Flexion Therapeutics Inc
Form 10-K
March 28, 2014
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(MARK ONE)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2013

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from ___ to ___

Commission File Number 001-36287

Flexion Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-1388364**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
10 Mall Road, Suite 301	
Burlington, Massachusetts	**01803**

(Address of principal executive offices) **(Zip Code)**

(781) 305-7777

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	**The NASDAQ Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x.

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ¨ No x

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer ¨	Accelerated filer ¨	Non-accelerated filer ¨	Smaller reporting company x (Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act). Yes ¨ No x

The registrant did not have a public float on the last business day of its most recently completed second fiscal quarter because there was no public market for the registrant s common equity as of such date.

The number of outstanding shares of the registrant s common stock as of March 25, 2014 was 15,609,039.

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FLEXION THERAPEUTICS, INC.

FORM 10-K ANNUAL REPORT

For the Fiscal Year Ended December 31, 2013

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PART I

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K, or this Annual Report, contains forward-looking statements that is, statements related to future, not past, events as defined in Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that reflect our current expectations regarding our future growth, results of operations, financial condition, cash flows, performance and business prospects, and opportunities, as well as assumptions made by, and information currently available to, our management. Forward-looking statements include any statement that does not directly relate to a current or historical fact. The Company has tried to identify forward-looking statements by using words such as believe, may, could, will, estimate, continue, anticipate, intend, seek, plan, ex Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: we have incurred significant losses since our inception resulting in an accumulated deficit of $66.2 million as of December 31, 2013, and we expect to incur substantial losses for the foreseeable future and may never achieve or maintain profitability; we have not generated any revenue from, or received regulatory approval for, any of our product candidates; we are a development stage company and will require additional capital, including prior to completing Phase 3 development of, filing for regulatory approval for, or commercializing, FX006 or any of our other product candidates; we have never conducted a pivotal clinical trial for FX006 or any of our other product candidates and may be unable to successfully complete the development of, obtain regulatory approval for, or commercialize any of our product candidates; we rely on third parties to manufacture and conduct the clinical trials of our product candidates, which could delay or limit their future development or regulatory approval; we currently do not have the infrastructure to commercialize any of our product candidates if such products receive regulatory approval; we may be unable to adequately maintain and protect our proprietary intellectual property assets, which could impair our commercial opportunities; and other risks detailed below in Item 1A. Risk Factors.

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

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Item 1. Business

Overview

We are a specialty pharmaceutical company focused on the development and commercialization of novel, injectable pain therapies. We are targeting anti-inflammatory and analgesic therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis, a type of degenerative arthritis, referred to as OA and post-operative pain. Our broad and diversified portfolio of product candidates addresses the OA pain treatment spectrum, from moderate to severe pain, and provides us with multiple opportunities to achieve our goal of commercializing novel, patient-focused pain therapies.

Our lead product candidate, FX006, is a first-in-class injectable, sustained-release, intra-articular, meaning in the joint, or IA, steroid treatment for patients with moderate to severe OA pain. FX006 was specifically designed to address the limitations of current IA therapies by providing long-lasting, local analgesia while avoiding systemic side effects, which are effects that occur throughout the body as a result of drug that is released from the site of injection into circulating blood. In a completed Phase 2b dose-ranging clinical trial, FX006 has demonstrated clinically meaningful and significantly better pain relief compared to the current injectable standard of care. Before pursuing Phase 3 clinical development, we expect to initiate a confirmatory Phase 2b clinical trial in the second quarter of 2014 to further identify a safe and well-tolerated dose of FX006 that demonstrates superior pain relief to placebo. We are also currently conducting a synovial fluid pharmacokinetic clinical trial to measure the duration that FX006 remains in the joint, which will inform us on the dosing regimen for a planned repeat dose safety clinical trial to assess when repeat dosing of FX006 can be safely administered.

We believe that FX006 has the potential to be a superior front line injectable treatment for OA pain management compared to existing therapies by providing safe, more effective and sustained pain relief to patients. We believe the following attributes make FX006 an attractive development candidate:

A first-in-class injectable, IA, sustained-release treatment for patients with moderate to severe OA pain that has demonstrated in clinical trials to date:

- clinically meaningful and significantly better pain relief.
- persistent therapeutic concentrations of drug in the joint and durable efficacy.
- an attractive safety profile with limited systemic exposures and the potential for fewer side effects.

