



# RBC Capital Markets

February 13, 2015

## Flexion Therapeutics Inc

### Defined pathway, differentiated offering and sizable market - Initiate at OP

**Our view:** Lead product FX006 offers an improved treatment option in a well established and sizable osteoarthritis knee market that has unmet need. With a clearly defined path to market, we see potential for a meaningful move in FLXN shares through upcoming pivotal data and a shift in focus to what we think could be a blockbuster opportunity.

#### Key points:

**(1) FX006 is targeting a sizable market with a differentiated, sustained release steroid approach via a lower risk, lower cost 505(b)(2) pathway that we think can deliver \$1.05 billion in peak 2023 sales.** Our unit volume market forecast of 5 million OA knee injections (immediate release steroid and hyaluronic acid) in 2017 at expected FX006 pricing of \$500 per injection implies a \$2.7 billion US market opportunity growing at 7% per year. Our peak forecast implies FX006 can take 26% of the market by its peak year in 2023 driving \$32 in NPV for lead product FX006 alone.

**(2) From our survey work, physician outreach indicates demand for a more efficacious alternative to IR steroid and HA.** We also think that showing statistical significance at eight weeks versus comparator is enough to drive a meaningful share of potentially more than 40% per our survey results, while statistically significant data up to 12 weeks is additive but not necessary.

**(3) Our sensitivity analysis points to potential for significant upside beyond the US OA knee market.** Based on our physician outreach, there is significant interest in use beyond knee, with a 20% penetration into the hip, ankle and shoulder patient market, potentially adding another ~\$13 per share in NPV. FLXN has worldwide rights leaving potential for ex-US partnerships as another lever of upside. Furthermore, should we see FX005 (end-stage pain) and FX007 (post-operative pain) approved, we could see further upside.

**(4) There is a catalyst-heavy path to 1H16 Phase III data.** We like the set-up from here into pivotal Phase IIb 2H15 data followed by a Phase III top-line data read in 1H16. Favorable data would drive our 22% discount rate lower, taking our price target higher on a de-risked path to approval while at the same time, in our view, introducing potential strategic take-out interest.

RBC Capital Markets, LLC  
Randall Stanicky, CFA  
(Analyst)  
212 618 3266  
randall.stanicky@rbcm.com

James C Chen, CFA  
(Associate)  
(212) 428-6970  
james.c.chen@rbccm.com

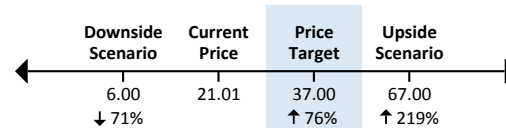
### Outperform

### Speculative Risk

NASDAQ: FLXN; USD 21.01

### Price Target USD 37.00

### Scenario Analysis\*



\*Implied Total Returns

### Key Statistics

Shares O/S (MM):	13.9	Market Cap (MM):	292
Dividend:	0.00	Yield:	0.0%
		Avg. Daily Volume:	79,934

### RBC Estimates

FY Dec	2014E	2015E	2016E
EBITDA, Adj	(27.7)	(59.3)	(82.5)
EPS, Adj Diluted	(2.23)	(2.64)	(3.17)
P/AEPS	NM	NM	NM
Revenue	0.0	0.0	0.0

EBITDA, Adj	Q1	Q2	Q3	Q4
2014	(6.4)A	(5.8)A	(7.0)A	(8.5)E
2015	(12.7)E	(14.8)E	(15.8)E	(16.0)E

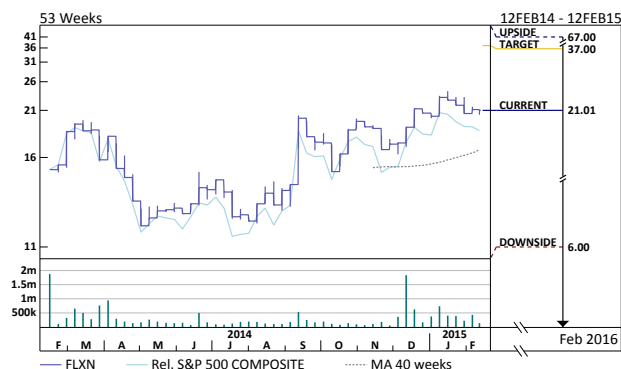
EPS, Adj Diluted	2014	2015
2014	(0.86)A	(0.38)A
2015	(0.57)E	(0.66)E

All values in USD unless otherwise noted.



## Target/Upside/Downside Scenarios

Exhibit 1: Flexion Therapeutics Inc



### Target price/base case

Our base case scenario sees a \$37 share price on the following assumptions:

- Progress toward successful Phase IIb and III results from the two pivotal trials and expected commercial launch in 2017,
- Peak combined share of the IR steroid and HA markets of 26% in 2023 on a \$500 pricing assumption growing at 3% annually,
- Injections per patient of 1.2 only slightly above the current estimated 1.1 today, and
- Discount rate of 22% that will move lower on successful trial completed and progress toward commercialization.

### Upside scenario

Our upside scenario sees a \$67 share price on the following assumptions:

- Progress toward successful Phase IIb and III results from the pivotal trials and expected commercial launch in 2017,
- Greater expected commercial opportunity with a combined IR steroid and HA market share assumption of 38%,
- Higher injections per patient of 1.3 and above the current estimated rate of 1.1, and
- Discount rate of 22% that will move lower on successful trial completed and progress toward commercialization

### Downside scenario

Our downside case scenario sees a \$6 share price on an early, unexpected halt to the pivotal studies. In this scenario, we assume modest value for platform technology, cash on hand and existing NOLs.

## Investment summary

FLXN's lead product FX006 is targeting the large Osteoarthritis (OA) knee market with a differentiated, sustained release version of the current immediate release (IR) standard of care used today. FX006 offers both efficacy benefits and potential for lower toxicity that we think can drive significant penetration into both the IR steroid market and the hyaluronic acid (HA) market, which is also used to treat OA knee pain. Our Outperform thesis on the stock rests on four main points:

(1) FX006 is well positioned to take meaningful share from the existing IR steroid and HA procedures in the OA knee market.

(2) There could be potentially meaningful upside from use outside of knee (i.e., hip, ankle and shoulder) and ex-US partnerships, though for now, we have assumed none.

(3) The 505(b)(2) pathway offers a low-cost and relative lower-risk path to market, and based on our survey work, we would expect to see physician interest in FX006 with statistically significant comparator data at eight weeks—we do not think the higher 12-week bar needs to be hit.

(4) We see FLXN well positioned in a pain market as a potential take-out off of positive Phase III pivotal data, given potential size of market and broader strategic interest in the pain area.

**Potential catalysts to focus on:** (1) Phase IIb data in 2H15, (2) Top-line Phase III data in 1H16, (3) NDA filing in 2H16 and (4) Approval in 2H17.

**Risks to our thesis:** We rate FLXN Speculative Risk given that it is pre-Phase III clinical data. Risks include: (1) a miss on primary endpoint on one or both of the two ongoing pivotal trials, (2) quicker cash burn leading to unexpected need for financing and (3) unexpected competitive threat to FX006.



## Key questions

### Our view

- 1. What is the market potential for lead product candidate FX006, and what kind of market share can it capture?**

**The intra-articular (IA) market for knee osteoarthritis (OA) is sizable with 4.1 million patients, and we estimate peak patient market share of 26% for FX006 driving \$1.05 billion in sales.** About 75% of IA patients receive immediate release (IR) steroid (i.e., triamcinolone acetonide or TCA) injections, while the remainder receives hyaluronic acid (HA). Our proprietary survey work indicates that 25% are dissatisfied with steroid and 45% with HA. Taking into account physician interest in FX006, we forecast FX006 taking 30% peak share of the slower growing HA market and 25% of the IR steroid market. Our estimates may prove conservative as our survey work also indicates a high level of interest in using FX006 to joints beyond the knee, which would expand the patient market further by +25%.
- 2. How is FX006 differentiated from other joint injection treatments?**

**FX006 is a sustained-release IA steroid (triamcinolone acetonide) that uses PLGA technology (proven in marketed products) to provide for the release of TCA over three months.** IA steroids are generally effective but with poor duration, as the drugs' efficacy are limited to a few weeks with limitations of injection frequency. The efficacy of HA, on the other hand, has been questioned with the American Academy of Orthopaedic Surgeons (AAOS) no longer recommending HA as a treatment for patients. FX006 combines TCA with PLGA (poly lactic-co-glycolic acid) to provide sustained therapeutic concentrations in the joint and persistent analgesic effect. In other words, the IA injection market lacks an efficacious treatment option that we think FX006 can fill.
- 3. What competitive product candidates are in development for knee OA, and how is FX006 differentiated?**

**We have looked at known knee OA candidates currently in development and believe FX006 is in a strong competitive position.** Of the five other candidates in development, Hymovis is HA based, which is a category that is falling out of favor with the AAOS, physicians and payors given its questionable efficacy. Hydros-TA is HA based with a low-dose steroid component and has not yet demonstrated significant improvement over the current standard of care. Cingal combines Monovisc (HA) with a steroid, though it appears that Anika may place more focus on ex-US opportunities. EP-104 is a steroid, but it is currently pre-clinical and uses an unproven delivery technology. Lastly, Ampion had shown efficacy only in severe OA (more niche) from its latest September 2014 data.
- 4. How does Flexion plan to commercialize the product, and do you think that a take-out off of favorable pivotal data is possible?**

**Management plans to launch FX006 with its own internal sales force, and we have modeled a 2H17 launch.** Management indicated that 60–100 sales reps could cover 9,000 orthopedists and rheumatologists who perform over 75% of injections. We have modeled 80 reps with sales leadership in place in 2016 ahead of a 2017 launch. We think take-out potential will pick up significantly off of favorable Phase III pivotal data introducing additional options.
- 5. Will Flexion need to raise funds again prior to the commercialization of FX006?**

**Flexion will likely have one more fund raise before commercialization of FX006, and we model an equity raise in 2016 following favorable Phase III data.** We have modeled a raise in 2H16, which was intended to bolster funds ahead of the commercial build-out and launch. We have modeled cash burn of \$15 million to \$20 million per quarter and believe Flexion would remain cash positive through NDA submission and instead choose to raise in advance of an anticipated infrastructure build for launch.



## Table of contents

(1) FX006 is targeting unmet need in the sizable Osteoarthritis IA market .....	5
(2) FX006 offers differentiation that should support substantial uptake .....	7
(3) FX006 worth close to \$32 per share with upside potential per sensitivity .....	14
(4) Clear catalyst driven path to approval – key pivotal data coming in 2H15.....	17
(5) FX006 duration could be extended, and FX005 and FX007 could add upside.....	19
(6) How we get to our \$37 target and upside potential on a post-data take-out .....	20
Background on Flexion and the key aspects of the story .....	22
Four primary risks to our Outperform rating and price target .....	25



## (1) FX006 is targeting unmet need in the sizable Osteoarthritis IA market

The primary value driver for Flexion is its lead pipeline product FX006 that is targeting a sizable US OA knee IA market. There are roughly 27 million people in the US with osteoarthritis, and we estimate closer to 16 million of which comprise OA in the knee, with aging demographics a factor in what we expect to be steady growth in incidence over the next 10–15 years. The treatment spectrum is broad, but, per Exhibit 2, of the 4.1 million patients that we estimate pursue injection treatments annually, about 75% of this market is made up of patients who receive IR steroid (i.e., TCA) injections, while 25% receive HA. There are well-understood shortcomings with both treatments. IA steroids are effective, but their duration is poor, with most of the drug leaving the joint in days and efficacy limited to a few weeks. The efficacy of HA, on the other hand, has been questioned with the AAOS no longer recommending HA as a treatment for patients with symptomatic OA of the knee. FX006 is a sustained-release TCA that is targeting longer efficacy duration with potentially lower systemic issues as seen with TCA IR. **In other words, the IA injection market for knee OA is sizable and lacks an efficacious treatment option, which is a void that we think FX006 can fill.**

**We forecast a \$2.7 billion market opportunity in 2017 when we expect FX006 to be approved.**

**We estimate that the OA IA knee market will be close to \$2.7 billion in 2017 at the time of an FX006 approval.** We get here by taking our forecasted 3.5 million patients using an IR steroid combined with 1 million on taking HA. Combined, that gets us a 4.5 million patient population, which at 1.2 injections per patient per year (we assume FX006 at 1.2 versus current 1.1 for the steroid/HA), drives a 5.4 million injection base in 2017. At an expected price per injection of FX006 of \$500, we get a \$2.7 billion market growing at 7% per year split between volume and price.

