

Flexion Therapeutics

(FLXN-NASDAQ)

Stock Rating: Outperform Industry Rating: Outperform

March 10, 2014

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Initiating With Outperform; Osteoarthritis Knee Pain Treatment

Investment Thesis

We are initiating coverage of Flexion Therapeutics with an Outperform rating and a \$33 price target. Flexion is a specialty pharmaceutical company developing injectable pain therapies targeting the osteoarthritis (OA) pain treatment spectrum. We believe that Flexion's lead product, a sustainedrelease steroid injection (FX006), could be a game changer in the treatment of osteoarthritic knee pain. Each year in the US there are approximately 3 million immediate-release steroid injections in the knee to alleviate OA knee pain. The current immediate-release steroid provides relief for only several weeks, while Flexion's FX006 has duration of approximately three months. We expect FX006 to enter Phase III studies in 1H15 and, if approved, reach the market in 2017. In this report we provide some of the results of our physician surveys on Flexion's FX006 - the physician feedback has been very positive, with 70% of polled physicians calling FX006 "a great advance" or stating that they would "prescribe this heavily." Physicians also indicated that they would use FX006 off-label for back, hip, and shoulder pain. Flexion has two other promising earlier-stage pipeline programs (FX007 and FX005) that we discuss in our report, but we consider these largely free options for our valuation consideration.

Forecasts & Valuation

Our forecasts are risk adjusted and do not include any off-label use. We forecast an 8.5% US market share in 2020 and peak US market share of 20%, half of physicians' indicated use of the product. We forecast FX006 sales of approximately \$357 million in 2020 and peak sales of more than \$1 billion. Our DCF valuation results in a \$33 price target, or approximately 72% from today's price. Our DCF extends to 2021 and uses a 20% weighted-average cost of capital and a 10x terminal value.

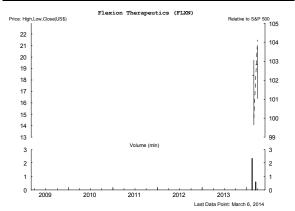
Recommendation

We are initiating coverage with an Outperform rating and a \$33 price target.

Securities Info

Price (7-Mar)	\$19.26	Target Price	\$33.00
52-Wk High/Low	\$21/\$14	Dividend	
Mkt Cap (mm)	\$283	Yield	
Shs O/S (mm, BASIC)	14.7	Float O/S (mm)	14.4
Options O/S (mm)	na	ADVol (30-day, 000s)	182

Price Performance



Valuation/Financial Data

(FY-Dec.)	2012A	2013E	2014E	2015E
EPS GAAP	na	na	-\$3.41	-\$2.78
P/E		na	na	na
FCF	na	na	-\$3.41	-\$2.84
P/FCF		na	nm	nm
EBITDA (\$mm)	na	na	-\$51	-\$47
EV/EBITDA		na	nm	nm
Rev. (\$mm)	na	na	\$0	\$0
Quarterly EPS	1Q	2Q	3Q	4Q
2012A	na	na	na	na
2013E	na	na	na	na
Balance Sheet Data (30-Sep)				
Net Debt (\$mm)	-\$16	TotalDebt/EBITDA		na
Total Debt (\$mm)	\$5	EBITDA/IntExp		na
Net Debt/Cap.	nm	Price/Book		-4.6x

Notes: All values in US\$.

Source: BMO Capital Markets estimates, Bloomberg, Thomson Reuters, and IHS Global Insight.

Key Points

Flexion, headquartered in Burlington, MA, is a clinical stage specialty pharmaceutical company developing injectable pain therapies targeting the osteoarthritis (OA) pain treatment spectrum, from moderate to severe pain to improve safety and prolong pain relief.

A Potential Game Changing Treatment for Osteoarthritic Knee Pain...and More

Flexion's lead program is FX006, a sustained-release steroid being studied for the treatment of osteoarthritis knee pain. Flexion's FX006 is a sustained-release version of the most commonly injected steroid (triamcinolone acetonide or TCA) and has the potential to last approximately 12 weeks versus the current immediate-release (IR) steroid, which lasts only several weeks. In the US there are approximately three million injections of immediate-release steroids for OA knee per year. Because treatment guidelines dictate that patients should not be injected more than once every three months with immediate-release steroids, many patients have extended periods of pain between injections, often turning to opioids and other pain relief medications.

We believe that if approved, FX006 has the opportunity to be a game changer and could rapidly replace immediate-release steroid injections. In addition, based on our extensive physician surveying, we believe that if FX006 is approved for OA knee pain, it will be used in many other areas such as shoulders, backs, hips, ankles, and necks, and for wrist pain, including carpal tunnel syndrome, and these off-label uses may be larger in aggregate than the on-label use. FX006 is in Phase II testing, and we expect it, if approved, to reach the market in 2017.

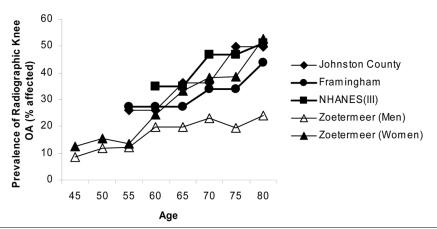
Osteoarthritis is a large and growing market, sitting at the nexus of two macro healthcare trends – the aging of America and the rising obesity epidemic – both leading factors to increased incidence of osteoarthritis, especially of the knee. OA is a leading cause of disability that affects more than 27 million adults in the US, and its prevalence increases with age. Osteoarthritis is a highly prevalent joint disorder estimated to affect more than 37% of adults over the age of 60, and it is a leading cause of pain and disability (*Third National Health and Nutrition Examination Survey 1991–94*. J Rheumatol 2006; 33:2271–2279).

Aging is a risk factor for OA knee. Between 2010 and 2020, the population is expected to increase by approximately 10%, but the number of people aged 65 and older will rise by approximately 36%. It is estimated that between 2010 and 2050, the population will grow by 40%; however, the number of people 65 and older will more than double.

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Exhibit 1: Prevalence of Radiographic Knee OA



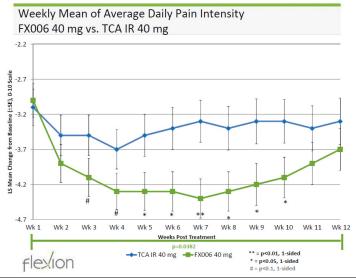
Source: NIH

Obesity is a leading cause of OA knee. Obesity rates are rising rapidly, especially among older Americans. In 2001, 31% of men aged 65–74 were obese; by 2009 it was 43%. Data from the first National Health and Nutrition Examination Survey (HANES I) indicated that obese women had nearly four times the risk of knee OA as compared with non-obese women. For obese men, the risk was nearly five times greater (Anderson J, Felson DT: Factors associated with osteoarthritis of the knee in the First National Health and Nutrition Examination (HANESI). *Am. J. Epidemiol.* 1988; 128:179-189). If all overweight and obese people reduced their weight by 5 kg or until their BMI was within the recommended normal range, 24% of surgical cases of knee OA (95% CI 19%-27%) might be avoided (Int J Obes Relat Metab Disord. 2001 May; 25(5):622-7).

So far, the data Flexion has generated on FX006 has been positive. FX006 40 mg showed statistically significantly better pain relief versus TCA IR 40mg. Flexion expects to initiate a confirmatory Phase IIb clinical trial in 2Q14 and a planned repeat dose safety clinical trial in 2H14 with a one-year follow-up. Flexion anticipates starting Phase III studies in 2H15 and a launch is expected in 2H17.

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Exhibit 2: FX006 40 mg - Significant Pain Relief vs. TCA IR 40 mg

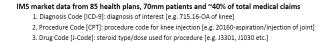


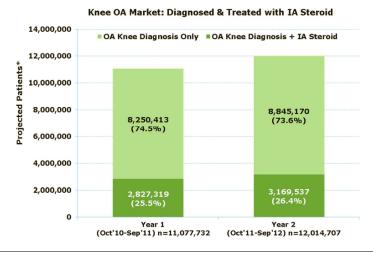
Source: Company presentation, December 2013.

Lower-than-average development risk, in our opinion. We believe that Flexion's approach is somewhat de-risked given the steroid and the drug delivery components are already known and approved. As Flexion is working on a known steroid, we do not expect to see any unusual side effects or toxicities (and have not so far), which is something that can occur when working with a new chemical entity.

Established market. In 2012, 3 million patients received steroid injections in the knee and another 8 million patients were diagnosed with knee OA.

Exhibit 3: FX006 Commercial Opportunity: Knee OA Market





Source: Company presentation, December 2013.

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Significant potential for other indications/uses. Our physician checks indicate that if FX006 is approved, it would likely be used significantly off-label in shoulders, hips, backs, hands, tennis elbow, rotator cuffs, etc. This could be bigger than on-label use.

Flexion has two other promising drugs in development, but they are not in our valuation consideration in a significant manner. The second product in Flexion's pipeline is FX007, a locally administered TrkA receptor antagonist for persistent relief of post-operative pain. Flexion plans to file an Investigational New Drug Application for FX007 in the 1H14 and complete a proof of concept clinical trial in 2H14 with anticipated launch in 2020. Flexion's third pipeline program is FX005, an intra-articular, sustained-release p38 mitogen-activated protein (MAP) kinase inhibitor for end-stage OA. Phase IIb starts 1Q14 with a launch expected in 2021.

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Upcoming Catalysts

2Q14: Expected data from synovial pharmacokinetic clinical trial

2Q14: Initiate a confirmatory Phase IIb clinical trial for FX006

1H14: Filing of an Investigational New Drug Application for FX007

2H14: Initiate a planned repeat dose safety clinical trial for FX006

2H14: Initiate proof of concept trial for FX007

1H15: Deliver data of confirmatory Phase IIb trial for FX006

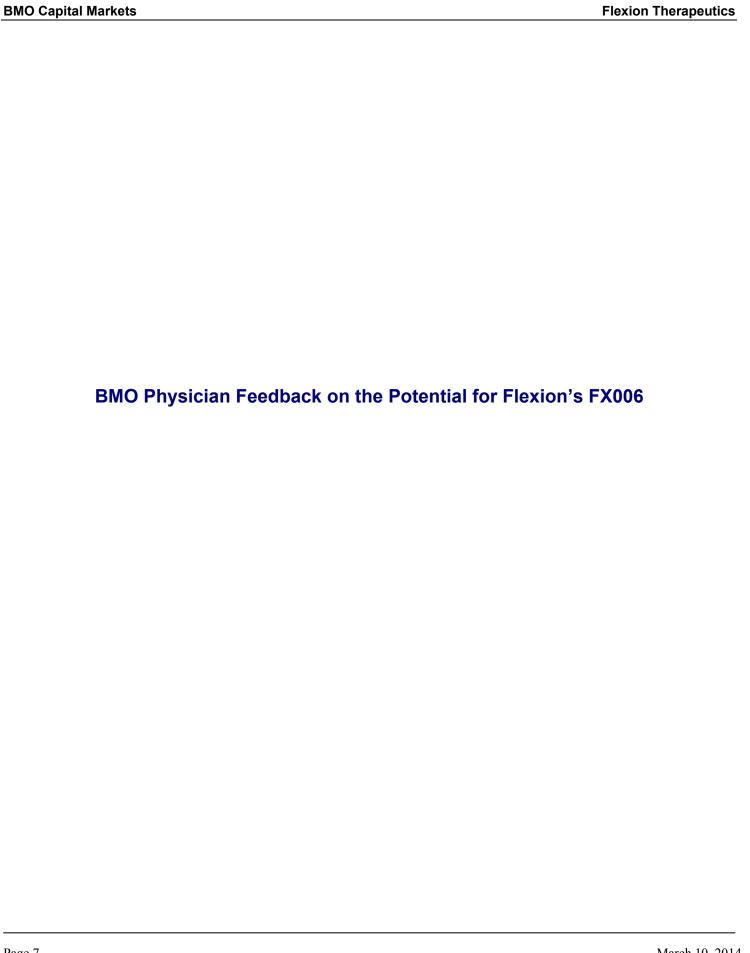
1H15: Deliver data of proof of concept trial for FX007

2H15: Initiate Phase III for FX006

2H17: Launch of FX006

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Physician Feedback on FX006 Is Very Positive

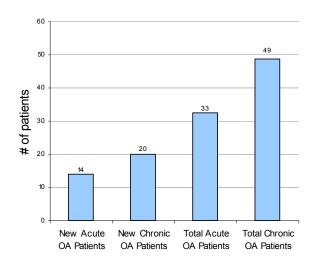
BMO has numerous physician interviews to help assess the potential commercial and clinical attractiveness of FX006. In support of this, we also conducted two surveys of orthopedic surgeons.

