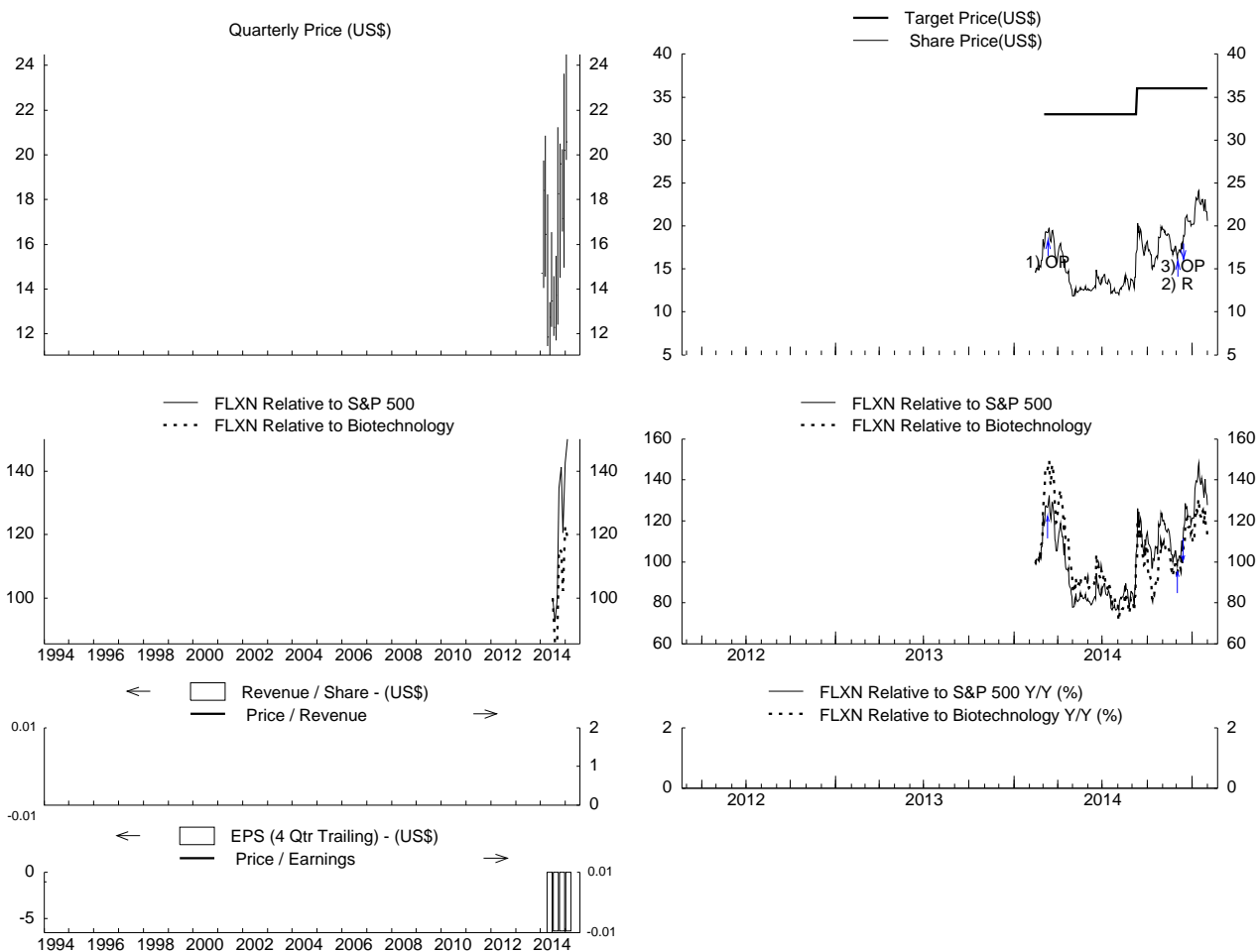
Flexion has announced the initiation of its Phase III trial of FX006 in the treatment of patients with osteoarthritis of the knee, following the dosing of its first patient. The Phase IIb trial has been completed, and we await the top-line data in the 2H15 and Phase III comparative results in 2016.

Our View:

- **Topline Phase IIb data expected in 2H15.** As we discussed in our [recent note](#) we believe Flexion is demonstrating solid execution in moving its program ahead. Top-line data from Flexion's Phase IIb trial against placebo is expected in 2H15, and in the approximately five months prior to the hold, Flexion recruited about half of the 300 patients for the Phase IIb trial. Given that the company is now recruiting from approximately 50 sites, compared with the 30 sites the study began with, we believe Flexion is well on its way to full recruitment.
- **Initiation of the Phase III trial in line with our expectations.** The Phase III trial is expected to take place at 60 clinical sites worldwide. Approximately 450 patients will be randomized to one of the three arms: 1) single IA injection of saline (placebo); 2) 40 mg of FX006; or 3) 40 mg of triamcinolone acetonide (TCA) and each patient will be evaluated for efficacy and safety at 7 outpatient visits over 24 weeks after receiving an injection. Phase III comparative results are expected in 2016, and we expected the NDA for FX006 to be filed in 2H16 – also in line with our estimates.
- **The launch of FX006 could be as early as late 2017.** Flexion plans to hire 60-100 sales people, beginning in 2016 and ramping up in 2017 to allow for as robust a launch as possible. With the data timeline on track, we believe the launch of FX006 could be as early as late 2017.
- Overall, the clinical program is moving ahead well, and we believe if the Phase II confirmatory study due to show results in 2H15 is positive, the shares could be substantially higher (>50%) than where they are now.
- We maintain our Outperform rating and \$36 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 %
Range*	na	na		NC			>15 >15	
Current*	-6.33	na	0.00	0.0	0	-4.2	-5.0	>50

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

Date	Rating Change	Share Price
1 11-Mar-14	NR to OP	\$19.29
2 2-Dec-14	OP to R	\$16.85
3 12-Dec-14	R to OP	\$18.91

* 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 (January 30, 2015): \$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 (December 31, 2014)

Rating Category	BMO Rating	BMOCM US Universe*	BMOCM US IB Clients**	BMOCM US IB Clients***	BMOCM Universe****	BMOCM IB Clients*****	Starmine Universe
Buy	Outperform	43.4%	16.2%	60.6%	42.6%	51.7%	55.6%
Hold	Market Perform	52.6%	8.1%	36.6%	53.0%	45.8%	39.5%
Sell	Underperform	3.9%	8.3%	2.8%	4.5%	2.5%	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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