Flexion Therapeutics

(FLXN-NASDAQ)

Stock Rating: **Outperform**
Industry Rating: **Outperform**

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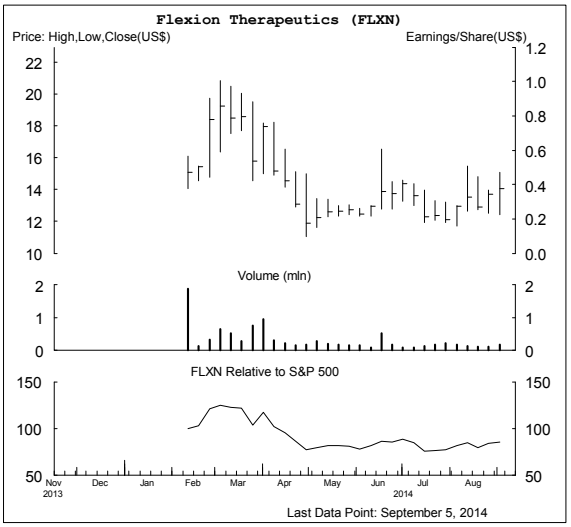
Positive Patent News and Model Update

Price (9-Sep)	$14.02	**52-Week High**	$20.85
Target Price	$36.00↑	**52-Week Low**	$11.06



Event

Flexion announced positive patent news, with a patent issued on its lead program that will take IP protection to 2031. This risk-mitigating positive news comes on the heels of positive news last week when Flexion announced that following a change in the FDA division responsible for reviewing Flexion's FX006 (for osteoarthritis knee pain) pipeline, Flexion and the new division responsible came to agreement on a clinical development plan that will shorten the development timeline for Flexion its lead product by approximately a year. We wrote about this last week and stated that we would update our model following discussions with the company and, with this note, we are updating our model for this news, as well as the recently announced 2Q14 results. Flexion now plans to initiate a Phase III trial by the end of 2014, one year ahead of schedule, and the product could reach the market approximately a year earlier as well.

Impact & Analysis

We updated our model with new timeline and 2Q14 results and adjusted our estimates accordingly; these changes are detailed in this note. We accelerated the FX006 development timeline by 6 months, risk adjusting the company's estimate it will accelerate a year, to account for any unforeseen delays to the initiation or completion of the Phase III clinical trial. 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.

Valuation & Recommendation

Updating our assumptions following 2Q14 and accelerating FX006 revenues, COGS, and R&D and SG&A spending by 6 months, while keeping a WACC of 20% and EV/EBITDA multiple of 10x, we arrive at a new price target of $36, up from our previous target of $33. We maintain our Outperform rating.

(FY-Dec.)	2012A	2013A	2014E	2015E
EPS	na	na	- $2.50↑	- $3.08↓
P/E			na	na
CFPS	na	na	- $2.55↑	- $3.14↓
P/CFPS			na	na
Rev. ($mm)	na	na	$0	$0
EV	na	$267	$202	$202
EBITDA ($mm)	na	na	-$21	-$21
EV/EBITDA	na	na	na	na

Quarterly EPS	**Q1**	**Q2**	**Q3**	**Q4**
2012A	na	na	na	na
2013A	na	na	na	na
2014E	-$0.85a	-$0.38a	-$0.73↑	-$0.66↑

Dividend	$0.00	**Yield**	0.0%
Book Value	-$4.15	**Price/Book**	-3.4x
Shares O/S (mm)	14.7	**Mkt. Cap (mm)**	$206
Float O/S (mm)	14.4	**Float Cap (mm)**	$202
Wkly Vol (000s)	312	**Wkly $ Vol (mm)**	$4.8
Net Debt ($mm)	-$5	**Next Rep. Date**	na

Notes: All values in US$
First Call Mean Estimates: FLEXION THERAPEUTICS INC (US$)
2014E: -$2.45; 2015E: -$2.92

Changes	Annual EPS	Annual CFPS	Quarterly EPS	Target
	2014E -$3.64 to -$2.50	2014E -$3.41 to -$2.55	Q3/14E -$0.87 to -$0.73	$33.00 to $36.00
	2015E -$2.78 to -$3.08	2015E -$2.84 to -$3.14	Q4/14E -$1.09 to -$0.66	

Please refer to pages 6 to 9 for Important Disclosures, including the Analyst's Certification.