Overall, the interviews and survey results support strong adoption of FX006:

- 70% of physicians polled indicated that they thought FX006 is "a great advance" or that they would "prescribe this heavily."
- In our surveys, approximately 64% said they currently inject triamcinolone acetonide for chronic OA knee pain – a higher percentage presumably use other steroids and compounds.
- Physicians indicated that they would use FX006 in 32% of their patients in the first year it is on the market and in 49% of patients by year five on the market.

BMO's surveys indicated that the average surgeon treats 81 acute and chronic OA patients in a typical week of which 42% are new patients. Flexion has estimated that 69% of OA patients receive IA injections from orthopedic surgeons and 31% receive IA injections from rheumatologists.

Exhibit 4: How many acute and chronic OA knee pain patients do you treat in a typical week?



Source: Physician Survey by BMO Capital Markets

In one survey, 71% of the 28 physicians said they currently inject TCA for chronic knee. The majority of physicians are using steroid injections, Depo-Medrol for example, in the treatment of chronic knee OA. When asked for what percentage of their OA knee patients were receiving injections of TCA for chronic knee pain, the average response was 46%.

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Of the physicians surveyed, their treatment of chronic OA knee patients was consistent with the standard care of treatment with physicians citing oral drugs and physical therapy for early-stage OA ranging to total knee replacement for severe OA progression, although tremendous variation is seen.

Exhibit 5: How do you currently treat chronic OA knee pain patients?

Selected Responses

- Conservative measures including NSAIDs/Tylenol, physical therapy (PT), activity modifications, weight loss, group therapy, viscosupplementation, rarely narcotics, TKA
- NSAID, exercise, ice, bracing for activity, intra-articular steroid injection, viscosupplementation, and narcotics.
- Medication, weight loss, therapy, bracing, viscosupplemention, total knee replacement, Synvisc
- Activity modification, acetaminophen, weight loss, corticosteroid injection, Synvisc, TKA
- Meds, weight loss, viscosupplementation, knee replacement
- NSAIDs, COX-2, steroid inj., HA inj., physical Rx, bracing, total knee replacement
- NSAID (oral and topical), exercise/PT, bracing, corticosteroid injection, HA injection, knee replacement
- Education, NSAIDS, activity modification, steroid injection, exercise/PT. Rarely arthroscopic debridement. TKA
- Anti-inflammatory, pain medications, steroid injections, hyaluronic acid injections, PT, TKA
- Start with injection and PT. Then consider arthroscopy or arthroplasty
- Activity modification, exercise, PT, weight loss, NSAIDs, brace, injections, uni-compartmental knee arthroplasty, total knee arthroplasty
- Anti-inflammatory medicine first, exercises, then cortisone injection if indicated. Some qualify for viscosupplementation injections.
- NSAIDs, injections of Synvisc, Euflexxa, and last resort, surgery
- Analgesics, NSAIDs, cortisone injections, viscosupplements, chondro-protective agents, bracing (unloader)
- NSAIDs; PT, HA injections, cortisone injections, local NSAID
- First line is corticosteroid injection, followed by hyalgan, then TKA
- 1) NSAIDS, rest, assistive devices, PT, brace; 2) injections; 3) surgery (scope v. TKA)
- Anti-inflammatories, chondroitin/glucosamine, cortisone injections, brace, tramadol/Tylenol
- Various modalities, NSAID (OTC and Rx), PT, weight loss, activity modification, shoe wear, injections (various types), cane/crutches/walker, bracing
- Oral NSAIDS, steroid injections, viscosupplementation, arthroscopic debridement, knee braces
- Injections, anti-inflammatories and visco injections. Total knee if fails.
- Usually viscosupplementation or cortisone injections first-line NSAIDs if tolerated
- Corticosteroid injections, viscosupplementation, total joint replacement.
- First line of treatment is exercise, normally with a combination of NSAIDS. After the occurrence of that has worn off, prescription drugs are attempted. Knee replacement surgery is the last form of treatment.
- Stepwise fashion with NSAIDs and PT, followed by injections. Possibly with arthroscopy. TKA if these fail.
- If NSAIDs, physical therapy, activity modification, injections, and narcotics have failed, then TKA
- NSAIDs, Tylenol, steroid injections, weight loss, therapy, viscosupplementation, bracing
- Periodic cortisone injections, viscosupplementation, topical NSAIDS
- Non-impact exercises, weight loss, soft sole shoes, OTC NSAID, intermittent steroid injections
- Corticosteroid injection, activity modification, hyaluronic acid injection, PT, TKA
- NSAIDs, physical therapy including aqua therapy, corticosteroid injections, possibly visco-suppl. injections
- As conservatively as possible with NSAIDS, physical therapy, etc. If that doesn't work I use opioid analgesia.

Source: Physician Survey by BMO Capital Markets

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We asked physicians to look at some clinical data on FX006 and then tell us their initial reaction to the data. The responses were favorable, and the following is a summary of some of the responses:

Exhibit 6: Initial Reactions

- Very promising drug
- If, in fact, it is longer acting and sustained it would be a breakthrough
- Great
- Looks promising
- Looks like a better alternative to triamcinolone
- It may be helpful.
- Might be a very reasonable alternative to typical steroid injections
- Very positive. makes me want to know about a) cost, and b) possible infection-related complications
- Impressive results
- Sounds like an improvement to TCA IR
- Very appealing
- Excellent idea
- Impressive
- Sounds too good to be true
- Sounds encouraging
- Sounds good if it actually works
- Looks good. I'd try it.

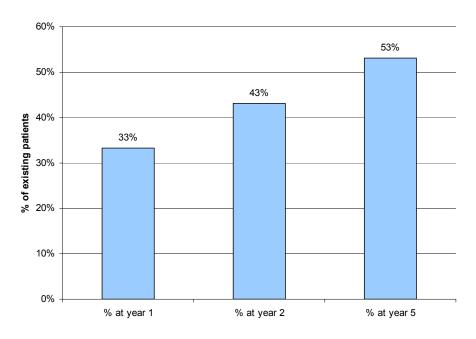
- Favorable
- Would be great to have less systemic affects, especially in diabetics
- Impressive. Would like to know cost comparison with traditional steroid.
- If it lasts longer, that's great.
- Could extend the duration of pain relief.
- Good idea allows for the longer-term treatment without the expense of multiple office visits
- A longer benefit would be tremendous
- A very long-lasting steroid sustained-release formulation is an excellent idea
- Sustained-release may provide longer relief
- I have been waiting for a long time for a more effective and new alternative to standard cortisone injections.
- I do a lot of injections, and this could be a great
- It seems like a huge step up from both steroids and HA
- I would like to see data. What is the minimum clinically important difference (MCID) for duration? One week? One month? One year?

Source: Physician Survey by BMO Capital Markets

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When we asked what their impression of actual use would be, our survey revealed that doctors would use FX006 for 33%, 43%, and 53% of their existing chronic OA knee patients in years one, two, and five, respectively.

Exhibit 7: What percentage of your existing chronic OA knee patients do you think you would use FX006 on for each of the following time periods below?



Source: Physician Survey by BMO Capital Markets

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When we asked physicians what were the top two single factors that would drive use of FX006, common responses listed price, efficacy, duration, and side effects. We believe that data on FX006 is good so far and that when priced at parity to existing treatments, the improved duration and fewer side effects of FX006 will drive additional use.

Exhibit 8: What would be the top two single factors that would drive your use of FX006, the new Flexion sustained-release steroid injection? If you say effectiveness, please specify by what measure.

Selected Responses

- Price to buy and long-term benefits
- Long-term relief and low-side-effect profile
- Effectiveness relative to pain/duration of pain relief and reduction in side effects compared with other steroids, viscosupplementation and NSAIDs
- Effectiveness compared with typical steroid injections, also can it be given more frequently
- Average duration of symptom relief (as compared with triamcinolone); and 2) cost
- Covered by insurance and works longer
- Longer duration of response, simple to administer
- Quick relief of symptoms less systemic effect
- Longer-term effectiveness and expense
- Insurance reimbursement and efficacy
- Duration of relief until another injection or other treatment is required. How well it is tolerated, potential adverse effects.
- More comparison data with other steroids and HA
- Rapid onset. Effective pain control and improved function.
- Better relief of pain by my patients' standards. Cheaper cost of product.
- Effectiveness in regard to quality of pain relief and duration of action, cost and formulary availability; also corporate decision as I am employed by a group
- Pain relief for substantial period of time, patient satisfaction
- Effectiveness by duration of clinically significant relief.
- Greater magnitude + longer duration of relief.
- Long acting and rapid onset of relief. Efficacy comparable to short-acting measures
- Longer benefit and hopefully less elevated glucose levels.
- Effective for at least five or six months and not cost prohibitive vs. generic steroid
- Effectiveness better than oral NSAIDs, or bracing duration of effect

- We have used it traditionally and find it cost effective based on percentage of patient responders
- Long-lasting pain relief, low side effects
- Long-term efficacy is greater, cost is reasonable from compounders
- More sustained relief reported by patients' favorable cost ease of instillation
- Double-blind studies that show decreased pain and increased function. Information about cost to the patient.
- Cost, ease of use, no insurance issues
- Elderly patient with medical comorbidities that prevent oral medication use and diabetes
- Lack of a flare response to the medication and duration of pain relief.
- Normal medication not working or reducing the pain at all, or the ability to specifically target the affected tissue by using the injection
- Temporary relief; unable to predict response
- Symptomatic relief, well-tolerated
- Lack of allergic reaction and decrease in pain score by at least 3 points on a visual analog scale
- I mostly use Celestone and when we run out of Celestone, I use Kenalog. I prefer Celestone because it is more powerful than Kenalog. So for me to use it more it would have to be as powerful and long-lasting as Celestone
- Request for a different steroid
- Short-term response, three months of effectiveness
- Duration of pain relief and lack of side effects
- Safe for intra-articular injections and soft tissue injections making its usage more universal than Depo-Medrol steroid medications
- Clinic availability and previous treatment for the knee pain
- Long-term safety, ability to provide analgesia for the patient without increasing demand for additional medication

Source: Physician Survey by BMO Capital Markets

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We also asked for which other indications they could see using FX006, the new Flexion sustained-release steroid injection. The results match well with our discussions with physicians, all of which indicated they would use FX006, if approved, in a large number of off-label areas.