Amongst the largest analgesic effects seen in OA clinical trials.

Strong proprietary position through a combination of patents, trade secrets and proprietary know-how, as well as eligibility for marketing exclusivity.

Well-defined 505(b)(2) regulatory pathway seeking approval of the already approved immediate-release steroid used by orthopedists and rheumatologists.

Potential for pharmacoeconomic benefits due to superior efficacy and durability and the potential to delay costly and invasive total joint replacement, also referred to as total joint arthroplasty, or TJA.

Our other product candidates include FX007 for post-operative pain and FX005 for the treatment of 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 TJA. We plan to initiate a Phase 2a proof of concept, or PoC, clinical trial, for FX007, in the second half of 2014. FX005 is a

sustained-release p38 MAP, or mitogen-activated protein, kinase inhibitor which has both analgesic and anti-inflammatory effects. FX005 successfully completed a Phase 2a PoC clinical trial demonstrating significant pain relief and function improvement. We will continue to evaluate further development of FX005 taking into consideration, among other factors, our available capital resources.

We have worldwide commercialization rights to all of our therapeutic candidates. We intend to market our products in the United States through our own sales force targeting specialty physicians, including orthopedists and rheumatologists. Outside of the United States, we are exploring selective partnerships with third parties for the development and commercialization of our product candidates. Each of our product candidates and our poly lactic-co-glycolic acid, referred to as PLGA, formulation technology is protected through a combination of patents, trade secrets and proprietary know-how, and we intend to seek marketing exclusivity for any approved products.

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 United States and OA is the most common joint disease, affecting 27 million Americans, with numbers expected to grow as a result of aging, obesity and sports injuries. Recent data suggest that OA accounts for over $185 billion of annual healthcare expenditures in the United States, which does not include loss of productivity costs. We estimate that by 2030, 45 million people will have OA. 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. As the disease progresses, it becomes increasingly painful and debilitating, culminating, in many cases, in the need for TJA.

Current therapies for OA are suboptimal, and, because there is no cure for the disease, controlling pain and delaying surgery are the primary goals for treatment regimens. Oral drugs, such as non-steroidal anti-inflammatory drugs, or NSAIDs, including COX II inhibitors and Cymbalta, as well as topical NSAIDs, are used to treat early-stage OA pain but have limited effect on pain and, given the amount and frequency of use in OA patients, are associated with serious side effects. For example, NSAIDs have shown increased risk of serious cardiovascular (CV) thrombotic events, myocardial infarction, and stroke. Furthermore, this class of drugs can cause serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines. These serious side effects are particularly worrisome because OA patients often have co-existing medical conditions, including diabetes and hypertension. For patients with moderate to severe OA pain, IA medicines, such as immediate-release steroids and hyaluronic acid, or HA, injected into the joint, are generally considered safe, but 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, a painful and expensive procedure. Further, because the initial joint replacement wears out over time, the younger the patient is 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, each year approximately ten million patients in the United States receive IA steroid injection treatments in the knee, hip, shoulder, hand and foot. Our clinical trials to date have treated patients with knee OA, which represents the most common joint treated with IA therapies for OA. In 2012, the number of patients that received knee injections of IA steroids increased approximately 12% to three million patients. We estimate that an additional 1.3 million patients received knee injections of IA HA, which the U.S. Food and Drug Administration, or FDA, has approved for use only in the knee. Sales of HA in the United States grew over 6% to approximately $690 million in 2012, 93% of which were related to knee therapy. Worldwide, HA sales are approaching $2 billion. However, recent negative guidance from specialty societies (e.g. the American Academy of Orthopedic Surgeons (AAOS), and the Osteoarthritis Research Society International (OARSI) may begin to put downward pressure on HA

sales. Our projections indicate that by 2030 approximately 23.5 million of the 45 million OA patients will have knee OA.

