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EQUITY RESEARCH
Company Report

April 28, 2015

Flexion Therapeutics (FLXN - $16.85)

Healthcare / Biotechnology

Initiation of Coverage

We are initiating coverage of Flexion Therapeutics (FLXN) with a BUY rating and a $35 price target. FLXN's lead product in development is FX006, a novel extended-release formulation of triamcinolone acetonide (TCA) for osteoarthritic (OA) pain that could take significant share of the market of three million US immediate-release (IR) TCA patients. FLXN launched a confirmatory dose-ranging phase IIb trial for FX006 in April 2014 (we anticipate data 2H15), and launched a phase III trial in February 2015 (we anticipate data 1H16). FLXN could be filing FX006 with the FDA by 2H16. FLXN has an interesting pipeline, including FX007 for post-operative pain, which could have proof-of-concept bunionectomy data in 4Q15 and start a phase II trial in 2016. FLXN has raised ~$165MM since its February 2014 IPO and has ample cash on hand, in our view. With a fairly straightforward development process for FX006 we believe FLXN faces a lower development risk pathway and that FX006 ought to demonstrate superior pain relief to IR TCA.

- **FX006 could transform the treatment of osteoarthritis of the knee**. Management believes FLXN's long-acting formulation of TCA presents a superior option to both IR TCA and to hyaluronic acid (HA) by lasting longer in the synovial fluid in the knee, leading to greater pain relief.

- **OA of the knee represents 3MM US patients alone**. There are approximately 3MM US patients annually who receive IR TCA injections. A 10% penetration of this established patient group could equate to ~$250MM in annual sales in the US alone. The ROW opportunity could be 4-5x as large as the US opportunity.

- **Significant pipeline catalysts over 2015-2016**. In 2H15 we anticipate results from an ongoing confirmatory phase IIb dose-ranging trial, and we anticipate results from an ongoing phase III trial in 1H16. Additionally FLXN's FX007 could have proof-of-concept data in a bunionectomy model by 4Q15.

- **Initiate with a BUY rating, $35 price target**. Our $35 price target is based on a sum-of-the-parts analysis, with FX006 valued at $30/share and cash (end 2015) and technology at $5/share.

Ticker:	FLXN
Rating:	**Buy**
Price Target:	**$35.00**

Trading Data:

Last Price (04/27/2015)	$16.85
52–Week High (03/20/2015)	$30.37
52–Week Low (05/01/2014)	$11.06
Market Cap. (MM)	$361.5
Shares Out. (MM)	21.45

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Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
FY16E	NA	NA	NA	NA	($2.10)	NA
FY15E	($0.47)	($0.49)	($0.50)	($0.50)	($1.95)	NA
FY14	($0.86)	($0.38)	($0.45)	($0.47)	($1.97)	NA
FY13	($6.13)	($6.13)	($6.12)	($4.65)	($23.02)	NA

Source: Laidlaw & Company estimates

Summary and Investment Thesis

We are initiating coverage of Flexion Therapeutics (FLXN) with a BUY rating and a $35 price target. FLXN's lead product in development is FX006, a novel extended-release formulation of triamcinolone acetonide (TCA) for osteoarthritic (OA) pain that could take significant share of the market of three million US immediate-release (IR) TCA patients. FLXN launched a confirmatory dose-ranging phase IIb trial for FX006 in April 2014 (we anticipate data 2H15), and launched a phase III trial in February 2015 (we anticipate data 1H16). FLXN could be filing FX006 with the FDA by 2H16. FLXN has an interesting pipeline, including FX007 for post-operative pain, which could have proof-of-concept bunionectomy data in 4Q15 and start a phase II trial in 2016. FLXN has raised ~$165MM since its February 2014 IPO and has ample cash on hand, in our view. With a fairly straightforward development process for FX006 we believe FLXN faces a lower development risk pathway and that FX006 ought to demonstrate superior pain relief to IR TCA.

- FX006 could transform the treatment of osteoarthritis of the knee. Management believes FLXN's long-acting formulation of TCA presents a superior option to both IR TCA and to hyaluronic acid (HA) by lasting longer in the synovial fluid in the knee, leading to greater pain relief.
- OA of the knee represents 3MM US patients alone. There are approximately 3MM US patients annually who receive IR TCA injections. A 10% penetration of this established patient group could equate to ~$250MM in annual sales in the US alone. The ROW opportunity could be 4x - 5x as large as the US opportunity.
- Significant pipeline catalysts over 2015-2016. In 2H15 we anticipate results from an ongoing confirmatory phase IIb dose-ranging trial, and we anticipate results from an ongoing phase III trial in 1H16. Additionally FLXN's FX007 could have proof-of-concept data in a bunionectomy model by 4Q15.
- Follow-on pipeline: FX007 in post-operative pain. The post-operative pain market is estimated to be ~$6B in the US with ~300MM IV units dosed per year. With the multi-modal analgesia as a standard of care and 75% of patients reporting adverse events from their pain medications, we believe FX007 should target a significant market. FX005 in end-stage osteoarthritis pain is an interesting longer-term compound, but we believe FLXN will focus its efforts on nearer-term prospects and will likely effectively "shelve" this compound for now.