Exhibit 2: There are over 4 million patients with knee OA that FLXN is targeting with FX006 in the US – the hypothetical patient capture at FX006 pricing implies a total market size of over \$3 billion in the osteoarthritis knee injection market alone

	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	
<b>Knee Osteoarthritis Market</b>		Est.	Est.	Est.	Est.	Est.	Est.	Est.	Est.	Est.	
Patients w/Knee Osteoarthritis (OA)	15.7	16.1	16.6	17.1	17.7	18.3	19.1	19.8	20.6	21.4	US CDC +6.5M new cases over decade
Growth		3.0%	3.0%	3.0%	3.5%	3.5%	4.0%	4.0%	4.0%	4.0%	Baby boomer generation through 2029
Patients w/knee OA on HA	1.0	1.0	1.0	1.0	1.0	1.1	1.1	1.1	1.1	1.1	HA = hyaluronic acid
Growth		1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	We model slowing HA volume vs recent trend
Avg Injections per patient	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	
Total HA injections	1.1	1.1	1.1	1.1	1.1	1.2	1.2	1.2	1.2	1.2	
Patients w/knee OA on SI	3.1	3.2	3.4	3.5	3.6	3.8	4.0	4.2	4.3	4.5	SI = steroid injections
Growth		4.0%	4.0%	4.0%	4.5%	4.5%	4.5%	4.5%	4.5%	4.5%	
Avg Injections per patient	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	
Total Steroid injections	3.4	3.5	3.7	3.8	4.0	4.2	4.4	4.6	4.8	5.0	
<b>Total Patients on Steroid &amp; HA</b>	<b>4.1</b>	<b>4.2</b>	<b>4.4</b>	<b>4.5</b>	<b>4.7</b>	<b>4.9</b>	<b>5.0</b>	<b>5.2</b>	<b>5.4</b>	<b>5.6</b>	
% of total knee OA patients	26.2%	26.3%	26.3%	26.4%	26.5%	26.5%	26.4%	26.4%	26.3%	26.3%	% of patients of seek injections
<b>Total Injections SI and HA</b>	<b>4.5</b>	<b>4.7</b>	<b>4.8</b>	<b>5.0</b>	<b>5.2</b>	<b>5.3</b>	<b>5.5</b>	<b>5.8</b>	<b>6.0</b>	<b>6.2</b>	>1M pts. non-knee OA steroid injection
Hypothetical FX006 market potential	2,460	2,540	2,624	2,710	2,895	3,093	3,305	3,532	3,776	4,037	Assumes 1.2 inject/patient at FX006 pricing

Source: Company reports, RBC Capital Markets estimates

**We see blockbuster potential for FX006 assuming ~30% share of HA patients and ~25% share of steroid patients in 2023.**

**We forecast a peak sales forecast of \$1.05 billion based on our base case combined IR steroid and HA penetration assumption of 26% on initial pricing of \$500 per injection.** There are several important assumptions to our peak forecast including: (1) We have FX006 taking a 30% peak share of a slower growing HA market compared to 25% of the IR steroid market, consistent with our survey work; (2) We have modeled a slight uptick in injections per patient per year from 1.1 to 1.2 on the assumption that better efficacy will lead to increased injection frequency, which can be given up to four times per year—this is arguably still a conservative assumption and major swing factor; and (3) We model initial pricing in 2017 at \$500 per injection, consistent with management expectations, growing at 3% per year. **Each 100 basis points of market share adds \$41 million in revenue to our peak estimate, while each additional 100 basis points of annual pricing increase boost our peak estimate by \$63 million.**



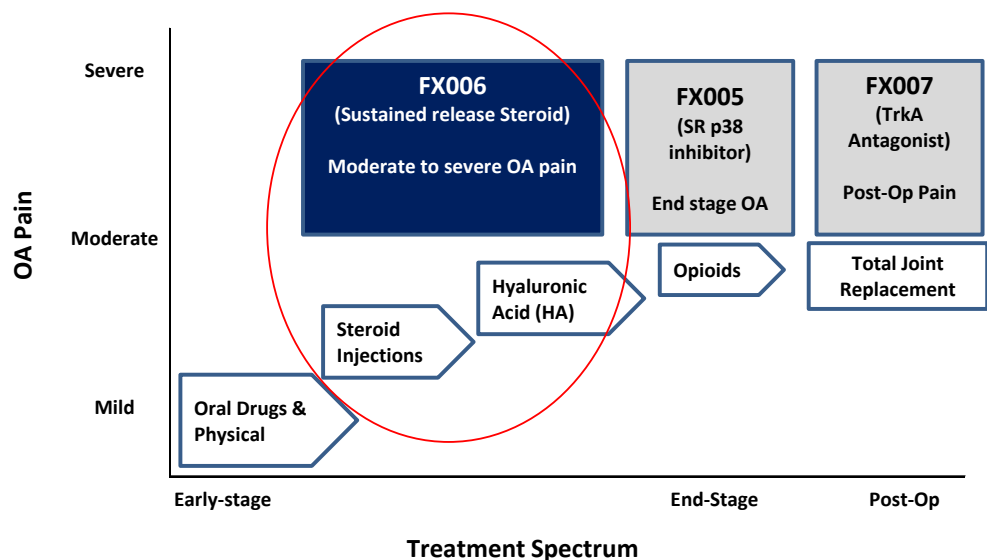
Exhibit 3: Our 'base case' implies a peak market penetration of 25% of immediate release 'steroid' patients and 30% of 'HA' patients – 26% on a blended basis

FX006 Market Share		2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	
FX006 market share of HA		0%	0%	0%	2%	5%	14%	23%	26%	28%	30%	FX006 patents to 2031, generic hurdles
FX006 market share - steroid		0%	0%	0%	2%	4%	9%	15%	20%	23%	25%	
Patient market share (% total IA)		0%	0%	0%	2%	4%	10%	17%	21%	24%	26%	
Injections per patient		1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	Potential for > injections per year
Market share scenario: HA patients		<div>BASE Share ▼</div> <div>PEAK</div>										
BASE Share		0%	0%	0%	2%	5%	14%	23%	26%	28%	30%	Below our survey penetration results
Upside		0%	0%	0%	6%	13%	22%	30%	40%	45%	50%	
Conservative		0%	0%	0%	1%	4%	11%	15%	17%	19%	20%	
Market share scenarios: Steroid		<div>BASE Share ▼</div>										
BASE Share		0%	0%	0%	2%	4%	9%	15%	20%	23%	25%	Below our survey penetration results
Upside		0%	0%	0%	4%	8%	13%	19%	28%	33%	35%	
Conservative		0%	0%	0%	1%	5%	8%	11%	13%	14%	15%	
FX006 injections administered		0.0	0.0	0.0	0.1	0.2	0.6	1.0	1.3	1.6	1.8	Expect US launch in 2H2017
FX006 price per injection		\$500	\$500	\$500	\$500	\$515	\$530	\$546	\$563	\$580	\$597	Per management expectation
Growth						3%	3%	3%	3%	3%	3%	Potentially conservative pricing assumption
FX006 Revenue		\$0	\$0	\$0	\$54	\$122	\$312	\$551	\$750	\$906	\$1,048	
Growth						125%	155%	77%	36%	21%	16%	

Source: Company reports, RBC Capital Markets estimates

The osteoarthritis pain spectrum is broad, and FX006 is targeting the moderate to severe phase where 'steroid injection' (SI) and HA injections are given. FX006 is targeting the area between early stage and end-stage OA pain, which comes as pain progresses beyond a level where acetaminophen or NSAIDs (Non-steroidal anti-inflammatory drugs) and other oral therapies may be sufficient, but before pain progression worsens to a point at which opioids and ultimately a total joint replacement (TJA) operation may be necessary. Exhibit 4 details the spectrum of care and where the 4.1 million patients sit within the broader 16 million who have OA of the knee. Flexion also has pipeline opportunities targeting end-stage OA and post-operative pain relief, though FX006 is going to be the value driver in the short to medium term.

Exhibit 4: The OA knee spectrum is broad with injections targeting moderate to severe pain



Source: Company reports



There are also toxicity and efficacy concerns in oral 'early stage' treatments. Per Exhibit 5, well known oral treatments in general offer limited pain relief, particularly as patients are progressing toward moderate to severe OA pain and come with toxicity concerns.

Exhibit 5: Current OA knee treatments – oral solutions offer limited efficacy and come with toxicity concerns

Type		Efficacy	Toxicity
ORAL	Acetaminophen	Limited pain relief	Liver/GI
	NSAIDs	Limited pain relief	GI bleeding, cardiovascular
	COX II inhibitors	Limited pain relief	Cardiovascular
	Duloxetine	Limited pain relief	Suicidality Liver
	Opioids	Good pain relief	Addiction, fracture in elderly
INTRA-ARTICULAR (joint injection)	Steroids	Limited duration of effect (wanes after 2-4 weeks)	Generally well tolerated
	Hyaluronic acid (HA)	AAOS "cannot recommend using HA" because of "lack of efficacy"	Generally well tolerated

Source: Company reports

## (2) Our survey work indicates that FX006 offers differentiation that should support substantial uptake

The value proposition that Flexion brings via FX006 is the first sustained-release TCA injection extending the potential of an already established therapy. In general, IR injections are well understood, safe and efficacious. However, the duration provides only limited pain relief, which is a major complaint. FX006 would effectively displace an already straightforward procedure with longer-acting pain relief. These injections take roughly one minute from start to finish, and the procedure would be unchanged with FX006. Exhibit 6 details the procedure and target area of injection. Our survey work indicates that there is significant physician dissatisfaction with the current standard of treatment (immediate-release steroid and HA).



Exhibit 6: OA injections target pain in the joint and FLXN's sustained-release version is targeting longer duration, better efficacy and reduced systemic issues



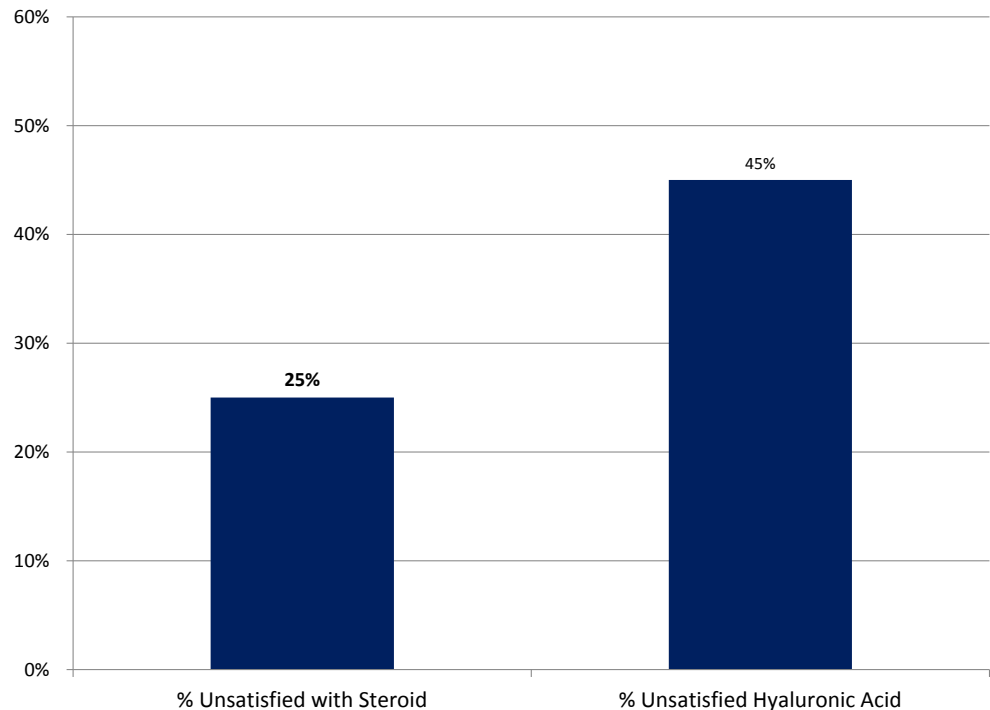
Source: Company reports

**There is clear dissatisfaction among physicians with the current standard of care.** Specifically, of the physicians whom we surveyed, there was 25% dissatisfaction with immediate-release steroid injections and 45% with HA. We reached out to a roughly equal split of physicians from the rheumatology and orthopaedic side (the two primary sources of OA IA procedures), and the results were generally consistent across both sets of specialties. 'Dissatisfaction' rates of 25% to 45% are relatively high given that no alternative treatment paradigm was offered, particularly for HA where we think growth for procedures are likely to be pressured over the next several years on the back of changes in AAOS guidelines and reimbursement challenges on questions of efficacy.



Exhibit 7: Our surveyed doctors highlighted some notable dissatisfaction with the current treatment options for OA knee injections (n=40)

Survey question: For knee osteoarthritis patients receiving intra-articular injections, are you satisfied with steroid and HA?



Source: RBC Capital Markets

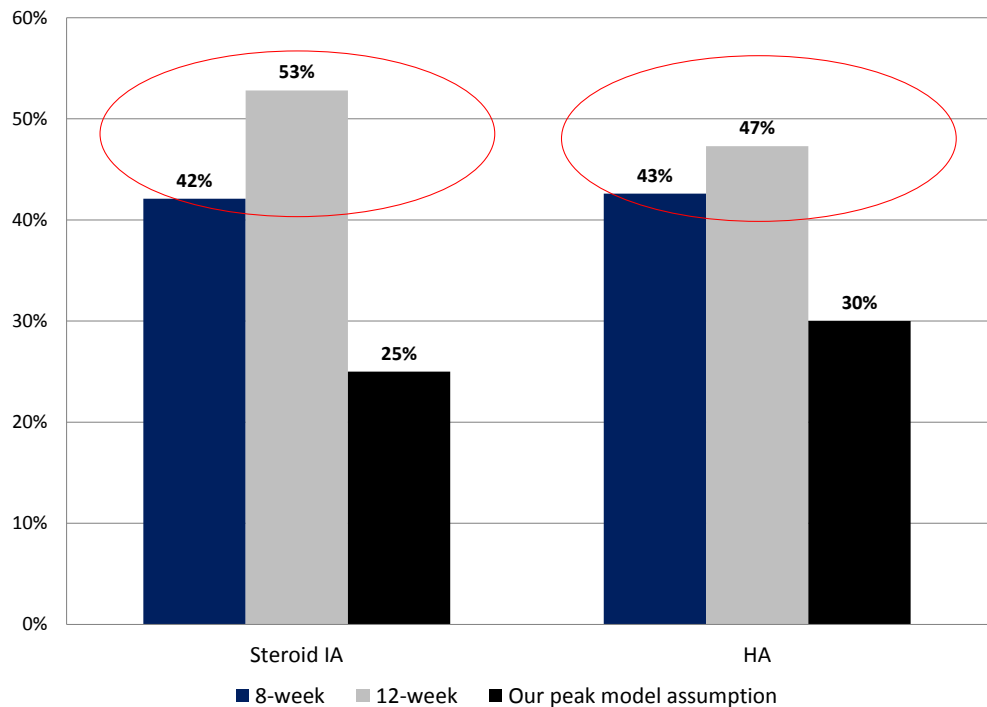
**Our survey work also indicated that physicians would look to switch a notable percentage of current steroids and HA patients to a new sustained-release FX006—and eight-week data with statistical significance seems be long enough.** Provided the option of a drug therapy with a clean safety profile and statistically significant pain relief over TCA immediate release for up to eight weeks, physicians we surveyed indicated that they would be likely to switch 42% of immediate-release steroid patients and 43% HA patients. These levels are both well above our peak modeled penetration share of 25% and 30% for each (total combined of 26%). However, and importantly, when asked the same question with respect to 12-week statistically significant data, the intended switch rates only went up moderately to 53% and 47% (up 900 basis points and 400 basis points, respectively). **This is key because it adds support to our view that the vast majority of the peak market opportunity would be available to Flexion with eight-week data, and while 12-week data would represent positive surprise, it is not necessary to hit our forecasts.**



Survey question: If there was a new sustained-release intra-articular steroid (TCA) that has a clean safety profile and statistically significant pain relief over TCA immediate release for up to 8 weeks, what % of patients are you likely to switch from HA or steroid to this new steroid? (Assume available reimbursement.)