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Our Strategy

Our goal is to cost-effectively develop and commercialize novel therapies that will provide safe and substantial analgesia, or pain relief. Initially, we intend to develop a diverse portfolio of product candidates for the treatment of OA and post-operative pain where we believe there are significant unmet needs. The principal elements of our strategy to accomplish this goal are the following:

Focus on novel product candidates that provide long-lasting analgesia locally while avoiding systemic side effects. We intend to develop anti-inflammatory and analgesic therapies for the treatment of patients with musculoskeletal conditions, beginning with OA and post-operative pain. Many OA patients will eventually require IA injection therapies to control their pain as the disease progresses. While the benefits of HA injections generally last for a longer period of time than steroid injections, they are only marginally more effective than placebo. As a result, we believe there is a significant unmet medical need for persistent, effective and safe OA pain relief that can be addressed by IA sustained-release injection therapies. We have therefore formulated our IA product candidates, FX006 and FX005, with the goal of achieving effective drug concentrations in the joint for months, while avoiding significant plasma concentrations of drug that have been linked to systemic side effects. FX007 is being developed to treat post-operative pain. 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.

Mitigate development risk and expedite regulatory timeline to product approval. We seek to mitigate development risk by selecting product candidates with validated mechanisms of action. Each of our product candidates also utilizes a unique mechanism of action for achieving analgesia and/or anti-inflammatory effects, which diversifies development risk across multiple targets. In addition, for FX006 and FX005, our sustained-release technology employs PLGA delivery systems, which are already used in approved sustained-release drug products outside of OA and in approved surgical devices. Because FX006 incorporates an already approved steroid in PLGA, we believe it qualifies for 505(b)(2) status under the Federal Food, Drug and Cosmetic Act, or FDCA, which can be an expeditious, cost-effective means to seek product approval, as well as potentially to expand indications for this product candidate. Section 505(b)(2) of the FDCA enables the applicant to rely, in part, on published literature or the FDA s findings of safety and efficacy for an existing product in support of its application.

Target multiple points in the OA pain treatment spectrum. To maximize the likelihood of bringing products to market successfully, our product candidates target different elements of the OA treatment continuum. FX006 is targeted for front line IA therapy in patients with moderate to severe OA pain, FX005 is targeted for patients who progress to end-stage disease and FX007 is targeted for patients with post-operative pain, including those undergoing TJAs.

Retain commercial rights in the United States and selectively partner outside of the United States. Because IA therapies in the United States are administered by a relatively small number of specialists, particularly orthopedists and rheumatologists, we believe that we can cost-effectively commercialize our product candidates, if approved, with our own specialty sales and marketing organization in the United States, and thereby retain more of the commercial value of these product candidates. In prior years, Genzyme Corp.,

which has been acquired by Sanofi, supported sales of Synvisc utilizing a sales force of approximately 100 representatives. We believe we can establish an effective U.S. commercial organization with our own specialty sales force of approximately 60 to 100 representatives that target orthopedists and rheumatologists. Outside of the United States, we are exploring selective partnerships with third parties for the development and commercialization of our product candidates.

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Osteoarthritis

Overview

OA, also referred to as degenerative joint disease, is the most common joint disease in the United States, affecting 27 million Americans, with numbers expected to grow as a result of aging, obesity and sports injuries.

- With the U.S. population between the ages of 45 and 64 having grown 31.5% from 2000 through 2010 and accounting for 26.4% of the total population, we expect changing demographics will likely contribute to a growing number of OA patients.

- Approximately 35.0% of U.S. adults are obese, which increases the risk of developing OA.

- Knee injury is common, particularly amongst young athletes, and increases the risk of developing OA by more than fivefold.

As an example, one in two Americans is expected to develop symptomatic knee OA, the most common form of OA, during their lifetime, according to the U.S. Centers for Disease Control and Prevention. Recent research estimates that the average age of physician-diagnosed knee OA has fallen by 16 years, from age 72 in the 1990s to age 56 in the 2010s. According to the same research, Americans between the ages of 35 and 84 in the early 2010s will account for approximately 6.5 million new cases of knee OA over the next decade.

There is no cure for OA. As a result, current treatments are intended to address symptoms, in particular relief of pain and improvement in functional status, and to delay TJA. The therapeutic regimen for OA becomes increasingly invasive with progression of the disease, culminating, in many cases, in TJA. In addition, because patients are being diagnosed with OA earlier in their lives, many patients will require repeat TJAs.

