Biopharmaceuticals — Company Update

Summer Street RESEARCH PARTNERS

Flexion Therapeutics, Inc. (FLXN)

Could FX006 Clinical Hold Be Resolved as Soon as December?

November 14, 2014

SUMMARY

FLXN reported 3Q14 results last night after the close, and commentary focused on the ongoing clinical hold for lead development product FX006, the company's sustained-release corticosteroid for osteoarthritis of the knee. Management reiterated that the primary focus of the FDA in the clinical hold was to make sure the source of the infection didn't come from FLXN's product, which we believe is a much more achievable task than trying to pinpoint the ultimate source of the patient's infection. We continue to expect FLXN will be able to demonstrate that the vials and drug in the batch used in the infected patient were not the source of the infection, and the FDA will quickly lift the clinical hold and allow the trial to continue. FLXN would not say if they have completed their testing and responded to the FDA, choosing instead to wait until the FDA replies back to them, but we believe that could be as soon as next month with the FX006 phase IIb trial restarting in 1H15. We continue to see little material change to our investment thesis, and we reiterate our BUY rating and $28 price target.

INTERPRETATION

FX006 culture results may already be completed. A typical culture sample can be completed in ~30 days, which we estimate could have been finished as soon as early November. We expect FLXN has — or soon will — send their clinical hold response to the FDA. Assuming the vial and batch tests were negative for bacterial contamination and assuming a standard 30-day response from the FDA, FLXN could get a notification from the FDA as soon as mid-December to remove the clinical hold.

Ex-US phase III could start before the hold is lifted. Most surprisingly, management indicated they may be able to get ex-US trial sites up and recruiting before the FDA lifts the clinical hold here in the US. This is atypical to our understanding, but it may be a moot point given that we expect the clinical hold to be lifted soon, possibly as soon as next month.

Already dosed patients still being followed. FLXN is continuing the 12-week follow-up on the 150 patients who received the FX006 injection before the trial was halted, so in one sense the trial is actually still ongoing — just no new patients are being recruited. Additionally, sites are still screening potential participants during the clinical hold. This is why we believe the trial should be able to quickly restart if the clinical hold is ultimately lifted by the FDA.

ACTION

Reiterate BUY rating, $28 price target. Our $28 price target is based on a sum-of-the-parts analysis, with FX006 valued at $22/share, FX007 at $0.50/share, and cash (end 2015) and technology at $5.50/share.

FLXN
Rating: BUY
Price Target: $28.00

Market Data	
Price:	$19.00
52-week high:	$21.23
52-week low:	$11.06
Shares out:	15.62MM
Shares short:	231.96K
Average volume (10-day):	17,938

Valuation Metrics	
Market cap:	$229.44MM
Enterprise value:	$229.44MM

Financial Highlights	
Cash/equivalents:	$71.99MM
Debt:	$4.57MM

REV ($MM)	2013	2014	2015E
Q1	0.0	0.0	0.0
Q2	0.0	0.0	0.0
Q3	0.0	0.0	0.0
Q4	0.0	0.0E	0.0
FY	0.0	0.0E	0.0

EPS ($)	2013	2014	2015E
Q1	(6.13)	(0.86)	(0.67)
Q2	(6.13)	(0.38)	(0.52)
Q3	(6.12)	(0.43)	(0.52)
Q4	(4.65)	(0.43)E	(0.52)
FY	(23.02)	(1.90)E	(2.20)

One-Year History

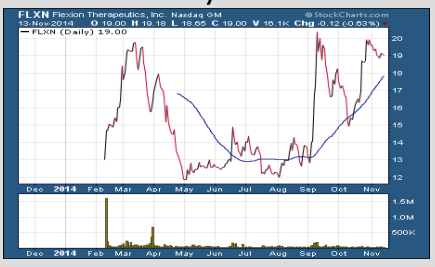

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Figure 1. Sum-of-the-Parts Analysis

Sum-of-the-parts value: Flexion		
Segment	Valuation (000's)	Per share value
FX006 value	$471,253	$22
FX007	$11,156	$0.5
Cash (end '15) & tech value	$112,963	$5.5
SUM	**$595,371**	**$28**
Shares out '15E (000)		21,432

