

Biotechnology

Flexion Therapeutics, Inc. (FLXN) - BUY

Price: **\$18.98**
Fair Value Estimate: \$25.00
52-Week Range: \$13.00-\$20.85
Market Cap (MM): \$294
Shr.O/S-Diluted (mm): 15.5
Average Daily Volume: NA

FYE: Dec	2013E	2014E	2015E
EPS:	\$(2.69)E	\$(3.42)E	--
Prior EPS:	NC	NC	NC
P/E:	NA	NA	--

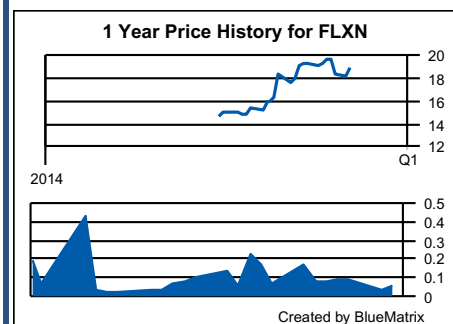
Quarterly EPS:

	2013E	2014E	2015E
Q1	\$(0.75)E	\$(0.43)E	--
Q2	\$(0.75)E	\$(0.57)E	--
Q3	\$(0.75)E	\$(0.67)E	--
Q4	\$(0.51)E	\$(0.77)E	--

FYE: Dec	2013E	2014E	2015E
Revenue (M):	\$0.0E	\$0.0E	--

Quarterly Revenue (M):

	2013E	2014E	2015E
Q1	\$0.0E	\$0.0E	--
Q2	\$0.0E	\$0.0E	--
Q3	\$0.0E	\$0.0E	--
Q4	\$0.0E	\$0.0E	--



Equity Research
Basic Report

FLXN: Initiate with a BUY Rating, \$25 FV: FX006 Spells Relief

INVESTMENT CONCLUSION:

We are initiating coverage on Flexion Therapeutics (FLXN) with a Buy rating and a \$25 fair value. FLXN is a specialty pharmaceutical company focused on the development and commercialization of novel, long-acting, injectable pain therapies with anti-inflammatory properties. The lead product candidate is FX006, a first-in-class injectable, sustained-release, intra-articular (IA) steroid treatment for patients with moderate to severe osteoarthritis (OA) pain. FX006 has successfully completed a clinical Phase 2b dose-ranging trial in which it demonstrated clinically meaningful and significantly better pain relief compared to the current injectable standard of care. A confirmatory Phase 2b trial is expected to initiate in 2Q14. We see FLXN as a de-risked product candidate that could be a potential market leader with the opportunity to quickly expand its proprietary delivery system and deliver long-term growth.

KEY POINTS:

- Fills a gap left open by current IA steroid and IA HA therapies:** Within the OA therapy space there is an obvious gap to be filled between IA steroid injections that have a powerful analgesic effect at first, but significantly reduces after several weeks and Hyaluronic acid (HA) that has a duration of months but has debatable efficacy. It is our opinion that FX006 offers the best of both worlds, with both efficacies in pain relief as well as a long duration of relief.
- Targets significant and growing markets:** OA is the most common form of arthritis in the country. This is not surprising as an aging and heavier US adult population drives up the prevalence. There are more than 27M US adults with OA and of those, 11M have symptomatic knee OA with approximately 3.1M receiving an IA steroid injection and an additional 1.3M receiving an IA HA injection. It is predicted that by 2030, between 60M-72M will develop OA in the US. Currently, HA market leader SYNVISIC sells just over \$500M annually, having not been endorsed by the American Academy of Orthopedic Surgeons in its recent treatment guidelines for OA.
- De-risked and straightforward path to FDA approval.** FLXN plans to utilize the 505(b)(2) regulatory pathway with FX006 as both triamcinolone acetonide (TCA) and PGLA are well known substances with a long history with the FDA. This should mean an accelerated path to FDA approval. The confirmatory Phase 2b for FX006 is expected to initiate in 2Q14 with top-line data in 1Q15. A Phase 3 trial is scheduled to initiate in 3Q15 with read-out in 3Q16. The NDA for FX006 is expected in late 2016/early2017.
- Initiate with a Buy rating, \$25 fair value.** We value FLXN at \$25/share based on a sum-of-the-parts with FX006 sales of \$20/share based on a 3.5x multiple of 2019 US sales discounted 5 years at 45% to account for risks remaining in this program. Our remaining \$5/share value is based on cash (end 2014) and technology value.

Research Analyst Certifications and Important Disclosures
are on pages 19 - 21 of this report

Summary and Investment Thesis

We are initiating coverage on Flexion Therapeutics (FLXN) with a Buy rating and a \$25 fair value. FLXN is a specialty pharmaceutical company focused on the development and commercialization of novel, long-acting, injectable pain therapies with anti-inflammatory properties. The lead product candidate is FX006, a first-in-class injectable, sustained-release, intra-articular (IA) steroid treatment for patients with moderate to severe osteoarthritis (OA) pain. FX006 has successfully completed a clinical Phase 2b dose-ranging trial in which it demonstrated clinically meaningful and significantly better pain relief compared to the current injectable standard of care. A confirmatory Phase 2b trial is expected to initiate in 2Q14. We see FLXN as a de-risked product candidate that could be a potential market leader with the opportunity to quickly expand its proprietary delivery system and deliver long-term growth.

Top Three Reasons to Own FLXN:

- 1) Fills a gap left open by current IA steroid and IA HA therapies:** Within the OA therapy space there is an obvious gap to be filled between IA steroid injections that have a powerful analgesic effect at first, but significantly reduces after several weeks and Hyaluronic acid (HA) that has a duration of months has debatable efficacy. It is our opinion that FX006 offers the best of both worlds, with both efficacies in pain relief as well as a long duration of relief.
- 2) Targets significant and growing markets:** OA is the most common form of arthritis in the country. This is not surprising as an aging and heavier US adult population drives up the prevalence. There are more than 27M US adults with OA and of those, 11M have symptomatic knee OA with approximately 3.1M receiving an IA steroid injection and an additional 1.3M receiving an IA HA injection. It is predicted that by 2030, between 60M-72M will develop OA in the US. Currently, HA market leader SYNVISCO sells just over \$500M annually, having not been endorsed by the American Academy of Orthopedic Surgeons in its recent treatment guidelines for OA.
- 3) De-risked and straightforward path to FDA approval.** FLXN plans to utilize the 505(b)(2) regulatory pathway with FX006 as both triamcinolone acetonide (TCA) and PGLA are well known substances with a long history with the FDA. This should mean an accelerated path to FDA approval. The confirmatory Phase 2b for FX006 is expected to initiate in 2Q14 with top-line data in 1Q15. A Phase 3 trial is scheduled to initiate in 3Q15 with read-out in 3Q16. The NDA for FX006 is expected in late 2016/early 2017.

Upcoming potential catalysts

EXHIBIT 1

Event	Expected Timing
FX006 PK Study Data	2Q14
FX006 Confirmatory Phase 2b Trial Initiation	2Q14
FX007 PoC Bunionectomy Trial Initiation	3Q14
FX006 Repeat-dose/LT Safety Trial Initiation	4Q14
FX006 Confirmatory Phase 2b Trial Top-Line Results	1Q15
FX007 PoC Bunionectomy Trial Top-Line Results	2Q15

Source: Janney estimates

Valuation

We value FLXN at \$25/share fair value based on a sum-of-the-parts. We value the US sales of FX006 for osteoarthritis pain at \$20/share based on a 3.5x multiple of 2019 US sales of \$540M discounted 5 years at 45%. Our remaining \$5/share value is based on cash (end 2014) and technology value.