Survey question: If there was a new sustained release intra-articular steroid (TCA) that has a clean safety profile and statistically significant pain relief over TCA immediate release for up to 12 weeks, what % of patients are you likely to switch from HA or steroid to this new steroid? (Assume available reimbursement.)

Exhibit 8: Physicians we surveyed indicated they would switch 42% of steroid and 43% of HA patients if given a sustained-release option with statistical significance of up to 8 weeks versus 53% and 47% with data up to 12-weeks (n=40)

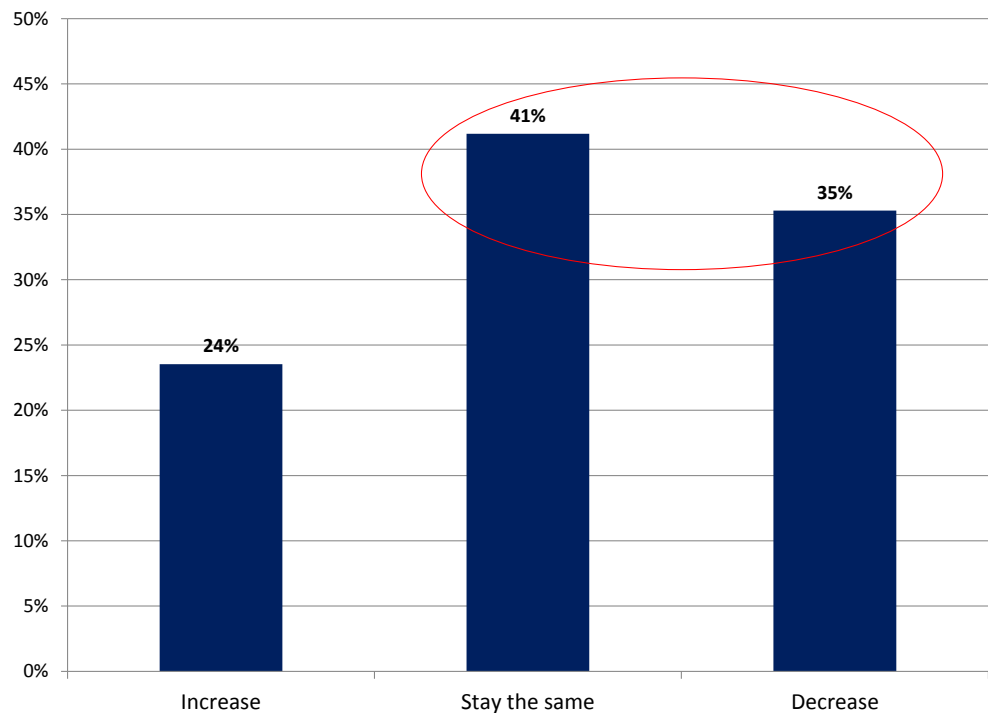


Source: RBC Capital Markets

**We see both real and anecdotal support for a reduction in HA procedures, which could represent a tailwind to an improved steroid option.** There has been ample support for a decline in HA growth led by recent declines in HA leader Synvisc sales, greater payor scrutiny and recent negative headline around efficacy (AAOS guidelines). The results from our survey of physicians seemingly add more support to this, as we show in Exhibit 9. We asked physicians about their intended growth of HA volumes in 2015 over last year. Notably, there is a clear bias for use of HA to be flat to down, with 76% expecting to perform the same number or fewer procedures in 2015 versus 24% expecting to increase volumes. We also asked for rationale for each answer, and it was notable that even among those expecting to increase use, an often-cited reason was due to lack of other treatment options or an aging population. We saw a number of physicians cite AAOS guidelines as a reason that they are likely to reduce use, along with insurance challenges.

Survey question: What percent growth (positive or negative) in HA intra-articular injections for knee osteoarthritis do you expect to perform in 2015 versus in 2014?

Exhibit 9: We anticipate pressure on HA procedures with a market share shift to steroid (n=34)

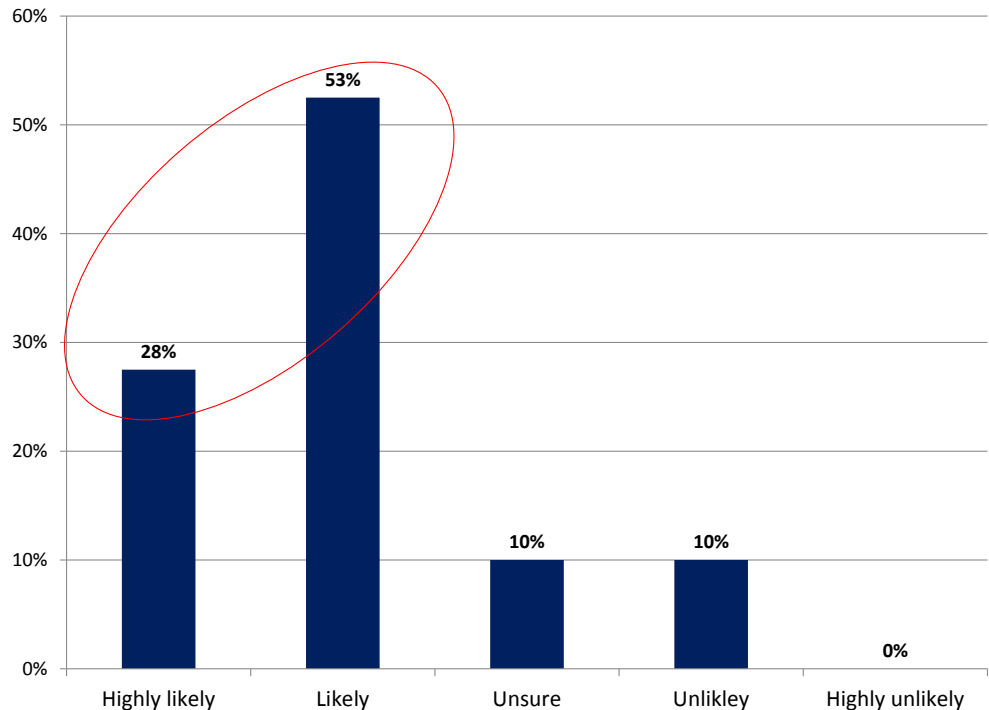


Source: RBC Capital Markets

**The other big wildcard is the potential for a new sustained-release steroid to be used beyond the knee with shoulder, hip, and ankle among other uses.** FX006 will not initially be approved for use beyond knee, but we expect management to pursue post-approval studies to broaden the indication ultimately to include uses in other areas. Nevertheless, TCA steroid injection is used regularly to treat broader joint pain, and the procedure is relatively simple. If approved, we would expect some broader use outside of knee, understanding that management has no intention to promote off label. Per Exhibit 10, 80% of the physicians we surveyed were either highly likely or likely interested in using a sustained-release steroid injection beyond knee if statistically significant over TCA IR for up to eight weeks. We think this adds some support for what could be significant upside for FX006 in use beyond the knee but also the notion that eight weeks of statistically significant comparator data being enough to drive changes in physician behavior.

Exhibit 10: We think there could be significant interest among physicians in a sustained-release steroid IA product for use in other joints, which was supported by our survey (n=40)

**Survey question: If there was a sustained-release intra-articular steroid (TCA) approved for knee osteoarthritis that has a clean safety profile and statistically significant pain relief over TCA IR for up to 8 weeks, would you be interested in using this product in procedures for osteoarthritis hips, shoulder and ankle?**

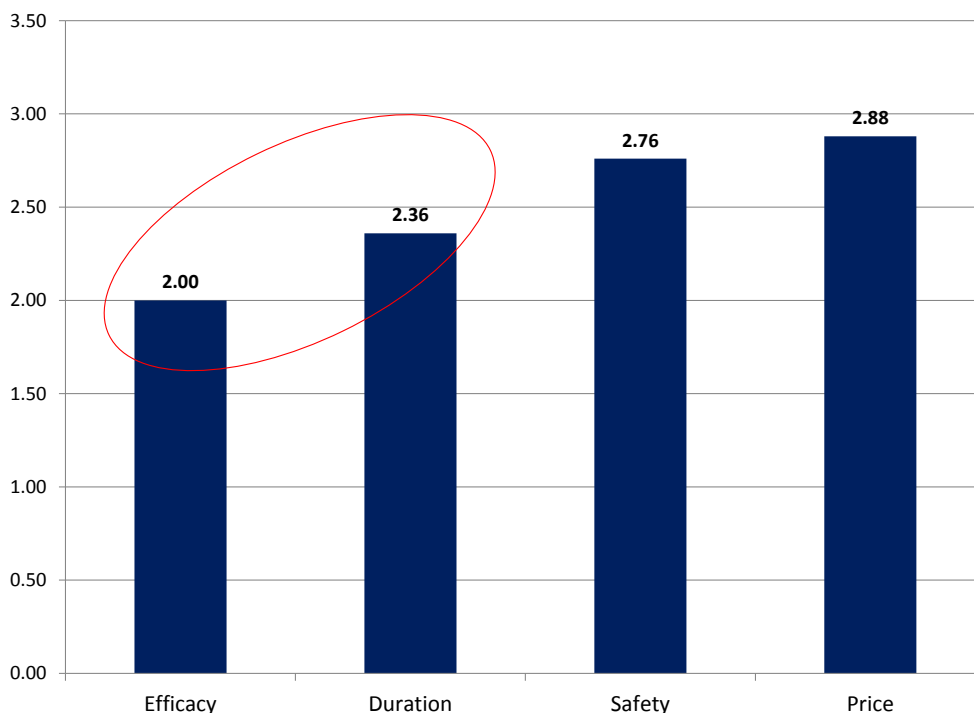


Source: RBC Capital Markets

**We do not expect pricing to be a hurdle if FX006 demonstrates clear unmet need.** While there is therapy cost comparability to opioid use (on a three-month basis) and HA, at an expected \$500 per injection, FX006 would come at a significant premium to a TCA immediate-release steroid that is a fraction of the cost though still subject to injection-fee and office-visit costs. However, the price difference is not as great relative to other drug alternatives. Cymbalta (a once-daily NSAID), for example, is currently priced at a WAC of \$7.30 per day and compared to the assumed 10-week duration for FX006, implies a cost of ~\$509. Cymbalta has also seen a 19% price increase CAGR 2010 to 2013. We asked physicians to rank the importance of cost along with efficacy, safety and duration, and not surprisingly, price came last per Exhibit 11. What was clear was that efficacy and duration (arguably both similar measures) were perceived to be much more important than safety and price. Specifically, 64% of respondents ranked efficacy or duration as the most important factor. We do not think there will be significant payor push-back and that there is a clear opportunity for pharmacoeconomic work to demonstrate broader cost savings in the context of delaying total joint replacement operations or multiple physician visits on the back of current treatment paradigms that lack efficacy or duration.

Survey question: Please rank in order of importance, which factors will determine if you use this product: (1) Price, (2) Efficacy, (3) Duration of relief and (4) Safety profile.

Exhibit 11: We don't expect pricing to be a hurdle – greater focus on unmet medical need (n=25)



Source: RBC Capital Markets

**There is a host of competitive offerings within IR steroid and HA markets, but none that stands out as differentiated.** Currently marketed intra-articular products include a mix of steroid and hyaluronic acid. Synvisc-One (HA) is the market leader with trailing 12-month sales of \$287 million per IMS, but as we said, we do not see HA as a threat, but we believe the market is under pressure with potential for market share to revert to the steroid market over time. **Differentiation will be the key factor driving market penetration, in our view, and we expect FX006 to be able to capture market share from both IR steroids and HA with an effective sustained release of TCA.**

Exhibit 12: Physicians we surveyed indicated they would switch 42% of steroid and 43% of HA patients if given a sustained-release option with statistical significance of up to 8 weeks

Product	Company	Type of Product	Notes
Synvisc	Sanofi	Hyaluronic Acid	Synvisc-One is the HA market leader; Franchise TTM sales \$376 million
Euflexxa	Ferring	Hyaluronic Acid	TTM sales \$207 million
Kenalog	Bristol Myers	Steroid	TTM sales \$139 million
Depo-Medrol	Pfizer	Steroid	TTM sales \$98 million
Orthovisc	JNJ	Hyaluronic Acid	TTM sales \$76 million
Hyalgan	Fidia	Hyaluronic Acid	TTM sales \$55 million
Betameth	Luitpold	Steroid	TTM sales \$45 million

Source: Company reports, IMS Health,

**The more important question, in our opinion, is whether a threat could emerge from competitive products undergoing clinical trials.** We have taken a closer look at known potential competitors. The one that may get some attention is Carbylan's Hydros-TA, given its recent initial public offering attempt. While it may get attention given its recent roadshow, there are several differences between this product and FX006, including the fact that Hydros-TA is a combination of HA and 10mg steroid, and in our view, it is more likely to target the existing HA market and be behind FX006, with an approval timing unlikely before 2018 and the IND (investigational new drug) being pursued currently. There are other HA and HA combination products in development that we see as less of a competitive threat.