Exhibit 9: What other indications do you think you would see using FX006, the new Flexion sustained-release steroid injection?

- Shoulder impingement, partial cuff tears. OA shoulder and hip
- All OA joints, especially back
- Degenerative hips, shoulders, elbows. Maybe even spine.
- Other joint chronic OA
- Other IA joint injections such as the basal joint of the thumb and the shoulder joint
- Similar to standard steroid injections
- Small joint injections -- hand and wrist, foot and ankle hip injections
- Synovitis, other joints. Chondromalacia
- Other joints for arthritis, post-op surgery
- Bursitis injection trigger finger, nerve root impingement
- Acute relief of chronic pain. Not as definitive treatment. Would not do within three months of anticipated OR date.

- Injection in other joints. Carpal tunnel injection.
- OA, RA, inflammatory arthritis, CTS
- Intra-articular hip injections
- Tenosynovitis or bursitis
- Intra-articular injections of other joints.
- Inflammatory forms of arthritis; gout, RA
- Chronic shoulder pain, adhesive capsulitis
- Other joints than the knee
- Adhesive capsulitis shoulder patients, epidural injections
- Rotator cuff tendinitis. Hip bursitis, tennis elbow
- Shoulder

Source: Physician Survey by BMO Capital Markets

Survey Results Summary

Both our survey work and our interviews with key opinion leading physicians indicate that if approved, FX006 would be used and rapidly take the place of IR TCA in the treatment of OA knee pain as well as other areas already being injected by doctors. Our forecasts do not include this sizable off-label use.

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A Closer Look at the Osteoarthritic Knee Market Opportunity

One in two Americans is expected to develop symptomatic knee OA.

Osteoarthritis, also referred to as OA or degenerative joint disease, is one of the most common forms of arthritis, affecting 27 million Americans, with numbers expected to grow as a result of aging, obesity, and sports injuries. OA is a chronic condition where the cartilage that cushions the joints breaks down and causes the bones to rub against each other, causing stiffness, pain and loss of joint movement.

There is no cure for OA; therefore, current treatments are intended to address symptoms, in particular relief of pain and improvement in functional status. Patients are being diagnosed with OA earlier in their lives, and many patients will require repeat total joint replacements.

Normal knee **OA** knee Femur one and cartilage Normal cartilage fragments Cartilage Joint fluid breaking down with high concentration **Eroded** of hyaluronan cartilage Joint fluid with low Meniscus concentration of hyaluronan **Normal bone Tibia** Fibula **Synovial** Osteophytes

Exhibit 10: Normal vs. OA Knee

Source: Company presentation, December 2013.

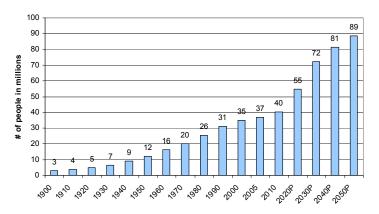
Flexion's treatment sits at the nexus of two macro trends an aging population and the obesity epidemic. According to the US Centers for Disease Control and Prevention, one in two Americans is expected to develop symptomatic knee OA, the most common form of OA, during their lifetimes.

Aging and obesity are major risk factors for knee OA. With the US population between the ages of 45 and 64 having increased 33% from 2000 through 2012 and accounting for 27% of the total population, we expect changing demographics will likely contribute to a growing number of OA patients.

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Exhibit 11: US Aging Population – Historical and Projected

US Population Aged 65 Years and Older

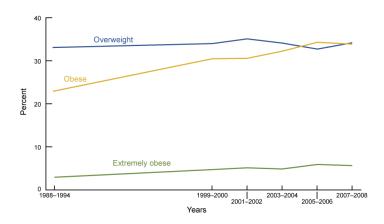


Source: US Census Bureau.

Obesity rates have been on the rise in the US over the past two decades and are at high levels, especially among older Americans. Approximately 36% of US adults are obese, which increases the risk of developing OA. In 2001, 31% of men aged 65–74 were obese; by 2009, it was 43%. Data from the first National Health and Nutrition Examination Survey (HANES I) indicated that obese women had nearly four times the risk of knee OA as compared with non-obese women. For obese men, the risk was nearly five times greater. If all overweight and obese people reduced their weight by 5 kg or until their BMI was within the recommended normal range, 24% of surgical cases of knee OA might be avoided.

Exhibit 12: US Trends in Overweight, Obesity and Extreme Obesity

Trends in overweight, obesity, and extreme obesity among adults aged 20 years and over: US, 1988-2008



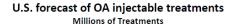
NOTES: Age-adjusted by the direct method to the year 2000 U.S. Census Bureau estimates, using the age groups 20–39, 40–59, and 60 years and over. Pregnant females were excluded. Overweight is defined as a body mass index (BMI) of 25 or greater but less than 30; obesity is a BMI greater than or equal to 30; extreme obesity is a BMI greater than or equal to 40.

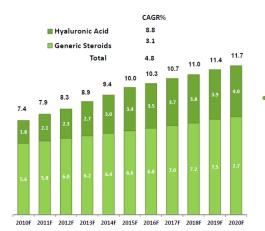
Source: CDC/NCHS, National Health and Nutrition Examination Survey III.

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Potential Front-Line IA Therapy in a Large and High-Growth Market

Exhibit 13: OA Market and Commercial Opportunity





- Injections are frequent and increasing
 - Specialist driven market
 - Straightforward procedure
 - · Well-established reimbursement
- Current products have limitations but usage continues to grow
 - Hyaluronic acid (HA) injections growing rapidly
 - Currently > \$1.8B worldwide, and >\$800M U.S. sales

Source: CDC; Millenium Market Research; US Census data; LEK analysis & interviews

Source: Company presentation, December 2013.

FX006 may reduce the need for additional analgesic therapy, lowering the cost and pill burden. Improved duration eliminates extra office visits and trips to the ER for continued discomfort and pain and can delay knee replacement surgeries. These benefits of FX006 support our view that reimbursement and payer acceptance will create a commercial opportunity for Flexion's suite of products.

We expect Flexion to benefit from continued growth in an already large US market as well as from global growth and potential additional indications for use. Of the 27 million patients in the US, 11 million have symptomatic knee OA, of which over 3 million have been treated with an IA steroid. Based on IMS data, Flexion has forecasted that an estimated 23.5 million of the 45 million OA patients will have knee OA by 2030. According to Centers for Disease Control (CDC) forecasts, injections are frequent and are expected to grow at a CAGR of 8.8% for hyaluronic acid and 3.1% for generic steroids from 2010 to 2020, representing a total CAGR of 4.8%. The IA injection market is driven by specialists and represents a straightforward procedure.

The cause of osteoarthritis is unknown. However, there are many factors that play a role in the development of OA. For example, incidences increase with age due to wear and tear on the joints. Increased body weight adds unnecessary stress to lower body joints, and recent research suggests that excess body fat produces chemicals that travel throughout the body and cause joint damage. Another group at higher risk of developing OA is athletes and people who have repetitive motion due to injury and increased stress on joints.

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Exhibit 14: OA – Large and Growing Market Opportunity (US)

> 100 Million Symptomatic OA patients in the 5 major markets



- Obesity, sports injuries, & aging drive prevalence (67MM in US with OA by 2030)
- Of the 27M patients in the US with OA, 11M have symptomatic knee OA
- Medical treatment inadequate as many patients ultimately require total knee replacements (TKR) – 1M TKR's in 2015

SOURCES: US: Arthritis Rheum (2008) 58: 26–35; Japan: J Bone Miner Metab (2009) 27:620–628; EU: groupH, 2010; IC: Models of Care in Arthritis (2010); J Bone Joint Surg Am. 2007;89:780-785, NIAMS estimates 2012; IMS Health Medical Claims 2011-12

Source: Company presentation, December 2013.

Established market with limited training required for physicians. In 2012, 3 million patients received steroid injections in the knee, an estimated 1.3 million patients received knee injections of HA and another 8 million patients were diagnosed with knee OA but didn't receive steroid or HA injections. Physicians are already administering steroid injections to this large population of patients so we do not expect the magnitude of lag that commonly occurs when physicians are learning new methods of administering drugs or treating patients in an unfamiliar fashion. In our survey of 55 orthopedic surgeons, they treated roughly 4,220 patients annually. We also asked what percentage of existing chronic OA knee patients they would treat with FX006 and the average response was approximately 50%.

OA is costly to payors, indicating that FX006 will likely secure coverage. Flexion has conducted multiple US payor assessments and believes that payors are seeking new therapies as OA is costly to insurers. Existing therapies (oral and IA) in the market are expensive, and we believe Flexion's products have better efficacy and offer potential medical savings, setting the stage for payor acceptance. Reimbursement codes for current injection therapies, expected to be used for FX006, are well known. Payors are willing to pay for drugs that extend magnitude and duration of pain relief – enter Flexion.

According to IMS data, HA therapy generated US sales of more than \$690 million in 2012, with an estimated cost to patient per treatment of \$500 to \$1,000, and provided only marginal pain relief over placebo. Worldwide, HA sales are approaching \$2 billion, and Flexion

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estimates that by 2030 approximately 23.5 million of the 45 million OA patients will have knee OA. In the HA market alone, we can fathom market share gains of 20% in the US, especially as the American Academy of Orthopedic Surgeons does not recommend HA treatment for symptomatic knee OA. As current OA therapies have limitations on pain relief and are often associated with side effects, FX006 will likely take share from growing hyaluronic acid and steroid treatments.

Other treatments are also very expensive; for example, total knee arthroplasty costs between \$25,000 and \$35,000 on average. In 2009, in-patient costs exceeded \$9 billion per year in the US for total knee arthroplasty alone, and some estimates indicated that the number of TKAs could increase sixfold between 2011 and 2030. An estimated 20% of patients are dissatisfied with the outcome of this costly procedure. As Flexion's products can delay TKA, we believe payors will reimburse the company's new OA therapies once approved.

Exhibit 15: Current OA Therapies

Туре		Efficacy	Toxicity
ORAL:	Acetaminophen	Limited pain relief	Liver/GI
	NSAIDs	Limited pain relief	Gl 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 infection)	Steroids	Limited duration of effect (wanes after 2 - 4 weeks)	Generally well tolerated
	Hyluronic acid (HA)	AAOS: "cannot recommend using HA" because of "lack of efficacy"1	Generally well tolerated

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

Source: Company presentation, December 2013.