Current Treatments for OA

Early-Stage OA Treatments. In early disease, treatment begins with non-pharmacologic therapy including exercise, weight control and physical therapy. As the disease progresses, physicians prescribe

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pharmacologic therapy, beginning with acetaminophen and progressing to oral NSAIDs, including COX II inhibitors, topical NSAIDs or Cymbalta. Available oral therapies have serious side effects. For example, Cymbalta may have a role in worsening depression and the emergence of suicidality in certain patients. In addition to their serious side effects, oral drugs provide limited pain relief and eventually become insufficient to control OA pain for many patients as the disease progresses.

IA Injection Treatments. When non-pharmacologic therapy and oral pain medications prove inadequate, physicians typically transition patients to IA injections. Steroids are first line IA therapy and when steroid therapy does not provide sufficiently durable pain relief, patients may progress to IA HA, a significantly more expensive, but currently reimbursable, therapy with only marginally greater effect than placebo. Triamcinolone acetonide, or TCA, the steroid used in FX006, is amongst the most commonly prescribed IA steroid injections. In 2012, the number of patients that received injections in the knee, the most commonly injected OA joint, of steroids increased approximately 12.0% to 3 million patients. Sales of HA in the United States grew over 6.0% in 2012. We estimate that approximately 1.3 million patients received knee injections of HA in 2012. Sales of HA in the United States in 2012 were over $690 million, with a cost to the patient per treatment ranging from $500 to $1,000. Worldwide, HA sales were approaching $2 billion as of 2012.

End-Stage Treatments. When patients progress to the point where IA injection therapies fail to adequately control OA pain, physicians may prescribe opioids as a medicine of last resort.

TJA and Post-Operative Pain Treatments. Due to severe pain that can no longer be controlled therapeutically, many patients opt to have TJA, which is costly and painful. One of the most prevalent TJA procedures in the United States is total knee arthroplasty. Compared to existing drug therapy, total knee arthroplasty is very expensive, costing between $25,000 and $35,000 on average, and as many as 20.0% of patients are 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. In 2009, inpatient costs exceeded $9 billion per year in the United States for total knee arthroplasty alone and based on some estimates the number of total knee arthroplasties is expected to increase sixfold between 2011 and 2030. Our own market research has indicated that healthcare payors would be willing to reimburse additional OA therapies that have the potential to delay the need for TJA.

Limitations of Current Treatments for OA

Current therapies for OA are suboptimal. Oral drugs, such as NSAIDs, while they may offer adequate analgesia for early-stage OA pain, are associated with serious side effects such as gastrointestinal bleeding and cardiovascular events, and, importantly, are eventually ineffective at managing OA pain as the disease progresses.

IA therapies, including steroids and HA preparations, are generally well-tolerated but provide pain relief that is insufficient or inadequate in duration. All IA therapies approved for OA are immediate-release suspensions or solutions that leave the joint within hours to days and are absorbed systemically, which may result in undesirable side effects. For example, IA immediate-release steroid injections are associated with elevation of blood glucose in diabetics, which can be of clinical concern. As a result of leaving the joint quickly, while IA steroids demonstrate large initial analgesic effects relative to other therapies, pain relief typically wanes after several weeks. In addition, current standards of care dictate that IA steroid suspensions not be administered more frequently than once every three months. Based on internal analysis, we believe approximately 44.0% of patients receiving IA immediate-release steroids are unsatisfied with the duration of benefit.

Despite U.S. sales of over $690 million in 2012, IA HA therapies, which are approved only for treatment in the knee, produce only marginally more effective pain relief than placebo and may have no

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discernible effect on a patient s ability to carry out their daily activities. In treatment guidelines for knee OA published in May 2013, the AAOS concluded that current published studies do not show any clinically effective response for HA injections. As a result, the guidelines do not recommend HA treatment for symptomatic knee OA and, most recently, certain insurance carriers are no longer providing policy coverage on HA.

For patients with advanced disease, opioids are the medicine of last resort. Opioids, however, are associated with significant side effects, particularly when administered chronically. These side effects include serious dependency and abuse potential, respiratory depression and cardiac events and, increasingly, deaths from unintentional overdose.