**Exhibit 13: There are several OA knee treatment therapies in development, but none we see targeting the FX006 opportunity**

Product	Company	Status	Timeline	Type of Product	Notes
<b>FX006</b>	Flexion	Phase 2b/3	Phase 3 start Jan 2015; NDA filing mid-2016	Steroid	Phase 2 data shows statistically significant pain relief over TCA IR for 10 weeks
<b>Hydros-TA</b>	Carbylan	Phase 3	Phase 3 start mid-2015; NDA filing early-2017	Steroid / HA Combination	For rapid and sustained pain relief to six months; Original study compared to Synvisc-One showed significance only at week 2
<b>Cingal</b>	Anika	Phase 3	Launch potentially late-2016 or early-2017	Steroid / HA Combination	Phase 3 clinical completed Sept 2014; Cingal combines Monovisc (marketed) with a steroid
<b>Hymovis</b>	Fidia	Phase 3	Data expected Jul 2015	Hyaluronic Acid	New Phase 3 started vs placebo in July 2014; Fidria had completed a Phase 3 Hymovis vs placebo Feb 2013
<b>Ampion</b>	Ampio	Phase 3	Data expected Apr 2015	Human serum albumin	Sept 2014 Ph3 data showed significance in most severe OA. Management cited improper drug storage temperature
<b>EP-104</b>	Eupraxia	Pre-Clinical	Pre-Clinical	Steroid	Plexis carrier technology (new delivery) combined with fluticasone steroid (not common for knee OA)
<b>TPX-100</b>	OrthoTrophix	Phase 2	Data expected Mar 2016	chondrogenic peptide	For regeneration and repair of cartilage; Recruiting for Phase 2 dose-ranging study
<b>Sprifermin</b>	Merck Serono	Phase 2	Data expected Aug 2016	Fcf18	Studied for bone regeneration, inhibiting structural damage, pain reduction, and physical function in patients

Source: Company reports, RBC Capital Markets

### **(3) FX006 worth close to \$32 per share with upside potential per sensitivity**

**Our net present value (NPV) model for FX006 gets us to \$32 per share, which includes only the US OA knee market.** In other words, we have not factored any upside from the joint market beyond knee where we see likely usage or ex-US revenue contribution where Flexion maintains global rights. We have made several assumptions including the following:

- Peak sales of \$1.05 billion based on blended penetration of 26%. This includes 30% of the HA market and 25% of the IR steroid market on 1.2 injections per patient per year and initial pricing of \$500 per injection growing at 3% per year. We assume penetration declines steadily beyond our peak 2023 year on other branded competitive threats before we apply a more aggressive negative terminal growth assumption of -40% beyond 2028. We have modeled 88% net gross margins reflective of some distribution cost.
- Our spending assumptions are likely on the conservative side. Specifically, our R&D spend could be lower, which we have continued to grow on the assumption that we would see some post-approval dose ranging study work, line extensions and potential life-cycle opportunity. We have assumed major reductions in spend beyond 2023, but we could also argue that R&D would see a sharp drop off well before then.



- We model some initial benefit from NOLs and a 22% discount rate. Flexion has roughly \$150 million in NOLs that we assume shield the company from cash taxes until 2020—a 500 basis point change in tax assumption (up or down) is worth about \$3 to our NPV model. In terms of our discount rate, we have assumed 22%, which we would expect to move lower as Flexion moves beyond successful pivotal data and ultimately approval. Each 100 basis point in discount rate affects our NPV by ~\$2.30.

Exhibit 14: Our NPV model derives ~\$32 in value per share for FX006 alone – no value for use beyond knee OA or ex-US

US P&L Build	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	
<b>US sales</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$54</b>	<b>\$122</b>	<b>\$312</b>	<b>\$551</b>	<b>\$750</b>	<b>\$906</b>	<b>\$1,048</b>	
Gross profit	\$0	\$0	\$0	\$48	\$108	\$274	\$485	\$660	\$797	\$923	
Gross margin	88%	88%	88%	88%	88%	88%	88%	88%	88%	88%	Reflects 90% GM plus distribution cost
S&M	-	-	20	41	45	47	50	52	55	58	
G&A	9	11	12	13	14	15	16	17	18	19	
R&D	18	48	50	45	48	50	53	55	58	29	
US EBIT	(\$28)	(\$59)	(\$82)	(\$52)	\$1	\$162	\$367	\$535	\$666	\$817	
EBIT margin	NM	NM	NM	NM	1%	52%	67%	71%	74%	78%	
Tax	0	0	0	0	0	0	128	187	233	286	
Tax %	NM	NM	NM	NM	0%	0%	35%	35%	35%	35%	~\$150M in NOLs - assume shield to '20
<b>Net Income</b>	<b>(\$28)</b>	<b>(\$59)</b>	<b>(\$82)</b>	<b>(\$52)</b>	<b>\$1</b>	<b>\$162</b>	<b>\$239</b>	<b>\$348</b>	<b>\$433</b>	<b>\$531</b>	
NPV			(68)	(35)	1	73	88	106	108	108	Growth to 2028 then negative terminal \$30M in terminal NPV in 2028+
Terminal value											
Total NPV		716									
Shares outstanding		23									
<b>NPV per share</b>		<b>32</b>									
<b>Cash per share (end of 2015)</b>		<b>4</b>									
<b>Total NPV</b>		<b>\$35</b>									
<b>NPV assumptions</b>											
Terminal growth		-40%									
Discount rate		22%									
Normalized tax rate		35%									

Source: Company reports, RBC Capital Markets estimates

**We have assumed no penetration into the other joint markets, but upside here is likely and could be significant.** As we have said previously, we expect Flexion to avoid off-label promotion, but we expect it to pursue an expanded label with a fairly straightforward study pathway here. This market could be sizable per Exhibit 15. We estimate another 1.2 million potential patients (in hip, ankle and shoulders alone), which at an average injection of 1.1 per year (again this could be higher) would lead to 1.3 million additional IR steroid injections per year (HA is not approved here). If we assume the same \$500 per injection pricing, then this would represent a \$700 to \$800 million market by the time FX006 is approved. In Exhibit 15, we have looked at the sensitivity upside to peak based on various share levels of this market. If we assume a reasonable 20% share, that would add \$220 million in peak sales on to our 2023 forecast or \$13 per share in NPV assuming limited incremental spend to drive sales.





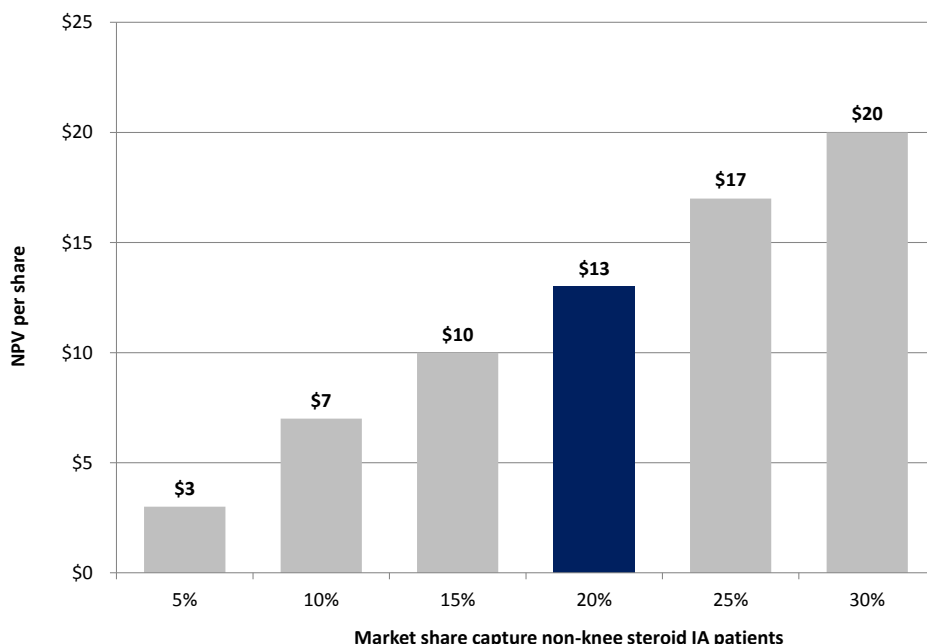
Exhibit 15: 5% to 30% share of the hip, shoulder and ankle (non-knee) IA steroid market would yield an incremental NPV of \$3 to \$20 per share

Non-Knee Patients	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	
Label expansion opportunities	Est.	Est.	Est.	Est.	Est.	Est.	Est.	Est.	Est.	Est.	
Hip patients (steroid)	0.40	0.41	0.42	0.44	0.45	0.47	0.49	0.51	0.53	0.55	
Shoulder patients (steroid)	0.50	0.52	0.53	0.55	0.57	0.59	0.61	0.63	0.66	0.68	
Ankle patients (steroid)	0.33	0.33	0.34	0.36	0.37	0.38	0.40	0.41	0.43	0.45	
Total patients (steroid, non-knee)	1.23	1.26	1.30	1.34	1.39	1.43	1.49	1.55	1.61	1.68	
Growth	3.0%	3.0%	3.0%	3.5%	3.5%	4.0%	4.0%	4.0%	4.0%	4.0%	Growth assumptions consistent with knee
Avg Injections per patient	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	Upside on higher per patient injections
Total non-knee injections	1.3	1.4	1.4	1.5	1.5	1.6	1.6	1.7	1.8	1.8	
FX006 price per injection	500	500	500	500	515	530	546	563	580	597	Same pricing assumption as knee
Total market opportunity (in M)	\$674	\$694	\$715	\$736	\$785	\$837	\$896	\$960	\$1,028	\$1,102	On full penetration of IR steroid market
Revenue add (in \$ mn's)	20% patient share ▼										
5% patient share	\$34	\$35	\$36	\$37	\$39	\$42	\$45	\$48	\$51	\$55	
10% patient share	\$67	\$69	\$71	\$74	\$78	\$84	\$90	\$96	\$103	\$110	
15% patient share	\$101	\$104	\$107	\$110	\$118	\$126	\$134	\$144	\$154	\$165	
20% patient share	\$135	\$139	\$143	\$147	\$157	\$167	\$179	\$192	\$206	\$220	\$220M rev add in peak year 2023
25% patient share	\$168	\$173	\$179	\$184	\$196	\$209	\$224	\$240	\$257	\$275	
30% patient share	\$202	\$208	\$214	\$221	\$235	\$251	\$269	\$288	\$309	\$330	
Non-Knee Patients Upside	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	
US sales	\$0	\$0	\$0	\$0	\$157	\$167	\$179	\$192	\$206	\$220	
Gross profit	\$0	\$0	\$0	\$0	\$138	\$147	\$158	\$169	\$181	\$194	
Gross margin	88%	88%	88%	88%	88%	88%	88%	88%	88%	88%	Reflects 90% GM plus distribution cost
Tax	0	0	0	0	0	0	55	59	63	68	
Tax %	NM	NM	NM	NM	0%	0%	35%	35%	35%	35%	~\$150M in NOLs - assume shield to '20
Net Income	\$0	\$0	\$0	\$0	\$138	\$147	\$103	\$110	\$118	\$126	
NPV		0	0	0	62	54	31	27	24	21	Growth to 2028 then negative terminal \$10M in terminal NPV in 2028+
Terminal value											
Total NPV	303										
Shares outstanding	23										
NPV per share	\$13										
NPV assumptions											
Terminal growth	-40%										
Discount rate	22%										
Normalized tax rate	35%										

Source: Company reports, RBC Capital Markets estimates

Based on our sensitivity analysis, a 5% to 30% share of the hip, shoulder and ankle (non-knee) IA steroid market would yield an incremental NPV of \$3 to \$20 per share. Again, we have not included any upside in our model or peak sales forecast to reflect any penetration into this market. However, our survey clearly suggested an interest here, with 80% either likely or highly likely to use a sustained-release TCA steroid if statistically significant to IR up to eight weeks.

Exhibit 16: The range of NPV add based on market share penetration into the hip, ankle and shoulder market is \$3 to \$20 per share based on assumed penetration of 5% to 30%



Source: Company reports, RBC Capital Markets estimates

#### (4) Clear catalyst driven path to approval – key pivotal data coming in 2H15

We expect Phase IIb and Phase III data in 2H15 and 1H16, respectively.

**Flexion should be ready to submit an NDA filing following completion of the ongoing Phase IIb study (data expected 2H15) and recently started Phase III trial (data expected 1H16).** FDA had given guidance in 2014 that a Phase II repeat-dose safety study would not be required for NDA submission, which moved forward the time to filing by a year. Flexion expects to file repeat-dose safety data in a supplemental NDA post-launch. As detailed in Exhibit 17, we expect Phase IIb pivotal data in 2H15, followed by top-line Phase III pivotal data in 1H16 with an NDA filing in 2H16 followed by approval and launch in 2017.

**First pivotal study for NDA submission – Phase IIb data read expected in 2H15.** A pivotal Phase IIb against placebo was initiated in April 2014 to identify a safe and well tolerated strength for FX006 that can demonstrate significant pain relief. The FDA allowed this study to be considered as one of two pivotal efficacy trials for the NDA filing. In this multi-center, randomized, double-blind study, ~300 patients with knee OA were randomized and given a single injection of 20mg FX006, 40mg FX006 or placebo. Patients were evaluated for up to 24 weeks. The primary endpoint was the weekly mean of the average daily pain intensity score (11-point scale) versus placebo at 12 weeks. As FX006 had demonstrated statistical significance versus TCA IR at 10 weeks, we believe FX006 should be successful in reaching its primary endpoint versus placebo at 12 weeks. Secondary endpoints include WOMAC (A: pain, B: stiffness and C: function), PGIC (patient global impression of change), CGIC (clinical global impression of change), time to onset of pain relief, rescue medication consumption and responder status.