Limitations of Current Treatments for OA

Current treatments for OA are associated with serious side effects and insufficient or inadequate duration and often provide limited pain relief. Oral drugs, such as NSAIDs, are used for the treatment of mild OA but are linked to serious side effects such as gastrointestinal bleeding and cardiovascular events and are eventually unsuccessful at managing OA pain as the disease progresses. Current injectable therapies, including steroids and HA preparations, approved for OA are immediate release and leave the joint within hours to days, and are absorbed systemically, which may result in undesirable side effects, including elevation of blood glucose in diabetics. IA steroids demonstrate large initial analgesic effects relative to other therapies, but pain relief typically wanes after several weeks. Current standards of care dictate that injectable steroid should not be administered more frequently than once every three months. We do not currently foresee restrictions on the frequency of FX006 injections, notably

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as it has potential to sustain prolonged, local therapeutic effects while reducing the potential for systemic side effects.

HA injections are not effective. US sales of HA therapies in 2012 were over \$690 million, even though these therapies, approved for the treatment of the knee, provide only marginally more effective pain relief over placebo and may have no discernible effect on a patient's ability to carry out his daily life. The American Academy of Orthopedic Surgeons concluded that current published studies do not show any clinically effective response for HA injections, and as a result, the treatment guidelines for knee OA do not recommend HA treatment for symptomatic knee OA. We believe this data supports our view that FX006 will be able to take market share from these existing treatments and achieve desired commercial opportunities.

Current treatments provide an inadequate magnitude and duration of pain relief, troublesome side effects, or functional impairment. Due to severe pain that can no longer be controlled therapeutically, many patients opt to have TJA, which is costly and painful. Control of post-operative pain is a priority for patients undergoing surgery. Numerous treatments exist, including local administration with the combination of existing drugs at the time of surgical wound closure, opioids, intravenous acetaminophen and NSAIDs and femoral nerve blocks. FX007, according to the company, is a novel therapy in development that is expected to safely provide persistent post-operative pain relief. FX007 is a small-molecule TrkA receptor antagonist – TrkA is the receptor for nerve growth factor (NGF), a small peptide that is release following tissue injury. In recent clinical trial of Pfizer's monoclonal antibody, tanezumab, systemic blockade of NGF showed market analgesia in a variety of painful conditions and human genetic studies showed that patients with a mutation in the TrkA gene have congenital insensitivity to pain.

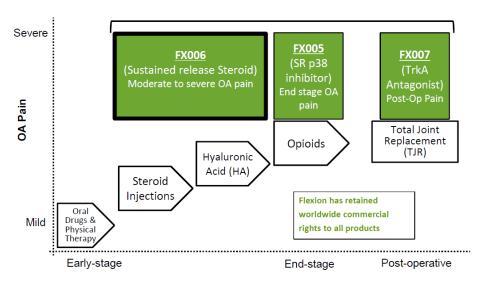
• While the current market for TCA IR in osteoarthritis knees is approximately \$50-\$100 million, we estimate that at branded prices, this would equate to a \$1.5-\$2.0 billion market in knees alone.

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Pipeline

Flexion targeting the entire treatment spectrum of OA. Potential for a diversified product offering for the treatment of OA in the entire treatment spectrum upon FDA approvals. Flexion is targeting multiple points in the OA pain treatment spectrum, from moderate to severe pain, to maximize the likelihood of successfully bringing its products to market. Each of the three product candidates targets a specific and unique method for achieving analgesia and/or anti-inflammatory effects. The company is developing FX006 for front-line IA therapy in patients with moderate to severe OA pain, FX005 for patients who progress to end-stage disease, and FX007 for patients with post-operative pain, including those undergoing total knee replacements. By providing a variety of treatment options for a range of patients, we believe Flexion could expand its market share and physician awareness and acceptance.

Exhibit 16: Flexion Products Span the OA Pain Spectrum



Source: Company presentation, December 2013.

Exhibit 17: Flexion Product Pipeline Preclinical Phase 1 Phase 2

Preclinical Phase 1 Phase 2 Phase 3

FX006 (Sustained-release Steroid)

Moderate to severe OA pain

FX007 (TrkA Antagonist)

Post-operative pain

FX005 (Sustained-release p38 Inhibitor)

End-stage OA pain

Source: Company presentation, December 2013.

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FX006 - Flexion's Lead Product

FX006, an injectable intra-articular, sustained-release treatment, is Flexion's leading product candidate aimed at patients with moderate to severe OA pain. FX006 combines a commonly administered steroid, triamcinolone acetonide (TCA), with poly lactic-co-glycolic acid (PLGA) to provide sustained therapeutic concentrations in the joint and persistent analgesic effect. FX006 demonstrated clinically meaningful and significantly better pain relief compared with the current injectable standard of care in a completed Phase IIb dose-ranging clinical trial.

FX006: Clinical trial – Phase II

Current IA therapies, such as steroids and hyaluronic acid (HA) preparations, approved for IA are immediate-release drugs and are by and largely well-tolerated but provide inadequate duration of pain relief and can result in undesirable side effects including elevated blood glucose in diabetics. Further, HA therapies are only marginally more effective than placebo and have no consistent effect on a patient's ability to carry out their daily activities. To date, two clinical trials have been conducted to test FX006 against immediate-release TCA injection. Flexion believes FX006 maintains persistent therapeutic concentrations of steroid in the joint, while minimizing systemic exposure to the drug, yielding a superior safety profile found in the completed Phase II clinical trials.

FX006 should be successful in taking market share from currently marketed injectable **TCAs**, including Kenalog. We believe Flexion's program could be disruptive to the market, and we consider that, for patients, the upside of eliminating extra office visits, experiencing better pain relief, suffering from fewer side effects and potentially delaying knee replacements is desirable and can help them remain active. For doctors, we expect that they too will like the idea of happier patients who aren't being rushed forward into surgery and will enjoy being compensated for the injection fee plus the cost of drug 6% above the wholesale price. In our opinion, FX006 will take market share from existing steroid injection as well as HA treatments. Our peak market share for FX006 in 2027 is 20% in the US, 25% in the EU, and 1% in Japan, but does not include eating into the HA market.

We believe the proprietary sustained-release technology meets an unmet medical need. We believe that current treatments, while effective, do not provide the level of pain relief expected from Flexion's IA product candidates. Further, we expect clinical data for FX006 and FX005 to support Flexion's goal of achieving effective drug concentrations in the joint for months while potentially avoiding significant plasma concentrations of drug known to cause side effects. In addition, Flexion's second pipeline drug, FX007, has low solubility characteristics that should allow it to remain in the tissues for a sufficient period of time to more effectively treat patients experiencing post-operative pain.

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Ineffective

Ineff

Exhibit 18: FX006 Sustained-Release Offers Prolonged Pain Relief

Source: Company presentation, December 2013.

Compared with existing injectable therapies, including steroids and hyaluronic acid (HA), FX006 appears to have a superior safety profile. In the completed Phase II clinical trials, Flexion's injectable sustained-release technology maintained persistent therapeutic concentrations of steroid in the joint, minimizing systemic exposure to the drug. In the Phase IIb trial, FX006 showed a well-tolerated systemic safety profile that is indistinguishable from the standard of care immediate-release steroid. We believe this yields a superior safety profile as demonstrated by the lack of any drug-related seriously adverse effects shown in the Phase II trial.

The Technology Behind It All

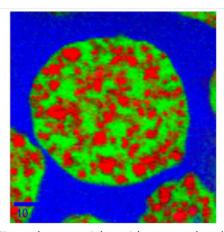
PLGA is a polymer metabolized by the body to carbon dioxide and water and has been used in approved sustained delivery drug products and surgical devices. The drug encapsulated in the microsphere is slowly released once the PLGA portion of the microsphere dissolves. The microsphere PLGA formulations in FX006 and FX005 have gone through numerous iterations and have been designed to deliver the drug substance with a controlled distribution of drug over an extended period of time. We believe Flexion's unique combination of manufacturing process and formulation has resulted in numerous trade secrets, including those that relate to precise pharmaceutical release profile. Further, this sustained-release technology is complex and the time, costs, and technical risks involved in demonstrating bioequivalence through clinical trials limit the ability of manufacturers to gain market approval for generic alternatives upon expiration of patents.

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Exhibit 19: Microsphere Manufacturing Process for FX006 and FX005



Microspheres are formed through a patented rotating disk atomizer as shown here



Microsphere particles with encapsulated drug uniformly dispersed inside

Green → polymer Red → dispersed drug in the microparticle

Source: Company presentation, December 2013.

Commercial Strategy

Flexion will market FX006 in the US and look for partnerships elsewhere. Flexion plans to commercialize its products in the US by creating a specialty sales force of approximately 60 to 100 representatives. Support for this team will include sales management, internal sales support, distribution support, and an internal marketing group. Outside of the United States, Flexion is exploring selective partnerships with third parties for the development and commercialization of its products.

According to Flexion, an estimated 69% of OA patients receive injections from orthopedic surgeons and 31% receive injections from rheumatologists. Out of the roughly 27,300 orthopedic specialists in the US, approximately 17,800 are active orthopedic surgeons and 5,700 are rheumatologists. Of these, Flexion estimates the top 40% to be the most relevant from an OA patient perspective, and this is the portion Flexion plans to target.

Due to the demonstrated meaningful pain relief and functional status compared with a commercially available treatments, coupled with anticipated payor acceptance, we believe Flexion will benefit from commercial opportunities and future indications, driving value over time. Flexion should be able to successfully execute future commercial plans given the simplicity of the procedure and the familiarity of steroid injections to both orthopedists and rheumatologists.

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Pricing

We expect FX006 will enter the market comparably to existing OA therapies, despite its superiority. The company plans on pricing FX006 at \$500 per injection in the US. As a result of initial data concerning increased patient satisfaction and the potential to delay total joint replacements, Flexion believes FX006 will be priced competitively with existing HA therapies. While the HA market is competitive, we believe the shown superiority over existing treatments and the less competitive nature of the steroid market will provide a pathway to market share gains and becoming the front-line IA therapy company.

Doctors will make more money with FX006. It is important to note that doctors will make more money prescribing and injecting FX006 than the current generic. Doctors will be reimbursed the average wholesale price plus 6% of the cost of the drug for the administration of the drug in office. With the current injection, the reimbursement is approximately \$2.00, while with Flexion's FX006 it will be approximately \$30.00. Based on our survey average of each physician seeing approximately 50 OA knee patients per week, and their estimate that they would use FX006 in 50% of OA knee patients, the average doctor might see an additional \$35,000 in income per year from using the higher-priced drug.

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Ongoing and Planned Studies

FX006

In November 2013, the company initiated a Phase IIa clinical trial of synovial fluid pharmacokinetics to measure the duration that FX006 remains in the joint. It is a multicenter, open-label study in up to 40 patients with OA of the knee. Patients will receive a single FX006 IA injection of either 10 or 40 mg, and synovial fluid will be collected via aspiration on day one just prior to the injection and again at weeks 12, 16, or 20 depending on the group assignment. This study will provide information on the dosing regimen for a planned repeat-dose safety clinical trial to assess when repeat dosing of FX006 can be safely administered.