For patients undergoing surgery, control of post-operative pain is an important priority. Numerous post-operative pain treatments exist, including local injection of existing drugs at the time of surgical wound closure, opioids, intravenous acetaminophen and NSAIDs and femoral nerve blocks but these all have limitations in terms of inadequate magnitude and duration of pain relief, troublesome side-effects, such as increased risk of CV and GI events, or functional impairment.

In sum, current therapies, for OA pain are inadequate and do not address the desire among physicians and healthcare payors to manage pain for longer periods of time, which can delay TJA. In addition, existing pain therapies provide suboptimal post-operative pain relief. As such, we believe there is a significant commercial opportunity for (i) a front line IA therapy that is well-tolerated and can deliver significant and durable analgesia to patients with moderate to severe pain, (ii) a novel and potent analgesic IA therapy that can provide safe and effective pain relief for end-stage OA patients prior to TJA, and (iii) a novel therapy that safely provides persistent post-operative pain relief.

The Flexion Portfolio

Our product candidates are designed to deliver established anti-inflammatory and analgesic effects directly to the site of disease, optimizing sustained local drug concentration to achieve a durable and clinically meaningful response. These product candidates are also designed to limit systemic exposure to the drugs and minimize systemic toxicities, a major concern in the many OA patients with comorbidities, which are co-existing medical conditions. We believe that our portfolio of product candidates has the potential to offer safe, durable pain relief and functional improvement for patients across the pain treatment spectrum. Moreover, by more effectively controlling and reducing pain over longer periods of time, our therapies, notably FX006, may result in delaying costly TJA procedures in OA patients.

Our sustained-release technology allows us to incorporate pharmaceuticals in PLGA microspheres for administration of FX006 and FX005. PLGA is a proven sustained-release delivery vehicle that is metabolized to carbon dioxide and water as it releases drug in the IA space and has been used in approved drug products and surgical devices. The technology is designed to enable novel formulations of pharmaceuticals by providing controlled, sustained release of drugs over time 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 our IA therapies is the ability to maintain persistent therapeutic concentrations of drug in the joint, while minimizing systemic exposure. We believe we are the first company to administer PLGA microspheres into a human joint, and preclinical and clinical data suggest that FX006, as well as FX005, may provide local therapeutic concentrations that could last for at least three months and result in very low systemic concentrations of drug. The Phase 2a clinical trial of FX006 provides direct evidence that following a single injection, therapeutic concentrations of TCA are maintained locally (in the joint) for at least six weeks, while very low concentrations of TCA enter systemic circulation. Furthermore, clinical data from the completed Phase 2b dose-ranging clinical trial of FX006 and the Phase 2a clinical trial of FX005 suggest that following a single injection, both drug candidates can provide local pain relief and functional improvement for 12 weeks while producing very low systemic concentrations and attractive systemic

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safety profiles. Together these data suggest that the local delivery of drug from PLGA microspheres as demonstrated by FX006 and FX005 have the potential to sustain prolonged, local therapeutic effects while reducing the potential for systemic side effects.

Our portfolio currently consists of three product candidates which address the OA treatment spectrum:

FX006 is an intra-articular, sustained-release TCA that was specifically designed to address the limitations of current IA therapies by providing long lasting, local analgesia while avoiding systemic side effects. In a completed Phase 2b dose-ranging clinical trial, FX006 demonstrated clinically meaningful and significantly better pain relief compared to the current standard of care and was very well-tolerated.

FX007 is a preclinical, small-molecule TrkA receptor antagonist designed to address post-operative pain. We plan to initiate a Phase 2a clinical PoC study for FX007 in the second half of 2014.

FX005 is a sustained-release p38 MAP, or mitogen-activated protein, kinase inhibitor that has both analgesic and anti-inflammatory properties. In a Phase 2a PoC clinical trial FX005 demonstrated significant effects on both pain relief and functional improvement and was very well-tolerated. We believe FX005 may prove to be an effective therapy for OA patients with end-stage disease.