A clinical hold on the Phase IIb study from September to December 2014 was determined to be unrelated to FX006. The FDA placed a clinical hold on the Phase IIb study on September 16, 2014 due to a single incidence to one patient with what was suspected to be septic

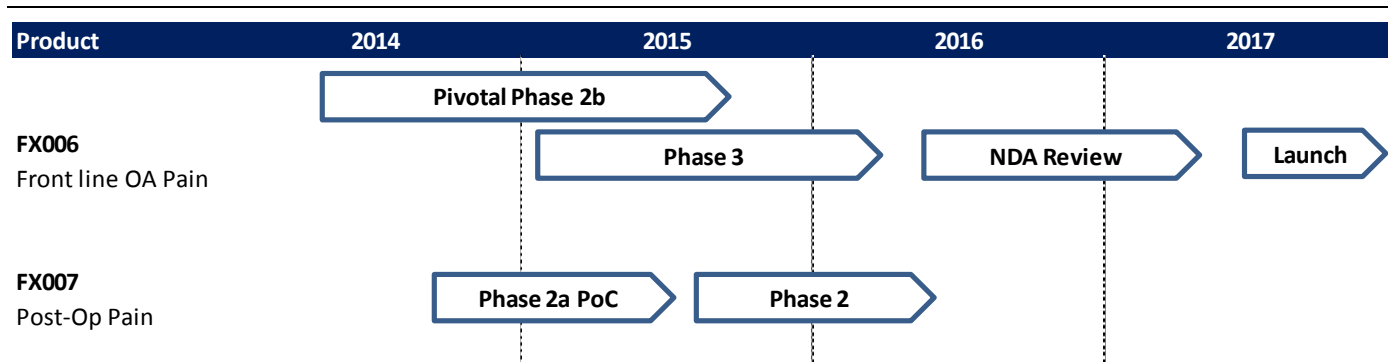


arthritis (an infection of the injected knee possibly related to drug treatment). The hold was lifted on December 1, 2014 following an investigation resulting in the change of diagnosis to inflammatory arthritis (unrelated to drug treatment), and thorough testing that determined there was no contamination of FX006 or any sterile procedures. The initial diagnosis was determined to be false positive, which occurs in ~5% of cases. In the over 300 patients treated, no other serious adverse events has been attributed to FX006.

**Second study for NDA submission – FX006 Phase III study was initiated in January 2015, and we anticipate (1) full enrollment status by mid-2015 and (2) data read 1H16.** The Phase III study with 450 patients with knee OA is an international, randomized, blinded, single-dose study with patients receiving 40mg FX006, 40mg TCA IR or placebo with evaluation follow-up for 24 weeks. The primary endpoint is efficacy at 12 weeks versus placebo (11-point scale) and will be the second pivotal efficacy data for NDA submission. Secondary endpoints will be comparisons to TCA IR at eight, 10, and 12 weeks, and also include: WOMAC, PGIC, CGIC, time to onset of pain relief, rescue medication consumption and responder status.

**NDA submission in 1H16.** Following Phase III data in 1H16, we anticipate Flexion filing its NDA 2H16 with a standard 10-month review and approval in 2017. We do not anticipate any issues that would block a launch shortly after approval. Management indicated that 60–100 sales reps should cover 9,000 orthopedists and rheumatologists who perform over 75% of injections.

Exhibit 17: The FX006 development timeline



Source: Company reports, RBC Capital Markets estimates

## (5) FX006 duration could be extended, and FX005 and FX007 could add upside

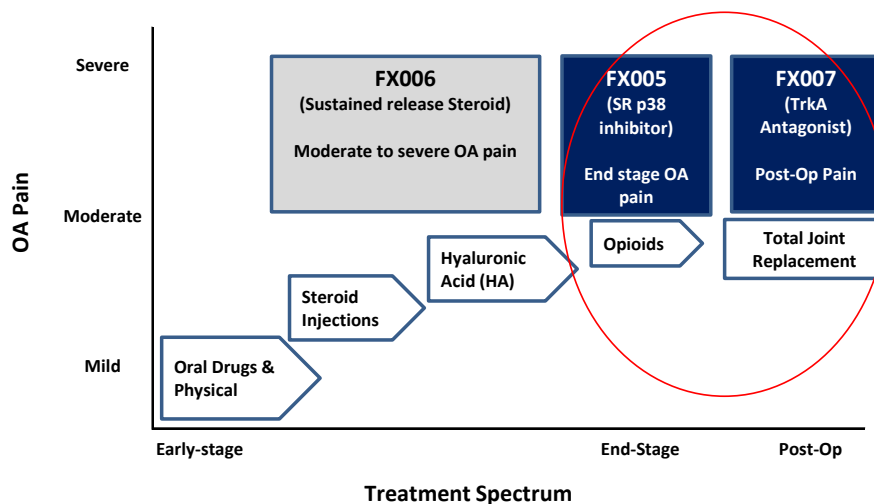
We see FX006 as having a long commercial life with a peak of 26% patient market share in 2023 and with label-expansion opportunities adding substantial upside to estimates. Our revenue projections estimate a peak in 2023 with market share declining beyond. We model patient population growth in line with projections by the US Center for Disease Control at an average of 3.6%, though this could prove conservative as the baby boomer generation reaches retirement age over the next two decades. We estimate that penetration into non-knee OA patients can increase the targeted patient base by another ~25%. A single study for safety and efficacy will be enough to get an indication expansion label for FX006.

**FX006 patents and manufacturing complexity should add protection from generic entry.** FX006 uses PGLA microspheres technology, which enables the sustained release of TCA and adds an additional level of complexity. FX006 currently has a composition of matter patent until 2031, which has resulted from unique specifications including drug loads, a specific release profile of polymers, specific polymer weight, and ratios and clinical efficacy within a specific-dose range. Additional method of manufacturing and method of use claims have been filed.

**Additional product candidates further Flexion's portfolio across the OA pain-treatment spectrum.** Flexion has worldwide rights to all of its product candidates, which are protected by patents, trade secrets and proprietary development know-how.

- **FX007 for the treatment of post-operative pain** is a locally administered TrkA receptor antagonist designed to provide persistent relief for post-operative pain (including patients who have undergone total joint arthroplasty). Flexion is conducting preclinical experiments and plans to initiate a proof of concept (PoC) clinical trial following preclinical data.
- **FX005 for the treatment of end-stage OA patients.** FX005 is a sustained-release mitogen-activated protein, kinase inhibitor that has both analgesic and anti-inflammatory effects. FX005 successfully completed a PoC study, which demonstrated pain relief and functional improvement at four weeks with the absolute magnitude of effect persistent through 12 weeks. FX005 was generally well tolerated.

Exhibit 18: The OA spectrum is broad with injections targeting moderate to severe pain



Source: Company reports, RBC Capital Markets



## (6) How we get to our \$37 target and upside potential on a post-data take-out

Our \$37 price target is an equal blend of (1) NPV for lead product FX006 of \$32 combined with cash of \$3, which get us to \$35 and (2) discounted cash flow analysis of \$38. Collectively, this gets us to a \$37 per share target.

- **NPV:** We arrive at ~\$32 per share for FX006 based on a peak sales forecast of \$1.05 billion, which reflects 26% market share penetration of the IR steroid and HA market combined. We assume that beyond 2023, penetration declines steadily before applying a more aggressive negative terminal growth rate of -40% beyond 2028. Our NPV model is based on the end of 2015 consistent with our 12-month price target outlook (i.e., where we see fair value in 12-months from now). Our full NPV model is in Exhibit 19 below and reflects a 22% discount rate. Our cash assumption is based on the year-end 2015 balance of \$83 million in cash and marketable securities post-2015 burn over a current, fully diluted share count (reflecting the December offering) of 22.6 million shares.

Exhibit 19: Our NPV model derives ~\$32 in value per share for FX006 alone – no value for use beyond knee OA or ex-US

US P&L Build	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	
US sales	\$0	\$0	\$0	\$54	\$122	\$312	\$551	\$750	\$906	\$1,048	
Gross profit	\$0	\$0	\$0	\$48	\$108	\$274	\$485	\$660	\$797	\$923	
Gross margin	88%	88%	88%	88%	88%	88%	88%	88%	88%	88%	Reflects 90% GM plus distribution cost
S&M	-	-	20	41	45	47	50	52	55	58	
G&A	9	11	12	13	14	15	16	17	18	19	
R&D	18	48	50	45	48	50	53	55	58	29	
US EBIT	(\$28)	(\$59)	(\$82)	(\$52)	\$1	\$162	\$367	\$535	\$666	\$817	
EBIT margin	NM	NM	NM	NM	1%	52%	67%	71%	74%	78%	
Tax	0	0	0	0	0	0	128	187	233	286	
Tax %	NM	NM	NM	NM	0%	0%	35%	35%	35%	35%	~\$150M in NOLs - assume shield to '20
Net Income	(\$28)	(\$59)	(\$82)	(\$52)	\$1	\$162	\$239	\$348	\$433	\$531	
NPV			(68)	(35)	1	73	88	106	108	108	Growth to 2028 then negative terminal \$30M in terminal NPV in 2028+
Terminal value											
Total NPV		716									
Shares outstanding		23									
NPV per share		32									
Cash per share (end of 2015)		4									
Total NPV		\$35									
<b>NPV assumptions</b>											
Terminal growth		-40%									
Discount rate		22%									
Normalized tax rate		35%									

Source: Company reports, RBC Capital Markets estimates

- **Discounted cash flow analysis (DCF):** Our DCF model reflects our explicit forecasts through 2028 with a -5% terminal growth outlook beyond on the assumption that Flexion can progress its pipeline and redeploy capital accretively over time—though per Exhibit 20 a more aggressive terminal growth assumption of -50% has a rather limited \$4 effect on our DCF. The main difference between our DCF and NPV is that our DCF captures greater platform spend, as we assume pipeline progression and a lower terminal growth rate reflecting some risk-adjusted ROI on FX005 and FX007.



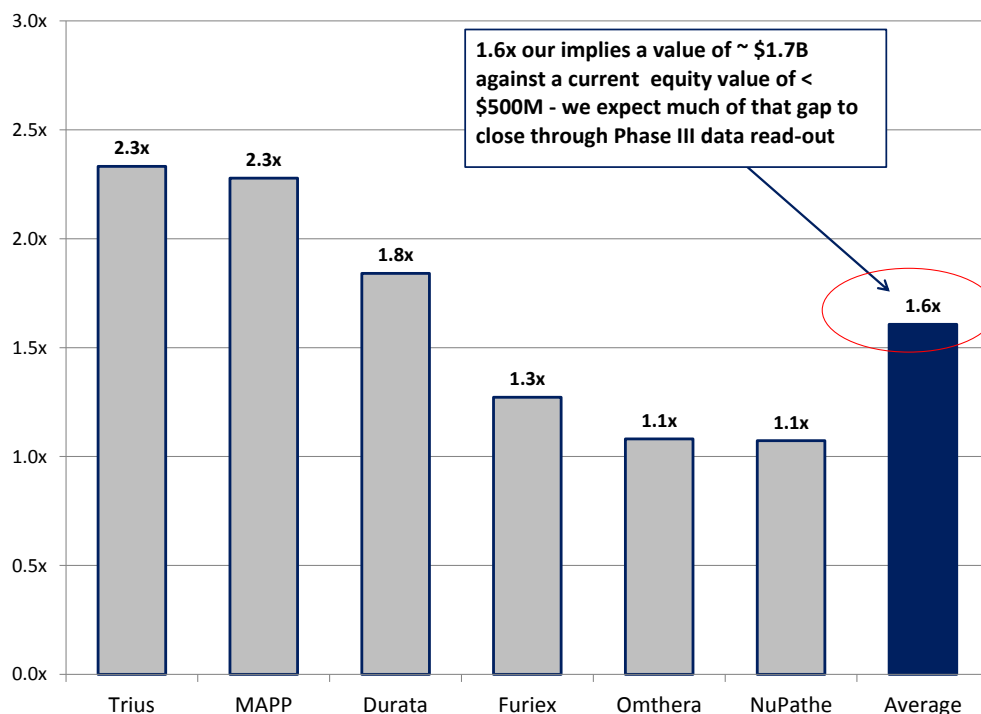
Exhibit 20: Our DCF derives a value of \$38 per share

FLXN DCF	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Free Cash Flow	(\$60)	(\$81)	(\$49)	\$5	\$152	\$224	\$327	\$407	\$524
PV of Terminal Value									
Perpetuity Growth									
WACC		-50.0%	-5.0%	0.0%	Enterprise Value				
18%		\$35	\$195	\$262		\$930	\$1,091	\$1,158	
20%		\$27	\$144	\$190		\$799	\$916	\$961	
22%		\$21	\$108	\$139		\$687	\$774	\$805	
24%		\$17	\$81	\$103		\$593	\$658	\$680	
26%		\$13	\$62	\$77		\$513	\$562	\$577	
Total Equity Value									
WACC		-50.0%	-5.0%	0.0%	Equity Value per Share				
18%		\$1,009	\$1,170	\$1,237		\$45	\$52	\$55	
20%		\$877	\$994	\$1,040		\$39	\$44	\$46	
22%		\$766	\$853	\$884		\$34	\$38	\$39	
24%		\$672	\$737	\$759		\$30	\$33	\$34	
26%		\$592	\$641	\$656		\$26	\$28	\$29	

Source: Company reports, RBC Capital Markets estimates

While management plans to pursue a go-it-alone strategy and launch FX006 with its own internal sales force, we think it is reasonable to view Flexion as a potential take-out target should we see positive data from its two pivotal trials. We see multiple players in the pain space that we think would be interested in a disruptive OA knee therapy alternative that could hold potential blockbuster status. In Exhibit 21, we looked at other post Phase III data but pre-launch companies that have been taken out, and we make several observations: (1) they have ranged from ~1.1x to 2.3x with an average 1.6x—that would imply a \$1.7 billion take-out valuation for Flexion based on our 2023 peak forecast of \$1.05 billion, (2) Pain is an attractive and highly sought after therapeutic area for M&A, and (3) Given the pick-up in consolidation with the specialty pharmaceuticals sector, there are several larger acquirers generating greater free cash flow that we expect will be deployed toward deals over the next several years—that positions Flexion well as we think about data readouts for its two pivotal trials by mid-2016. The one caveat is that we assumed full earn-out credit for the purposes of our analysis.

Exhibit 21: Recent post-data but pre-launch take-outs have been on average in the 1.6x forecasted peak sales range – that would imply ~ \$1.7 billion in value for FLXN



Source: Company reports, Factset, RBC Capital Markets

## Background on Flexion and the key aspects of the story

**Flexion (NASDAQ: FLXN) is a clinical-stage specialty pharmaceutical** founded by Michael Clayman, MD (Chief Executive Officer) and Neil Bodick, MD, PhD (Chief Medical Officer) on November 5, 2007 and is headquartered in Burlington, MA. The company went public on February 18, 2014 by selling 5.75 million shares (including 750,000 option exercise) at \$13 per share and raising net proceeds of \$67.3 Million. The company's lead pipeline candidate is FX006 (sustained-release TCA) for moderate to severe knee osteoarthritis patients, which is currently in Phase III with an anticipated launch in 2017. Two additional product candidates include: FX007, a locally administered TrkA receptor antagonist for post-operative pain, and FX005, an intra-articular, sustained-release MAP kinase inhibitor for end-stage osteoarthritis patients.