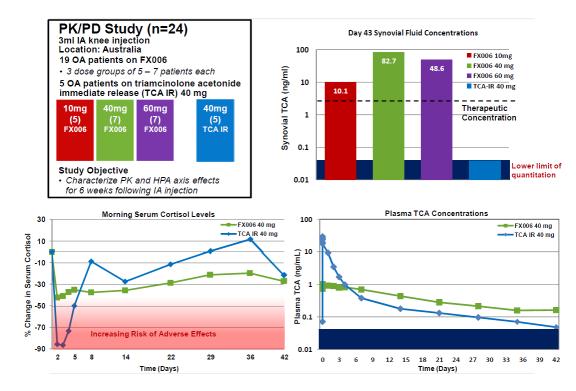
Flexion expects to initiate a confirmatory Phase Ilb clinical trial in 2Q14 to further identify a safe and well-tolerated dose of FX006 that demonstrates superior pain relief to placebo. It will be a multi-center, randomized, double-blind study involving approximately 400 patients with OA of the knee and will assess the safety, tolerability, and efficacy of certain doses of FX006. Patients will be randomized and treated with a single injection of FX006 or placebo and will be evaluated for up to 26 weeks. The primary endpoint is the weekly mean of the average daily pain intensity score as assessed using an 11-point numerical rating scale while the secondary endpoints include WOMAC, PGIC, CGIC, and a responder status.

In addition, a synovial fluid pharmacokinetic clinical trial to measure the duration that FX006 remains in the joint is under way. This study will provide information on the dosing regimen for a planned repeat-dose safety clinical trial to assess when repeat dosing of FX006 can be safely administered.

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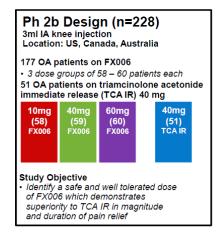
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Exhibit 20: FX006 PK - Supports Differential Efficacy and Safety



Source: Company presentation, December 2013.

Exhibit 21: FX006 Phase IIb Demonstrated Superiority to TCA IR



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 presentation, December 2013.

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Competition

There are currently two marketed classes of IA products that would compete with FX006: IR steroids and HA. In addition, other companies have OA product candidates in advanced stages of clinical development, including Fidia Farmaceutici's Hymovis, a physical hydrogel based on HA with properties that appear to be similar to most approved HA products, and Ampio Pharmaceuticals' Ampion, a derivative of human serum albumin with anti-inflammatory properties, which is formulated for immediate release and we believe has not been studied past 30 days. Other programs, such as Carbylan BioSurgery's Hydros-TA, Merck Serono's FGF-18, and Allergan's botulinum toxin have not yet entered Phase III clinical trials. Stem cell approaches to OA are being explored, but these are in the early stages of development, bear significant technical risks, and it is undetermined how applicable they will be to the treatment of OA. Finally, several new oral therapies are in development for OA pain, but Flexion believes that FX006 will expose patients to fewer systemic safety risks.

Also on the market are platelet-rich plasma injections which require on-site preparation from blood drawn from the patient. Because platelet-rich plasma is a therapy derived from the individual patient's blood, it does not require and has not received FDA review or approval. This treatment has generated questionable efficacy in controlled clinical trials, and it is unlikely that it will become a broadly embraced therapeutic option for OA patients.

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Intellectual Property

Potential for long-term exclusivity is viable, in our opinion. Flexion relies upon a combination of patents, trade secret protection, confidentiality agreements, and proprietary know-how, and intends to seek marketing exclusivity for any approved product but does not have any issued patents covering FX006 to date. For example, it maintains trade secrets with respect to certain aspects of the formulation and manufacturing techniques related to the TCA-formulated PLGA microspheres in FX006, including those that relate to precise pharmaceutical release. We believe there is a high level of confidence in Flexion's ability to obtain a patent covering the commercially contemplated product. Further, we are not aware of any third-party that would prevent the patent approval and view the potential of patent coverage until 2031 positively.

Based on feedback from the company's patent counsel, we believe that Flexion will have significant proprietary protection for FX006. We believe this will become clearer in the coming year.

Exhibit 22: Intellectual Property Portfolio

	<u>Status</u>	
FX006 (SR steroid)	US	EU
Composition of matter, method of manufacture and	Published	Published
method of use		
Potential for coverage into 2031		
FX005 (SR p38 inhibitor)		
Composition of matter	Granted	Granted
Formulation	Published	Granted
Potential for coverage into 2029		
FX007 (SR TrkA antagonist)		
Composition of matter	Granted	Granted
Formulation	Published	Pending
Potential for coverage into 2030		

Source: Company presentation, December 2013.

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Other Product Candidates

FX007

FX007: Pre-clinical for relief of post-operative pain.

FX007 is a locally administered TrkA receptor antagonist for persistent relief of post-operative pain, including in patients who have received total joint replacement or total joint arthroplasty (TJA). Flexion plans to file an Investigational New Drug application for FX007 in the 1H14.

Flexion has conducted preclinical proof of concept studies using models of OA and post-operative pain and demonstrated efficacy in both. FX007's low solubility characteristics should allow it to remain in the tissues for a sufficient period of time to effectively treat patients experiencing post-operative pain. As a result, Flexion does not believe that FX007 will need to be formulated with PLGA, which should expedite the development. An Investigational New Drug Application for FX007 is anticipated to be filed in 1H14 and a proof of concept trial is expected to be initiated in 2H2014.

FX007 Competition

There are numerous post-operative pain treatments, including combinations of existing analgesic and anti-inflammatory drugs at the time of surgical wound closure, opioids, intravenous acetaminophen and NSAIDs, and femoral nerve blocks. However, these treatments all have limitations in terms of inadequate magnitude and duration of pain relief, serious side effects, or functional impairment. In addition, Pacira Pharmaceuticals launched EXPAREL, a product that combines bupivacaine with the DepoFoam drug delivery platform to provide up to 24 hours of postsurgical pain control following a single intraoperative administration. But we believe FX007 could be a better treatment.

FX005

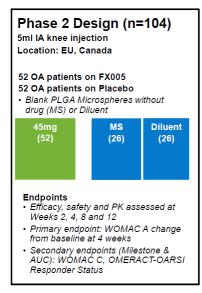
FX005: For endstage OA as an alternative to opioids. FX005 is an intra-articular, sustained-release p38 mitogen-activated protein (MAP) kinase inhibitor formulated with PLGA for sustained-release delivered via IA injection, which has both analgesic and anti-inflammatory effects. FX005 is intended to treat patients with end-stage OA, particularly those patients awaiting TJA, as an alternative to opioids. Opioids have numerous systemic side effects, such as respiratory depression, hypotension and constipation, cause a higher incidence of falls and fractures in older OA patients, and are increasingly associated with deaths from unintentional overdose.

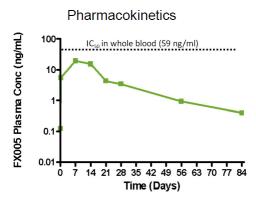
Flexion completed a placebo-controlled Phase IIa clinical trial of FX005 consisting of a single ascending dose (SAD) phase followed by a single-dose PoC phase. This trial demonstrated significant effects for three months on both pain and function, effects that increased substantially in a subpopulation of patients with higher baseline pain scores. In the SAD phase, FX005 was well-tolerated at each dose level and the highest dose of 45 mg was advanced to the next phase.

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In the PoC Phases, 52 patients were randomized to receive the 45 mg of FX005 blank PLGA microspheres as a placebo control and diluent as a placebo control, each as a single IA injection. Patients were then followed for 12 weeks after the injection for safety, pharmacokinetics, and efficacy. FX005 demonstrated pain relief and functional improvement at four weeks, and the absolute magnitude of effect in both subscales was persistent through 12 weeks and also demonstrated efficacy in responder analysis. Overall, FX005 has been proven to be well-tolerated systemically and local tolerability was similar to that documented for marketed HA preparations. **Flexion plans to advance FX005 as resources allow.**







Efficacy

- Placebos meet criterion for combination
- Primary and subset analyses (baseline pain ≥ 60 mm on a 100 mm scale)

Safety

- No serious adverse events
- No evidence of p38 toxicity
- · Local effects similar to HA

Source: Company presentation, December 2013.

FX005's major competition will be against oral opioids, as patients require very strong analgesic therapy prior to receiving a TJA. Competitors for FX005 include new formulations of existing opioids, including Janssen Pharmaceuticals' Nucynta ER and Johnson & Johnson's OROS. For those with end-stage OA, monoclonal anti-NGF antibodies have the potential to offer powerful pain relief, but were associated with accelerated progression to joint replacement in controlled clinical trials. The FDA placed these agents on clinical hold in 2010 for the treatment of OA by the FDA. Flexion is not aware of any ongoing trials of monoclonal anti-NGF antibodies in OA.

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Management Team

We have had several discussions with Flexion's management team and found them to be forthright and open to our questions. The management team has a collective 95 years of experience in the life sciences space and is accomplished in pharmaceutical development, regulatory approval, and commercial operations. We believe management is highly capable in the design and implementation of efficient and effective drug development programs and have experience building sales forces and bringing new therapies to market.

Executive Officers

Michael D. Clayman, M.D., president, chief executive officer, and director. Dr. Clayman was a co-founder and has served as a director since Flexion's inception in 2007. He has over 20 years of experience in pharmaceutical development. Previously, Dr. Clayman had a lengthy career at Eli Lilly where he was most recently vice president of Lilly Research Laboratories, and general manager of Chorus, Lilly's early-phase development accelerator. 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., Ph.D., chief medical officer. Dr. Bodick was a co-founder and has served as the chief medical officer since Flexion's inception in 2007. Previously, Dr. Bodick was at Eli Lilly, where he founded Chorus and served as chief medical officer and chief operating officer. 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.

Frederick W. Driscoll., chief financial officer. Mr. Driscoll has served as Flexion's chief financial officer since May 2013. Prior to Flexion, Mr. Driscoll was chief financial officer at Novavax. Mr. Driscoll earned a bachelor's degree in accounting and finance from Bentley University.

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

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Risks

As with any development-stage company, a main risk is that the programs fail to gain approval, leaving Flexion with a decision to pursue other indications or to try again to gain approval for existing indications. In either case, Flexion would need to source additional financing and delay profitability.

In the Phase IIb dose-ranging clinical trial, the 60 mg dose of FX006 unexpectedly showed inferior efficacy to the 40 mg dose. This led the company to plan a confirmatory Phase IIb clinical trial to be initiated in 2Q14 to further identify a safe and well-tolerated dose of FX006 that demonstrates superior pain relief to placebo before pursuing Phase III clinical development. Flexion's issue with the Phase IIb dose-ranging clinical trial for FX006 means that the planned confirmatory Phase IIb clinical trial is not guaranteed to show the same positive results. Flexion has investigated potential causes but cannot guarantee that the underlying cause is unique to the 60 mg dose or that it will not affect the doses they tend to study in the planned confirmatory Phase IIb clinical trial. While there is a risk that the underlying cause of decreased efficacy may not be unique to the 60 mg dose, we believe that this is a common finding presented to the FDA and that there is a good probability that once FX006 is measured against placebo it will be approved. The 60 mg dosing, in our view, is a classic example of diminishing returns and that comparing FX006 against placebo will give the FDA a better sense of the product and is an outcome it often sees. We believe that data expected to be released in 2015 should help mitigate this risk. All of the clinical trials completed to date have been with single doses of FX006.