Details & Analysis

Strong 2Q14 Results

Flexion reported solid second quarter results, with a loss per share lower than our expectation and consensus, but we reiterate that, as with most development-stage companies, Flexion's actual financial results are less important that recent and upcoming clinical milestones.

Flexion's net loss was $5.9 million in Q2 compared with our estimate of $12.6 million and consensus of $8.2 million. Adjusted EPS was ($0.38), beating our estimate of ($0.80) and consensus of ($0.51), due to lower-than-anticipated spending.

On the spending, R&D was $3.6 million below our estimate of $11 million, and SG&A was $2.2 million versus our $1.6 million forecast. Flexion had $72 million in cash, cash equivalents, and marketable securities at June 30, 2014, compared with $78.5 million as of March 31, 2014. We've slightly lowered our R&D spending estimates for 3Q14 and 4Q14, as Flexion spent less than expected in the 1H14. Our R&D estimate for 3Q14 is now $9.8 million, down from $12.0 million, and we anticipate Flexion will spend $8.8 million in R&D in 4Q14 versus our previous estimate of $15.6 million.

FX006 Timeline Acceleration

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.

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 expect that the cost impact of this timeline acceleration will be minimal. Flexion continues to expect its current cash balance will support the company's needs until late 2015.

The Phase III trial will last 12 weeks and include 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

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.

We believe this is very positive news, as it moves up Flexion's estimated timeline for its lead product candidate a full year. However, to risk-adjust for the possibility of a delay to the initiation or completion of the Phase III study or the filing of the NDA, we accelerated the FX006 timeline by 6 months in our model. **We now anticipate FX006 will reach the market in 1Q17 and contribute $60 million in revenue in 2017.**

The changes to our estimates are shown in Exhibit 1.

Exhibit 1: Flexion EPS Estimates

	2Q14A	FY2014E	FY2015E	FY2016E	FY2017E	FY2018E	FY2019E	FY2020E	FY2021E
BMO EPS (New)	**($0.38)A**	**($2.50)**	**($3.08)**	**($2.70)**	**($2.45)**	**($0.46)**	**$2.67**	**$6.35**	**$9.18**
BMO EPS (Previous)	($0.80)	($3.64)	($2.78)	($2.85)	($2.94)	($1.19)	$2.08	$5.75	$8.30
Consensus	($0.51)	($2.46)	($2.91)	($2.79)	($2.31)	($1.23)	N/A	N/A	N/A

Source: Company reports, BMO Capital Markets and Thomson Reuters

Exhibit 2: FLXN Income Statement (in millions, except per share data)