**Flexion raised \$92.1 million in net proceeds with a secondary offering after lifting of the Phase IIb clinical hold in December 2014.** Flexion sold 5.796 million shares (including the exercise of 15% overallotment option with 756,000 shares) at \$17 per share. The company intends to use the net proceeds from this offering to complete its planned Phase III clinical trial for FX006, the NDA submission, preparatory activities for commercial launch of FX006, development of FX007, and for general development expenses, working capital and other general corporate purposes. We have assumed one additional capital raise following Phase III data in mid-2016 to help fund commercialization in 2017.

**Knee OA is the most common form of OA, a joint disease affecting ~27 million patients.** There is an estimated 16 million patients with knee OA, and its prevalence is expected to continue growing given the increases in demographics from aging, obesity and injury.



According to US Centers for Disease Control and Prevention, knee OA is expected to afflict one in two Americans during their lifetime. Current treatment options can range from weight-loss routines, knee braces, NSAIDs, viscosupplementation (HA), cortisone injection (steroid injection) to total knee joint replacement surgery for severe OA. We estimate a peak 26% market share capture of overall knee OA patients currently using HA or steroid injection (or 8% of all knee OA patients). Given the differentiation of FX006, we see potential further upside to our estimates with both growth of knee OA prevalence and market penetration.

**In a Phase IIb study, FX006 had previously demonstrated statistically significant pain relief up to 10 weeks against the current standard of care: TCA IR.** The study (Exhibit 22) enrolled 228 patients and tested FX006 at 10mg, 40mg and 60mg against TCA IR 40mg with primary endpoints of pain relief at 8, 10 or 12 weeks.

[Exhibit 22: Study design from the prior completed Phase IIb where separation at 10 weeks was demonstrated](#)

**Ph 2b Design (n=228)**  
3ml IA knee injection  
Location: US, Canada, Australia

**177 OA patients on FX006**  
• 3 dose groups of 58 – 60 patients each

**51 OA patients on triamcinolone acetonide immediate release (TCA IR) 40 mg**

FX006 10 mg (58)	FX006 40mg (59)	FX006 60mg (60)	TCA IR 40mg (51)
------------------------	-----------------------	-----------------------	------------------------

**Study Objective**  
• Identify a safe and well tolerated dose of FX006 which demonstrates superiority to TCA IR in magnitude and duration of pain relief

**Pain measured on 0 – 10 Numeric Rating Scale**

- 0 = no pain; 10 = pain as bad as you can imagine
- Baseline index knee pain between 5 and 9
- Primary outcome measure - weekly mean of average daily pain intensity score
- Primary endpoint predicated on demonstrating pain relief with 60 mg at 8, 10 or 12 weeks

**Secondary outcome measures**

- Pain by WOMAC A (pain), B (stiffness), C (function)
- Time to onset of pain relief
- Responder status
- Patient and clinical global impression of change
- Rescue medication consumption

**Treatment groups well balanced**

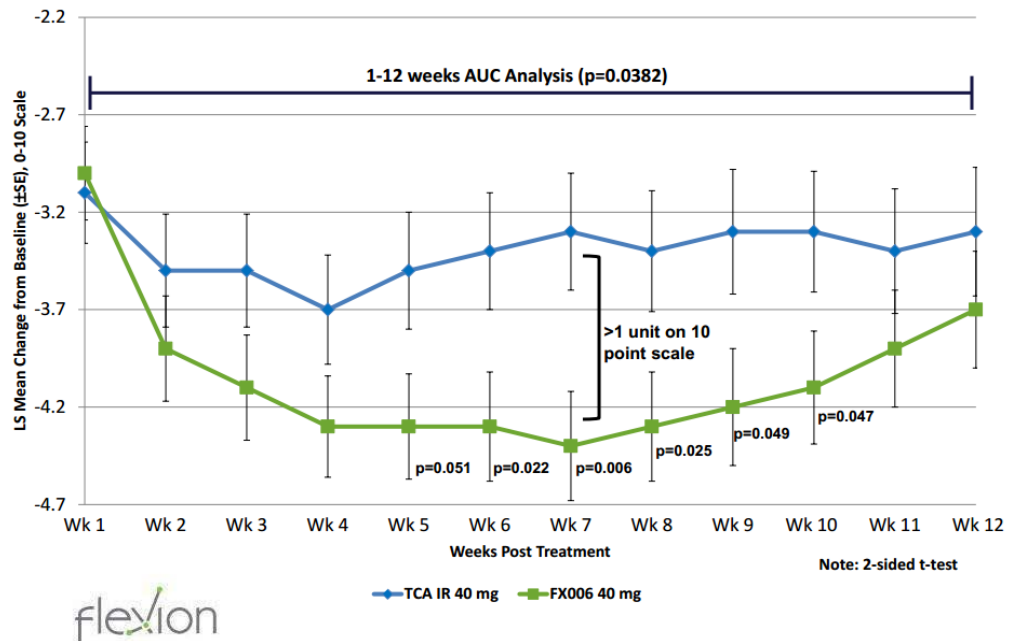
- Gender, race, age, BMI, OA grade by X-ray
- Mean pain at baseline = 6.4 – 6.6

Source: Company reports

**FX006 40mg demonstrated separation from TCA IR at up to 10 weeks (Exhibit 23).** The 12-week dose-ranging study also demonstrated FX006 has a well tolerated safety profile comparable to TCA IR. Two PK studies also showed that FX006 40mg had measurable concentrations of drug in synovial fluid compared to TCA IR, which had fallen below the level of quantitation. This suggests that FX006 prolongs the local exposure to TCA while reducing systemic exposure.

Exhibit 23: FX006 40mg demonstrated statistically significant pain relief up to 10 weeks versus TCA IR 40mg

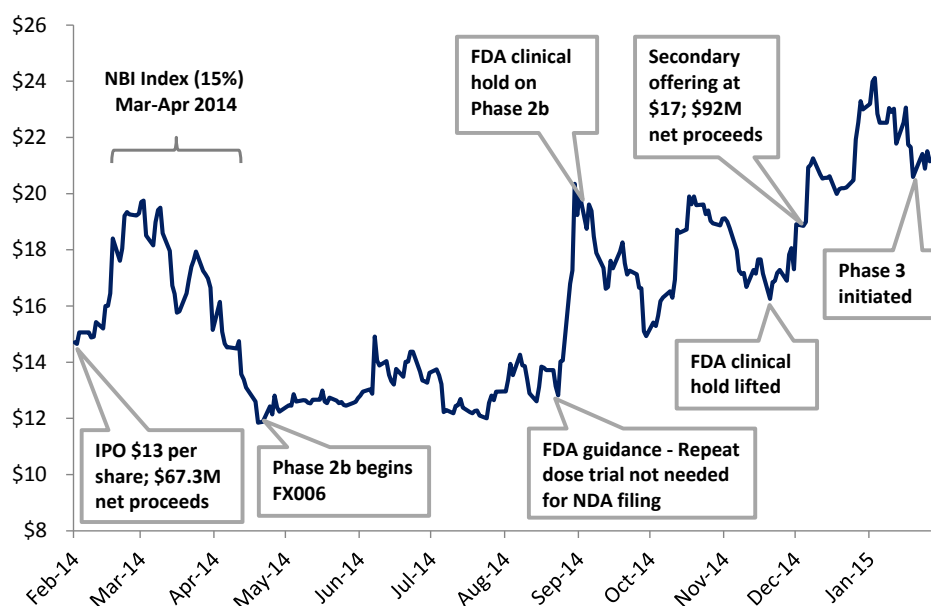
## FX006 40 mg: Highly Significant, Clinically Meaningful



Source: Company reports

**There were two major events in 2014 that drove significant volatility.** The first important update came September 3, when the FDA told Flexion that it could use its ongoing Phase IIb study as one of the two pivotal studies and that a second placebo-controlled trial would be enough for submission. It also indicated that it would not need to include data from a repeat-dose safety trial in the NDA package, which accelerated the timeline by moving the expected approval timing up by a year. The second unexpected update was the clinical hold from September 16, which resulted from a suspected case of septic arthritis. Flexion subsequently ran testing that showed that the product was not contaminated and unrelated to the drug. On December 1, the hold was released—this was consistent with the fact that no production batch of FX006 has ever failed sterility testing. Exhibit 24 details the stock path since IPO, which has come with a decent amount of volatility.

Exhibit 24: FLXN shares have been volatile since the IPO in February 2014



Source: Factset, RBC Capital Markets

## Four primary risks to our Outperform rating and price target

- (1) **Regulatory risk:** The current Phase IIb and Phase III studies are the next step toward an NDA submission likely in 2H16. Any FDA delays or adverse results would have a material effect on the stock. There are several angles to this beyond a lack of success in the trial, as any significant delay could affect the timing and ability to launch and potentially create the need to raise additional funds. Upcoming data needs to confirm the differentiation of FX006 with longer-duration pain relief and a well tolerated safety profile.
- (2) **Commercialization risk:** Currently marketed intra-articular OA therapies of steroids and HA have readily available low-cost alternatives. While we have assumed that Flexion creates and builds out a commercialization platform, execution risk is something that needs to be considered. It will be particularly important for the Phase IIb and Phase III trials to confirm its superior pain relief to leading treatments.
- (3) **Financing risk:** We anticipate another funding raise prior to commercialization efforts in the US that could likely come in mid-2016 following the release of Phase III data. The company completed a \$92 million (net proceeds) secondary offering in December 2014, thereby bringing overall cash of \$159 million pro forma for the recent raise against the most recently reported 3Q14. We estimate near-term cash burn in the \$15 million to \$20 million range with Flexion not seeing breakeven until 2018.
- (4) **Competitive risk:** Market acceptance and uptake for FX006 could face competitive headwinds with multiple branded and generic alternatives for knee OA joint injection already on the market. We believe FX006 is differentiated with clinical data that show sustained-release properties of a proven steroid using PLGA microspheres technology currently used in marketed products such as Consta and Vivitrol. In PK studies, FX006 PK data show a 6x increase in duration of joint residency and a dosing interval of three to four months. The other competitive risks are the approval of another knee OA product targeting the same indication, which could affect market-share assumptions.

Our model reflects an additional financing in 2016 to fund launch costs and commercialization with break-even in 2018.



## Exhibit 25: FLXN P&amp;L 2013 to 2018E

FLXN - Income Statement (\$ in millions)	FY2012 Actual	FY2013 Actual	Mar-14	Jun-14	Sep-14	Dec-14E	FY2014 Est.	Mar-15E	Jun-15E	Sep-15E	Dec-15E	FY2015 Est.	FY2016 Est.	FY2017 Est.	FY2018 Est.	Comments
<b>Revenue</b>																
FX 006	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	54.2	122.2	See our FX006 market model
Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	We assume no other pipeline conversion
<b>Total revenue</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>54.2</b>	<b>122.2</b>	Risk adjusted at 75%
Cost of goods sold	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	6.5	14.7	
<b>Total gross profit</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>47.7</b>	<b>107.6</b>	
Research and development (R&D)	11.1	11.1	4.2	3.6	4.7	6.0	18.4	10.0	12.0	13.0	13.0	48.0	50.4	45.4	47.6	2015 reflects spend on pivotal trials, F007 progression
General and administrative (G&A)	3.9	6.7	2.3	2.2	2.3	2.5	9.3	2.7	2.8	2.8	3.0	11.3	12.1	12.9	13.8	
Sales and marketing (S&M)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	20.0	41.0	45.1	We have assumed 80 reps (60 to 100 expected)
<b>Operating income (adjusted)</b>	<b>(15.0)</b>	<b>(17.8)</b>	<b>(6.4)</b>	<b>(5.8)</b>	<b>(7.0)</b>	<b>(8.5)</b>	<b>(27.7)</b>	<b>(12.7)</b>	<b>(14.8)</b>	<b>(15.8)</b>	<b>(16.0)</b>	<b>(59.3)</b>	<b>(82.5)</b>	<b>(51.6)</b>	<b>1.0</b>	
Interest expense	(0.2)	(0.4)	(0.1)	(0.1)	(0.1)	(0.6)	(0.9)	(0.1)	(0.1)	(0.1)	(0.1)	(0.4)	(0.2)	0.0	0.0	Some minor cash on cash return on balance
Interest income and other	0.2	0.0	0.0	0.0	0.0	(0.1)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Total interest & other	0.0	(0.4)	(0.1)	(0.1)	(0.1)	(0.7)	(0.9)	(0.1)	(0.1)	(0.1)	(0.1)	(0.4)	(0.2)	0.0	0.0	
<b>Earnings before income taxes (adj)</b>	<b>(15.0)</b>	<b>(18.2)</b>	<b>(6.5)</b>	<b>(5.9)</b>	<b>(7.0)</b>	<b>(9.2)</b>	<b>(28.6)</b>	<b>(12.8)</b>	<b>(14.9)</b>	<b>(15.9)</b>	<b>(16.1)</b>	<b>(59.7)</b>	<b>(82.6)</b>	<b>(51.6)</b>	<b>1.0</b>	
Income tax (adjusted)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	We assume full taxation - potentially conservative
<b>Net earnings</b>	<b>(15.0)</b>	<b>(18.2)</b>	<b>(6.5)</b>	<b>(5.9)</b>	<b>(7.0)</b>	<b>(9.2)</b>	<b>(28.6)</b>	<b>(12.8)</b>	<b>(14.9)</b>	<b>(15.9)</b>	<b>(16.1)</b>	<b>(59.7)</b>	<b>(82.6)</b>	<b>(51.6)</b>	<b>1.0</b>	
<b>EPS (pro-forma), diluted</b>	<b>(\$27.6)</b>	<b>(\$23.0)</b>	<b>(\$0.86)</b>	<b>(\$0.38)</b>	<b>(\$0.45)</b>	<b>(\$0.55)</b>	<b>(\$2.23)</b>	<b>(\$0.57)</b>	<b>(\$0.66)</b>	<b>(\$0.70)</b>	<b>(\$0.71)</b>	<b>(\$2.64)</b>	<b>(\$3.17)</b>	<b>(\$1.95)</b>	<b>\$0.04</b>	We have break-even in 2018 - sharp profit ramp
Basic shares outstanding																
Diluted shares outstanding	0.5	0.8	7.6	15.6	15.6	16.8	13.9	22.6	22.6	22.6	22.6	22.6	26.0	26.4	26.7	Assume equity raise in 2016 post Phase 3 data
EBITDA	(15.0)	(17.8)	(6.4)	(5.8)	(7.0)	(8.5)	(27.7)	(12.7)	(14.8)	(15.8)	(16.0)	(59.3)	(82.5)	(51.6)	1.0	
EBITDA margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-95.2%	0.8%	
<b>Growth analysis Y-O-Y</b>	<b>FY2012</b>	<b>FY2013</b>					<b>FY2014</b>					<b>FY2015</b>	<b>FY2016</b>	<b>FY2017</b>	<b>FY2018</b>	
Revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	125%	
COGS	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	125%	
Gross profit	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	125%	
Research and development (R&D)	NM	NM	NM	NM	NM	NM	66%	141%	232%	179%	117%	161%	5%	-10%	5%	We assume ongoing spend to support pipeline
General and administrative (G&A)	NM	NM	NM	NM	NM	NM	39%	18%	25%	22%	20%	21%	7%	7%	7%	Modest infrastructure build out ahead of launch
Sales and marketing (S&M)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	10%	We have assumed 80 reps (60 to 100 expected)
Operating income (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-37%	-102%	
Net earning (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-38%	-102%	
EPS (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	
<b>Margin analysis</b>	<b>FY2012</b>	<b>FY2013</b>					<b>FY2014</b>					<b>FY2015</b>	<b>FY2016</b>	<b>FY2017</b>	<b>FY2018</b>	
Gross margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	88%	88%	88%	
R&D	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	84%	39%	
G&A	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	24%	11%	
Sales and marketing (S&M)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	76%	37%	
Operating income (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-95%	1%	
Interest expense	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0%	0%	
Interest income and other income (expense)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0%	0%	
Tax rate	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0%	0%	
Net earnings (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-95%	1%	-\$150M in NOLs - assume shield to '20

