Summer Street RESEARCH PARTNERS

Flexion Therapeutics, Inc. (FLXN)

FDA Lifts Clinical Hold, the Trial Is Back On

December 2, 2014

SUMMARY

FLXN reported last night that the FDA has lifted the clinical hold on FX006 for osteoarthritis (OA) of the knee following FLXN demonstrating to the FDA's satisfaction that FX006 was not the source of a patient's infection. It also appears that the principal investigator has changed the serious adverse event (SAE) diagnosis from septic arthritis related to study drug to inflammatory arthritis unrelated to study drug. In any event, FLXN expects to ramp the phase IIb back up quickly, as potential clinical trial patients had been identified during the clinical hold in expectation of the hold being ultimately lifted. FLXN is also guiding to the phase III trial starting in 1Q15, ahead of our prior expectations of a 2Q15 start. We continue to like FLXN here, reiterate BUY rating and $28 price target.

INTERPRETATION

Principal investigator even changes the SAE designation. Surprisingly, the principal investigator has even changed the designation of the SAE from "septic arthritis possibly related to drug treatment" to "inflammatory arthritis, unrelated to drug treatment" based on the patient's clinical course following diagnosis. The initial diagnosis of infection in the synovial fluid appears to have been a "false positive" reading, which can happen ~5% of the time. It would seem that the whole clinical hold was for naught, as it appears that the patient never even had an infection in the first place.

Phase III expected to start in 1Q15. We have moved our phase III trial initiation up to 1Q15 (from 2Q15 previously), and while we have kept the expected trial readout in 1H16 (see Figure 2: Potential Clinical Trial Timelines) this could prove conservative should the recruitment proceed more quickly than anticipated.

Already dosed patients were still being followed. FLXN had continued 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 was still ongoing — just no new patients had been started. Since trial sites were still identifying potential participants during the clinical hold we believe the trial should be able to quickly restart now that the clinical hold has been lifted by the FDA.

Conference call this AM. FLXN management will hold a conference call at 9 a.m. ET to discuss the clinical hold being lifted. The dial-in number is 855-770-0022.

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:	$16.25
52-week high:	$21.23
52-week low:	$11.06
Shares out:	15.63MM
Shares short:	231.96K
Average volume (10-day):	15,580

Valuation Metrics	
Market cap:	$253.94MM
Enterprise value:	$205.5MM

Financial Highlights	
Cash/equivalents:	$66.59MM
Debt:	$4.08MM

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

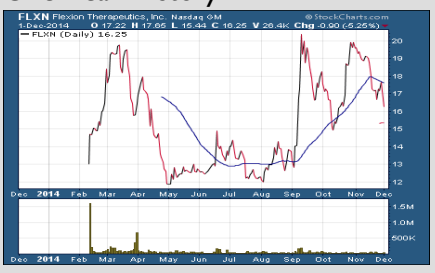

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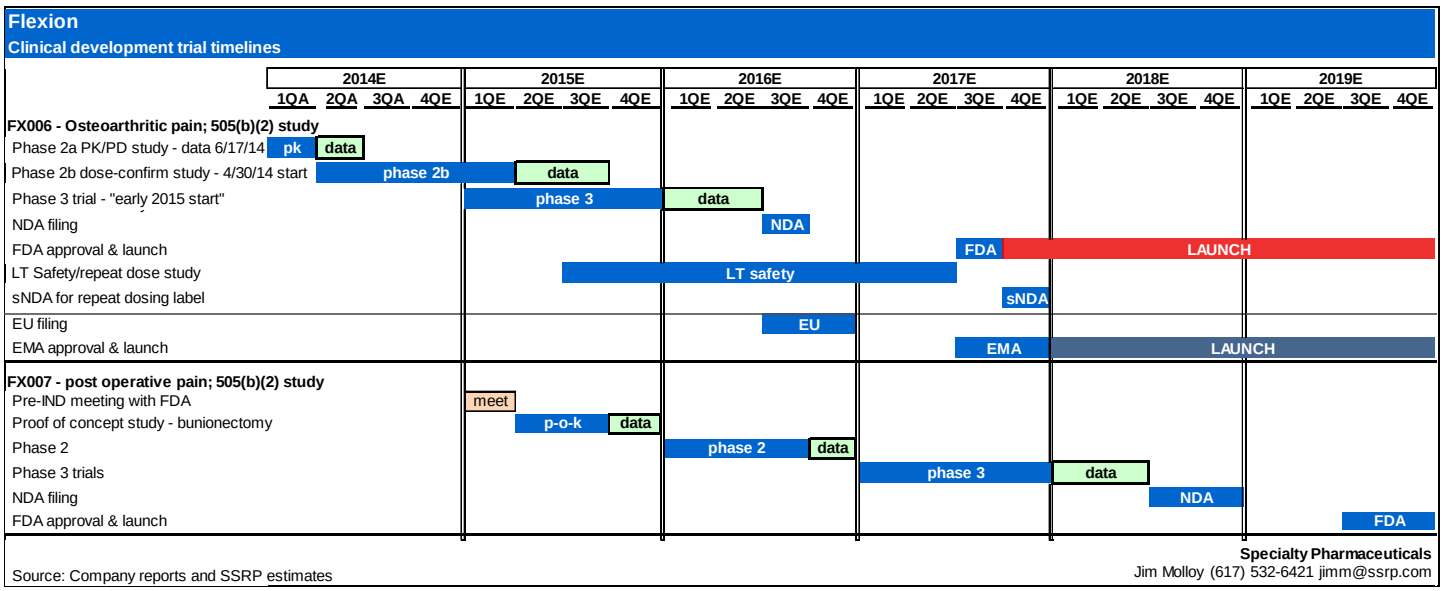
Figure 1. Sum-of-the-Parts Analysis

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



Source: Company reports and SSRP estimates

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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

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