Flexion Therapeutics

(FLXN-NASDAQ)

Stock Rating: **Outperform**
Stock Price: **US$13.15**
Target Price: **US$33.00**

September 3, 2014
Specialty Pharmaceuticals

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Good News – Timeline Moves Up by About a Year

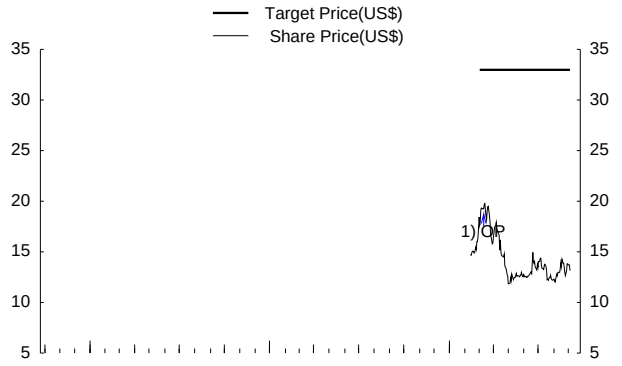
Flexion announced the FDA will no longer require data from a repeat-dose safety trial of its lead drug candidate, a sustained-release steroid injection (FX006), for approval. As a result, Flexion is accelerating its development timeline and plans to initiate a Phase III trial of FX006 by the end of 2014, one year ahead of schedule. The company expects the study will be completed by the end of 2015, also a year earlier than previously anticipated. The FDA indicated to Flexion that the company's ongoing Phase IIb confirmatory trial of FX006 (the data readout of the ongoing study will still be in the 1H15), along with data from the Phase III trial, will suffice for registration as a single-dose administration.

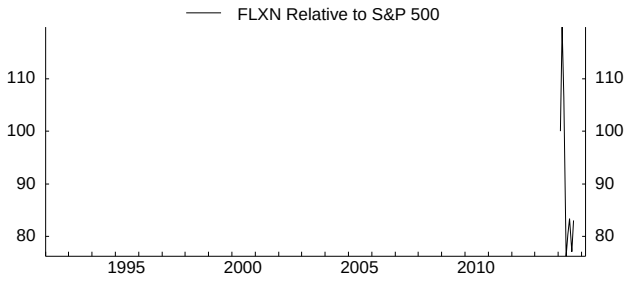
Our View:

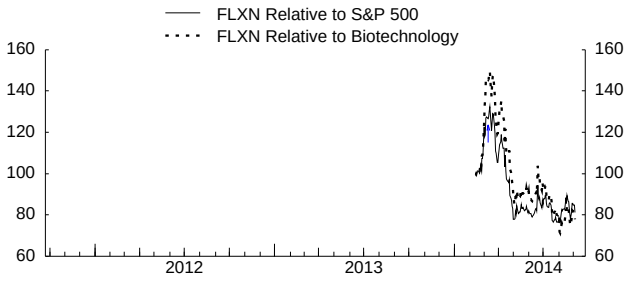
- Following a meeting, the FDA's Division of Pulmonary, Allergy, and Rheumatology decided that it would be more appropriate for DAAAP (Division of Anaesthesiology, Analgesia, and Addictive Products) to review FX006, and the new clinical plan came following a subsequent meeting with DAAAP. We spoke with the company and anticipate the cost impact of this timeline acceleration will be minimal. We believe this is very positive news, as it moves up the timeline for Flexion's lead product candidate a full year. Flexion continues to expect its current cash balance will support the company's needs until late 2015. We will revisit our model after the conference call the company is hosting Thursday morning.
- The Phase III trial will last 12 weeks and include approximately 463 patients. It will have three arms - one group that will receive a 40 mg dose of FX006, one placebo group, and one group that will receive a 40 mg dose of immediate-release TCA (the same steroid that is in long-acting FX006). The endpoint for the phase III will be reduction in pain as measured by the numerical rating score versus against placebo at 12 weeks (a weekly mean of the average daily pain intensity score (11 point numerical score)). This trial will generate critical direct-to-comparator data that Flexion believes will support the inclusion of a comparative data set in FX006's label. Flexion plans to collect repeat-dose safety data and submit it to the FDA as a supplement shortly after approval of FX006. We believe another side benefit for investors of this move is that it may also accelerate partnering discussions as the company will now be a Phase III company with data in 2015.
- Flexion will hold a conference call and webcast at 8:30 a.m. EDT Thursday, September 4, 2014. The dial-in number for the conference call is (855) 770-0022 for domestic participants and (908) 982-4677 for international participants.

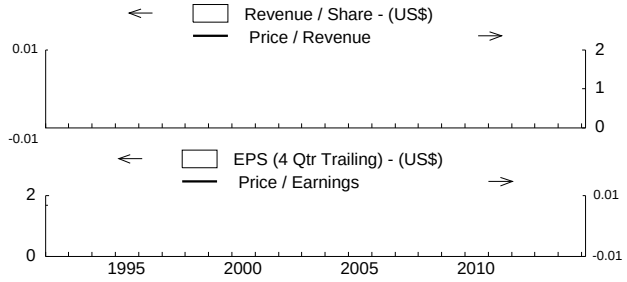
Please refer to pages 2 to 5 for Important Disclosures, including the Analyst's Certification.

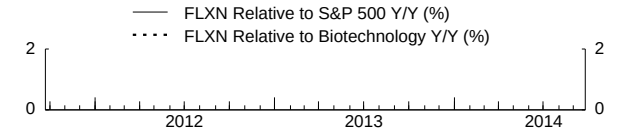
Flexion Therapeutics (FLXN)











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 Q1/2014.
* 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 2, 2014): $13.15
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 (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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