Source: Company reports, RBC Capital Markets estimates



Exhibit 26: FLXN Balance sheet 2013 to 2018E

FLXN - Balance Sheet (\$ in millions)	FY2012 Actual	FY2013 Actual	Mar-14	Jun-14	Sep-14	Dec-14E	FY2014 Est.	Mar-15E	Jun-15E	Sep-15E	Dec-15E	FY2015 Est.	FY2016 Est.	FY2017 Est.	FY2018 Est.	Comments
<b>Assets</b>																
Cash and cash equivalents	12.8	16.2	35.8	12.0	14.4	12.6	12.6	15.2	16.1	18.0	15.7	15.7	19.6	16.0	20.6	
Marketable securities	16.5	0.3	42.7	60.0	52.2	130.2	130.2	115.2	99.2	81.2	67.2	67.2	67.2	22.2	22.2	We assume a raise in 2016 off of Phase III data
Total cash & marketable	29.4	16.4	78.5	72.0	66.6	142.8	142.8	130.4	115.3	99.2	83.0	83.0	86.8	38.2	42.9	
Prepaid expenses and other assets	0.5	0.2	0.8	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	1.0	2.5	4.3	
<b>Total current assets</b>	<b>29.9</b>	<b>16.6</b>	<b>79.4</b>	<b>72.7</b>	<b>67.3</b>	<b>143.6</b>	<b>143.6</b>	<b>131.1</b>	<b>116.0</b>	<b>99.9</b>	<b>83.7</b>	<b>83.7</b>	<b>87.8</b>	<b>40.7</b>	<b>47.2</b>	
Property, plant and equipment, net	0.1	0.4	0.4	0.4	0.7	0.9	0.9	1.1	1.3	1.5	1.7	1.7	2.7	3.7	4.8	
Deferred financing costs, net	0.0	1.6	0.0	0.0	0.0	6.4	6.4	6.4	6.4	6.4	6.4	6.4	11.4	11.4	11.4	
Other assets	0.1	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	
<b>Total assets</b>	<b>30.0</b>	<b>18.8</b>	<b>79.9</b>	<b>73.2</b>	<b>68.1</b>	<b>151.1</b>	<b>151.1</b>	<b>138.8</b>	<b>123.9</b>	<b>108.0</b>	<b>91.9</b>	<b>91.9</b>	<b>102.1</b>	<b>56.0</b>	<b>63.5</b>	
<b>Liabilities and equity</b>																
Accounts payable	0.5	1.3	1.8	1.0	1.5	1.5	1.5	2.0	2.0	2.0	2.0	2.0	4.0	6.0	9.8	
Accrued expenses	2.2	2.3	1.6	1.5	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	3.5	7.0	9.8	
Debt, ST	0.0	1.5	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	
Warrant liability	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Other current liabilities	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
<b>Total current liabilities</b>	<b>2.7</b>	<b>5.0</b>	<b>5.4</b>	<b>4.4</b>	<b>6.2</b>	<b>6.2</b>	<b>6.2</b>	<b>6.7</b>	<b>6.7</b>	<b>6.7</b>	<b>6.7</b>	<b>6.7</b>	<b>9.5</b>	<b>15.0</b>	<b>21.6</b>	
Other LT liabilities	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	
Debt, LT	0.0	3.5	3.1	2.6	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	
<b>Total liabilities</b>	<b>2.7</b>	<b>8.7</b>	<b>8.5</b>	<b>7.1</b>	<b>8.3</b>	<b>8.3</b>	<b>8.3</b>	<b>8.8</b>	<b>8.8</b>	<b>8.8</b>	<b>8.8</b>	<b>8.8</b>	<b>11.6</b>	<b>17.1</b>	<b>23.7</b>	
Common stock	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Conv Preferred stock	74.8	74.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Additional paid-in capital	0.5	1.5	144.1	144.7	145.4	237.5	237.5	237.5	237.5	237.5	237.5	237.5	327.5	327.5	327.5	
Accumulated other income	0.0	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Deficit accumulated	(48.0)	(66.2)	(72.7)	(78.6)	(85.7)	(94.8)	(94.8)	(107.6)	(122.5)	(138.4)	(154.5)	(154.5)	(237.1)	(288.7)	(287.7)	
Retained earnings	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
<b>Shareholders' equity</b>	<b>27.3</b>	<b>10.1</b>	<b>71.4</b>	<b>66.1</b>	<b>59.8</b>	<b>142.7</b>	<b>142.7</b>	<b>129.9</b>	<b>115.0</b>	<b>99.2</b>	<b>83.1</b>	<b>83.1</b>	<b>90.4</b>	<b>38.8</b>	<b>39.8</b>	
<b>Total liabilities and equity</b>	<b>30.0</b>	<b>18.8</b>	<b>79.9</b>	<b>73.2</b>	<b>68.1</b>	<b>151.1</b>	<b>151.1</b>	<b>138.8</b>	<b>123.9</b>	<b>108.0</b>	<b>91.9</b>	<b>91.9</b>	<b>102.1</b>	<b>56.0</b>	<b>63.5</b>	

Source: Company reports, RBC Capital Markets estimates



Exhibit 27: FLXN Cash flow 2013 to 2018E

FLXN - Statement of Cash Flows	FY2012 Actual	FY2013 Actual	Mar-14	Jun-14	Sep-14	Dec-14E	FY2014 Est.	Mar-15E	Jun-15E	Sep-15E	Dec-15E	FY2015 Est.	FY2016 Est.	FY2017 Est.	FY2018 Est.	Comments
Net earnings	(15.0)	(18.2)	(6.5)	(6.0)	(7.0)	(9.2)	(28.7)	(12.8)	(14.9)	(15.9)	(16.1)	(59.7)	(82.6)	(51.6)	1.0	Break-even in 2018 - sharp ramp beyond
Non-cash items included in net earning	0.3	1.3	0.5	0.8	0.8	0.0	2.1	0.1	0.1	0.1	0.1	0.5	0.5	0.5	0.5	
Depreciation	0.0	0.1	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.5	0.5	0.5	0.5	
Amortization on marketing securities	0.1	0.2	0.0	0.1	0.1	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Stock-based compensation	0.1	1.0	0.4	0.7	0.7	0.0	1.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Other non-cash items	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Changes in working capital	0.7	0.7	(0.4)	(0.6)	1.7	0.0	0.6	0.5	0.0	0.0	0.0	0.5	2.5	4.0	4.7	
Prepaid expenses and other assets	(0.2)	0.3	(0.7)	0.2	0.2	0.0	(0.4)	0.0	0.0	0.0	0.0	0.0	(0.3)	(1.5)	(1.8)	
Accounts payable and accrued exp	(0.2)	0.5	0.7	(0.7)	0.3	0.0	0.3	0.5	0.0	0.0	0.0	0.5	2.0	2.0	3.8	
Other assets	1.1	(0.1)	(0.4)	(0.1)	1.2	0.0	0.7	0.0	0.0	0.0	0.0	0.0	0.8	3.5	2.7	
Cash from operations	(14.0)	(16.2)	(6.5)	(5.8)	(4.6)	(9.1)	(25.9)	(12.2)	(14.8)	(15.8)	(16.0)	(58.7)	(79.7)	(47.1)	6.2	
Capital expenditures	(0.0)	(0.4)	(0.0)	(0.0)	(0.3)	(0.3)	(0.6)	(0.3)	(0.3)	(0.3)	(0.3)	(1.2)	(1.5)	(1.5)	(1.5)	Limited need for capex spend
Change in restricted cash	0.0	(0.1)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Purchases of marketable securities	(28.5)	(15.0)	(42.7)	(19.5)	(10.2)	(78.0)	(150.4)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Redemption of marketable securities	19.0	31.2	0.3	2.1	17.8	0.0	20.2	15.0	16.0	18.0	14.0	63.0	0.0	45.0	0.0	
Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Cash used in investing	(9.5)	15.6	(42.5)	(17.4)	7.4	(78.3)	(130.8)	14.7	15.7	17.7	13.7	61.8	(1.5)	43.5	(1.5)	
Proceeds from issuance of term loan	0.0	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Cash paid for financing costs	(0.0)	(1.1)	(1.1)	(0.2)	0.0	(6.4)	(7.7)	0.0	0.0	0.0	0.0	0.0	(5.0)	0.0	0.0	
Proceeds issuance Conv Pref Series A	13.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Proceeds issuance Conv Pref Series B	19.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Proceeds issuance common stock	0.0	0.0	69.5	0.0	0.0	92.1	161.6	0.0	0.0	0.0	0.0	0.0	90.0	0.0	0.0	Assume \$90M raise after Phase 3 data in mid-2016
Proceeds exercise stock options	0.0	0.0	0.2	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Other items, net	0.0	0.0	0.0	(0.5)	(0.5)	0.0	(1.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Cash from financing	33.0	3.9	68.6	(0.6)	(0.5)	85.7	153.2	0.0	0.0	0.0	0.0	0.0	85.0	0.0	0.0	
Net increase in cash	9.5	3.345	19.6	(23.8)	2.3	(1.7)	(3.6)	2.5	0.9	1.9	(2.3)	3.1	3.8	(3.6)	4.7	
Beginning cash	3.4	12.8	16.2	35.8	12.0	14.4	16.2	12.6	15.2	16.1	18.0	12.6	15.7	19.6	16.0	
Effect of exchange rate changes on cash	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Cash at year end	12.8	16.2	35.8	12.0	14.4	12.6	12.6	15.2	16.1	18.0	15.7	15.7	19.6	16.0	20.6	

Source: Company reports, RBC Capital Markets estimates



## Required disclosures

### Conflicts disclosures

The analyst(s) responsible for preparing this research report received compensation that is based upon various factors, including total revenues of the member companies of RBC Capital Markets and its affiliates, a portion of which are or have been generated by investment banking activities of the member companies of RBC Capital Markets and its affiliates.

Please note that current conflicts disclosures may differ from those as of the publication date on, and as set forth in, this report. To access current conflicts disclosures, clients should refer to <https://www.rbccm.com/GLDisclosure/PublicWeb/DisclosureLookup.aspx?entityId=1> or send a request to RBC CM Research Publishing, P.O. Box 50, 200 Bay Street, Royal Bank Plaza, 29th Floor, South Tower, Toronto, Ontario M5J 2W7.

A member company of RBC Capital Markets or one of its affiliates managed or co-managed a public offering of securities for Flexion Therapeutics Inc in the past 12 months.

A member company of RBC Capital Markets or one of its affiliates received compensation for investment banking services from Flexion Therapeutics Inc in the past 12 months.

A member company of RBC Capital Markets or one of its affiliates expects to receive or intends to seek compensation for investment banking services from Flexion Therapeutics Inc in the next three months.

RBC Capital Markets, LLC makes a market in the securities of Flexion Therapeutics Inc.

RBC Capital Markets is currently providing Flexion Therapeutics Inc with investment banking services.

RBC Capital Markets has provided Flexion Therapeutics Inc with investment banking services in the past 12 months.

### Explanation of RBC Capital Markets Equity rating system

An analyst's 'sector' is the universe of companies for which the analyst provides research coverage. Accordingly, the rating assigned to a particular stock represents solely the analyst's view of how that stock will perform over the next 12 months relative to the analyst's sector average. Although RBC Capital Markets' ratings of Top Pick (TP)/Outperform (O), Sector Perform (SP), and Underperform (U) most closely correspond to Buy, Hold/Neutral and Sell, respectively, the meanings are not the same because our ratings are determined on a relative basis.

#### Ratings

**Top Pick (TP):** Represents analyst's best idea in the sector; expected to provide significant absolute total return over 12 months with a favorable risk-reward ratio.