We believe Flexion's programs are slightly de-risked since the underlying steroids and PLGA polymers are already approved and have been in the market but note that the company intends to study FX006 in a separate repeat dose safety clinical trial. Flexion will be the first to administer this formulation into the human joint and the risk of the unknown outcome of the repeat dose FX006 Phase IIb study remains.

We believe the FDA's familiarity with steroids for such indications increase the likelihood of approval. Flexion is set to seek FDA approval for FX006 through the 505(b)(2) regulatory pathway. PLGA polymers have a long history and safety record having been on the market for more than 40 years, starting with the Dexon structure in 1970. Further, as Flexion is not changing the steroid itself, but rather encapsulating it in PLGA with microspheres, we believe there is less risk than in developing a new, unknown molecule. While we view the probability of approval to be good, this technology is complex and there is the potential that the issue in the dose-ranging study could result in regulatory delays or need for additional studies prior to seeking or obtaining regulatory approval.

We are aware that some investors will point to the complexity of the formulation and concerns of the risk to approval since no other company has been able to produce this formulation. However, we believe that the FDA is familiar with steroids and PLGA and that this is not a singular risk to Flexion or other Phase II companies. The FDA often requires companies to do multiple Phase II studies, and providing cleaner data on studies of a product

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like FX006, consisting of two already approved and marketed elements, shouldn't be a higher risk to Flexion over many other Phase II companies.

The physician survey indicates 40% believe FX006 will be a niche product. Some color around their view of FX006 as a niche product includes the opinion that it will be used only for patients that have no effect from existing treatments or as an alternative treatment, and concerns regarding the length of therapeutic effect and potential that cost could be a prohibitive factor for a patient. But we believe as more data is released, confirming the superior efficacy and duration, these physicians will take a more positive view on the range of patients they would treat with FX006. We think our view is supported by the other 60% who listed other off-label indications for which they would use the product Further, if Flexion's view of payer acceptance is confirmed, potential cost burdens to patients would be diminished. The majority of orthopedic surgeons surveyed responded that FX006 is either a great advance or would be used for both new and existing patients, and prescribed heavily.

The company has a limited operating history and has incurred significant losses since the its inception. We expect Flexion will continue to incur losses for the foreseeable future. Although this is common with many Phase II specialty pharmaceutical companies, we do not expect Flexion to become profitable until 2019 with net income of almost \$55 million, two years following the launch of FX006. Any delays in approval will delay profitability even further and could require additional financing.

We expect Flexion will need to raise additional capital. We believe the IPO proceeds will provide adequate capital through late 2015, but this will not be enough to complete Phase III trials of FX006 required for approval and the proposed launch in 2017. Of the proceeds, roughly \$40 million, or 62%, will be direct costs of FX006, consisting of the completion of the synovial fluid PK trial and confirmatory Phase IIb trial, the initiation of the repeat-dose safety trial, and the initiation of Phase III clinical trials. Flexion is heavily reliant on the approval of FX006, and we expect it will need to raise additional capital – a minimum of \$75 million after Phase III data in 2H15. Failure to obtain this capital when needed could cause a delay or termination of the product development, operations, or commercialization efforts.

Common to specialty pharmaceutical companies, any adverse events could limit the scope of any approved labels or market acceptance. If any of Flexion's products cause serious or unexpected side effects after approval, this could cause regulatory authorities to withdraw their approval of Flexion's products or impose restrictions on its distribution. Other potential consequences include but are not limited to regulatory authorities requiring additional labeling statements, changing the way a product is administered, or requesting additional clinical studies. However, we believe current data suggests that FX006 has an attractive safety profile with limited systemic exposure and potential for fewer side effects.

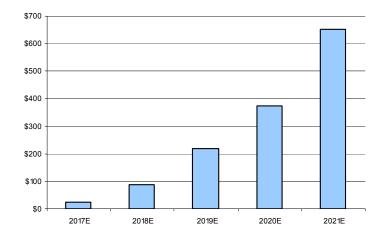
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Valuation

Financials and Valuation

- We expect FX006 to be launched in 2017 for the treatment of OA knee pain and believe that Flexion's FX006 can gain a 9% share of the market for US IA knee injections by 2020 and 20% in 2027, and peak US sales will be about \$290 million by 2020 and \$760 million by 2027.
- We have risk adjusted our market share forecasts, and they may reflect less than half of
 actual eventual use, leaving substantial room for our forecasts as clinical successes are
 met.
- We believe that FX007 will be launched in 2020 for the treatment of post-operative pain and will have peak sales of \$322 million by 2027.
- We believe FX005 will be launched in 2021 for the treatment of post-operative pain and will have peak sales of \$197 million by 2027.
- We expect total sales in 2017 of approximately \$25 million, increasing to \$88 million in 2018, \$218 million in 2019, and \$373 million in 2020.
- We expect net income to be approximately \$55 million in 2019 and \$151 million in 2020.
- Our model does not include off-label use (shoulders, hips, tennis elbow, hand/trigger thumb/carpal tunnel syndrome, etc.), which could be as larger than the OA knee indication.

Exhibit 24: BMO Global FX006 Revenue Projections



Source: BMO Capital Market Estimates

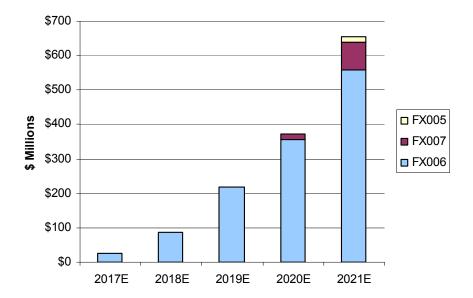
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• We assume that Flexion will market its own products in the US. We believe that Flexion intends to use partnerships outside of the US, as such our forecasts for SG&A might be high.

- We estimate that Flexion will end 1Q14 with approximately \$75 million in cash and cash equivalents and marketable securities and become profitable in 2019.
- We arrive at a \$33 price target based on our DCF, a summary of which is provided below. Our DCF assumes a 10x EV/EBITDA multiple, compared with the current sector average of 12.8x, and a 20% WACC, which we believe is conservative given our forecasts are already risk adjusted. Our DCF forecast period runs through the year 2021 and also assumes dilution of an additional 10 million shares to account for potential additional financings, although the company could raise additional funds throughout licensing territories or other non-equity-linked methods.
- As an alternative valuation approach, we also take 2020 earnings of \$151 million, or \$5.75 per share, discount that back by 20% per year and apply a sector earnings multiple of 15x, which results in a \$35.00 price target.
- On a peer basis, we consider Pacira a good target peer company. While Pacira is further along and not working in the same exact area as Flexion, both are working the pain area in large and established markets. Given Pacira is a commercial company with significant and growing revenues, the comparison is not appropriate as a current comparison, but rather we believe that Pacira is a good peer for investors to compare if considering how Flexion's value might rise as FX006 reaches commercialization. Pacira currently has a \$2.5 billion market value and approximately \$120 million in revenues (last quarter annualized).
- Longer term, we believe that if FX006 is approved, Flexion could be worth \$1.4 billion, or approximately \$60 per share (assuming additional dilution for additional share raises) or more (or approximately 5x its current value), based on 4x sales in 2020.

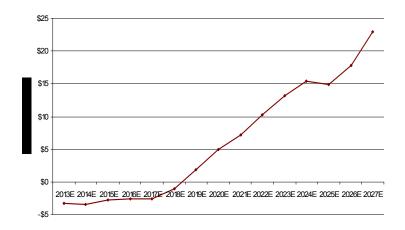
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Exhibit 25: Flexion Revenue Projections



Source: BMO Capital Markets Estimates

Exhibit 26: Flexion EPS Projections



Source: BMO Capital Markets Estimates

We estimate 2014-2018 per share losses of -\$3.41, -\$2.78, -\$2.85, -\$2.94, -\$1.19, and a profit of \$2.08 per share in 2019.

Taking into consideration our DCF, discounted EPS, and target peer valuation approaches, we arrive at our 12-month price target of \$33.

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Exhibit 27: Flexion Discounted Cash Flow (\$ millions)

WACC Terminal Value EV/EBITDA Multiple	20.0% 10.0x								
Unlevered Free Cash Flows		<u>2014</u>	<u>2015</u>	<u>2016</u>	<u>2017</u>	<u>2018</u>	<u>2019</u>	<u>2020</u>	<u>2021</u>
Net Sales Growth Rate		0.0	0.0	0.0	24.8	88.1 256%	217.7 147%	372.7 71%	653.6 <i>75%</i>
EBIT Margin		-51.5	-47.4	-63.6	-71.9	-31.3	60.5 28%	171.5 46%	297.9 46%
Pre-tax income		-51.5	-47.4	-63.6	-71.9	-31.3	60.5	171.5	297.9
Tax		\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	(\$6.1)	(\$20.6)	(\$110.2)
Tax rate							10.0%	12.0%	37.0%
EBIAT		(\$51.5)	(\$47.4)	(\$63.6)	(\$71.9)	(\$31.3)	\$54.5	\$150.9	\$187.7
Plus: Depreciation and Amortization		\$0.5	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1	\$0.1
Less: Capital Expenditures		(\$0.5)	(\$1.1)	(\$1.1)	(\$2.1)	(\$4.0)	(\$4.0)	(\$4.0)	(\$8.0)
Less: Change in Net Working Capital		\$0.0	\$0.0	\$0.0	\$0.5	\$1.2	\$5.0	\$6.8	\$10.7
Unlevered Free Cash Flow	=	(\$51.5)	(\$48.4)	(\$64.6)	(\$73.5)	(\$34.0)	\$55.6	\$153.7	\$190.5
Cumulative Unlevered FCF Terminal Value ²	\$153.5 \$2,980.3	0.5	1.5	2.5	3.5	4.5	5.5	6.5	7.5
PV of Free Cash flow PV of Terminal Value	(\$130.3) \$911.1	-\$51.5	-\$48.4	-\$64.6	-\$73.5	-\$34.0	\$20.4	\$47.0	\$48.5
Implied Enterprise Value	\$780.8	Implied Eq	uity Value	Sensitivit	y Table				
Plus: Cash & Equivalents (1Q14E)	\$74.6		EBITDA M	ultiple Teri	minal Valu	е			
Less: Total Debt (1Q14E)	\$5.0	ပ္ပ	\$33.09	11.0x	12.0x	13.0x			
Implied Value of Equity Diluted Shares Outstanding	\$850.3 25.7	WACC	15.0% 20.0%	\$50.56 \$36.63	\$55.24 \$40.18	\$59.91 \$43.72			
Implied Value per Share	\$33.09		26.0%	\$30.03 \$24.77	\$27.35	\$29.94			

Source: BMO Capital Markets estimates.