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Figure 1. Upcoming Potential Catalysts

Event	Expected Timing
Confirmatory p2 dose ranging FX006 study top-line	2H15
Start LT safety study FX006	2H15
Proof of concept data FX007	4Q15
Phase 3 trial data FX006	1H16

Source: Company Reports: Laidlaw & Company estimates

VALUATION

Our $35 price target is based on a sum-of-the-parts analysis, with FX006 valued at $30/share split between $27/share for US sales based on a 4x multiple of FY19 sales of $340M discounted 4 years at 20%, and $3/share for ex-US royalties based on a 6x multiple of FY19 royalties of $22M discounted 4 years at 20%. Cash (end ’15) and technology value is $5/share.

Figure 2. Sum-of-the-Parts Analysis

Sum-of-the-parts value: FLXN		
Segment	Valuation (000's)	Per share value
FX006 value	$713,621	$30
Cash (end '15) & tech value	$116,842	$5
SUM	**$830,463**	**$35**
Shares out '15E (000)		23,870

Source::Laidlaw & Company estimates

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COMPANY DESCRIPTION

FLXN targets anti-inflammatory and analgesic therapies for musculoskeletal conditions, including OA pain and post-operative pain. FLXN's lead product is FX006 a sustained-release, intra-articular (IA) injection of TCA for patients with moderate to severe OA pain. FX006 provides long-lasting, local analgesia while avoiding systemic side effects. In a completed phase IIb dose-ranging clinical trial, FX006 has demonstrated clinically meaningful and significantly better pain relief compared to the IR TCA injection, which is the current standard of care. FLXN initiated a confirmatory phase IIb trial in April 2014, and a phase 3 trial in December 2014 to further identify the best dose of FX006 that demonstrates superior pain relief to placebo. We anticipate top-line results for the phase 2b trial in 2H15. In February 2015 FLXN initiated the second confirmatory phase 3 trial for FX006, and we anticipate top-line results from this trial in 1H16.

FLXN's other product candidates are FX007 for post-operative pain and FX005 for treating end-stage OA patients. FX007 is a locally administered TrkA receptor antagonist that is designed to provide persistent relief of post-operative pain, including in patients who have undergone total joint arthroplasty (TJA, or knee replacement surgery). FLXN plans to initiate a phase IIa proof-of-concept bunionectomy trial for FX007 in 1H15 (data expected 4Q15). 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. FLXN feels that systemic blockade of NGF should demonstrate analgesia in post-operative pain.

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FLEXION OSTEOARTHRITIS PLATFORM

FLXN uses PLGA microspheres to incorporate pharmaceuticals into sustained release (SR) products for both FX006 (OA pain) and FX005 (end-stage OA pain). PLGA is poly-lactic-co-glycolic acid that is used in a variety of FDA approved therapeutic devices due to its biodegradability and biocompatibility. PLGA is metabolized to carbon dioxide and water as it releases drug in the IA space, and the physical properties of the polymer-drug matrix can be varied to achieve specified drug loads and release rates. Key to the success of FLXN's IA therapies is the ability to maintain therapeutic concentrations of drug in the joint while minimizing systemic exposure. The phase IIa trial of FX006 provides evidence that therapeutic concentrations of TCA are maintained locally (in the joint) for at least six weeks following a single injection, with low concentrations of TCA entering into systemic circulation.

FX006: Sustained-Release Steroid for Moderate to Severe OA Pain

FX006 is a SR injection of the steroid TCA, for moderate to severe OA pain. FX006 combines standard-of-care IR TCA with PLGA to create sustained-release TCA. In two clinical trials to date, a total of 252 patients have been exposed to either IR TCA or FX006 (196 FX006, 56 IR TCA). In a completed phase IIb dose-ranging clinical trial of patients with knee OA, 40 mg FX006 demonstrated clinically meaningful and significant improvements in pain relief and functional status relative to 40 mg IR TCA. Data from the 12-week dose-ranging trial show that 40 mg FX006 has a well-tolerated systemic and local safety profile to 40 mg IR TCA.

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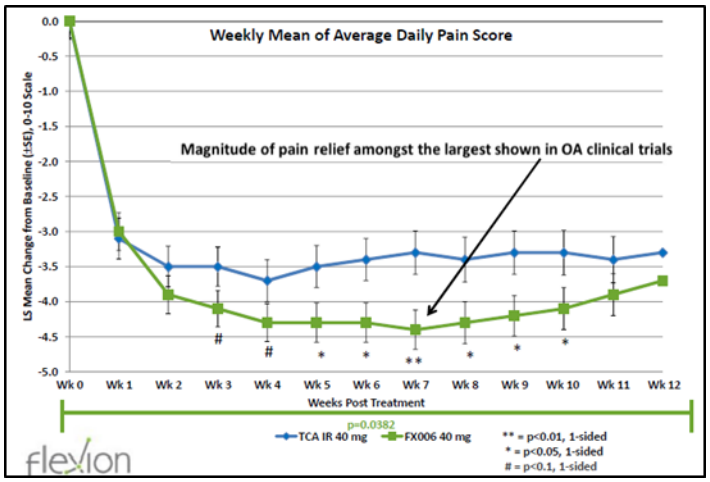
Figure 3. 40 mg FX006 vs. 40 mg TCA IR



Source: Company Presentation

FLXN's clinical data suggests that peak steroid concentrations in the joint with FX006 are orders of magnitude lower than those produced by IR TCA. A PK study in patients has demonstrated that FX006 avoids the marked suppression of the hypothalamic-pituitary-adrenal (HPA) axis (which determines the body's ability to make its own naturally occurring steroids) that occurs with commercially available steroid suspensions. The 40 mg IR TCA also produced maximal plasma concentrations (peak plasma concentrations measured over the given sampling period) that were 30x higher than 40 mg of FX006. Preclinical data demonstrate not only that FX006 is well tolerated, but in an inflammatory arthritis rat model it has the potential to prevent joint damage and do so more effectively than IR steroids. FLXN is conducting a synovial fluid PK trial to measure the duration of exposure to TCA from FX006 in the joint.