**Outperform (O):** Expected to materially outperform sector average over 12 months.

**Sector Perform (SP):** Returns expected to be in line with sector average over 12 months.

**Underperform (U):** Returns expected to be materially below sector average over 12 months.

#### Risk Rating

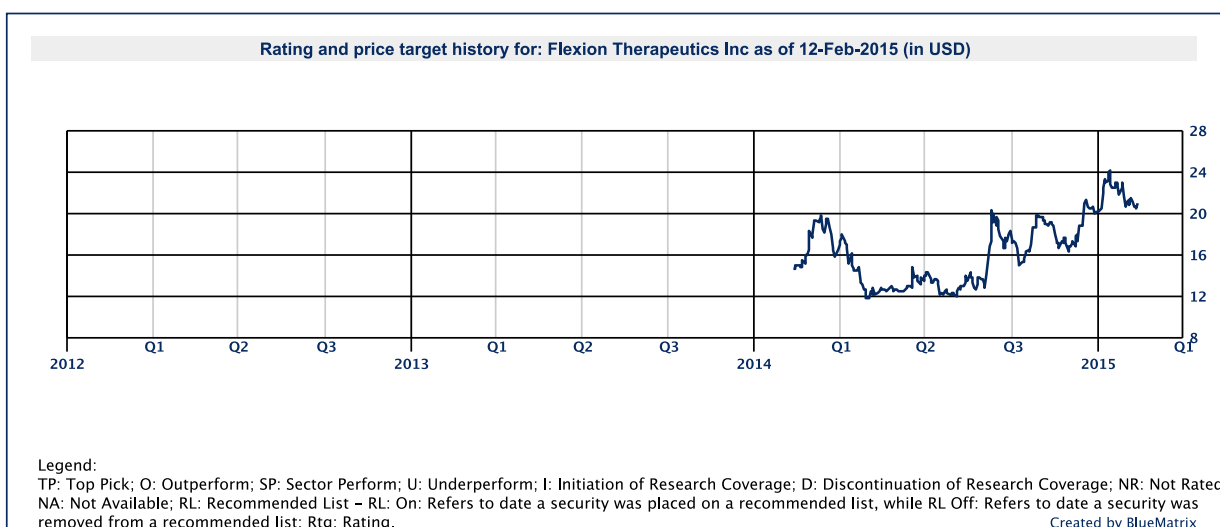
As of March 31, 2013, RBC Capital Markets suspends its Average and Above Average risk ratings. The **Speculative** risk rating reflects a security's lower level of financial or operating predictability, illiquid share trading volumes, high balance sheet leverage, or limited operating history that result in a higher expectation of financial and/or stock price volatility.



## Distribution of ratings

For the purpose of ratings distributions, regulatory rules require member firms to assign ratings to one of three rating categories - Buy, Hold/Neutral, or Sell - regardless of a firm's own rating categories. Although RBC Capital Markets' ratings of Top Pick(TP)/ Outperform (O), Sector Perform (SP), and Underperform (U) most closely correspond to Buy, Hold/Neutral and Sell, respectively, the meanings are not the same because our ratings are determined on a relative basis (as described below).

Distribution of ratings				
RBC Capital Markets, Equity Research				
As of 31-Dec-2014				
Rating	Count	Percent	Investment Banking Serv./Past 12 Mos.	
			Count	Percent
BUY [Top Pick & Outperform]	897	52.92	290	32.33
HOLD [Sector Perform]	686	40.47	137	19.97
SELL [Underperform]	112	6.61	6	5.36



References to a Recommended List in the recommendation history chart may include one or more recommended lists or model portfolios maintained by RBC Wealth Management or one of its affiliates. RBC Wealth Management recommended lists include the Guided Portfolio: Prime Income (RL 6), the Guided Portfolio: Large Cap (RL 7), the Guided Portfolio: Dividend Growth (RL 8), the Guided Portfolio: Midcap 111 (RL 9), the Guided Portfolio: ADR (RL 10), and the Guided Portfolio: Global Equity (U.S.) (RL 11). RBC Capital Markets recommended lists include the Strategy Focus List and the Fundamental Equity Weightings (FEW) portfolios. The abbreviation 'RL On' means the date a security was placed on a Recommended List. The abbreviation 'RL Off' means the date a security was removed from a Recommended List.

## Equity valuation and risks

For valuation methods used to determine, and risks that may impede achievement of, price targets for covered companies, please see the most recent company-specific research report at <https://www.rbcinsight.com> or send a request to RBC Capital Markets Research Publishing, P.O. Box 50, 200 Bay Street, Royal Bank Plaza, 29th Floor, South Tower, Toronto, Ontario M5J 2W7.

## Conflicts policy

RBC Capital Markets Policy for Managing Conflicts of Interest in Relation to Investment Research is available from us on request. To access our current policy, clients should refer to



<https://www.rbccm.com/global/file-414164.pdf>

or send a request to RBC Capital Markets Research Publishing, P.O. Box 50, 200 Bay Street, Royal Bank Plaza, 29th Floor, South Tower, Toronto, Ontario M5J 2W7. We reserve the right to amend or supplement this policy at any time.

## Dissemination of research and short-term trade ideas

RBC Capital Markets endeavors to make all reasonable efforts to provide research simultaneously to all eligible clients, having regard to local time zones in overseas jurisdictions. RBC Capital Markets' equity research is posted to our proprietary website to ensure eligible clients receive coverage initiations and changes in ratings, targets and opinions in a timely manner. Additional distribution may be done by the sales personnel via email, fax, or other electronic means, or regular mail. Clients may also receive our research via third party vendors. RBC Capital Markets also provides eligible clients with access to SPARC on the Firms proprietary INSIGHT website, via email and via third-party vendors. SPARC contains market color and commentary regarding subject companies on which the Firm currently provides equity research coverage. Research Analysts may, from time to time, include short-term trade ideas in research reports and / or in SPARC. A short-term trade idea offers a short-term view on how a security may trade, based on market and trading events, and the resulting trading opportunity that may be available. A short-term trade idea may differ from the price targets and recommendations in our published research reports reflecting the research analyst's views of the longer-term (one year) prospects of the subject company, as a result of the differing time horizons, methodologies and/or other factors. Thus, it is possible that a subject company's common equity that is considered a long-term 'Sector Perform' or even an 'Underperform' might present a short-term buying opportunity as a result of temporary selling pressure in the market; conversely, a subject company's common equity rated a long-term 'Outperform' could be considered susceptible to a short-term downward price correction. Short-term trade ideas are not ratings, nor are they part of any ratings system, and the firm generally does not intend, nor undertakes any obligation, to maintain or update short-term trade ideas. Short-term trade ideas may not be suitable for all investors and have not been tailored to individual investor circumstances and objectives, and investors should make their own independent decisions regarding any securities or strategies discussed herein. Please contact your investment advisor or institutional salesperson for more information regarding RBC Capital Markets' research.

## Analyst certification

All of the views expressed in this report accurately reflect the personal views of the responsible analyst(s) about any and all of the subject securities or issuers. No part of the compensation of the responsible analyst(s) named herein is, or will be, directly or indirectly, related to the specific recommendations or views expressed by the responsible analyst(s) in this report.

The Global Industry Classification Standard ("GICS") was developed by and is the exclusive property and a service mark of MSCI Inc. ("MSCI") and Standard & Poor's Financial Services LLC ("S&P") and is licensed for use by RBC. Neither MSCI, S&P, nor any other party involved in making or compiling the GICS or any GICS classifications makes any express or implied warranties or representations with respect to such standard or classification (or the results to be obtained by the use thereof), and all such parties hereby expressly disclaim all warranties of originality, accuracy, completeness, merchantability and fitness for a particular purpose with respect to any of such standard or classification. Without limiting any of the foregoing, in no event shall MSCI, S&P, any of their affiliates or any third party involved in making or compiling the GICS or any GICS classifications have any liability for any direct, indirect, special, punitive, consequential or any other damages (including lost profits) even if notified of the possibility of such damages.

## Disclaimer

RBC Capital Markets is the business name used by certain branches and subsidiaries of the Royal Bank of Canada, including RBC Dominion Securities Inc., RBC Capital Markets, LLC, RBC Europe Limited, RBC Capital Markets (Hong Kong) Limited, Royal Bank of Canada, Hong Kong Branch and Royal Bank of Canada, Sydney Branch. The information contained in this report has been compiled by RBC Capital Markets from sources believed to be reliable, but no representation or warranty, express or implied, is made by Royal Bank of Canada, RBC Capital Markets, its affiliates or any other person as to its accuracy, completeness or correctness. All opinions and estimates contained in this report constitute RBC Capital Markets' judgement as of the date of this report, are subject to change without notice and are provided in good faith but without legal responsibility. Nothing in this report constitutes legal, accounting or tax advice or individually tailored investment advice. This material is prepared for general circulation to clients and has been prepared without regard to the individual financial circumstances and objectives of persons who receive it. The investments or services contained in this report may not be suitable for you and it is recommended that you consult an independent investment advisor if you are in doubt about the suitability of such investments or services. This report is not an offer to sell or a solicitation of an offer to buy any securities. Past performance is not a guide to future performance, future returns are not guaranteed, and a loss of original capital may occur. RBC Capital Markets research analyst compensation is based in part on the overall profitability of RBC Capital Markets, which includes profits attributable to investment banking revenues. Every province in Canada, state in the U.S., and most countries throughout the world have their own laws regulating the types of securities and other investment products which may be offered to their residents, as well as the process for doing so. As a result, the securities discussed in this report may not be eligible for sale in some jurisdictions. RBC Capital Markets may be restricted from publishing research reports, from time to time, due to regulatory restrictions and/or internal compliance policies. If this is the case, the latest published research reports available to clients may not reflect recent material changes in the applicable industry and/or applicable subject companies. RBC Capital Markets research reports are current only as of the date set forth on the research reports. This report is not, and under no circumstances should be construed as, a solicitation to act as securities broker or dealer in any jurisdiction by any person or company that is not legally permitted to carry on the business of a securities broker or dealer in that jurisdiction. To the full extent permitted by law neither RBC Capital Markets nor any of its affiliates, nor any other person, accepts any liability whatsoever for any direct or consequential loss arising from any use of this report or the information contained herein. No matter contained in this document may be reproduced or copied by any means without the prior consent of RBC Capital Markets.



Additional information is available on request.

**To U.S. Residents:**

This publication has been approved by RBC Capital Markets, LLC (member FINRA, NYSE, SIPC), which is a U.S. registered broker-dealer and which accepts responsibility for this report and its dissemination in the United States. Any U.S. recipient of this report that is not a registered broker-dealer or a bank acting in a broker or dealer capacity and that wishes further information regarding, or to effect any transaction in, any of the securities discussed in this report, should contact and place orders with RBC Capital Markets, LLC.

**To Canadian Residents:**

This publication has been approved by RBC Dominion Securities Inc.(member IIROC). Any Canadian recipient of this report that is not a Designated Institution in Ontario, an Accredited Investor in British Columbia or Alberta or a Sophisticated Purchaser in Quebec (or similar permitted purchaser in any other province) and that wishes further information regarding, or to effect any transaction in, any of the securities discussed in this report should contact and place orders with RBC Dominion Securities Inc., which, without in any way limiting the foregoing, accepts responsibility for this report and its dissemination in Canada.

**To U.K. Residents:**

This publication has been approved by RBC Europe Limited ('RBCEL') which is authorized by the Prudential Regulation Authority and regulated by the Financial Conduct Authority ('FCA') and the Prudential Regulation Authority, in connection with its distribution in the United Kingdom. This material is not for general distribution in the United Kingdom to retail clients, as defined under the rules of the FCA. However, targeted distribution may be made to selected retail clients of RBC and its affiliates. RBCEL accepts responsibility for this report and its dissemination in the United Kingdom.

**To Persons Receiving This Advice in Australia:**

This material has been distributed in Australia by Royal Bank of Canada - Sydney Branch (ABN 86 076 940 880, AFSL No. 246521). This material has been prepared for general circulation and does not take into account the objectives, financial situation or needs of any recipient. Accordingly, any recipient should, before acting on this material, consider the appropriateness of this material having regard to their objectives, financial situation and needs. If this material relates to the acquisition or possible acquisition of a particular financial product, a recipient in Australia should obtain any relevant disclosure document prepared in respect of that product and consider that document before making any decision about whether to acquire the product. This research report is not for retail investors as defined in section 761G of the Corporations Act.

**To Hong Kong Residents:**

This publication is distributed in Hong Kong by RBC Capital Markets (Hong Kong) Limited and Royal Bank of Canada, Hong Kong Branch (both entities which are regulated by the Hong Kong Monetary Authority ('HKMA') and the Securities and Futures Commission ('SFC')). Financial Services provided to Australia: Financial services may be provided in Australia in accordance with applicable law. Financial services provided by the Royal Bank of Canada, Hong Kong Branch are provided pursuant to the Royal Bank of Canada's Australian Financial Services Licence ('AFSL') (No. 246521). RBC Capital Markets (Hong Kong) Limited is exempt from the requirement to hold an AFSL under the Corporations Act 2001 in respect of the provision of such financial services. RBC Capital Markets (Hong Kong) Limited is regulated by the HKMA and the SFC under the laws of Hong Kong, which differ from Australian laws.

**To Singapore Residents:**

This publication is distributed in Singapore by the Royal Bank of Canada, Singapore Branch, a registered entity granted offshore bank licence by the Monetary Authority of Singapore. This material has been prepared for general circulation and does not take into account the objectives, financial situation, or needs of any recipient. You are advised to seek independent advice from a financial adviser before purchasing any product. If you do not obtain independent advice, you should consider whether the product is suitable for you. Past performance is not indicative of future performance. If you have any questions related to this publication, please contact the Royal Bank of Canada, Singapore Branch. Royal Bank of Canada, Singapore Branch accepts responsibility for this report and its dissemination in Singapore.

**To Japanese Residents:**

Unless otherwise exempted by Japanese law, this publication is distributed in Japan by or through RBC Capital Markets (Japan) Ltd., a registered type one financial instruments firm and/or Royal Bank of Canada, Tokyo Branch, a licensed foreign bank.

® Registered trademark of Royal Bank of Canada. RBC Capital Markets is a trademark of Royal Bank of Canada. Used under license.

Copyright © RBC Capital Markets, LLC 2015 - Member SIPC  
Copyright © RBC Dominion Securities Inc. 2015 - Member CIPF  
Copyright © RBC Europe Limited 2015  
Copyright © Royal Bank of Canada 2015  
All rights reserved