

Flexion Therapeutics

(FLXN-NASDAQ)

Stock Rating: Outperform
Industry Rating: Outperform

January 19, 2015

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Enrollment Moving Along Well

Event

The BMO Specialty Pharmaceuticals team met with many companies and industry leaders this week in San Francisco, including Flexion. This note contains the takeaways from our meeting and our related commentary.

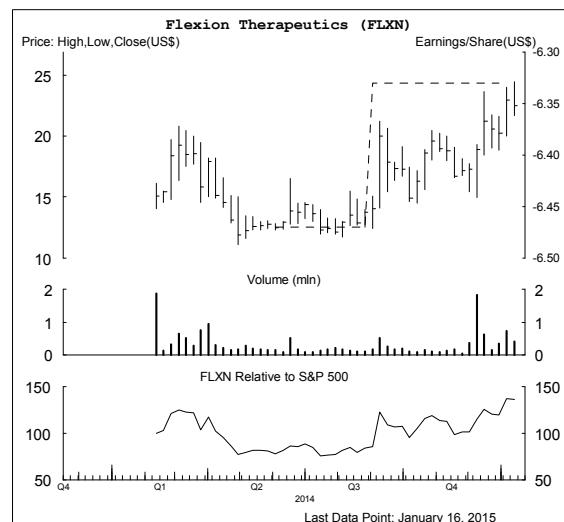
Impact & Analysis

Following the FDA's lift of the clinical hold on Flexion's Phase IIb confirmatory study of FX006, enrollment is back on track and the company expects to have top-line data in hand in 2H15. Enrollment is moving ahead nicely according to the company, helped in large part by as many as 50 clinical sites now recruiting versus the 30 when the clinical hold was put in place. Flexion's Phase III should begin, as expected, in 1Q15 and deliver results in 1H16. 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.

Valuation & Recommendation

We continue to believe that Flexion has the potential to be a game-changer in knee pain treatment and maintain our Outperform rating and \$36 price target.

Price (19-Jan) \$22.52 **52-Week High** \$24.48
Target Price \$36.00 **52-Week Low** \$11.06



(FY-Dec.)	2013A	2014E	2015E	2016E
EPS	na	-\$2.18	-\$3.08	-\$2.70
P/E		na	na	na
CFPS	na	-\$2.23	-\$3.14	na
P/CFPS		na	na	na
Rev. (\$mm)	na	\$0	\$0	na
EV	\$267	\$865	\$865	na
EBITDA (\$mm)	na	-\$29	-\$52	na
EV/EBITDA	na	na	na	na
Quarterly EPS	Q1	Q2	Q3	Q4
2013A	na	na	na	na
2014E	-\$0.85a	-\$0.38a	-\$0.45a	-\$0.66
2015E	-\$0.75	-\$0.75	-\$0.82	-\$0.75
Dividend	\$0.00			Yield 0.0%
Book Value	-\$4.15			Price/Book -5.4x
Shares O/S (mm)	14.7			Mkt. Cap (mm) \$331
Float O/S (mm)	14.4			Float Cap (mm) \$324
Wkly Vol (000s)	324			Wkly \$ Vol (mm) \$5.5
Net Debt (\$mm)	-\$5			Next Rep. Date na

Notes: All values in US\$

First Call Mean Estimates: FLEXION THERAPEUTICS INC (US\$)
 2014E: -\$1.97; 2015E: -\$2.54; 2016E: -\$2.60

Details & Analysis

Flexion says enrollment in its pivotal Phase IIb trial of FX006 is going well and has been strong since the FDA's clinical hold was lifted on December 1. In the approximately five months prior to the hold, Flexion recruited about half of the 300 patients it plans to enroll in the 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.** The trial protocol indicates patients will be monitored through a sixth month follow-up visit, allowing for top-line results approximately seven months after the final patient is enrolled. Flexion anticipates results in 2H15, but has not specified a quarter.

EU Partnership – This is not as high a priority for FLXN as it is to us, as we would love to see some further nondilutive financing. Investors, however, never really ask us about this, so we suspect that if, or when, this happens it will be upside to the shares.