EXHIBIT 2

Sum-of-the-parts value: Flexion		
Segment	Valuation (000's)	Per share value
FX006 value	\$294,941	\$20.0
Cash (end '14) & tech value	\$67,524	\$5.0
SUM	\$362,465	\$25
Shares out '14E (000)		14,746

Source: Janney estimates

Company Description:

Flexion Therapeutics is a development stage specialty pharmaceutical company that is focused on the development and commercialization of novel, long-acting, injectable pain therapies. Its lead product candidate is FX006, which is a first-in-class intra-articular (IA) injectable, sustained-released steroid for patients with moderate to severe osteoarthritis pain. FX006 has successfully completed a Phase 2b dose-ranging clinical study demonstrating clinically meaningful better pain relief compared to the current injectable standard of care. A Phase 2b is expected to be initiated in 2Q14 to further identify a safe and well tolerated dose.

Additional pipeline products include FX007, which is a small molecule TrkA receptor antagonist for the persistent relief of post-operative pain. FX007 has been effective in preclinical models of OA and post-operative pain. FLXN plans to initiate a Proof of Concept (PoC) bunionectomy clinical trial in 2H14.

Lastly is FX005, which is a p38 MAP kinase inhibitor formulated to use the microspheres for sustained-release and delivered locally using injection. FX005 has completed two Phase 2a clinical trials successfully demonstrating positive effects in pain and was well-tolerated.

What is Osteoarthritis?

Osteoarthritis (OA) is the most common form of arthritis and is a degenerative joint disease, which means that there is a slow progression of the disease over time. OA mostly affects the cartilage of a joint. Healthy cartilage allows bones to glide over one another at the joint and absorbs energy from the impact of physical movement. In OA, the surface layer of cartilage breaks down and wears away, allowing the bones to directly rub together. This rubbing can cause pain, swelling and loss of motion of the actual joint itself. Over time, the joint may lose its normal shape.

OA can severely depreciate the quality of life of sufferers by effecting daily activities. OA can cause weakness and disability as well as interfere with the ability to work. Eventually OA can lead to joint replacement, which is not only a costly procedure but one that requires additional support through physical therapy.

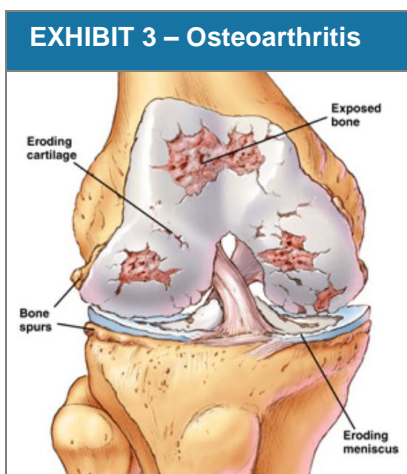
Stages of OA:

As OA is a slow progressive disease, it is categorized into several phases:

Stage 0: Classified as "normal" knee health. The knee shows no signs of OA and the joint functions without any impairment or pain.

Stage 1: At this stage, a person is showing very minor bone spur growth. Likely a person at Stage 1 OA is not experiencing any pain or discomfort as a result of the very minor wear on the components of the joint.

Stage 2: This is considered a "mild" stage. X-rays of the knee joint can reveal greater bone spur growth, but the cartilage likely remains at a healthy size. Synovial fluid is also typically still present at sufficient levels for

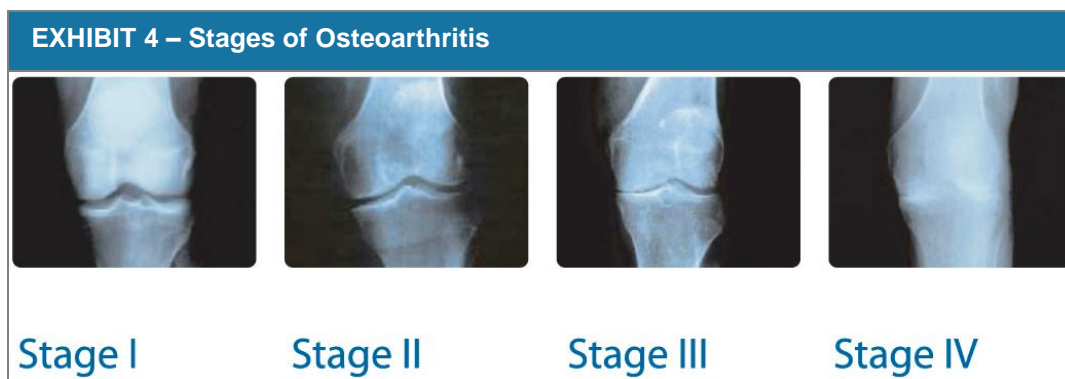


Source: kneecenters.com

normal joint motion. This is the stage at which people may first begin to experience symptoms such as pain after a long day or exercise and stiffness if joint is not used for several hours.

Stage 3: At this stage, OA is considered “moderate”. The cartilage between the bones is showing obvious damage and the space between the bones is narrowing. Individuals with Stage 3 are likely experiencing joint stiffness after sitting for long periods of time or when waking up in the morning. Joint swelling may also be present after extended periods of motion.

Stage 4: Stage 4 is considered severe. Individuals with Stage 4 OA of the knee are experiencing a great deal of pain and discomfort when walking or moving the joint. The space between the joint has been greatly reduced – the cartilage is almost gone, leaving the joint **still** and potentially immobile. The synovial fluid is dramatically reduced, and it no longer helps to reduce the friction among the moving parts of the joint.



Source: medicalgrapevineasia.com

Patient Population:

The prevalence of OA in the US population is quite high with an estimated 27 million adults with OA in the US in 2005. Of that 27 million, 11 million had symptomatic knee OA. The number of adults with OA is estimated to increase to between 60 million to 72 million by 2030.

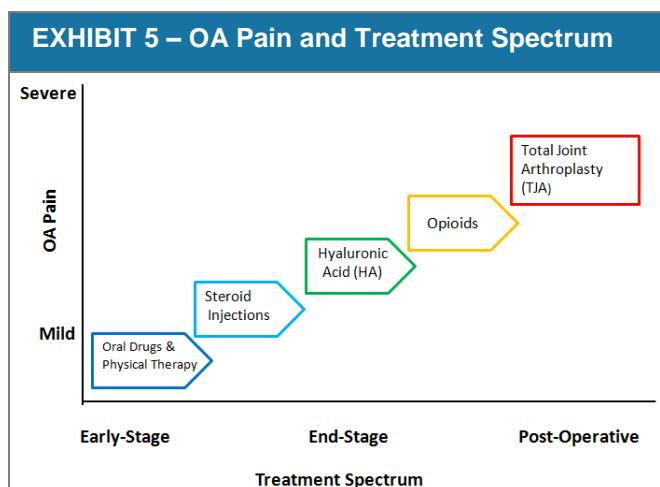
Breaking this down even further, according to IMS Heath data, in 2012 the number of patients that received a diagnosis of osteoarthritis of the knee was ~12 million, with approximately 3.1 million of that 12 million receiving not only the OA diagnosis but also an intra-articular steroid injection. This was a 12% increase from the previous year. FLXN also estimates that there are approximately 1.3 million individuals who received intra-articular knee injections of hyaluronic acid (HA), which is only approved for the knee.

Current Standard of Care for OA:

Treatment for OA is fairly linear in nature do the nature of the disease. The general goals of treatment are to reduce pain and improve function of the affected joint. Most often, this is done through a mixture of physical measures as well as drug therapy.