FX006: Development Program

In June 2013 FLXN completed its phase IIb dose-ranging clinical trial in 228 patients with knee OA, assessing the safety, tolerability, and efficacy of FX006. The clinical trial was conducted at a total of 22 sites in Australia, Canada, and the US, with the objective of the study to identify a safe and well-tolerated dose of FX006 that demonstrates superiority to IR TCA and to provide an assessment of the magnitude and duration of pain relief.

The 228 patients were randomized and treated with a single IA injection of 10 mg, 40 mg, or 60 mg of FX006 or 40 mg of IR TCA (current standard of care). 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 a 10-point numerical rating scale. The primary efficacy endpoint was the change from baseline to each of weeks eight, 10, and 12. 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 Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), patient

global impression of change (PGIC), clinical global impression of change (CGIC), and rescue medication consumption.

Figure 4. Phase IIb Trial Design

Phase 2b: FX006 Dose-ranging study 10mg, 40mg, 60mg vs. IR TCA	
Aim	Dose-ranging safety & tolerability & efficacy of 3 doses of FX006 vs. IR TCA
Design	12 week trial to determine magnitude & duration of pain relief; Mean baseline pain scores between 6.4 - 6.6
Dosing	Single intra-articular injection of 10mg, 40mg, 60mg of FX006 or 40mg IR TCA
Endpoints	1': change in weekly mean average daily pain intensity score on 10 pt scale from baseline to weeks 8, 10 & 12 2': time to onset of analgesia, responder status, pain, stiffnes & function on WOMAC scale; Patient Global Impression of Change (PGIC), Clinical Global Impression of Change (CGIC) & rescue meds consumption
Patients	N = 228
Safety	comparable to the same dose of IR TCA; well tolerated, systemic exposure < IR TCA
Results - 6/26/13	1': 40mg dose showed stat sig. improvement from weeks 5 to 10 (p<0.05); Stat sig improvement across weeks 1 to 12 (p=0.0382); 10mg dose showed improvement, but no stat sig difference; 60mg dose showed no improvement; 2': 40mg pain stiffness, function, PGIC, CGIC & responder status (p<0.05); 10mg dose showed improvement, but no stat sig difference; 60mg dose showed no improvement.

Source: Company Reports

FX006: Clinical hold episode shows management at its best

On September 17, 2014 FLXN announced that the FDA had placed FX006 on clinical hold following a reported possible infection in one patient in the phase 2b clinical trial. Given the issues with steroid infections at compounding pharmacies resulting in patient deaths, the FDA was correctly cautious in halting the FLXN clinical trial until FX006 could be ruled out as the likely source of the infection. While FX006 was ultimately ruled out, and the clinical hold was lifted on December 1st, 2014; we came away from the entire episode with a more positive viewpoint of management and the upfront way in which they handled the disclosures throughout the entire episode. Too often in pharma one can see management obfuscate or distract during times of real crisis to clinical programs, which this certainly was for FLXN. It is our opinion that management handling of investor communications was very well done indeed. This is reflected in the fact that during the clinical hold the stock was only off ~27% from its 52 week high at its lowest point; a remarkable achievement for a small, essentially single product company on FDA clinical hold. One would typically expect the company stock to be cut in thirds, if not more, in such circumstances. As it turned out the entire episode was somewhat of a red herring, as the patient was ultimately determined never to have had an infection at all.

FX007: For Post-Operative Pain

FX007 is a small molecule TrkA receptor antagonist that is in development for the persistent relief of post-operative pain. TrkA is the receptor for 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. In recent clinical trials of Pfizer's monoclonal antibody, tanezumab, systemic blockade of NGF demonstrated marked analgesia in a variety of painful conditions. Additionally, human genetic studies demonstrated that patients with a mutation in the TrkA gene have congenital insensitivity to pain. These data indicate that interruption of the NGF-TrkA pathway produces a profound analgesic effect, and in preclinical pharmacology experiments FX007

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has demonstrated both high affinity for the TrkA receptor and analgesic effects in OA and post-operative pain. However, systemic and persistent blockade of NGF has been associated with rapidly progressive OA requiring TJA. FX007 is being developed for acute, local administration, which has the potential to avoid side effects associated with chronic systemic use.

According to the International Association for the Study of Pain, more than 46MM inpatient and 53MM outpatient surgeries are performed annually in the US. Moderate to severe pain in a hospital or other medical setting is most often treated with injectable analgesics. The US IV/injectable analgesic therapy market primarily consists of mu opioid agonists, such as morphine, hydromorphone, and fentanyl, and certain non-opioid analgesics, such as Toradol (and related generic IV ketorolac products), Caldolor (IV ibuprofen), and Ofirmev (IV acetaminophen). According to GBI Research, the postoperative pain relief market, with sales of $5.9B in 2010, accounted for approximately 20% of the total pain management market. Despite the size of this market, however, post-operative pain management remains a challenge for healthcare providers, with studies reporting that up to 80% of patients experience inadequate pain relief after surgery.