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Summary

We believe that Flexion offers a potential game-changing opportunity in the pain market, with its lead program, FX006, as well as two less important but promising pipeline programs, FX007 and FX005. We believe that if approved, FX006 will replace immediate-release steroids for the treatment of OA knee pain. In addition, although our forecasts do not include off-label use, we are convinced that if approved, the off-label use may be larger than the on-label use based on the current use of immediate-release steroids and a unique opportunity within the growing osteoarthritis treatment market, with three promising programs in its pipeline. We believe that its lead product, FX006, will capture a large part of the market based on indication for knee OA and there is additional upside in off-label uses.

Our valuation results in a \$33 price target, which is approximately 72% higher than where the shares are trading. We think longer term, that if FX006 is approved, Flexion shares have a potential to be several times higher than where they are today, but with that potential reward, investors should be cognizant of the potential risks. If FX006 is not approved, or fails somewhere along the road in its development, Flexion shares could permanently lose significant value. Therefore, we think investors should consider Flexion's development stage carefully when considering investment.

To us, the Flexion and FX006 situation reminds us a lot of the MGI Pharma and Aloxi scenario from years ago, when MGI was entering the market with a new and better version of an older anti-emetic that was about to go generic. At the time, many investors thought that payors would push back on the more expensive drug. Doctors, however, embraced the new drug because it was both better and provided a higher reimbursement level.

Overall, we believe Flexion's three main development programs represent potential paradigm shifts in the osteoarthritis and knee pain treatment area market, and we are initiating coverage with an Outperform rating.

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Exhibit 28: Flexion Income Statement (\$ millions, except per-share data)

Flexion Income Statement	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
FX006	\$ -	\$ -	\$ -	\$ 24.8	\$ 88.1	\$ 217.7	\$ 357.1	\$ 558.6
US	\$ -	\$ -	\$ -	\$ 24.8	\$ 85.1	\$ 184.9	\$ 290.2	\$ 433.5
EU	\$ -	\$ -	\$ -	\$ -	\$ 3.0	\$ 32.8	\$ 66.8	\$ 125.0
Japan	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 0.0	\$ 0.1	\$ 0.1
FX007	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 15.5	\$ 80.9
US	\$ -	\$ -	\$ -	\$ - \$ -	\$ -	\$ -	\$ 15.5	\$ 60.5
EU	\$ -	\$ -	\$ -		\$ -	\$ -	\$ -	\$ 14.6
Japan	\$ -	\$ -	\$ - \$ -	\$ - \$ -	\$ -	\$ - \$ -	\$ -	\$ 5.8 \$ 14.0
FX005 US	\$ -	\$ - \$ -	\$ - \$ -	\$ - \$	\$ - \$	\$ - \$ -	\$ -	\$ 14.0 \$ 14.0
EU	\$ - \$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 14.0
Japan	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ - \$ -
Japan		φ -	, -	φ -	• -	, - I	Ψ -	φ -
Total revenues	\$0.0	\$0.0	\$0.0	\$24.8	\$88.1	\$217.7	\$372.7	\$653.6
% growth	1 1	1			255.5%	147.2%	71.2%	75.4%
cogs	\$0.0	\$0.0	\$0.0	\$2.8	\$9.8	\$40.5	\$81.6	\$146.4
Milestone/Other fees	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$12.0	\$12.0	\$45.0
Royalty Expenses	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$3.0
Gross profit Gross margin	\$0.0	\$0.0	\$0.0	\$21.9 88.6%	\$78.2 88.8%	\$165.1 75.9%	\$279.1 74.9%	\$459.2 70.3%
R&D	\$45.1	\$36.5	\$37.2	\$50.6	\$61.0	\$54.4	\$35.7	\$39.9
R&D as % of sales	00.4	0400	200.4	204.2%	69.3%	25.0%	9.6%	6.1%
SG&A	\$6.4	\$10.9	\$26.4	\$43.3	\$48.5	\$50.3	\$71.9	\$121.3
SG&A as % of sales					55.1%	23.1%	19.3%	18.6%
Operating profit	-\$51.5	-\$47.4	-\$63.6	-\$71.9	-\$31.3	\$60.5	\$171.5	\$297.9
Operating margin						27.8%	46.0%	45.6%
Interest expense (income)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Other expense (income)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Pretax income	-\$51.5	-\$47.4	-\$63.6	-\$71.9	-\$31.3	\$60.5	\$171.5	\$297.9
Pretax income Pretax margin	-\$51.5	-\$41.4	-903.6	-p/ 1.9	-po 1.3	\$60.5 27.8%	\$171. 5 46.0%	\$297.9 45.6%
Taxes	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$6.1	\$20.6	\$80.1
Tax rate	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	12.0%	26.9%
Net income	-\$51.5	-\$47.4	-\$63.6	-\$71.9	-\$31.3	\$54.5	\$150.9	\$217.8
Net margin						25.0%	40.5%	33.3%
Shares out (diluted)	15.1	17.0	22.3	24.5	26.2	26.2	26.2	26.2
Earnings per share	-\$3.41	-\$2.78	-\$2.85	-\$2.94	-\$1.19	\$2.08	\$5.75	\$8.30
EPS % growth	2.0%	-18.4%	2.2%	3.3%	-59.4%	-274.1%	177.0%	44.3%

Source: Company report, BMO Capital Markets estimates.

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Exhibit 29: Flexion Balance Sheet (\$ millions)

Flexion Balance Sheet	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
Assets								
Cash and cash equivalents	\$22	\$41	\$75	\$52	\$18	\$73	\$227	\$448
Marketable securities	\$8	\$8	\$8	\$8	\$8	\$8	\$8	\$8
Deferred issuance costs - IPO	\$1	\$1	\$1	\$1	\$1	\$1	\$1	\$1
Prepaid expenses and other current	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Total current assets	\$31	\$50	\$84	\$60	\$26	\$82	\$235	\$456
PP&E, net	\$1	\$2	\$3	\$5	\$9	\$13	\$17	\$25
Other assets	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Restricted cash	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Total assets	\$31	\$52	\$87	\$65	\$35	\$95	\$252	\$481
Liabilities								
Current liabilities								
Accounts payable	\$0	\$0	\$0	\$0	\$2	\$7	\$13	\$24
Accrued expenses and other current liabs.	\$2	\$2	\$2	\$2	\$2	\$2	\$2	\$2
Current portion of long-term debt	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Total current liabilities	\$2	\$2	\$2	\$3	\$4	\$9	\$16	\$27
Long-term debt	\$4	\$2	\$0	\$0	\$0	\$0	\$0	\$0
Total liabilities	\$6	\$4	\$2	\$3	\$4	\$9	\$16	\$27
Shareholder's Equity								
Preferred stock	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Common stock	\$80	\$80	\$80	\$80	\$80	\$80	\$80	\$80
Additional paid-in capital	\$2	\$2	\$2	\$2	\$2	\$2	\$2	\$2
Retained earnings	(\$56)	(\$34)	\$3	(\$19)	(\$50)	\$4	\$155	\$373
Accum. other comprehensive income	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Total equity	\$25	\$48	\$84	\$62	\$31	\$85	\$236	\$454
Total liabilities and equity	\$31	\$52	\$87	\$65	\$35	\$95	\$252	\$481

Source: Company report, BMO Capital Markets estimates.

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Exhibit 30: Flexion Cash Flow Statement (\$ millions)

Flexion Cash Flow	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
Net earnings	(\$51.5)	(\$47.4)	(\$63.6)	(\$71.9)	(\$31.3)	\$54.5	\$150.9	\$217.8
Cash flows from operating activities:								
Depreciation	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Stock-based comp expense	\$0	\$0 \$0	\$0 \$0	\$0 \$0	\$0	\$0	\$0 \$0	\$0
Amortiz. Of premium (discount) on marketable	Ψ.	ΨΟ	ΨΟ	ΨΟ	ΨΟ	Ψ.	Ψ	Ψ
securities	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Loss on disposal of property and equipment	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Other	1	, ,	, , ,		, ,	1	, , ,	, ,
Other non-cash items	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Changes in operating activities								
Prepaid expenses, other current and long-term assets	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Accounts payable	\$0	\$0	\$0	\$0	\$1	\$5	\$7	\$11
Accrued expenses and other current liabs.	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Net cash provided by op activities	(\$51.0)	(\$47.3)	(\$63.5)	(\$71.4)	(\$30.0)	\$59.6	\$157.7	\$228.6
Cash flows from investing activities:								
Capital expenditures	(\$0)	(\$1)	(\$1)	(\$2)	(\$4)	(\$4)	(\$4)	(\$8)
Change in restricted cash	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Redemption of marketable securities	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Purchase of marketable securities	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Net cash provided by financing activities	(\$0.5)	(\$1.1)	(\$1.1)	(\$2.1)	(\$4.0)	(\$4.0)	(\$4.0)	(\$8.0)
Cash flows from financing activities:								
Proceeds of issuance of related-party notes	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Paymets on related-party notes	(\$2)	(\$2)	(\$2)	\$0	\$0	\$0	\$0	\$0
Proceeds from borrowing under term loan	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Payments of debt issuance costs	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Proceeds of IPO issuance	\$65	\$70	\$100	\$50	\$0	\$0	\$0	\$0
Proceeds from issuance of series A convert. preferred								
stock, net of issuance costs	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Proceeds from issuance of series B convert. preferred								
stock, net of issuance costs	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Conversion of preferred stock to common stock	(\$75)	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Proceeds from issuance of common stock	\$80	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Proceeds from the exercise of stock options	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Net cash provided by financing activities	\$68.5	\$67.8	\$98.5	\$50.0	\$0.0	\$0.0	\$0.0	\$0.0

Source: Company report, BMO Capital Markets estimates.