Stage 0-1 – At the initial onset of OA and through the first two stages, there is only minor discomfort to the sufferer. Recent guidelines from the American Academy of Orthopedic Surgeons (AAOS) recommend lifestyle changes such as strength training, exercise, physical therapy as well as weight loss for patients with BMI ≥ 25 . As the disease progresses, over-the-counter medications can be used such as acetaminophens and progressing to NSAIDs. Patients also have the option to move to prescription strength as well as other COX II inhibitors, topical NSAIDs or Cymbalta, those these are not without certain undesired side effects.

Though acupuncture, bracing, massage or transcutaneous electric nerve stimulation (TENS) are available options for treatment, there is inconclusive evidence of any medical benefit.



Source: company presentation

Stage 2-3 – Once the symptoms and pain of OA are moderate to severe, certain intra-articular injections become options such as corticosteroids and hyaluronic acid also known as viscosupplementation. Steroids are a first line IA therapy. Steroid injections have been shown to provide short-term relief lasting between four to eight weeks. These injections are usual given with a local anesthetic to ensure that the correct area has been injected. Repeat injections are possible at the same joint, but usual practice is limited to four injections annually.¹

Though there has been recent debate about the effectiveness of viscosupplementation, a recent Conchrane review concluded that it was an effective treatment, relieving pain and improving joint function for up to four months.² The cost however may be prohibitory, though reimbursable, at ~\$900 per treatment.

There have been head-to-head trials of corticosteroid injections versus hyaluronic acid. A meta-analysis of knee injections found that corticosteroids had a better short-term response rate and were equal to hyaluronic acid in the intermediate four- to eight-week range, but were inferior to hyaluronic acid after eight weeks from the time of injection³. Therefore, in patients with flare-ups, a corticosteroid may be preferred due to its better short term outcomes where as a hyaluronic acid may be more appropriate for chronic OA pain.

Stage 4 – At stage 4, IA injections with pain reliever are no longer adequate to control pain. As a last resort, doctors can prescribe opioids, though there is the risk of development of dependence and abuse. Surgery is reserved for patients whose symptoms have not responded to any treatments. The standard for indication for surgery is continued pain and disability despite treatment. Though somewhat effective, with 80% patients satisfied with their outcome, total knee replacements are expense with the average cost between \$23,700 and \$35,000, not counting the rehabilitation services.

Current Limitations with Treatments:

The current OA treatments are not complete. Many of the over-the-counter drugs or prescription drugs offer pain relief, but have serious side effects such as liver toxicity, GI bleeding and cardiovascular events. Even once these loose effectiveness, opioids may offer pain relief, but the risks of dependence, addiction or abuse are great.

IA therapies such as steroids and HA are well-tolerated but are known to provide pain relief that is either insufficient or inadequate in duration.

Currently, all IA therapies approved for OA are immediate-release. While this approach does initially deliver a large analgesic impact on the joint, there are serious potential side effects. With a steroid injection, the quick elevation of blood glucose could be a concern if the patient is diabetic. Remember that being overweight or obesity is a risk factor for OA with new research indicating that 30% of overweight individuals and 50% of those who are obese have diabetes, though this number may be conservative.

EXHIBIT 6 – Current OA Therapies with Serious Side Effects

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 (elderly)
INTRA-ARTICULAR: (joint injection)	Steroids	Limited duration of effect (waned after 2 – 4 weeks)	Generally well tolerated
	Hyaluronic acid (HA)	AAOS: "cannot recommend using HA" because of "lack of efficacy" ¹	Generally well tolerated

¹American Academy of Orthopedic Surgeons, "Treatment of Osteoarthritis of the Knee," Evidence-Based Guideline, 2nd Edition, May 18, 2013

Source: company presentation

¹ Bettencourt RB, Linder MM. Arthrocentesis and therapeutic joint injection: an overview for the primary care physician. *Prim Care*. 2010;37(4):691–702

² Bellamy N, Campbell J, Robinson V, Gee T, Bourne R, Wells G. Viscosupplementation for the treatment of osteoarthritis of the knee. *Cochrane Database Syst Rev*. 2006;(2):CD005321

³ Bannuru RR, Natov NS, Obadan IE, Price LL, Schmid CH, McAlindon TE. Therapeutic trajectory of hyaluronic acid versus corticosteroids in the treatment of knee osteoarthritis: a systematic review and meta-analysis. *Arthritis Rheum*. 2009;61(12):1704–1711

With the current IA steroid injections, pain relief is usually felt within the first few weeks, but wanes away. The current standard of practice, as noted before is that IA steroid injections are to be given once every three months, leaving many patients dissatisfied and in pain.

Intra-articular HA injections or viscosupplementation, which are only approved for treatment in the knee, are still under debate with some medical bodies claiming efficacy lasting months while others claim only marginally benefit. In recent treatment guidelines for OA of the knee published in May 2013 by the AAOS concluded that current published studies do not show any clinically effective response to HA injections and as such, the guidelines do not recommend HA treatment for symptomatic knee OA.

The Flexion Difference: FX006

The lead product candidate is FX006, which is a first-in-class, sustained release, intra-articular steroid injection for patients with moderate to severe OA of the knee. The key to FX006 is the delivery system, which is encapsulated triamcinolone acetonide (TCA) in poly lactic-co-glycolic acid (PGLA) microspheres. These particles, once injected into the joint, slowly dissolve into carbon dioxide and water, thus slowly releasing the drug directly into the joint. This makes FX006 unique in that it can deliver a controlled, sustained-release steroid directly to the joint for patients suffering from OA.

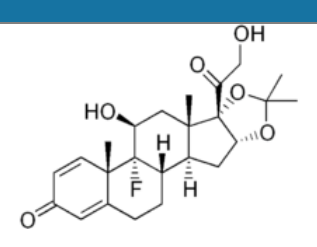
What is TCA?

Triamcinolone acetonide is an FDA approved generic immediate-release injectable synthetic corticosteroid. This active pharmaceutical is well known to the FDA and has many years of clinical safety and efficacy data behind it.

What is PGLA?

Poly(lactic co-glycolic acid) is a copolymer that is biodegradable through hydrolysis into lactic acid and glycolic acid. These two byproducts are easily dealt with in the body as they are also the byproducts of many metabolic pathways. The FDA has approved PGLA in a host of drug delivery platforms or medical devices, ranging from micro particles and liquids to implants.

Exhibit 7: TCA



Source: wikipedia

Clinical Trials:

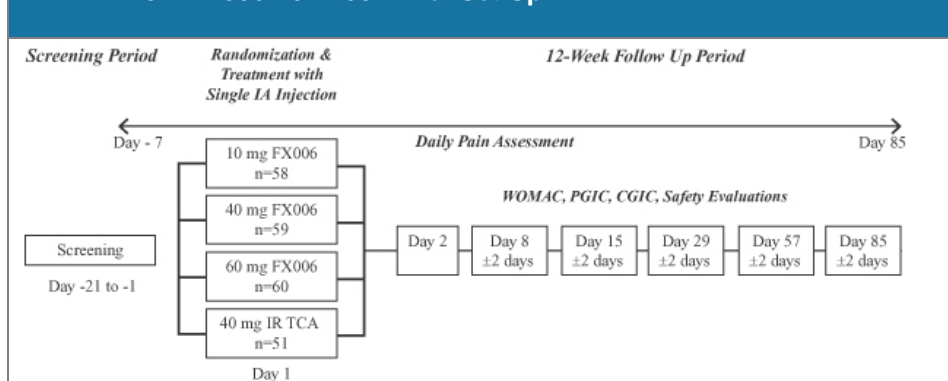
FX006 has completed two clinical trials, a Phase 2a to establish pharmacokinetics and pharmacodynamics and a Phase 2b dose-ranging clinical trial.