FLXN has conducted initial preclinical studies for FX007 using models of OA and post-operative pain and demonstrated efficacy in both; the company plans to start a proof-of-concept trial for FX007 in 2H14.

FX005: For End-Stage OA Pain

FX005 is being studied for end-stage OA pain, particularly those patients awaiting TJA as an alternative to opioids. FX005 is a p38 mitogen-activated protein (MAP) kinase inhibitor formulated for sustained-release delivered via IA injection. It 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 up regulates in response to stress and culminates in the elaboration of multiple pro-inflammatory cytokines, including interleukin 1 and tumor necrosis factor, as well as enzymes like matrix metalloproteinases that have the potential to destroy cartilage. In other studies, multiple oral p38 MAP kinase inhibitors have been evaluated in inflammatory diseases and pain and, while efficacy has been demonstrated, serious toxicity affecting multiple organ systems has been frequently observed.

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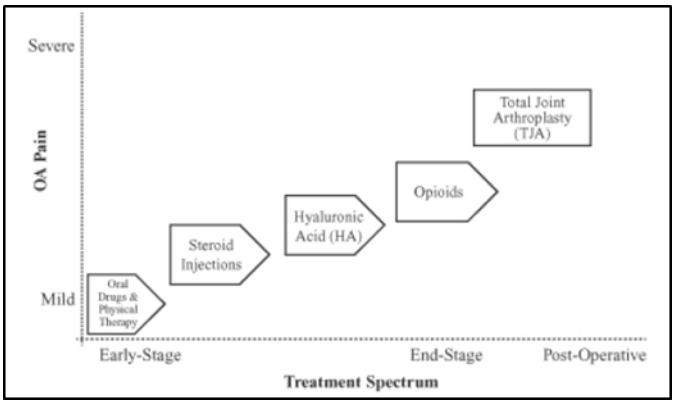
Figure 5. Weekly Pain Treatment Spectrum



Source: Company Presentation

FX005: Development Program

In May 2012 FX005 completed a phase IIa clinical trial in which 70 patients were randomized to FX005 and 70 patients were randomized to placebo. The phase IIa 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.

A phase IIa clinical trial (Study FX005-2010-001) 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 (SAD) phase followed by a single-dose proof-of-concept phase. In the SAD phase of the study escalating doses of 1mg, 10 mg, 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.

In the proof-of-concept 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 pre-specified 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.

At this point the FX005 clinical trial program has been put on hold by FLXN as the company focuses its resources on the nearer-term opportunities for FX007 and FX006.

FX006: Competition

IR steroids and HA are currently the two marketed classes of IA products that would compete with FX006. IR steroids are generic and widely used as first-line therapy but leave the joint rapidly after injection and have efficacy that typically wanes within several weeks. FX006 has demonstrated that it persists in the joint at therapeutic concentrations for at least six weeks following injection, whereas there is no measurable IR TCA in the joint by that time. FX006 also provides prolonged analgesia significantly better than that seen with IR TCA. In addition to IR steroids, FX006 will compete with HA in patients considering something beyond an IR steroid injection. HA therapy, which has demonstrated only marginal pain relief over placebo in knee OA patients, generated US sales of $504MM in 2013. The magnitude of pain relief demonstrated by FX006 to date is much greater than that seen in historic HA clinical trials. Also on the market are platelet-rich plasma injections, but these require on-site preparation from blood drawn from the patient, have generated questionable efficacy in controlled clinical trials, and are unlikely to be a broadly embraced therapeutic option for OA patients. 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.

Other OA product candidates in clinical development include Anika Therapeutics' Cingal, a combination HA (Monovisc) product that combines HA with an active steroid ingredient (triamcinolone hexacetonide) in a one-shot therapy. Anika recently reported positive top line data for their combination study (13-01) demonstrating superiority over saline in treating pain over 12 weeks. The full data is expected to be reported later in 2015. Fidia Farmaceutici's (Private) is developing Hymovis, a physical hydrogel based on HA with properties that appear to be similar to most approved HA products. Ampio Pharmaceuticals' Ampion, which has a derivative of human serum albumin that is an IR product with anti-inflammatory properties, launched a Phase III program to treat pain due to osteoarthritis (OA) of the knee. Carbylan therapeutics have formulated a Hydros-TA combination product with the goal of achieving both short term pain relief through a low dose steroid component, and sustained pain relief of up to six months with Hydros, which is their proprietary HA. Their first of two pivotal Phase 3 trials began enrollment in mid-January 2014.

Other programs include: OrthoTrophix's TPX-100; Carbylan BioSurgery's Hydros-TA; Merck Serono's FGF-18; and Allergan's botulinum toxin. Autologous cartilage transplantation products, like Carticel, are appropriate for focal defects in cartilage, not the kind of diffuse disease that is seen with OA.

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Eupraxia's EP-104 is a preclinical/phase 1 therapy that combines an unapproved carrier technology (Plexis) with a steroid (fluticasone) that is not commonly used for the treatment of knee OA. Stem cell approaches to OA are also being explored but are earlier in development.