Flexion Income Statement	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
FX006	$ -	$ -	**$ -**	**$ 59.9**	**$ 128.7**	**$ 268.1**	**$ 425.4**	**$ 628.0**
FX007	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ 15.5**	**$ 80.9**
FX005	$ -	$ -	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ 14.0**
Total revenues	**$0.0**	**$0.0**	**$0.0**	**$59.9**	**$128.7**	**$268.1**	**$441.0**	**$722.9**
% growth					*114.9%*	*108.4%*	*64.5%*	*63.9%*
COGS	$0.0	$0.0	$1.4	$6.3	$25.2	$60.2	$108.7	$164.4
Milestone/Other fees	$0.0	$0.0	$0.0	$0.0	$0.0	$12.0	$12.0	$45.0
Royalty Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$3.0
Gross profit	**$0.0**	**$0.0**	**-$1.4**	**$53.5**	**$103.5**	**$195.9**	**$320.3**	**$510.5**
Gross margin				89.4%	80.4%	73.1%	72.6%	70.6%
R&D	$26.4	$34.6	$33.5	$51.1	$60.9	$53.7	$37.3	$41.6
R&D as % of sales				85.4%	47.3%	20.0%	8.5%	5.7%
SG&A	$7.7	$17.9	$25.4	$62.5	$54.7	$64.2	$93.5	$143.2
SG&A as % of sales					42.5%	24.0%	21.2%	19.8%
Operating profit	**-$34.1**	**-$52.5**	**-$60.3**	**-$60.1**	**-$12.1**	**$77.9**	**$189.4**	**$325.7**
Operating margin						29.1%	43.0%	45.1%
Pretax income	**-$34.2**	**-$52.5**	**-$60.3**	**-$60.1**	**-$12.1**	**$77.9**	**$189.4**	**$325.7**
Pretax margin						29.1%	43.0%	45.1%
Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$7.8	$22.7	$84.9
Tax rate	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	12.0%	26.1%
Net income	**-$34.2**	**-$52.5**	**-$60.3**	**-$60.1**	**-$12.1**	**$70.1**	**$166.7**	**$240.8**
Net margin						26.2%	37.8%	33.3%
Shares out (diluted)	13.7	17.0	22.4	24.5	26.2	26.2	26.2	26.2
Earnings per share	**-$2.50**	**-$3.08**	**-$2.70**	**-$2.45**	**-$0.46**	**$2.67**	**$6.35**	**$9.18**
EPS % growth							*137.6%*	*44.4%*

