Biopharmaceuticals — Company Update

Flexion Therapeutics, Inc. (FLXN)

FDA Clinical Hold Not Great but Likely Fixable in a Reasonable Timeframe

September 18, 2014

SUMMARY

Yesterday after the close FLXN announced that the FDA has put the current phase IIb trial for FX006 on clinical hold following a single incident of infection in the clinical trial. Given the rarity of this occurrence (estimated to be less than one in 1,000) and the potential severity of a deep tissue infection, it's reasonable for the FDA to side with caution, but we believe that ultimately the infection will prove to be non-drug related and the clinical trial will be allowed to continue. The final timing to resolve this clinical hold remains a huge question mark, but we believe it will likely be sooner rather than later (less than one year). FX006 has been dosed in more than 400 patients to date in clinical trials with no infection signals, and the active ingredient (TCA) is used in more than three million OA injections of the knee annually with a very low infection signal, leading us to conclude that the drug is safe and the infection will be found to be non-drug related. Our valuation year is based on our 2019 sales estimates and pending a clinical delay of greater than one year we see no need to change our $28 price target. We reiterate our BUY rating.

EVENT

The FDA put a clinical hold on FX006 due to a reported infection in one patient.

INTERPRETATION

Trial hold a negative, but may be resolved relatively quickly. While it's a negative to have FLXN's clinical trial put on hold by the FDA, we believe there's a real chance FLXN could expeditiously resolve the hold and resume FX006's clinical trial program. TCA has been used for years and is a well understood drug, and we expect that the source of the infection should be quickly identified.

Unlikely that the infection is drug related, in our opinion. The underlying drug, TCA, has been around for decades, and the procedure is well understood with three million OA injections completed annually in the US. Thus, we believe it's most likely that the infection is patient-related. Additionally, FX006 has been used in more than 400 patients to date with no potential infection-related signal observed so far.

Move timeline out six months to account for delay. We have pushed our FX006 timeline out by six months to account for the potential delay to resolve this infection issue. We now project phase IIb topline data in mid-2H15 (from 1H15 previously) and an FDA approval in 2H17 (from 1H17 previously).

ACTION

Maintain BUY rating, $28 PT. 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. We estimate another fund raise in 2015 of ~$85MM.

FLXN
Rating: BUY
Price Target: $28.00

Market Data	
Price:	$19.38
52-week high:	$21.23
52-week low:	$11.06
Shares out:	15.62MM
Shares short:	190.38K
Average volume (10-day):	84,357

Valuation Metrics	
Market cap:	$302.79MM
Enterprise value:	$238.97MM

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

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

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

One-Year History

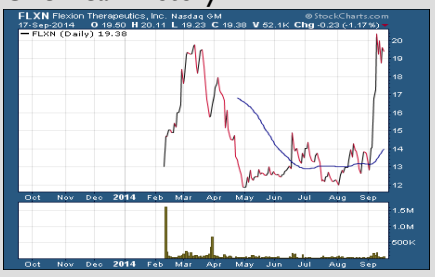

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Figure 1. Sum-of-the-Parts Analysis