FX007 and FX005: Competition

Numerous post-operative pain treatments exist, including local administration with combinations of existing analgesic and anti-inflammatory drugs at the time of surgical wound closure, opioids, intravenous acetaminophen and NSAIDs, and femoral nerve blocks. Pacira Pharmaceuticals has Exparel, a combination of bupivacaine and PCRX's DepoFoam delivery platform, to provide up to 24 hours of postsurgical pain control following a single intraoperative administration. FX005 would be positioned against oral opioids, as patients require very strong analgesic therapy prior to receiving a TJA. Opioids have numerous systemic side effects, including addiction and constipation, and also cause a higher incidence of falls and fractures in an older OA patient population.

AstraZeneca Partnership

FX007. In 2010 FLXN partnered with AstraZeneca for the exclusive, royalty-bearing, worldwide rights to FX007. FLXN will owe AZN up to $21MM upon the achievement of certain regulatory and development milestones for a first licensed product for OA indications or up to an aggregate of $15MM upon the achievement of certain regulatory and development milestones for a first licensed product for non-OA indications. Upon commercialization of a product that results from the technology licensed under the agreement, FLXN will owe AZN tiered low-single-digit to low-double-digit royalties based on net sales, as well as up to $75MM based on sales milestones. FLXN will pay royalties to AZN until the later of 12 years after the first commercial sale or the expiration of AZN's patents.

FX005. In 2009 FLXN partnered with AZN for worldwide rights to FX005. FLXN will owe up to $17MM upon the achievement of certain regulatory and development milestones for a first licensed product for OA indications or up to an aggregate of $11MM upon the achievement of certain regulatory and development milestones for a first licensed product for non-OA indications. FLXN will owe AZN tiered low- to high-single-digit royalties net sales as well as up to $45MM in sales milestones. FLXN will also pay royalties to AZN on FX005 until the later of 12 years after the first commercial sale or the expiration of AZN's patents.

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OSTEOATHRITIS BACKGROUND

OA is a type of degenerative arthritis that is caused by the progressive breakdown and eventual loss of cartilage in one or more joints. Arthritis is the most common cause of disability in the US and OA is the most common joint disease, affecting 27MM Americans. A recent study in the journal Arthritis & Rheumatism suggest that OA accounts for more than $185B of annual healthcare expenditures in the US. OA commonly affects large weight-bearing joints like the knees and hips, but also occurs in the shoulders, hands, feet, and spine. Patients with OA suffer from joint pain, tenderness, stiffness, and limited movement that in many cases results in TJA.

Current therapies for OA focus on controlling pain and delaying surgery with oral and topical NSAIDs used to treat early stage pain. They have a limited effect on pain and are associated with serious side effects, including increased risk of serious cardiovascular (CV) thrombotic events, myocardial infarction, and stroke. These drugs can also cause serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines. For patients with moderate to severe OA pain, IA medicines, such as IR steroids and HA are injected into the joint. These are generally considered safe drugs, but they can leave the joint rapidly and fail to produce or maintain meaningful pain relief. For patients who progress to end-stage OA, physicians prescribe opioids, which, in addition to the risk of addiction, have numerous systemic side effects, such as respiratory depression, hypotension, and constipation, and cause a higher incidence of falls and fractures in older OA patients. As a result of these suboptimal therapies, many OA patients experience persistent and worsening pain, which ultimately, for many patients, results in the decision for TJA. Further, because the initial joint replacement wears out over time, the younger the patients are at the time of the joint replacement, the more likely it is that they will require repeat surgery in their lifetime.

According to IMS Health, approximately 10MM patients in the US per year receive IA steroid injection treatments in the knee, hip, shoulder, hand, or foot, with knee OA the most common. In 2012 the number of knee injections of IA steroids increased ~12% to 3MM patients, with an additional ~1.3MM patients who got HA knee injections. However, recent negative guidance from the American Academy of Orthopedic Surgeons (AAOS) and the Osteoarthritis Research Society International (OARSI) may begin to put downward pressure on HA sales.

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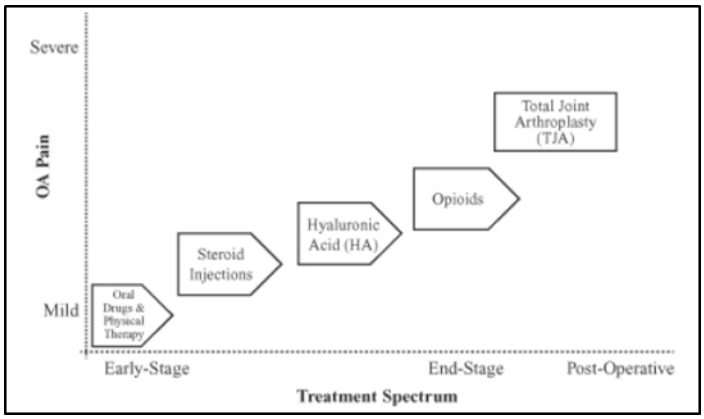
Figure 6. OA Pain Treatment Spectrum



Source: Company Presentation

TJA and Post-Operative Pain Treatments

Due to severe pain that can no longer be controlled therapeutically, many patients opt to have knee replacement surgery (or TJA) which is both costly and painful. Total knee arthroplasty can cost between $25,000 and $35,000 on average, and as many as 20% of patients can be dissatisfied with the outcome of this procedure. The earlier a patient receives TJA, the more likely the patient may need repeat replacement surgery in following years.