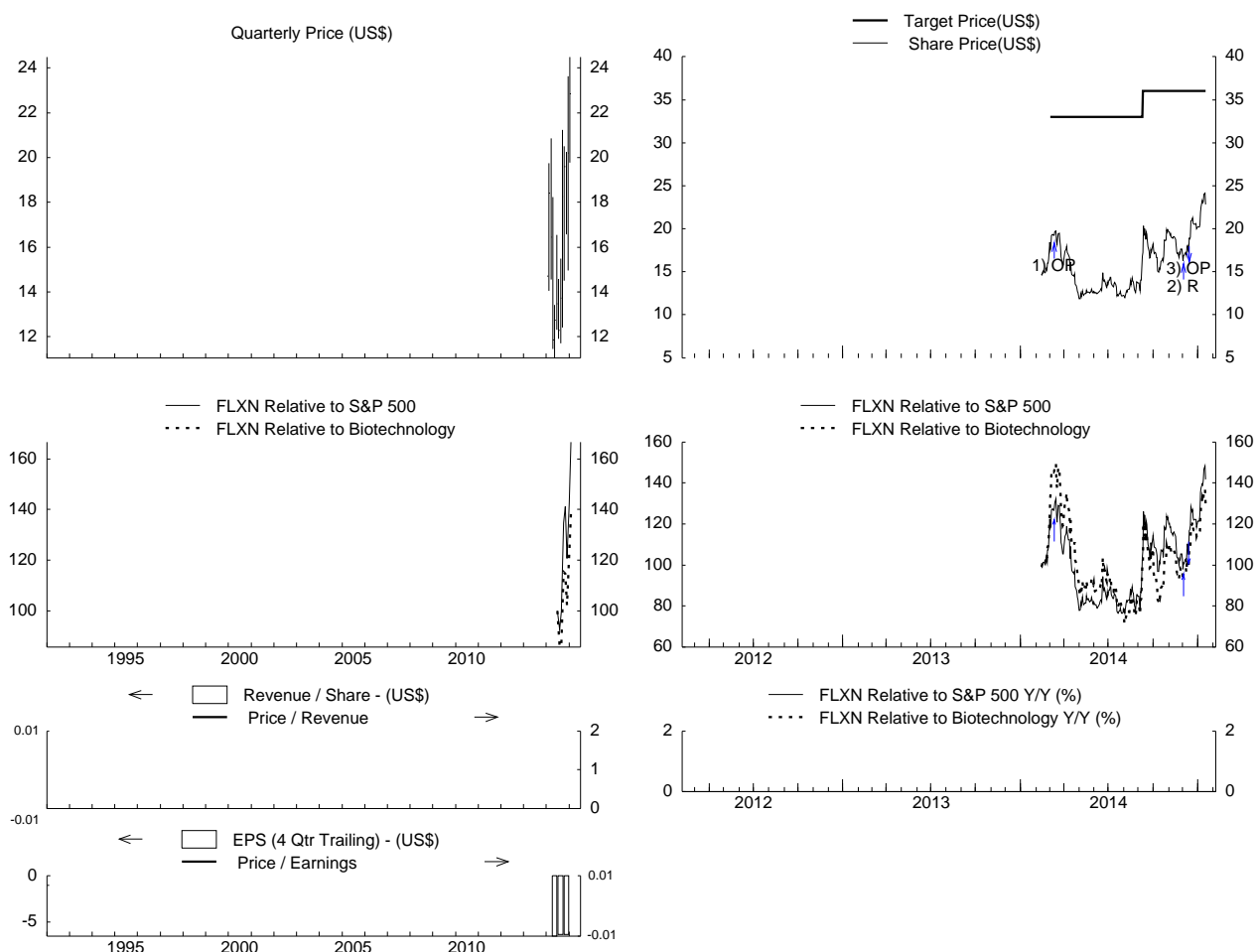
Flexion noted that unlike with many other drugs, Japan may not be a big opportunity as steroids are used very, very sparingly in Japan, where doctors prefer to treat with frequent HA injections. This standard of care varies significantly from how North American and European orthopedists treat osteoarthritis.

Pricing. Flexion has done four rounds of research, which support that pricing of \$500 a dose will be supported by payors. We understand as a treatment gets closer to \$600 per dose, payors pay closer attention, while a price lower than \$400 per dose can potentially lead to the drug being less closely managed at pharmacies, etc. Flexion's research also shows HA has been removed from many practicing physician's armamentariums, increasing their appetite for a substitute or better alternative. At reasonable penetration rates, Flexion's projections indicate FX006 has blockbuster potential.

Flexion expects to submit its NDA for FX006 to the FDA in 2H16, allowing for a possible launch 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.

We are encouraged with the leadership responsible for commercializing FX006, as Flexion's vice president of Commercial previously was responsible for the marketing and launch of Synvisc at Genzyme. This experience with selling an injectable treatment to orthopedists should lend itself to a smooth launch of FX006.

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	-4.9	

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 15, 2015): \$22.84
 Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

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Methodology and Risks to Price Target/Valuation

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.

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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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Mkt = Market Perform - Forecast to perform roughly in line with the analyst's coverage universe on a total return basis

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(S) = speculative investment;

NR = No rating at this time;

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