Source: SSRP Estimates

Figure 2. Potential Clinical Trial Timelines

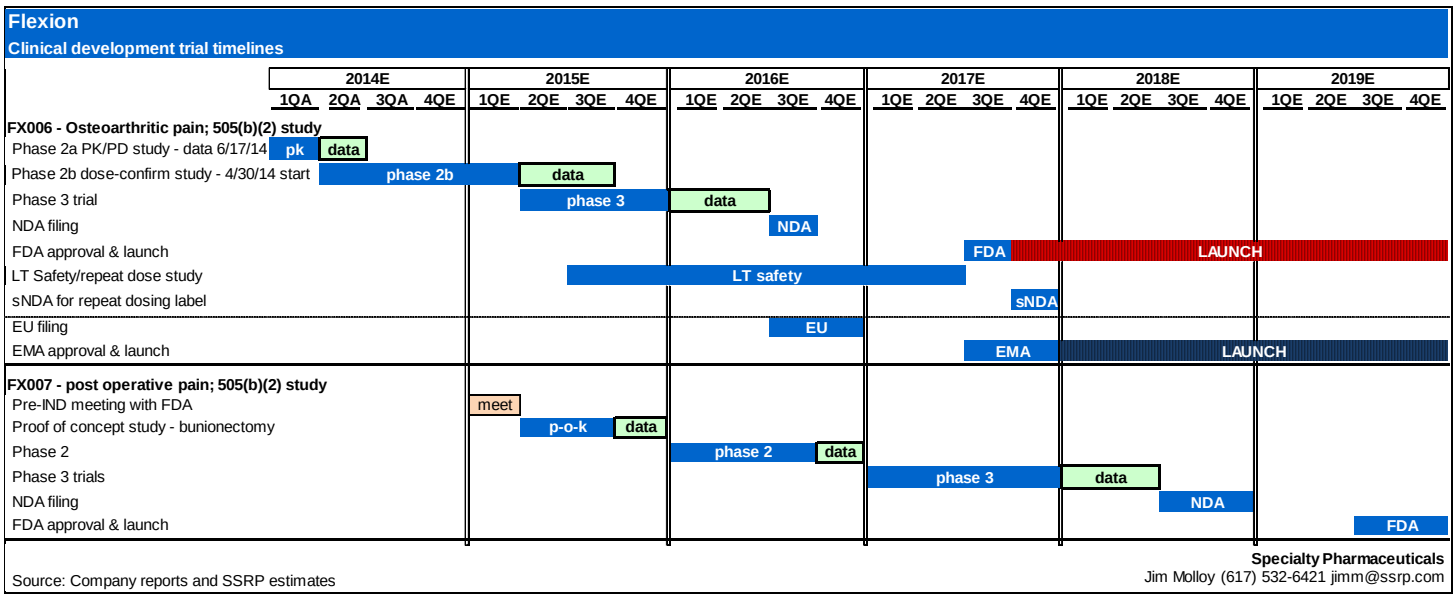

Figure 3. Quarterly Income Statement

Flexion
Quarterly income statement

($000 except per share)	2013A 1QA	2013A 2QA	2013A 3QA	2013A 4QA	2013A Year	2014E 1QA	2014E 2QA	2014E 3QA	2014E 4QE	2014E Year
Revenues										
Total Revenue										
Expenses:										
Cost of Revenue (COGS)										
Gross Margin	-	-	-	-		-	-	-	-	**0**
Research and development	2,950	2,950	2,942	2,219	11,061	4,151	3,615	4,658	4,750	17,174
General and administrative	1,788	1,788	1,788	1,340	6,704	2,284	2,234	2,304	2,300	9,122
Total operating expenses	4,738	4,738	4,729	3,560	17,765	6,435	5,849	6,962	7,050	26,296
Income (loss) from Operations	**(4,738)**	**(4,738)**	**(4,729)**	**(3,560)**	**(17,765)**	**(6,435)**	**(5,849)**	**(6,962)**	**(7,050)**	**(26,296)**
Interest income (expense), net	(39)	(39)	(39)	(98)	(215)	(81)	28	56	50	53
Other income (exp)	(64)	(64)	(64)	(15)	(207)	(26)	(110)	(130)	(100)	(366)
Income (loss) before taxes	**(4,841)**	**(4,841)**	**(4,832)**	**(3,673)**	**(18,187)**	**(6,542)**	**(5,931)**	**(7,036)**	**(7,100)**	**(26,609)**
Income tax exp (benefit)	-	-	-	-						
Net Income (Loss)	**(4,841)**	**(4,841)**	**(4,832)**	**(3,673)**	**(18,187)**	**(6,542)**	**(5,931)**	**(7,036)**	**(7,100)**	**(26,609)**
Earning per Share (EPS)	**($6.13)**	**($6.13)**	**($6.12)**	**($4.65)**	**($23.02)**	**($0.86)**	**($0.38)**	**($0.45)**	**($0.45)**	**($1.95)**
Weighted avg. shares (000)	789	790	790	790	790	7,633	15,619	15,625	15,775	13,663