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The following chart illustrates the current status of development of our product candidates, for which we have worldwide commercialization rights:

We believe our product candidates and technology will be protected primarily through a combination of patents, trade secrets and proprietary know-how, and we intend to seek marketing exclusivity for any approved products. We have filed a composition of matter, method of manufacture and method of use patent application for FX006, which, if issued as a patent, would have patent terms until 2031. Further, considerable expertise and effort was required to carry out the large body of original work underlying the formulation of FX006, including experimenting with, and observing the effects of, over 50 steroid and PLGA formulations. We believe our extensive know-how and trade secrets relating to the manufacturing process for FX006, including those that relate to precise pharmaceutical release profiles, represent a competitive advantage.

FX006 Front Line IA Therapy for Patients with Moderate to Severe OA Pain

Overview

FX006 is a steroid, TCA, formulated for sustained-release, delivered via IA injection and designed to treat moderate to severe OA pain. FX006 combines commonly administered TCA with PLGA, the cornerstone of our injectable IA sustained-release technology.

To date, two clinical trials have been conducted to test FX006 against immediate-release TCA injection. A total of 252 patients were enrolled in these two clinical trials, of which 196 patients received FX006 and 56 patients received immediate-release TCA. In a completed Phase 2b dose-ranging clinical trial of patients with knee OA, FX006 demonstrated clinically meaningful and significant improvements in pain relief and functional status relative to a commercially available 40 mg immediate-release TCA. Data from this completed 12-week Phase 2b dose-ranging clinical trial show that FX006 has a well-tolerated systemic safety profile that is indistinguishable from the standard of care immediate-release steroid. Further, the local safety profile for FX006 in the completed 12-week Phase 2b dose-ranging clinical trial was attractive and comparable to that seen with the same dose of immediate-release steroid comparator.

Our clinical data suggest that, due to sustained-release, peak steroid concentrations in the joint with FX006 are orders of magnitude lower than those produced by currently available steroid suspensions. A pharmacodynamic study in patients has demonstrated that FX006 avoids the marked suppression of the hypothalamic-pituitary-adrenal, or HPA, axis (which determines the body s ability to make its own naturally occurring steroids) seen with commercially available steroid suspensions. The immediate-release TCA 40mg

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dose produced maximal plasma concentrations (peak plasma concentrations measured over the given sampling period) that were 30-fold higher than 40mg 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 immediate-release steroids. We are currently conducting a synovial fluid pharmacokinetic clinical trial to measure the duration of exposure to TCA from FX006 in the joint. A confirmatory Phase 2b clinical trial of FX006 is expected to begin in the second quarter of 2014 and a planned repeat dose safety clinical trial of FX006 is expected to begin in the second half of 2014.

FX006 Development Program

Study FX006-2011-001. In June 2013, we completed a Phase 2b 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 United States. The objective of the study was to identify a safe and well-tolerated dose of FX006 that demonstrates superiority to immediate-release TCA and to provide an assessment of the magnitude and duration of pain relief, while differentiating it from current front line IA therapy.

229 patients were randomized and 228 patients were treated with a single IA injection of 10, 40, or 60 mg of FX006 or 40 mg of immediate-release TCA, the labeled dose and 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 an 11-point numerical rating scale, with zero being no pain and 10 being pain as bad as you can imagine. The primary efficacy endpoint was the change from baseline to each of weeks 8, 10 and 12 for that primary outcome measure. Secondary endpoints included change from baseline in the primary outcome measure for each week not addressed in the primary endpoint, time to onset of analgesia, responder status, pain, stiffness and function measured using the Western Ontario and McMaster Universities Osteoarthritis Index, known in the industry as WOMAC, patient global impression of change, or PGIC, clinical global impression of change, or CGIC, and rescue medication consumption.

The responder status endpoint was based upon three responder analyses:

- the proportion of patients meeting the OMERACT-OARSI (Outcome Measures in Rheumatoid Arthritis clinical trials-Osteoarthritis Research Society International) responder criteria which uses a combination of pain, function and patient assessment to derive a composite endpoint,
- the proportion of patients achieving a greater than 30% improvement from baseline in the primary outcome measure, and
- the proportion of patients achieving a greater than 20% improvement from baseline in the primary outcome measure.

The rescue medication consumption endpoint was based upon the mean number of rescue medication tablets (i.e. acetaminophen) used per week to provide additional pain relief.