FX006-2011-001:

This was a Phase 2b dose-ranging clinical trial conducted in 22 sites in Australia, Canada, and the US consisting of 228 patients with knee OA that looked to assess safety, tolerability, and efficacy. The objective of the study was to identify a safe and well-tolerated dose of FX006 that demonstrated superiority in magnitude and duration of pain relief to immediate-release TCA, the standard of care.

229 patients were randomized and 228 patients were treated with a single IA injection of 10, 40, or 60mg of FX006 or 40mg of immediate-release TCA. Each patient was evaluated for a total of 12 weeks. The primary outcome measure was the weekly mean of the average daily pain intensity score as assessed using an 11-point numerical scale, with zero being “no pain” and 10 being “pain as bad as you can imagine”. The primary efficacy endpoint was the change from baseline to each of the weeks 8, 10 and 12 for that outcome measure. Secondary endpoints included change from baseline in the primary outcome measure for each week not addressed in the primary endpoint, time to onset of analgesia, responder status, pain, stiffness and function measured using the WOMAC, PGIC, and CGIC.

EXHIBIT 8 – FX006-2011-001 Trial Set Up



Source: company presentation

The Missed Primary Endpoint:

FX006-2001-001 missed its primary endpoint. As this was a dose-ranging study, the statistical analysis assumed that the magnitude of pain relief would increase with dose. That was not the case as the 60mg dose primary outcome measure and secondary outcome measure did not represent a material improvement over the 40mg dose. After Week 6 the 60mg dose was numerically inferior to the 40mg dose.

The Explanation:

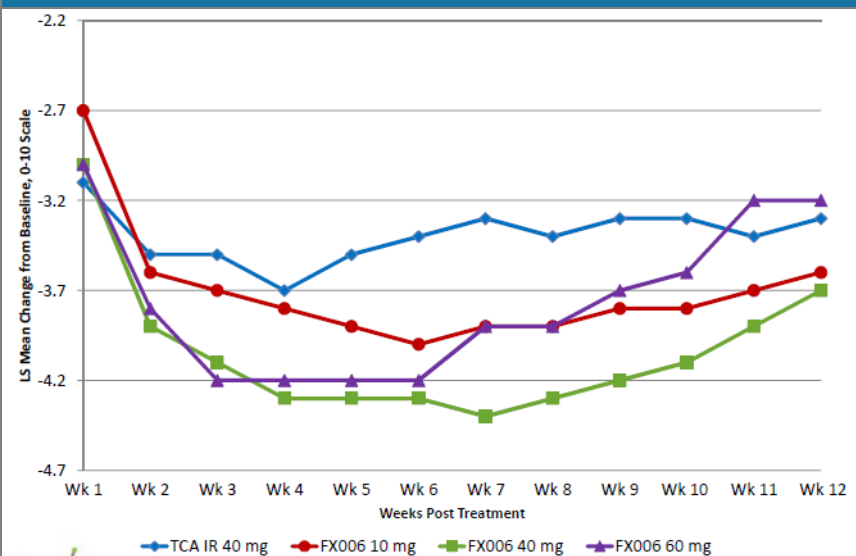
In order to increase the dosage of FX006, one must increase the number or concentration of PGLA microspheres within the suspension solution. For example, to go from 10mg to 40mg, there is 4x the number of microspheres. A known

phenomenon in PGLA microspheres is that of aggregates, or clumping that can occur when there are too many spheres in the environment. The kinetics between the particles is suboptimal generating an environment in which the microspheres actually degrade faster, causing premature release of TCA. FLXN believes that it was this clumping phenomenon that caused the poor performance of FX006 at 60mg.

The Phase 2b Results:

Treatments arms were well-balanced with regards to demographic and baseline characteristics, with the baseline average daily pain score of 6.4 to 6.6. FX006 at 40mg dose was significantly better than the immediate-release TCA at improving pain relief beginning at Week 5 and continuing to Week 10 ($p < .05$ at each time point). FX006 60mg dose demonstrated significant improvement as well compared to immediate-release TCA over a longer period of time, from Week 1 to Week 12 ($p = 0.0382$). Even the 10mg dose produced a result that was a consistent improvement over the TCA.

EXHIBIT 9– Weekly Mean of Ave. Daily Pain Intensity Scores



Source: company presentation

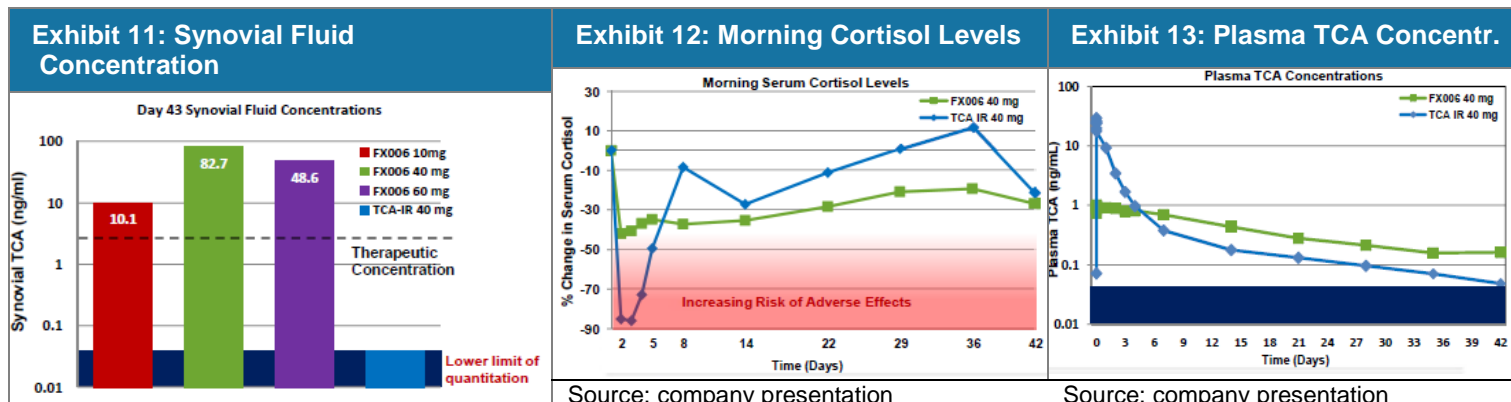
EXHIBIT 10:

Phase 2b: FX006-2011-001	
Aim	Safety, efficacy and pharmacokinetics of FX006 in patients with osteoarthritis of the knee
Design	Double-blind, randomized, parallel group receiving a single IA injection of 10, 40 or 60mg of FX006 or 40mg of TCA
Dosing	Single IA injection of 10, 40 or 60mg of FX006 or 40mg of TCA with evaluation of 12 weeks.
Endpoints	1 ^o : Change from Baseline to each of Weeks 8, 10 and 12 in weekly mean of the average daily (24-hour) pain intensity score. 1 ^o : Incidence of treatment emergent adverse events 2 ^o : Change from Baseline to each of Weeks 1, 2, 3, 4, 5, 6, 7, 9 and 11 in weekly mean of the average (24-hour) pain intensity score 2 ^o : Time of onset of pain relief 2 ^o : Continuous responder at each study week 2 ^o : WOMAC A, A1, B C and total change from Baseline at 1, 2, 4, 8 and 12 weeks 2 ^o : Percent of responders according to OMERACT-OARSI criteria 2 ^o : Change in patient's and clinical observer's global impression of change scores 2 ^o : Average weekly and total consumption of rescue medications 2 ^o : Pharmacokinetic profile
Patients	N = 229
Results	Missed on primary endpoint due to 60mg FX006 not providing increased magnitude of pain relief. FX006 at 40mg was significantly better than IR-TCA in improving pain relief from Week 5-Week 10 ($p < .05$) FX006 at 40mg demonstrated significant improvement over IR-TCA in ave. change from baseline from Week 1-Week 12 ($p = 0.0382$)

Source: Company Reports and Janney estimates

FX006-2011-002:

The Phase 2a clinical trial was a multi-center, randomized, double-blind trial with 24 patients with OA looking at the PK/PD profiles of FX006. Patients were randomized to a single IA injection of 10, 40, or 60mg of FX006 or 40mg of immediate-release TCA. Each patient was evaluated for a total of six weeks after treatment. Measurements were taken from plasma drug concentration as well as cortisol during one 48-hour in-patient period, two 24-hour periods at days 14-15 and days 42-43, and seven out-patient visits at days 3,4,5,8,22,29 and 36.