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

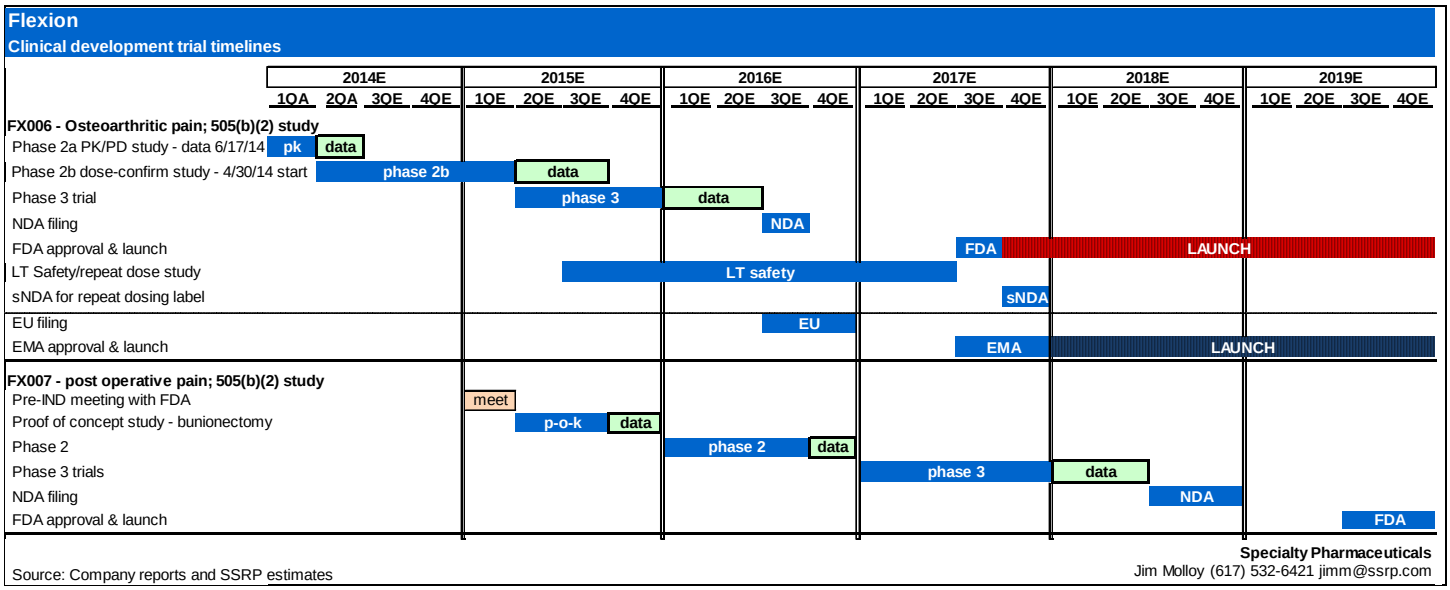

Figure 3. Quarterly Income Statement

Flexion
Quarterly income statement

($000 except per share)	2013A 1QA	2013A 2QA	2013A 3QA	2013A 4QA	2013A Year	2014E 1QA	2014E 2QA	2014E 3QE	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	4,250	4,250	16,266
General and administrative	1,788	1,788	1,788	1,340	6,704	2,284	2,234	2,500	2,500	9,518
Total operating expenses	4,738	4,738	4,729	3,560	17,765	6,435	5,849	6,750	6,750	25,784
Income (loss) from Operations	**(4,738)**	**(4,738)**	**(4,729)**	**(3,560)**	**(17,765)**	**(6,435)**	**(5,849)**	**(6,750)**	**(6,750)**	**(25,784)**
Interest income (expense), net	(39)	(39)	(39)	(98)	(215)	(81)	28	(25)	(25)	(103)
Other income (exp)	(64)	(64)	(64)	(15)	(207)	(26)	(110)	(50)	(50)	(236)
Income (loss) before taxes	**(4,841)**	**(4,841)**	**(4,832)**	**(3,673)**	**(18,187)**	**(6,542)**	**(5,931)**	**(6,825)**	**(6,825)**	**(26,123)**
Income tax exp (benefit)	-	-	-	-						
Net Income (Loss)	**(4,841)**	**(4,841)**	**(4,832)**	**(3,673)**	**(18,187)**	**(6,542)**	**(5,931)**	**(6,825)**	**(6,825)**	**(26,123)**
Earning per Share (EPS)	**($6.13)**	**($6.13)**	**($6.12)**	**($4.65)**	**($23.02)**	**($0.86)**	**($0.38)**	**($0.43)**	**($0.43)**	**($1.90)**
Weighted avg. shares (000)	789	790	790	790	790	7,633	15,619	15,769	15,919	13,735

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	16,266	32,250	34,500	35,250	37,500	38,000	
G&A	6,704	9,518	12,550	15,250	17,000	49,250	72,500	Self-launch FX006 in US
Total op exp	17,765	25,784	44,800	49,750	52,250	86,750	110,500	
Inc/(loss) from Ops	**(17,765)**	**(25,784)**	**(44,800)**	**(49,750)**	**(50,843)**	**97,421**	**201,437**	
Int income (exp), net	(215)	(103)	(100)	(100)	(100)	(100)	(99)	
Other expenses, net	(207)	(236)	(200)	(200)	(200)	(200)	(199)	
Inc/(loss) before taxes	**(18,187)**	**(26,123)**	**(45,100)**	**(50,050)**	**(51,143)**	**97,121**	**201,139**	
Income tax exp (benefit)	-	-	-	-	-	-	50,285	
Net Income (Loss)	**($18,187)**	**($26,123)**	**($45,100)**	**($50,050)**	**($51,143)**	**$97,121**	**$150,854**	
Earning per Share	**($23.02)**	**($1.90)**	**($2.20)**	**($2.30)**	**($2.20)**	**$3.50**	**$4.95**	
Weighted avg. shares (000)	790	13,735	20,482	21,732	23,232	25,732	28,232	
Fully diluted shares (000)	1,439	14,748	21,432	22,732	24,482	27,732	30,482	
Cash balance	$16,566	$67,718	$107,963	$61,263	$13,970	$115,716	$268,720	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 4/1/14 through 6/30/14:

Rating	Count	Percentage	Investment Banking Services (12 months)
BUY	33	80%	12%
NEUTRAL	8	20%	0%
SELL	0	0%	0%
Companies under coverage at 6/30/14	**41**	**100%**	**10%**

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

FLXN

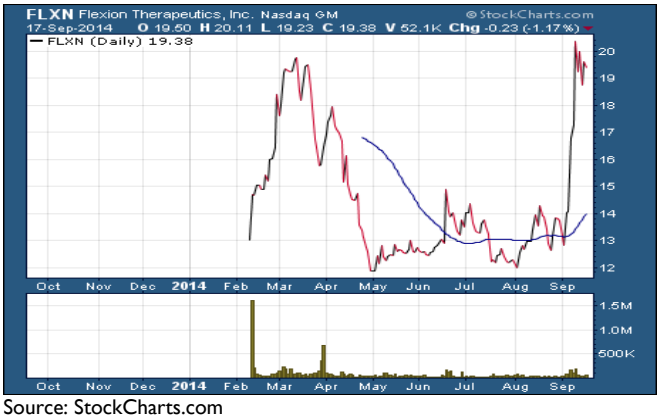
Ratings History

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