Major Risks

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

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

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

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

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MANAGEMENT

Michael D. Clayman, MD, Co-founder, President, CEO, and Director. Dr. Clayman has served since FLXN's 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 of 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 BA, cum laude, from Yale University and an MD 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, MD, PhD, co-founder, and CMO. Dr. Bodick has served as chief medical officer since FLXN's 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 AB from Cornell University, a PhD in neuroscience from Columbia University, an MD from the Albert Einstein College of Medicine, and an MBA from the Wharton School of the University of Pennsylvania.

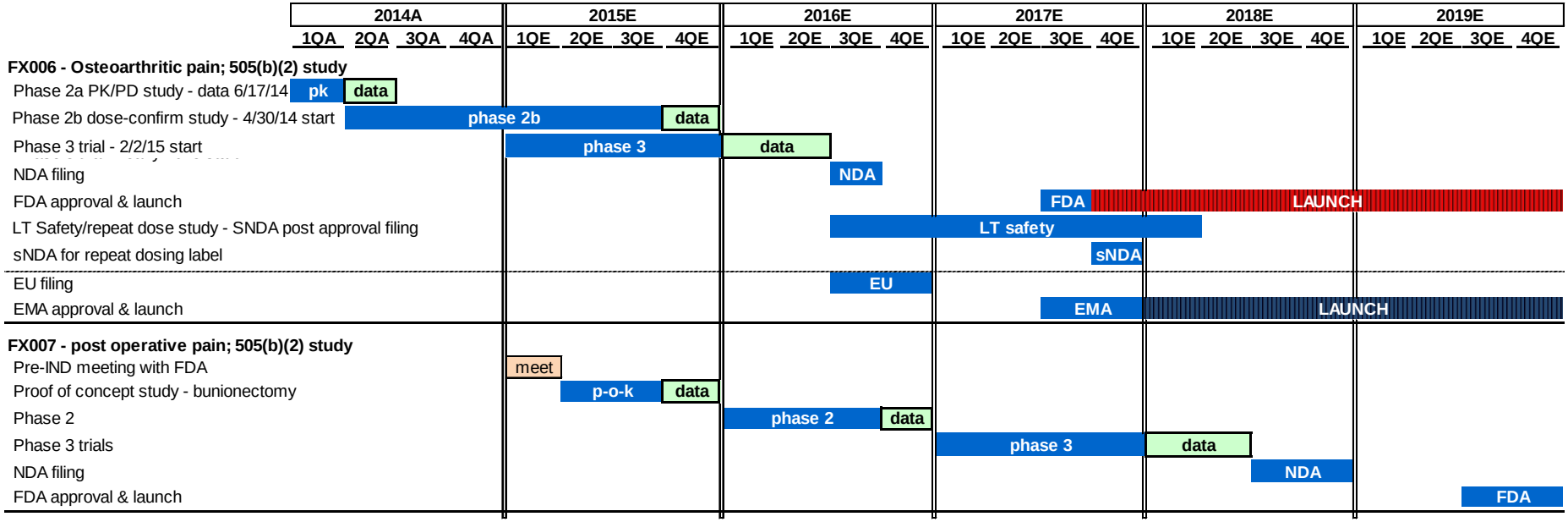
Frederick W. Driscoll, CFO. Mr. Driscoll has served as chief financial officer since May 2013. Prior to joining FLXN Mr. Driscoll was chief financial officer at Novavax, Inc., a publicly traded biopharmaceutical company since 2009. Previously, Mr. Driscoll also served as chief financial officer from 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.

Anjali Kumar, PhD, FAHA Vice President of Nonclinical R&D and Scientific Affairs. Dr. Kumar brings FLXN ~15 years of experience in drug discovery, pharmacology, and preclinical development gained in large pharmaceutical companies, small biotech, and a consulting company environment. She has experience advancing several small molecules and proteins into initial clinical development and continuing to support them through later stages of development and eventual regulatory approval. Dr. Kumar has worked in the area of inflammation in musculoskeletal, respiratory, and cardiovascular diseases. She was previously vice president of R&D at Clinquest, Inc., where she led the strategic drug development consulting team that worked on multiple programs in both the US and in Europe. Prior to that, she was senior director, pharmacology, at Critical Therapeutics, Inc. and principal scientist and project leader at Wyeth Research/Genetics Institute. She received her postdoctoral training at Pharmacia and Upjohn and holds a PhD in bioengineering from Georgia Institute of Technology and a bachelor's degree in chemical engineering from the Indian Institute of Technology.

Flexion

Clinical development trial timelines



Source: Company reports and Laidlaw estimates

Specialty Pharmaceuticals
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Quarterly Income Statement