Source: Company reports and SSRP estimates

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Figure 4. Annual Income Statement

Flexion
Annual income statement

($000 except per share)	2013A	2014E	2015E	2016E	2017E	2018E	2019E	Comments
Revenues								
FX006 - OA pain					$1,655	$200,497	$340,745	FDA 2H17 due to trial delay
FX007 - post operative pain							0	2020 launch estimated
FX006 ex-US royalties						13,748	22,303	Partner ex-US
Total Revenue	**$0**	**$0**	**$0**	**$0**	**$1,655**	**$214,246**	**$363,049**	
Expenses:								
Cost of Revenue (COGS)	-	-	-	-	248	30,075	51,112	
Gross Margin	**-**	**-**	**-**	**-**	**1,407**	**184,171**	**311,937**	
R&D	11,061	17,174	32,250	34,500	35,250	38,500	39,500	
G&A	6,704	9,122	12,250	15,250	17,000	49,250	72,500	Self-launch FX006 in US
Total op exp	17,765	26,296	44,500	49,750	52,250	87,750	112,000	
Inc/(loss) from Ops	**(17,765)**	**(26,296)**	**(44,500)**	**(49,750)**	**(50,843)**	**96,421**	**199,937**	
Int income (exp), net	(215)	53	200	200	250	300	450	
Other expenses, net	(207)	(366)	(400)	(200)	(200)	(200)	(199)	
Inc/(loss) before taxes	**(18,187)**	**(26,609)**	**(44,700)**	**(49,750)**	**(50,793)**	**96,521**	**200,188**	
Income tax exp (benefit)	-	-	-	-	-	-	50,047	
Net Income (Loss)	**($18,187)**	**($26,609)**	**($44,700)**	**($49,750)**	**($50,793)**	**$96,521**	**$150,141**	
Earning per Share	**($23.02)**	**($1.95)**	**($2.20)**	**($2.30)**	**($2.20)**	**$3.50**	**$4.95**	
Weighted avg. shares (000)	790	13,663	20,338	21,588	23,088	25,588	28,088	
Fully diluted shares (000)	1,439	14,801	21,338	22,588	24,338	27,588	30,338	
Cash balance	$16,566	$67,232	$107,877	$61,477	$14,534	$115,680	$267,971	IPO cash through 2H15

Source: Company reports and SSRP estimates

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RISKS TO PRICE TARGET ESTIMATE

Exogenous events could impact our outlook. We believe pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies.

Actual clinical results and the FDA's conclusions may deviate from expectations. Many of our assumptions are based on a review of incomplete clinical trial data available in the public domain. Often, our conclusions are drawn from early stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations. Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

Legal risks could lead to additional liabilities and revenue loss. In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

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Investment Rating Distribution for the Period 7/1/14 through 9/30/14:

Rating	Count	Percentage	Investment Banking Services (12 months)
BUY	25	89%	16%
NEUTRAL	3	11%	0%
SELL	0	0%	0%
Companies under coverage at 9/30/14	**28**	**100%**	**14%**

We have assigned an investment rating for the following subject companies mentioned in this report:

FLXN

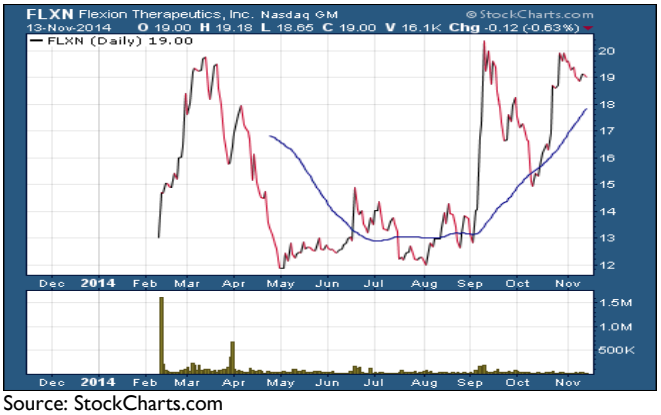
Ratings History

Date	Rating	Share Price	Price Target
8/14/14	BUY	$13.37	$25.00
9/5/14	BUY	$14.02	$28.00

FLXN Investment Risks

- Exogenous events could impact our outlook. Pharmaceutical companies have the least control over competitive, political, and regulatory risks.
- Actual clinical results and the FDA's conclusions may deviate from expectations.
- Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations.
- Legal risks could lead to additional liabilities and revenue loss.

Valuation Method for Price Target: Sum of the parts



Source: StockCharts.com