The Results:

The synovial fluid concentrations reinforced the idea that the microspheres clumped and degraded early at the 60mg dose as was theorized by the FX006-2011-001 trial. In the 002 results, the 40mg dose concentration had a higher concentration than the 10mg dose, but not the 60mg dose as less drug would have been present at Day 42 due to the premature degradation. The immediate-release TCA produced a concentration that was at the lower limit of the measureable quantitation. Overall, results supported prolonged therapeutic effect.

Cortisol is a steroid hormone naturally produced by the body that plays a central role in blood sugar metabolism and in the body's response to stress. Measurements of the morning serum cortisol showed that the immediate-release TCA 40mg dose reduced the serum cortisol levels by almost 90%. These kinds of levels could potentially product adverse events in patients, especially those who are diabetic. FX006 at 40mg, on the other hand, produced approximately a 40% reduction in serum levels and remained relatively stable.

Lastly, the plasma concentrations show the immediate-release TCA produced maximal plasma concentrations that were 30-fold higher than 40mg of FX006. This makes sense as TCA is an immediate-release delivery system, but it also opens the door for unwanted side effects. FX006 produced less of a spike, which means that there is the potential for a reduction in systemic side effects.

EXHIBIT 14

Phase 2b: FX006-2011-001	
Aim	Safety, efficacy and pharmacokinetics of FX006 in patients with osteoarthritis of the knee
Design	Double-blind, randomized, parallel group receiving a single IA injection of 10, 40 or 60mg of FX006 or 40mg of TCA
Dosing	Single IA injection of 10, 40 or 60mg of FX006 or 40mg of TCA with evaluation of 12 weeks.
Endpoints	1 ^o : Change from Baseline to each of Weeks 8, 10 and 12 in weekly mean of the average daily (24-hour) pain intensity score. 1 ^o : Incidence of treatment emergent adverse events 2 ^o : Change from Baseline to each of Weeks 1, 2, 3, 4, 5, 6, 7, 9 and 11 in weekly mean of the average (24-hour) pain intensity score 2 ^o : Time of onset of pain relief 2 ^o : Continuous responder at each study week 2 ^o : WOMAC A, A1, B C and total change from Baseline at 1, 2, 4, 8 and 12 weeks 2 ^o : Percent of responders according to OMERACT-OARSI criteria 2 ^o : Change in patient's and clinical observer's global impression of change scores 2 ^o : Average weekly and total consumption of rescue medications 2 ^o : Pharmacokinetic profile
Patients	N = 229
Results	Missed on primary endpoint due to 60mg FX006 not providing increased magnitude of pain relief. FX006 at 40mg was significantly better than IR-TCA in improving pain relief from Week 5-Week 10 ($p < .05$) FX006 at 40mg demonstrated significant improvement over IR-TCA in ave. change from baseline from Week 1-Week 12 ($p = 0.0382$)

Source: Company Reports and Janney estimates

Continued Path Forward:

Confirmatory Phase 2b: FLXN plans to initiate a confirmatory Phase 2b clinical trial in the 2Q14 to further identify a safe and well tolerated dose of FX006. Instead of a head to head with a comparator, the FDA has asked that this trial be compared to placebo. With the results seen from the direct head-to-head trial of FX006 to immediate release TCA, it is our opinion that getting a positive result from a placebo based trial is a very de-risked prospect.

The Phase 2b trial will be a multi-center, randomized, double-blind study with approximately 400 patients with OA of the knee. Patients will be randomized and treated with a single injection of FX006 (multiple doses will be tested) or placebo and will be evaluated for up to 26 weeks. The primary endpoint will be the weekly means of the average daily pain intensity score as assessed by using an 11-point numerical scale with secondary endpoints including WOMAC, PGIC, CGIC and responder status. Results from this trial would be expected 1H15.

Repeat Dose Phase 2a: In November of 2013, a Phase 2a clinical trial was initiated to establish the duration of exposure to TCA from FX006 in the joint through synovial fluid PK. This trial will help to determine the time to repeat dose safely. This is a multi-center, open-label study in up to 40 patients with OA of the knee with patients being assigned to one of five groups to receive a single FX006 IA injection of either 10 or 40mg. Synovial fluid will be collected on the day before treatment administration and again at weeks 12, 16 or 20. This trial is fully enrolled and should read out later in the 1H14.

Once this has been completed, a repeat dose one year safety study will be initiated in 2H14 with anticipated top-line data in 2016.

The Pivotal Phase 3:

Lastly, after an end of Phase 2 meeting is conducted with the FDA, a pivotal Phase 3 study is expected to initiate in late 2H15.

Faster Path to Approval Through 505(b)(2) Trials

FLXN plans to utilize the 505(b)(2) regulatory pathway with FX006, as its active pharmaceutical is already well known to the FDA as well as the PGLA component. This should mean an accelerated, less expensive path to FDA approval.

ADDITIONAL PIPELINE:

FX007 and Post Operative Pain:

Pain and surgery tend to go hand in hand and postoperative pain is a substantial market of the overall pain marketplace at \$5.9B in 2010. A recent study indicated that there are over 46 million inpatient⁴ and 53 million outpatient⁵ surgeries are performed in the US annually. According to the updated Practice Guidelines developed by the American Society of Anesthesiologists, the current standard for surgical pain management is a multimodal approach. This would consist of administration of two or more drugs that act on different pain mechanisms.

Post-surgical pain is usually administered via IV and is usually a product containing mu-opioids such as oxycodone, oxycodone and hydrocodone. But these therapies have unwanted risks such as respiratory depression, constipation, as well as development for tolerance, which can lead to addiction and abuse. Non-opioid therapies can be limiting due to their limited efficacy and side effects such as liver toxicity, bleeding, serious GI complications including ulcers, kidney damage, and even more serious cardiovascular thrombotic events such as stroke and heart attack.

FX007- the TrKA receptor antagonist:

FX007 is for persistent relief of acute post-operative pain to be administered locally. FX007 is a small molecule TrKA receptor antagonist with no PGLA formulation. TrKA is the receptor for nerve growth factor (NGF), a small peptide that is released following tissue injury. NGF binds to TrKA on the surface of pain sensing neurons and renders these cells more responsive to external stimuli.