The WOMAC Osteoarthritis Index is an osteoarthritis-specific questionnaire completed by the patient that consists of 24 questions covering the areas of pain, stiffness and physical function.

PGIC is a single item questionnaire that uses a 7-point scale (1= very much improved; 7= very much worse) to measure the patient s impression of change regarding his or her overall status.

CGIC is a single item questionnaire that uses a 7-point scale (1= very much improved; 7= very much worse) to measure the physician s impression of change regarding a patient s overall status.

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The clinical trial design of our completed Phase 2b dose-ranging clinical trial for FX006 is outlined as follows:

Treatment arms were well-balanced with respect to demographic and baseline characteristics, with a mean baseline average daily pain score of 6.4 to 6.6. With respect to the primary outcome measure, the FX006 40 mg dose was significantly better than immediate-release TCA at improving pain relief beginning at Week 5 and continuing to Week 10 ($p<0.05$ at each time point) (see Figure 1). The FX006 40 mg dose also demonstrated significant improvement compared to immediate-release TCA in the average change from baseline in the primary outcome measure across Weeks 1 to 12 ($p=0.0382$) (see Figure 1) and in key secondary outcomes including pain, stiffness, function, PGIC, CGIC and responder status at Week 8 ($p<0.05$). The 10 mg dose of FX006 produced effects in the primary outcome measure that were consistently improved relative to immediate-release TCA but of lessor magnitude than those produced by the 40 mg dose. In clinical trials, the p-value is the probability that the result was obtained by chance. For example, a p-value of 0.10 would indicate that there is a 10% likelihood that the observed results could have happened at random. By convention, a p-value that is less than 0.05 is considered statistically significant.

The performance of the 60 mg dose in the primary outcome measure and secondary outcome measure did not represent a material improvement relative to the 40 mg dose, and following Week 6 the 60 mg dose was numerically inferior to the 40 mg dose (see Figure 2). Based on subsequent investigation, we believe that the inferior pain relief achieved by the 60 mg dose compared to lower doses of FX006 after week 6 was the result of the increased concentration of PLGA microspheres in the 60 mg dose. Following injection, we expect this resulted in aggregates, a more acidic microenvironment and accelerated degradation of microspheres, causing premature release of TCA. In this exploratory dose-ranging study, the statistical analysis assumed that the magnitude of pain relief would increase with dose. This was not the case and, for that reason, the primary endpoint was not achieved.

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Figure 1: Weekly Mean of Average Daily Pain Intensity Scores

# indicates p<0.1 for comparison of FX006 40 mg compared with immediate-release TCA; * indicates p<0.05; ** indicates p<0.01

Figure 2: Weekly Mean of Average Daily Pain Intensity Scores

All treatments were well-tolerated and there were no drug-related serious adverse events (see Figure 3). Adverse events, or AEs, were generally mild to moderate and unrelated to study drug. Local knee-related AEs, laboratory assessments, electrocardiograms and vital signs were unremarkable and similar across all treatments.

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Figure 3: FX006 Phase 2b Summary of Adverse Events

	FX006 10 mg	FX006 40 mg	FX006 60 mg	TCA IR 40 mg
	N=58	N=59	N=60	N=51
	n (%)	n (%)	n (%)	n (%)
Number of Patients with at Least 1 TEAE	27 (46.6)	33 (55.9)	34 (56.7)	28 (54.9)
Number of Patients with at Least 1 Serious TEAE	0	2 (3.4)*	1 (1.7)#	0
Number of Patients with at Least 1 TEAE Leading to Study Withdrawl	1 (1.7)	0	0	0
Number of Patients with TEAEs by Maximum Severity				
Mild	17 (29.3)			
Moderate	9 (15.5)	20 (33.9)	19 (31.7)	14 (27.5)
		13 (22.0)	15 (25.0)	12 (23.5)
Severe	1 (1.7)	0	0	2 (3.9)
Number of Patients with TEAEs by Maximum Relationship	17 (29.3)	24 (40.7)	22 (36.7)	15 (29.4)
	3 (5.2)	4 (6.8)	5 (8.3)	4 (7.8)
Not Related	3 (5.2)	2 (3.4)	4 (6.7)	3 (5.9)
Unlikely	2 (3.4)	3 (5.1)	2 (3.3)	5 (9.8)
Possibly Related	2 (3.4)	0	1 (1.7)	1 (2.0)
Probably Related	7 (12.1)	5 (8.5)	7 (11.7)	9 (17.6)
Definitely Related				

