Summer Street RESEARCH PARTNERS

Flexion Therapeutics, Inc. (FLXN)

New FDA Guidance a Significant Positive, Raising Price Target to $28

September 5, 2014

SUMMARY

Yesterday morning FLXN held a conference call to discuss the recent significantly positive news from the company's meeting with the FDA's Division of Anesthesia, Analgesia, and Addiction Products (DAAAP), which we believe should move the launch of FX006 forward by approximately one year. Assuming positive clinical trial data, FLXN could launch FX006 as early as 2017 (from 2018 previously). Prior to yesterday, FLXN had expected to need a long-term repeat-dosing trial, which was the prior guidance from the FDA's Division of Pulmonary, Allergy, and Rheumatology Products (DPARP), which was previously handling the review of FLXN's FX006. Additionally, the FDA will consider the current ongoing phase IIb dose-ranging study of FX006 to be one of the two registration trials required, to be followed by a second phase III trial to start in 2H14. We see this new development a real positive for FLXN, and we have adjusted our model to account for FX006 coming to market in the US in 1H17; we are raising our price target to $28 from $25 and reiterating our BUY rating.

EVENT

Following FLXN's recent FDA meeting to discuss the FX006 clinical development plan, the FDA has removed the requirement for a long-term repeat-dose trial prior to NDA filing.

INTERPRETATION

New timeline a significant positive. It's rare to see clinical trials move forward by a year; typically in pharma they go the other direction, so this move gives some comfort that the FDA is familiar with the underlying drug (TCA), and we believe it reduces some of the FDA risk — assuming the trials read out.

New phase III trial design should help marketing and EU filing. By building in an active comparator arm (IR TCA) for a secondary endpoint, FX006 should be well positioned vs. the standard of care should it repeat the statistically significant reduction in pain shown in an earlier phase II trial. By comparing to IR TCA the trials ought to be sufficient for both FDA and EU filing requirements.

No change to spend as trials effectively "swapped." FLXN still anticipates being funded through 2H15 from its 1Q14 IPO as the company has effectively moved spend from a planned LT repeat-dose trial to a registration phase III trial.

ACTION

Reiterate BUY rating, raising PT to $28. 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 (from $25)

Market Data	
Price:	$14.02
52-week high:	$20.85
52-week low:	$11.06
Shares out:	15.62MM
Shares short:	190.38K
Average volume (10-day):	32,257

Valuation Metrics	
Market cap:	$219.05MM
Enterprise value:	$151.63MM

Financial Highlights	
Cash/equivalents:	$71.9MM
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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Second phase III trial design details. The second trial will enroll 462 patients and have three arms: 40 mg FX006, 40 mg immediate-release (IR) TCA, and placebo. The trial is now anticipated to read out in 2H15 (from 2H16 previously). The primary endpoint will be efficacy of FX006 vs. placebo at 12 weeks, with a secondary endpoint of comparing FX006 vs. IR TCA. Should this trial replicate the efficacy of FX006 vs. IR TCA that a previous dose-ranging phase II trial demonstrated, this should go a long way toward helping FX006 position itself competitively against the approximately three million injections of IR TCA for osteoarthritis (OA) pain in the US annually.

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

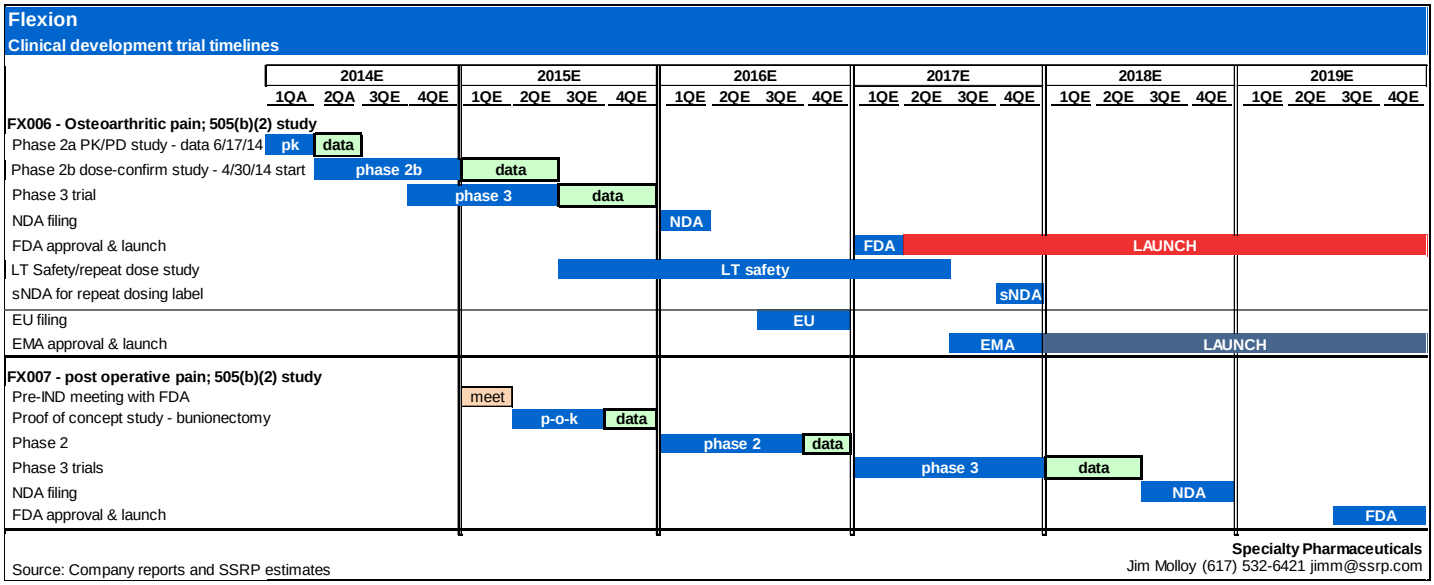

Figure 3. Quarterly Income Statement

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					$7,118	$200,497	$340,745	Moved up 1 yr, FDA now 1H17
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**	**$7,118**	**$214,246**	**$363,049**	
Expenses:								
Cost of Revenue (COGS)	-	-	-	-	1,068	30,075	51,112	
Gross Margin	**-**	**-**	**-**	**-**	**6,050**	**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	19,400	49,250	72,500	Self-launch FX006 in US
Total op exp	17,765	25,784	44,800	49,750	54,650	86,750	110,500	
Inc/(loss) from Ops	**(17,765)**	**(25,784)**	**(44,800)**	**(49,750)**	**(48,600)**	**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)**	**(48,900)**	**97,121**	**201,139**	
Income tax exp (benefit)	-	-	-	-	-	-	50,285	
Net Income (Loss)	**($18,187)**	**($26,123)**	**($45,100)**	**($50,050)**	**($48,900)**	**$97,121**	**$150,854**	
Earning per Share	**($23.02)**	**($1.90)**	**($2.20)**	**($2.30)**	**($2.10)**	**$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	$16,213	$117,959	$270,963	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