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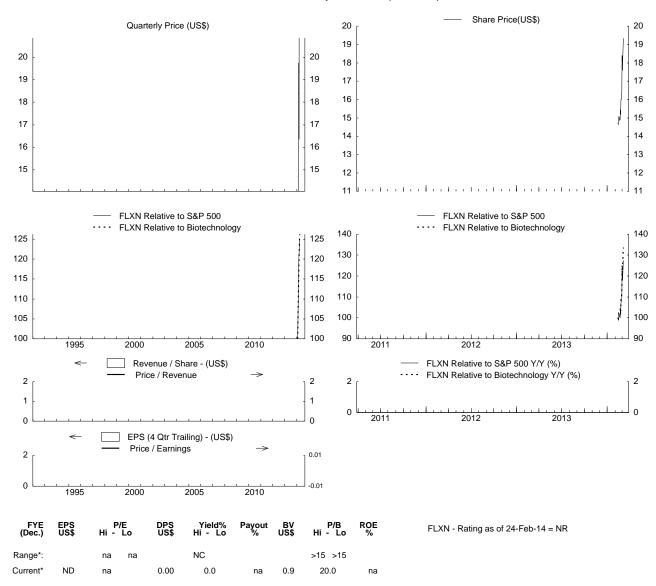
Other companies mentioned (priced as of the close on March 7, 2014):

Ampio Pharmaceuticals, Inc. (AMPE, \$6.89, Not Rated) Merck (MRK, \$57.34, Outperform), covered by Alex Arfaei Allergan, Inc. (AGN, \$127.99, Outperform) Pacira Pharmaceuticals (PCRX, \$74.43, Not Rated) Johnson & Johnson (JNJ, \$93.32, Not Rated) Pfizer Inc. (PFE, \$32.43, Outperform), covered by Alex Arfaei

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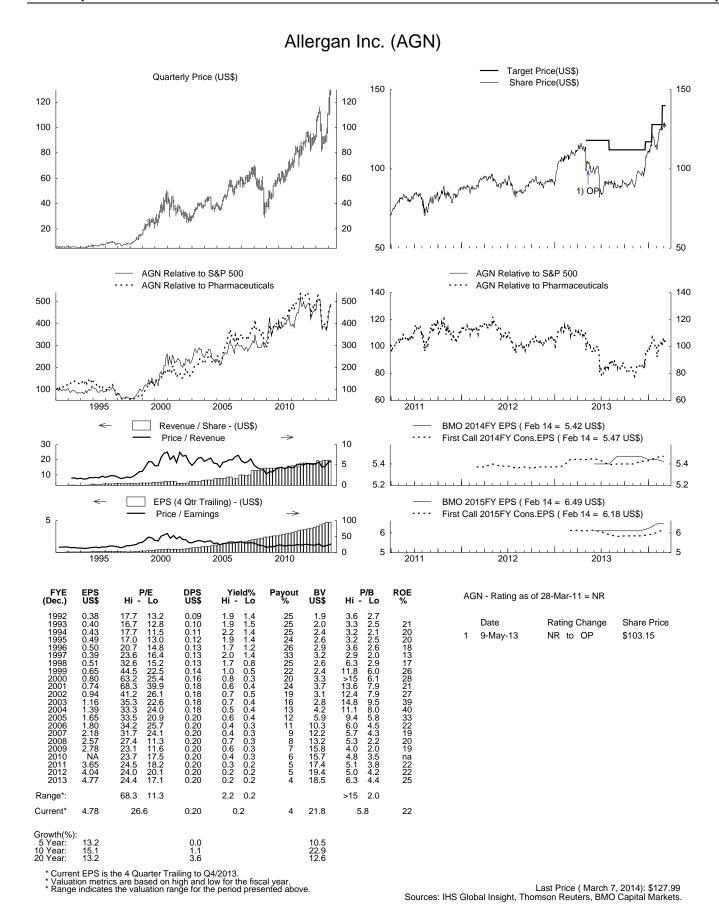
Flexion Therapeutics (FLXN)



Last Price (March 6, 2014): \$19.34 Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

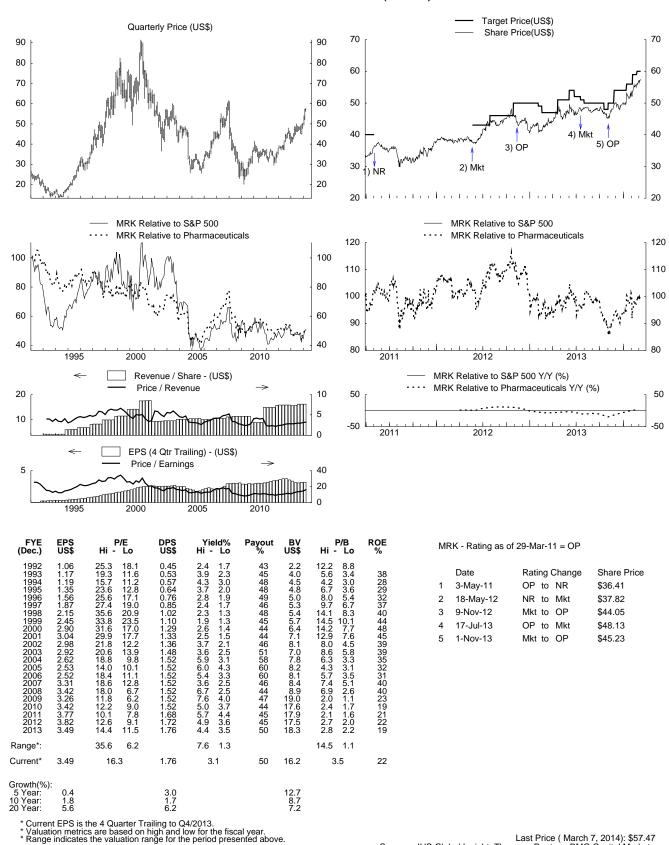
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^{*} Current EPS is the 4 Quarter Trailing to Q4/2013.
* Valuation metrics are based on high and low for the fiscal year.
* Range indicates the valuation range for the period presented above.



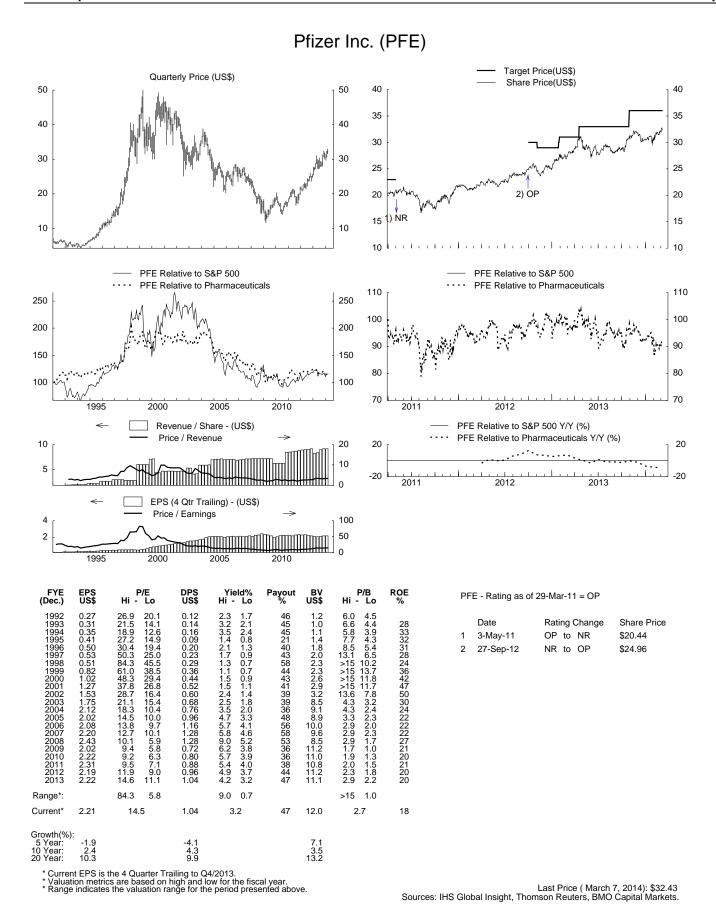
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Merck & Co. Inc. (MRK)



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Last Price (March 7, 2014): \$57.47 Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.



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Important Disclosures

Analyst's Certification

I, David Maris, hereby certify that the views expressed in this report accurately reflect my personal views about the subject securities or issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

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Disclosure 2: BMO Capital Markets has provided investment banking services with respect to this issuer within the past 12 months.

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Disclosure 6: This issuer is a client (or was a client) of BMO Nesbitt Burns Inc., BMO Capital Markets Corp., BMO CM Ltd. or an affiliate within the past 12 months: Investment Banking Services.

Methodology and Risks to Our Price Target/Valuation

Methodology: We arrive at our target price using a discounted cash flow analysis, as well as a sector multiple applied to discounted earnings.

Risks: In addition to the normal risks inherent in pharmaceutical companies, such as regulatory, reimbursement, and competitive risks, our valuation of FLXN carries several other risks. Among the risks to our valuation is FLXN's dependence on approval of their lead product and anticipated sales and profitability to drive the value of FLXN.

Unseen side effects, safety issues, and competitive threats have not been taken into account in our valuation and if any of these were to emerge, it is likely FLXN shares would be significantly and negatively impacted. FLXN is currently running at a substantial loss, and with this fact comes several other risks, including the potential need for financing. One cannot be certain that FLXN would be able to secure additional financing and at what cost. Our valuation includes a value for the current pipeline of additional products FLXN is investigating. We have estimated a public market value for these assets based on what a similar company might be valued in a public market. Less is known about these programs relative to FLXN's lead program and given their early naure, they carry substantial development risk.

Company Specific Disclosures for AGN

Methodology and Risks to Our Price Target/Valuation

Methodology: We arrive at our target price using a discounted cash flow analysis.

Risks: Risks to our rating and target price include greater impact from competition for Botox, pipeline delays and failures, negative impact from Affordable Care Act, increased regulatory oversight, and other market and industry risks.

Company Specific Disclosures for MRK

9 - BMO Capital Markets makes a market in this security.

Methodology and Risks to Our Price Target/Valuation

Methodology: DCF: Free Cash Flow To Equity and P/E multiple.

Risks: Uncertainty of Phase 3 Pipeline.

Company Specific Disclosures for PFE

9 - BMO Capital Markets makes a market in this security.

Methodology and Risks to Our Price Target/Valuation

Methodology: DCF: Free Cash Flow To Equity.

Risks: Uncertainty of Phase 3 Pipeline.

Distribution of Ratings (December 31, 2013)

1	Distribution of Ratings (December 51, 2015)									
	Rating		BMOCM US	BMOCM US	BMOCM US	BMOCM	BMOCM	Starmine		
	Category	BMO Rating	Universe*	IB Clients**	IB Clients***	Universe****	IB Clients****	Universe		
	Buy	Outperform	38.0%	20.4%	49.0%	38.8%	50.4%	52.5%		
	Hold	Market Perform	56.1%	13.8%	49.0%	54.0%	46.5%	41.8%		
	Sel1	Underperform	5.8%	5.6%	2.0%	7.2%	3.1%	5.7%		

^{*} Reflects rating distribution of all companies covered by BMO Capital Markets Corp. equity research analysts.

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^{**} Reflects rating distribution of all companies from which BMO Capital Markets Corp. has received compensation for Investment Banking services as percentage within ratings category.

- *** Reflects rating distribution of all companies from which BMO Capital Markets Corp. has received compensation for Investment Banking services as percentage of Investment Banking clients.
- **** Reflects rating distribution of all companies covered by BMO Capital Markets equity research analysts.
- **** Reflects rating distribution of all companies from which BMO Capital Markets has received compensation for Investment Banking services as percentage of Investment Banking clients.

Rating and Sector Key (as of April 5, 2013)

We use the following ratings system definitions:

OP = Outperform - Forecast to outperform the analyst's coverage universe on a total return basis;

Mkt = Market Perform - Forecast to perform roughly in line with the analyst's coverage universe on a total return basis;

Und = Underperform - Forecast to underperform the analyst's coverage universe on a total return basis;

(S) = Speculative investment;

NR = No rating at this time; and

R = Restricted – Dissemination of research is currently restricted.

BMO Capital Markets' seven Top 15 lists guide investors to our best ideas according to different objectives (CDN Large Cap, CDN Small Cap, US Large Cap, US Small Cap, Income, CDN Quant, and US Quant have replaced the Top Pick rating).

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http://researchglobal.bmocapitalmarkets.com/documents/2013/prior rating system.pdf

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