Flexion
Quarterly income statement

($000 except per share)	2014A 1QA	2014A 2QA	2014A 3QA	2014A 4QA	2014A Year	2015E 1QE	2015E 2QE	2015E 3QE	2015E 4QE	2015E Year
Revenues										
Total Revenue										
Expenses:										
Cost of Revenue (COGS)						-	-	-	-	-
Gross Margin	**-**	**-**	**-**	**-**	**0**	**-**	**-**	**-**	**-**	**0**
Research and development	4,151	3,615	4,658	5,499	17,923	8,000	8,150	8,100	8,000	32,250
General and administrative	2,284	2,234	2,304	2,242	9,064	2,500	3,000	3,250	3,500	12,250
Total operating expenses	6,435	5,849	6,962	7,741	26,987	10,500	11,150	11,350	11,500	44,500
Income (loss) from Operations	**(6,435)**	**(5,849)**	**(6,962)**	**(7,741)**	**(26,987)**	**(10,500)**	**(11,150)**	**(11,350)**	**(11,500)**	**(44,500)**
Interest income (expense), net	(81)	28	56	75	78	50	50	50	50	200
Other income (exp)	(26)	(110)	(130)	(138)	(404)	(100)	(100)	(100)	(100)	(400)
Income (loss) before taxes	**(6,542)**	**(5,931)**	**(7,036)**	**(7,804)**	**(27,313)**	**(10,550)**	**(11,200)**	**(11,400)**	**(11,550)**	**(44,700)**
Income tax exp (benefit)										
Net Income (Loss)	**(6,542)**	**(5,931)**	**(7,036)**	**(7,804)**	**(27,313)**	**(10,550)**	**(11,200)**	**(11,400)**	**(11,550)**	**(44,700)**
Earning per Share (EPS)	**($0.86)**	**($0.38)**	**($0.45)**	**($0.47)**	**($1.97)**	**($0.47)**	**($0.49)**	**($0.50)**	**($0.50)**	**($1.95)**
Weighted avg. shares (000)	7,633	15,619	15,625	16,699	13,894	22,495	22,745	22,995	23,245	22,870
Fully diluted shares (000)	8,575	16,828	16,859	18,054	15,079	23,495	23,745	23,995	24,245	23,870

Source: Company reports and Laidlaw estimates

Specialty Pharmaceuticals
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Annual Income Statement

Flexion
Annual income statement

($000 except per share)	2014A	2015E	2016E	2017E	2018E	2019E	Comments
Revenues							
FX006 - OA pain				$1,655	$200,497	$340,745	US launch late 2017
FX007 - post operative pain						0	2020 launch estimated
FX006 ex-US royalties					13,748	22,303	Partner ex-US
Total Revenue	**$0**	**$0**	**$0**	**$1,655**	**$214,246**	**$363,049**	
Expenses:							
Cost of Revenue (COGS)	-	-	-	248	30,075	51,112	
Gross Margin	**-**	**-**	**-**	**1,407**	**184,171**	**311,937**	
R&D	17,923	32,250	35,500	36,000	38,000	45,250	
G&A	9,064	12,250	15,250	16,750	43,750	73,750	Self-launch FX006 in US
Total op exp	26,987	44,500	50,750	52,750	81,750	119,000	
Inc/(loss) from Ops	**(26,987)**	**(44,500)**	**(50,750)**	**(51,343)**	**102,421**	**192,937**	
Int income (exp), net	78	200	200	250	300	450	
Other expenses, net	(404)	(400)	(200)	(200)	(200)	(199)	
Inc/(loss) before taxes	**(27,313)**	**(44,700)**	**(50,750)**	**(51,293)**	**102,521**	**193,188**	
Income tax exp (benefit)	-	-	-	-	-	28,978	Sig. tax loss carryforwards
Net Income (Loss)	**($27,313)**	**($44,700)**	**($50,750)**	**($51,293)**	**$102,521**	**$164,210**	
Earning per Share	**($1.97)**	**($1.95)**	**($2.10)**	**($2.00)**	**$3.40**	**$5.00**	
Weighted avg. shares (000)	13,894	22,870	24,120	25,620	28,120	30,620	
Fully diluted shares (000)	15,079	23,870	25,120	26,870	30,120	32,870	
Cash balance	$151,753	$109,842	$62,442	$14,999	$122,145	$288,505	IPO cash through 2H15

Source: Company reports and Laidlaw estimates

Specialty Pharmaceuticals
Jim Molloy (617) 283-5521 jmolloy@laidlawltd.com

Balance Sheet

Flexion
Balance sheet

($000's except per share)	2013A	1Q14A	2Q14A	3Q14A	2014A	2015E	2016E	2017E	2018E	2019E
ASSETS:										
Current assets										
Cash and cash equivalents	16,188	35,789	12,015	14,365	103,098	**109,842**	**62,442**	**14,999**	**122,145**	**288,505**
Marketable securities	250	42,723	59,977	52,224	48,527					
Related party receivable										
Prepaid expenses and other	182	845	684	710	502					
Other										
Total current assets	**16,620**	**79,358**	**72,676**	**67,299**	**152,127**	**111,092**	**63,942**	**16,499**	**123,895**	**290,755**
PP&E	375	393	388	682	1,109	425	425	450	500	500
Def financing costs	1,624									
Deposits & other	29	25	21	17	12					
Restricted cash	128	128	128	128	128					
Total Assets	**18,776**	**79,903**	**73,212**	**68,125**	**153,377**	**111,517**	**64,367**	**16,949**	**124,395**	**291,255**
LIABILITIES										
Total current liabilities	**5,037**	**5,383**	**4,447**	**6,195**	**6,799**	**4,750**	**5,000**	**5,500**	**5,600**	**5,750**
Total liabilities	**83,480**	**8,522**	**7,085**	**8,334**	**8,435**	**10,250**	**11,500**	**12,750**	**15,000**	**15,250**
Shareholders Equity										
Common stock	1	16	16	16	21	20	20	20	20	20
Additional paid-in-capital	1,459	144,070	144,744	145,447	238,403	239,424	241,774	244,399	247,074	249,474
Other comp income	(0)	1	3	1	(5)					
Accumulated deficit	(66,163)	(72,705)	(78,636)	(85,672)	(93,477)	(138,177)	(188,927)	(240,220)	(137,699)	26,511
Total shareholders' equity	**(64,704)**	**71,381**	**66,127**	**59,791**	**144,942**	**101,267**	**52,867**	**4,199**	**109,395**	**276,005**
Total liabilites & net worth	**18,776**	**79,903**	**73,212**	**68,125**	**153,377**	**111,517**	**64,367**	**16,949**	**124,395**	**291,255**