Recent clinical trials have shown that systemic blockage of NGF demonstrated marked analgesia in a variety of painful conditions. Added to that, human genetic studies have demonstrated that patients with a mutation in the TrKA gene have congenital insensitivity to pain. Data indicates that interruption of the NGF-TrKA pathway

⁴ National Center on Addiction and Substance Abuse

⁵ International Association for the Study of Pain

produces profound analgesic effect. To that end, FX007 has demonstrated both a high affinity for the TrKA receptor and analgesic effects in OA and post-operative pain. However, FX007 is not for chronic or sustained use as systemic and persistent blockage of NGF has been associated with rapidly progressive OA requiring TJA.

Usually delayed or uncontrolled post-operative pain can lead to complications and delay recoveries. Getting pain under control after post-operative total joint arthroplasty (TJA) is relevant as successful recoveries are linked to getting patients into rehabilitation. The less pain a patient is in, the sooner the patient can begin therapy and recovery.

Path Forward for FX007:

FLXN has conducted preclinical Proof of Concept studies and demonstrated efficacy in both OA and post-operative pain models. FLXN expects to request a pre-IND meeting with the FDA in the 1H14 with the IND filing in 1H14 as well. A Proof of Concept clinical trial initiation is also expected in the 2H12.

FX005 and End Stage OA Pain

The last pipeline compound is FX005 for end-stage OA pain. FX005 is a p38 MAP kinase inhibitor formulated for sustained-release delivered via IA injection using microspheres. With this localized delivery system, FX005 is designed to have both analgesic and anti-inflammatory benefits without the systemic side effects of oral p38 MAP kinase inhibitors.

p38 MAP kinase is an enzyme in an inflammatory cascade that upregulates in response to stress and culminates in the elaboration of multiple proinflammatory cytokines, including interleukin 1 and tumor necrosis factor, as well as enzymes like matrix metalloproteinases that have potential to destroy cartilage.

Clinical Trials:

Phase 2a: FX005 has completed a Phase 2a clinical trial in which 70 patients were randomized to FX005 and 70 patients were randomized to placebo. The Phase 2a clinical trial demonstrated positive effects of FX005 on both pain and function. These effects increased substantially in a sub-population of patients with higher baseline pain scores.

Phase 2a - FX005-2011-001: A Phase 2a clinical trial in 140 patients with knee OA was conducted as a multi-center, randomized, double-blind, placebo-controlled trial and consisted of a single ascending dose phase, or SAD Phase, followed by a single dose PoC Phase. In the SAD Phase of the study, escalating doses of 1, 10, and 45 mg of FX005 were compared to blank PLGA microspheres and diluent in three cohorts of twelve patients, with six patients receiving FX005, three patients receiving blank PLGA microspheres and three patients receiving diluent in each cohort. Diluent is a placebo containing all components of the FX005 formulation except the active drug and the PLGA microspheres. Each patient in the SAD Phase was followed for safety and pharmacokinetics for six weeks after a single IA injection. FX005 was well-tolerated at each dose level and, as a result, the highest dose of 45 mg was advanced to the next phase.

Proof of Concept: In the PoC Phase, 52 patients were randomized to receive 45 mg of FX005, 26 patients were randomized to receive blank PLGA microspheres as a placebo control, and 26 patients were randomized to receive diluent as a placebo control, each as a single IA injection. Each patient was followed for 12 weeks after the injection for safety, pharmacokinetics, and efficacy. The primary endpoint was the change from baseline in the WOMAC pain subscale at four weeks. Secondary efficacy assessments included the WOMAC function subscale and responder status. FX005 demonstrated pain relief and functional improvement at four weeks, and the absolute magnitude of effect in both subscales was persistent through 12 weeks. These effects were substantially enhanced in a prespecified exploratory subset analysis of patients with high baseline pain. FX005 also demonstrated efficacy in responder analysis. Overall, FX005 was well-tolerated systemically and local tolerability was similar to that documented for marketed HA preparations.

Repeat dose toxicology studies demonstrated that FX005 can be associated with synovial inflammation, articular cartilage damage and alterations to joint structure. These findings were not present in animals treated with blank PLGA microspheres so toxicity appears to be specific to the p38 MAP kinase inhibitor itself. To guide the appropriate future development path for FX005, additional toxicology studies using lower doses of FX005 were conducted to determine the appropriate dose level.

These additional toxicology studies show that at the human equivalent dose of 3 and 1 mg, there was no evidence of the damage to cartilage that had been associated with doses greater than or equal to 10 mg. Based

on this, we expect that any further development of FX005, if any, would involve a dose substantially lower than the doses studied in the previously-conducted Phase 2a clinical trial.

The Phase 2 trial monitored 53 patients who were who were randomized to a single intra-articular injection of 45 mg of FX005, blank microspheres, or diluent. The primary endpoint was change in WOMAC pain score from baseline to 4 weeks post treatment. Flexion combined both placebo arms for the analysis of the data as both groups met pre-specified criteria for similarity. Unfortunately, the primary endpoint was not met, and there was not a statistically significant difference between the placebo groups and FX005 group at 4 weeks. The p value was 0.0535, very close to the commonly accepted value for significance of 0.05. A sub-analysis of patients with a higher baseline pain score demonstrated a significant difference between placebo and FX005 ($p = 0.024$). With efficacy being the major issue for the AAOS and HA, Flexion will need to find a subset of patients or use a better dosing structure to improve the efficacy in their upcoming Phase IIb trial expected to launch in 2014.

Management

Michael D. Clayman, M.D., Co-Founder and CEO – Dr. Clayman is a co-founder and has served as President, Chief Executive Officer, and as one of the directors since inception in 2007. Previously, Dr. Clayman had a lengthy career at Eli Lilly and Company, a global pharmaceutical company, where he was most recently Vice President, Lilly Research Laboratories, and General Manager of Chorus, Lilly's early-phase development accelerator. During his career at Lilly, Dr. Clayman also led its Global Regulatory Affairs division, the Cardiovascular Discovery Research and Clinical Investigation, Research and Development at Advanced Cardiovascular Systems, a medical device subsidiary of Lilly, the Internal Medicine Division, the Lilly Clinic, Lilly's dedicated Phase 1 unit, and served as Chair of Lilly's Bioethics Committee. Prior to his tenure at Lilly, Dr. Clayman was an Assistant Professor in the School of Medicine at the University of Pennsylvania, where his research centered on the immunopathogenesis of renal disease. Dr. Clayman is the recipient of the Physician Scientist Award from the National Institutes of Health. Dr. Clayman earned a B.A., cum laude, from Yale University and an M.D. from the University of California, San Diego School of Medicine. Following an internship and residency in Internal Medicine at the University of California, San Francisco Moffitt Hospitals, Dr. Clayman completed clinical and research fellowships in Nephrology at the University of Pennsylvania.

Neil Bodick, M.D, PhD, Co-Founder & Chief Medical Officer – Dr. Bodick is a co-founder and has served Chief Medical Officer since inception in 2007. Previously, Dr. Bodick was at Eli Lilly and Company, where he founded Chorus and served as Chief Medical Officer and Chief Operating Officer. Prior to that, Dr. Bodick was responsible for early-phase clinical investigation at Lilly Research Laboratories. Dr. Bodick also was Assistant Professor in the School of Medicine at the University of Pennsylvania, where his research centered on the development of computer-based systems to support image-intensive diagnosis. Dr. Bodick holds 13 patents in the areas of neuroscience and computer science and is the recipient of the Biomedical Research Service Award and the New Investigator Research Award from the National Institutes of Health. Dr. Bodick earned an A.B. from Cornell University, a Ph.D. in neuroscience from Columbia University, an M.D. from the Albert Einstein College of Medicine and an M.B.A. from the Wharton School of the University of Pennsylvania.