Source: Company reports and BMO Capital Markets Estimates

Exhibit 3: FLXN DCF

Flexion FLXN-us
Discounted Cash Flow Analysis
$ Millions, except per share

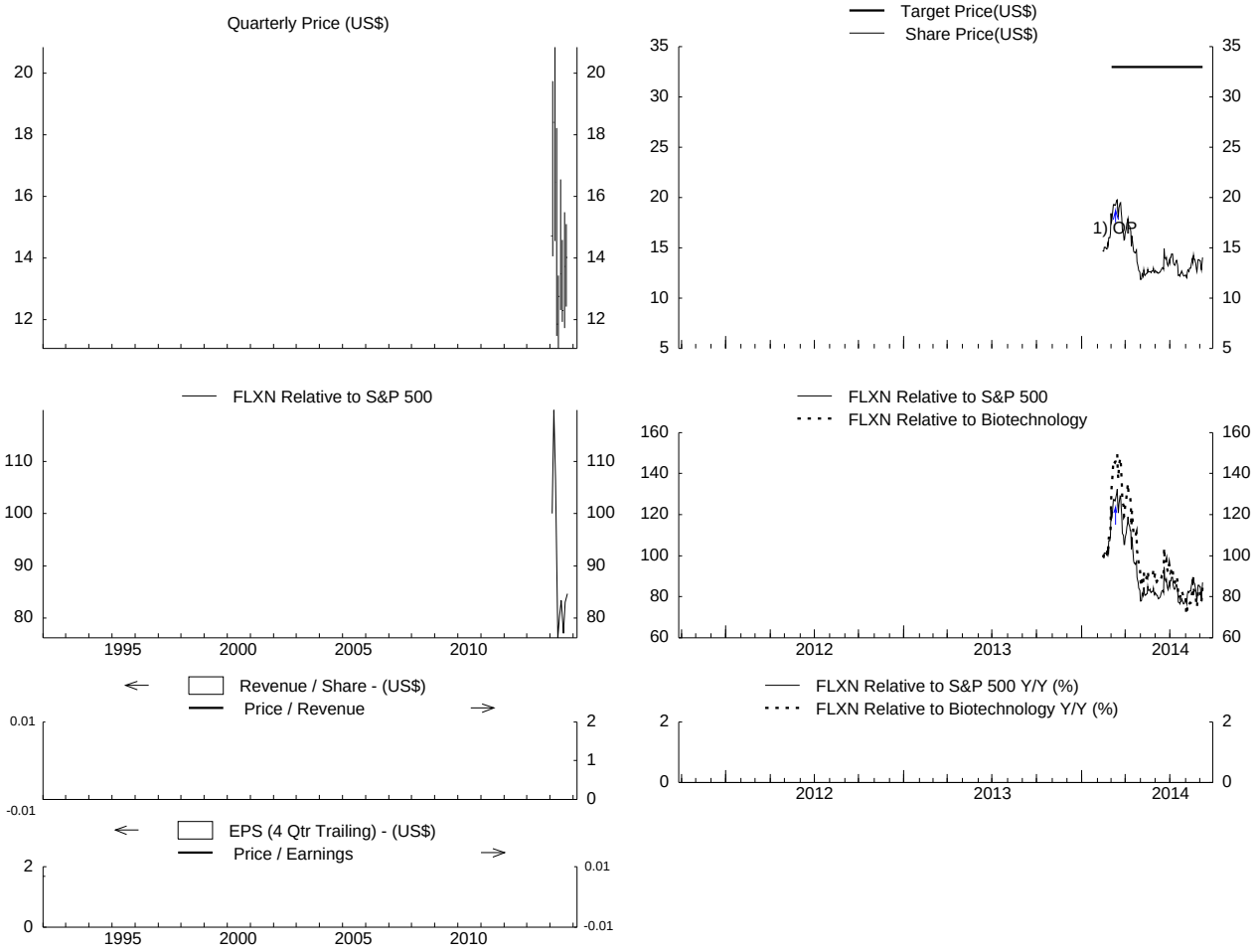
WACC	**20.0%**								
Terminal Value EV/EBITDA Multiple	**10.0x**								
Unlevered Free Cash Flows									
		2014	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
Net Sales		0.0	0.0	0.0	59.9	128.7	268.1	441.0	722.9
Growth Rate						*115%*	*108%*	*64%*	*64%*
EBIT		-34.1	-52.5	-60.3	-60.1	-12.1	77.9	189.4	325.7
Margin							*29%*	*43%*	*45%*
Pre-tax income		-34.2	-52.5	-60.3	-60.1	-12.1	77.9	189.4	325.7
Tax		$0.0	$0.0	$0.0	$0.0	$0.0	($7.8)	($22.7)	($120.5)
Tax rate							10.0%	12.0%	37.0%
EBIAT		($34.1)	($52.5)	($60.3)	($60.1)	($12.1)	$70.1	$166.7	$205.2
Plus: Depreciation and Amortization		$0.3	$0.1	$0.1	$0.1	$0.1	$0.1	$0.1	$0.1
Less: Capital Expenditures		($0.3)	($1.1)	($1.1)	($2.1)	($4.0)	($4.0)	($4.0)	($8.0)
Less: Change in Net Working Capital		($1.7)	$0.0	$0.2	$0.8	$3.1	$5.8	$8.0	$9.2
Unlevered Free Cash Flow		**($35.8)**	**($53.5)**	**($61.0)**	**($61.3)**	**($12.9)**	**$72.0**	**$170.8**	**$206.5**
Cumulative Unlevered FCF	$260.67	0	1	2	3	4	5	6	7
Terminal Value[2]	$3,258.7								
PV of Free Cash flow	($44.9)	-$35.8	-$53.5	-$61.0	-$61.3	-$12.9	$28.9	$57.2	$57.6
PV of Terminal Value	$909.4								
Implied Enterprise Value	$864.6								
Plus: Cash & Equivalents **(2Q14E)**	$72.0								
Less: Total Debt **(1Q14E)**	$4.6								
Implied Value of Equity	$932.0								
Diluted Shares Outstanding	25.7								
Implied Value per Share	**$36.26**								

Implied Equity Value Sensitivity Table

WACC	***EBITDA Multiple Terminal Value***			
	$36.26	**8.0x**	**10.0x**	**12.0x**
	15.0%	$40.70	$50.24	$59.77
	20.0%	$29.19	**$36.26**	$43.34
	25.0%	$20.90	$26.22	$31.54

Source: Company reports and BMO Capital Markets Estimates

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 4, 2014): $14.02
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 naure, 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
Buy	Outperform	44.1%	21.1%	67.5%	43.3%	58.6%	55.4%
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%

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