Source: Company reports and Laidlaw estimates

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Cash flow Statement

Flexion
Statement of cash flows

($000's except per share)	2013A	1Q14A	2Q14A	3Q14A	2014A	2015E	2016E	2017E	2018E	2019E
Operating Activities										
Net Income (Loss)	($18,187)	($6,542)	($12,473)	($19,508)	($27,314)	($44,700)	($50,750)	($51,293)	$102,521	$164,210
Adjustments:										
Depreciation	80	27	53	85	120	100	100	100	125	150
Stock-based comp exp	996	436	1,094	1,752	2,451	1,750	1,750	2,000	2,250	2,250
Amort mktbl securities	151	9	100	227	366					
Loss on disposal of Equip	14									
Other non-cash charges	63	4	8	12	17					
Changes in assets and liab	695	(422)	(1,043)	618	1,215	1,067	1,000	1,250	2,000	(250)
Net cash from operations	**(16,187)**	**(6,487)**	**(12,261)**	**(16,814)**	**(23,145)**	**(41,783)**	**(47,900)**	**(47,943)**	**106,896**	**166,360**
Investing Activities										
Purchase of equipment	(405)	(45)	(62)	(327)	(802)	(1,000)	(1,000)	(1,000)	(1,000)	(1,000)
Changes in restricted cash	(98)									
Purchase mktble securities	(15,016)	(42,732)	(62,183)	(72,360)	(79,384)					
Sales of mktble securities	31,160	250	2,360	20,160	30,735					
Net cash from investing	**15,641**	**(42,526)**	**(59,884)**	**(52,526)**	**(49,451)**	**(1,000)**	**(1,000)**	**(1,000)**	**(1,000)**	**(1,000)**
Financing Activities										
Proceeds from term loan	5,000									
Payments of debts	(41)		(500)	(1,000)	(1,500)					
Payment of IPO costs	(1,073)	(1,097)	(1,283)	(1,283)	(1,517)					
Proceeds from common		69,518	69,518	69,518	162,138	48,527				
Proceeds from ESOP					81					
Proceeds from stock options	12	193	238	283	304	500	1,000	1,000	1,000	1,000
Net cash from financing	**3,899**	**68,614**	**67,973**	**67,517**	**159,505**	**49,027**	**1,000**	**1,000**	**1,000**	**1,000**
Net change in cash	**3,353**	**19,601**	**(4,173)**	**(1,823)**	**86,909**	**6,245**	**(47,900)**	**(47,943)**	**106,896**	**166,360**
Cash at beginning of year	12,835	16,188	16,188	16,188	16,188	103,098	109,342	61,442	13,499	120,395
Cash at end of year	**16,188**	**35,789**	**12,015**	**14,365**	**103,098**	**109,342**	**61,442**	**13,499**	**120,395**	**286,755**

Source: Company reports and Laidlaw estimates

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DISCLOSURES:

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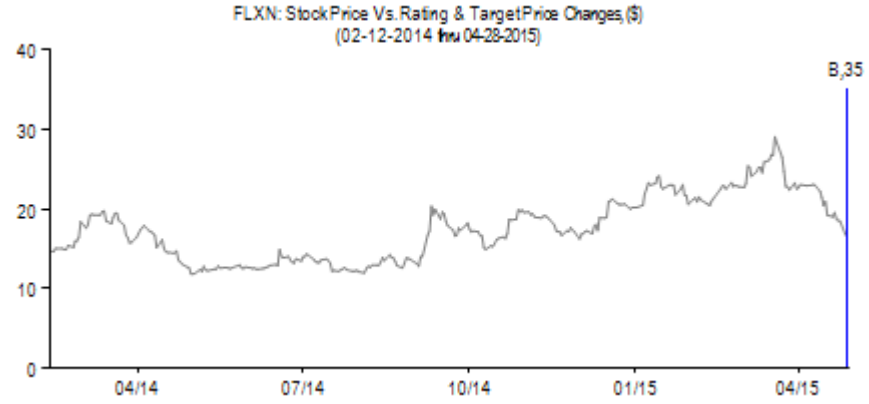
Additional information available upon request.

‡ Laidlaw & Company has received compensation from the subject company for investment banking services in the past 12 months and expects to receive or intends to seek compensation for investment banking services from the company in the next three months.

RATINGS INFORMATION

Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
04/28/2015	Buy (B)	16.80*

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
04/28/2015	35.00	16.80*

** Previous Close4/27/2015*

Source: Laidlaw & Company **Created by: Blue-Compass.net**

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	70.83%	33.33%	8.33%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.17%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Pfizer (PFE-NR)
Anika Therapeutics (ANIK-NR)
Ampio Pharmaceuticals (AMPE-NR)
Merck Serono (MRK.DE-NR)
Allergan (AGN-NR)
Pacira Pharmaceuticals (PCRX-NR)
AstraZeneca (AZN-NR)

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