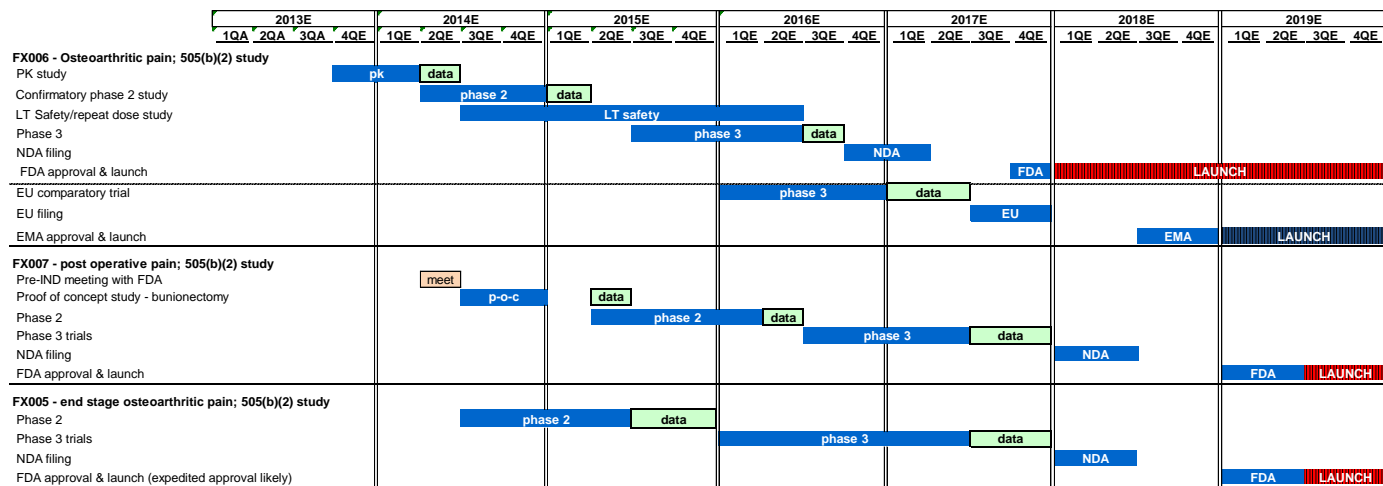
Art Fratafico Chief Business Officer – Mr. Fratafico has served as Chief Business Officer since June 2012. Prior to joining FLXN, Mr. Fratafico led the business development efforts, including overseeing numerous licensing transactions and acquisitions, at private biotechnology companies including Trevena, Inc. from 2011 to 2012, Gemin X Pharmaceuticals, Inc. from 2008 to 2011 and MGI Pharma, Inc. from 1999 to 2008. Mr. Fratafico earned a bachelor's degree in pharmacy from the Philadelphia College of Pharmacy and an M.B.A. from Drexel University.

Fred Driscoll, Chief Financial Officer – Mr. Driscoll has served as Chief Financial Officer since May 2013. Prior to joining FLXN, Mr. Driscoll was Chief Financial Officer at Novavax, Inc., a publicly traded biopharmaceutical company since 2009. Previously, Mr. Driscoll also served as Chief Financial Officer from 2007 to 2008, and subsequently Chief Executive Officer from 2008 to 2009, at Genelabs Technologies, Inc., a publicly traded biopharmaceutical and diagnostics company, Chief Financial Officer at Astraris, Inc., a private biotechnology company, from 2006 to 2007, and Chief Executive Officer at OXiGENE, Inc., a biopharmaceutical company, from 2002 to 2006. Mr. Driscoll earned a bachelor's degree in accounting and finance from Bentley University.

Lisa Davidson, MBA, Vice President of Finance and Administration - Ms. Davidson has more than 20 years of broad corporate finance experience encompassing treasury management, strategic planning, operations finance, and controllership. Most recently, she served as Director of Finance at OmniSonics Medical Technologies, Inc.. Prior to that, she served in various finance, strategy and administration positions at Fisher Scientific International, Inc., Pepsi Bottling Group, and PerkinElmer Inc. Ms. Davidson has been involved in a number of M&A transactions, venture debt and equity financing totaling \$90 million, and numerous product launches. She holds a BA and an MBA, both from the University of New Hampshire.

Flexion

Clinical development trial timelines



Specialty Pharmaceuticals

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Source: Company reports and Janney estimates

Flexion

Quarterly income statement

	2012 Year	2013E				2013E Year	2014E				2014E Year
		1QA	2QA	3QA	4QE		1QE	2QE	3QE	4QE	
(\$000 except per share)											
Revenues											
FX006 - OA pain											
FX007 - post operative pain											
FX005 - end stage OA pain											
Total Revenue											
Expenses:											
Cost of Revenue (COGS)	-										
Gross Margin	-	-	-	-	-	0	-	-	-	-	0
Research and development	11,065	2,950	2,950	2,942	3,000	11,842	4,000	6,000	7,500	8,900	26,400
General and administrative	3,947	1,788	1,788	1,788	1,850	7,214	2,250	2,350	2,500	2,750	9,850
Total operating expenses	15,012	4,738	4,738	4,729	4,850	19,055	6,250	8,350	10,000	11,650	36,250
Income (loss) from Operations	(15,012)	(4,738)	(4,738)	(4,729)	(4,850)	(19,055)	(6,250)	(8,350)	(10,000)	(11,650)	(36,250)
Interest income (expense), net	194	(39)	(39)	(39)	(40)	(157)	(25)	(25)	(25)	(25)	(100)
Other income (exp)	(164)	(64)	(64)	(64)	(65)	(257)	(50)	(50)	(50)	(50)	(200)
Income (loss) before taxes	(14,982)	(4,841)	(4,841)	(4,832)	(4,955)	(19,469)	(6,325)	(8,425)	(10,075)	(11,725)	(36,550)
Income tax exp (benefit)	-	-	-	-	-						
Net Income (Loss)	(14,982)	(4,841)	(4,841)	(4,832)	(4,955)	(19,469)	(6,325)	(8,425)	(10,075)	(11,725)	(36,550)
Earning per Share (EPS)	(\$3.39)	(\$0.75)	(\$0.75)	(\$0.75)	(\$0.51)	(\$2.69)	(\$0.43)	(\$0.57)	(\$0.67)	(\$0.77)	(\$2.44)
Adj EPS ex-1x & non-cash items											
Weighted avg. shares (000)	4,417	6,416	6,416	6,416	9,741	7,248	14,746	14,896	15,046	15,196	14,971

Specialty Pharmaceuticals

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Source: Company reports and Janney estimates

Flexion

Annual income statement

(\$000 except per share)	2013E	2014E	2015E	2016E	2017E	2018E	2019E	Comments
Revenues								
FX006 - OA pain						\$199,887	\$540,141	FDA approval 1Q18
FX007 - post operative pain							15,000	FDA approval 2H19
FX005 - end stage OA pain							8,000	FDA approval 2H19
Total Revenue	\$0	\$0	\$0	\$0	\$0	\$199,887	\$563,141	
Expenses:								
Cost of Revenue (COGS)	-	-	-	-	-	29,983	84,471	
Gross Margin	-	-	-	-	-	169,904	478,670	
R&D	11,842	26,400	43,000	37,000	30,000	30,000	45,000	
G&A	7,214	9,850	10,800	12,800	15,000	45,000	83,250	100 person sales team
Total op exp	19,055	36,250	53,800	49,800	45,000	75,000	128,250	
Inc/(loss) from Ops	(19,055)	(36,250)	(53,800)	(49,800)	(45,000)	94,904	350,420	
Int income (exp), net	(157)	(100)	(100)	(100)	(100)	(100)	(99)	
Other expenses, net	(257)	(200)	(200)	(200)	(200)	(200)	(199)	
Inc/(loss) before taxes	(19,469)	(36,550)	(54,100)	(50,100)	(45,300)	94,604	350,122	
Income tax exp (benefit)	-	-	-	-	-	-	87,530	
Net Income (Loss)	(\$19,469)	(\$36,550)	(\$54,100)	(\$50,100)	(\$45,300)	\$94,604	\$262,591	
Earning per Share	(\$2.69)	(\$2.44)	(\$3.42)	(\$2.93)	(\$2.44)	\$3.77	\$9.61	
Weighted avg. shares (000)	7,248	14,971	15,821	17,071	18,571	20,071	21,821	
Fully diluted shares (000)	-	16,721	18,571	20,071	22,071	25,071	27,321	

Source: Company reports and Janney estimates

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Flexion

Balance sheet

(\$000's except per share)	<u>2011A</u>	<u>2012A</u>	<u>2013E</u>	<u>2014E</u>	<u>2015E</u>	<u>2016E</u>
ASSETS:						
Current assets						
Cash and cash equivalents	3,357	12,835	11,460	42,240	55,570	4,880
Marketable Securities	7,185	16,548	7,600			
Deferred Issuance Costs IPO			1,300			
Prepaid expenses and other	266	488	300			
Other						
Total current assets	10,808	29,872	20,660	42,240	55,570	4,880
PP&E	72	64	400	450	500	550
Other assets	28	42	50	50	55	60
Total Assets	10,939	30,008	21,240	51,890	65,775	15,640
			9,380	9,200	9,705	10,210
LIABILITIES						
Total current liabilities	1,785	2,725	5,500	6,000	6,500	7,000
Long-term debt			4,000	3,000	2,000	1,000
Total liabilities	1,785	2,725	9,500	9,000	8,500	8,000
Shareholders Equity						
Conv. Pref Stock (Series A & E	41,836	74,806				
Common	4	6	79	79	79	79
Additional paid-in-capital	308	444	79,106	146,806	215,291	215,756
Other comp income	1	2	1	1	1	1
Accumulated deficit	(32,995)	(47,976)	(67,445)	(103,995)	(158,095)	(208,195)
Total shareholders' equity	(32,682)	(47,523)	11,741	42,891	57,276	7,641
Total liabilities & net worth	10,939	30,008	21,241	51,891	65,776	15,641

Source: Company reports and Janney estimates

Flexion

Statement of cash flows

(\$000's except per share)	<u>2011A</u>	<u>2012A</u>	<u>2013E</u>	<u>2014E</u>	<u>2015E</u>	<u>2016E</u>
<u>Operating Activities</u>						
Net Income (Loss)	(11,447)	(\$14,982)	(\$19,469)	(\$36,550)	(\$54,100)	(\$50,100)
Adjustments:						
Depreciation and Amortization	106	43	72	75	80	85
Derivative (loss) gain						
Accretion of debt discount						
Stock-based compensation expense	83	96	1,031	780	800	800
Changes in assets and liabilities	618	725	694	(1,000)	(1,000)	(1,750)
Net cash from operations	(10,350)	(13,980)	(17,479)	(36,545)	(54,070)	(50,815)
<u>Investing Activities</u>						
Purchase of equipment	(40)	(35)	(550)	(75)	(100)	(125)
Purchase of marketable securities	(16,815)	(28,466)	(20,018)			
Net cash from investing	(4,102)	(9,534)	11,148	(75)	(100)	(125)
<u>Financing Activities</u>						
Proceeds from borrowing under term loan	MidCap		5,000			
Payments of debt issuance costs		(21)	(41)			
Payments of IPO issuance costs			(54)			
Proceeds from issuance of Preferred Stock	13000	32,970				
Proceeds from common stock offerings				67,300	67,300	
Proceeds from stock options	-	42	50	100	200	250
Net cash from financing	13,000	32,991	4,955	67,400	67,500	250
Net change in cash	(1,452)	9,478	(1,376)	30,780	13,330	(50,690)
Cash at beginning of year	4,810	3,357	12,835	11,460	42,240	55,570
Cash at end of year	3,357	12,835	11,460	42,240	55,570	4,880

Source: Company reports and Janney estimates

RISKS TO FAIR VALUE ESTIMATE:

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

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

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

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

IMPORTANT DISCLOSURES

Research Analyst Certification

I, Kimberly Lee, the Primarily Responsible Analyst for this research report, hereby certify that all of the views expressed in this research report accurately reflect my personal views about any and all of the subject securities or issuers. No part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views I expressed in this research report.

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Flexion Therapeutics, Inc. currently is, or during the past 12 months was, a Janney Montgomery Scott LLC client. Janney Montgomery Scott LLC, provided investment banking related services.

Janney Montgomery Scott LLC managed or co-managed a public offering of securities for Flexion Therapeutics, Inc. in the past 12 months.

Janney Montgomery Scott LLC received compensation for investment banking services from Flexion Therapeutics, Inc. in the past 12 months.

Janney Montgomery Scott LLC intends to seek or expects to receive compensation for investment banking services from Flexion Therapeutics, Inc. in the next three months.

The research analyst is compensated based on, in part, Janney Montgomery Scott's profitability, which includes its investment banking revenues.

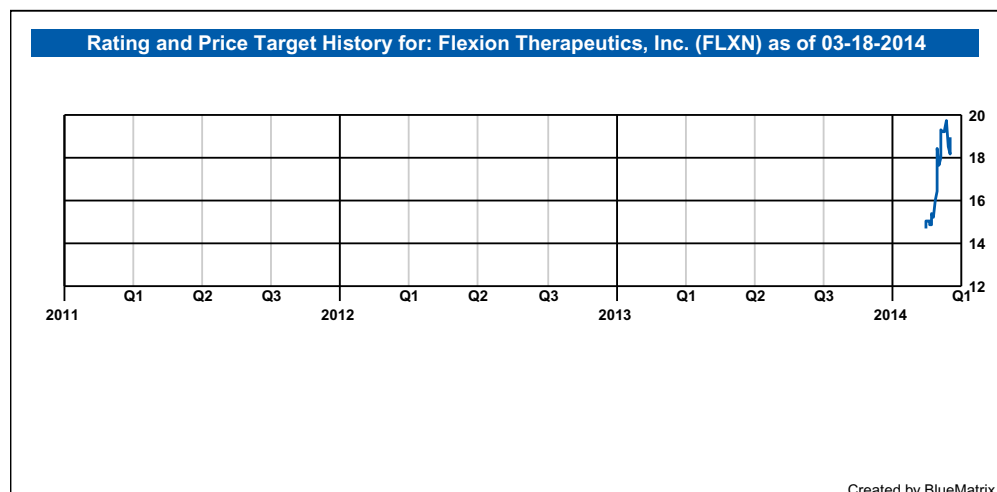
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BUY: Janney expects that the subject company will appreciate in value. Additionally, we expect that the subject company will outperform comparable companies within its sector.

NEUTRAL: Janney believes that the subject company is fairly valued and will perform in line with comparable companies within its sector. Investors may add to current positions on short-term weakness and sell on strength as the valuations or fundamentals become more or less attractive.

SELL: Janney expects that the subject company will likely decline in value and will underperform comparable companies within its sector.

Price Charts



Janney Montgomery Scott Ratings Distribution as of 12/31/13

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [B]	247	53.00	30	12.10
NEUTRAL [N]	211	45.50	13	6.20
SELL [S]	7	1.50	0	0.00

***Percentages of each rating category where Janney has performed Investment Banking services over the past 12 months.**

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