	Possibly, Probably, or Definitely Related

TEAE = Treatment Emergent Adverse Event

*Coronary artery disease and stroke both judged to be not related to drug treatment

#Axillary abscess judged to be not related to drug treatment

Study FX006-2011-002. In December 2012, we completed a multi-center, randomized, double-blind, Phase 2a clinical trial in 24 patients with OA, which was conducted to characterize systemic pharmacokinetic profiles and pharmacodynamic effects on the HPA axis of FX006 relative to 40 mg immediate-release TCA. This study also explored the local drug concentrations of FX006 in the synovial fluid of the joint.

Twenty-four patients were randomized to single IA injections of 10, 40, or 60 mg of FX006 or 40 mg of immediate-release TCA. Each patient was evaluated for a total of six weeks after treatment. Safety was evaluated and specimens were collected for plasma drug concentration and cortisol (the body s naturally occurring steroid) measurements during one 48-hour in-patient period (day 1-2), two 24-hour in-patient periods (days 14-15 and 42-43) and seven out-patient visits (days 3, 4, 5, 8, 22, 29 and 36). Synovial fluid was also collected via aspiration on day 1 just prior to study treatment administration and again on day 43, when possible.

FX006 produced systemic exposures and maximal plasma concentrations that increased in a dose proportional manner. The immediate-release TCA 40 mg dose produced maximal plasma concentrations (peak plasma concentrations measured over the given sampling period) that were 30-fold higher than 40 mg of FX006 (see Figure 4). Direct measures of synovial fluid (fluid found in the cavity of a synovial joint, in this case the knee) concentrations on day 43 demonstrated mean synovial fluid concentration of TCA for 10, 40, and 60 mg of FX006 that were above the projected therapeutic concentration of 4 ng/mL. For 40 mg of FX006, this was 82.7 ng/ml which contrasts with 40 mg of immediate-release TCA which produced a mean synovial fluid concentration of TCA that was at the lower limit of quantitation, or less than 0.05 ng/mL (see Figure 5). These data are consistent with the production of low acute systemic exposures following IA injection of 10, 40, and 60 mg of FX006 as compared to 40 mg of immediate-release TCA and the maintenance therapeutic synovial concentrations of TCA at and beyond day 43 following IA injection of 10, 40, and 60 mg of FX006 as compared to 40 mg of immediate-release TCA.

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Figure 4. Plasma TCA Concentrations over Time **Figure 5. Synovial Fluid Concentrations at Day 43**

The higher concentrations of TCA in synovial fluid produced by FX006 at day 43 are consistent with our belief that FX006 will prolong local therapeutic effects relative to immediate-release TCA. Further, we believe the lower plasma concentrations produced by FX006 on days 1-3 following injection have the potential to reduce systemic side effects (adverse effects that occur throughout the body as opposed to at a certain location) associated with immediate-release TCA treatments. Further, the pharmacodynamic effects of immediate-release TCA and FX006 IA injections can be described in terms of alterations in the HPA axis, as measured by suppression of circulating serum cortisol (a steroid hormone naturally produced by the body that plays a central role in blood sugar metabolism and in the body s response to stress). During the first three days following injection, the immediate-release TCA 40 mg dose reduced serum cortisol by almost 90%, a level that could cause an increased risk of adverse events. In contrast, the FX006 40 mg dose produced approximately a 40% reduction in serum cortisol, a magnitude that is typically not associated with adverse systemic effects. FX006 doses of 10 and 60 mg had proportionately less and more effect, respectively, on serum cortisol relative to the FX006 40 mg dose.

Other On-Going and Planned Studies

We plan to initiate a confirmatory Phase 2b clinical trial in the second quarter of 2014 to further identify a safe and well-tolerated dose of FX006 that demonstrates superior pain relief compared to placebo. The confirmatory Phase 2b clinical trial will be a multi-center, randomized, double-blind study in approximately 300 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 (multiple doses will be tested) or placebo and will be evaluated for up to 20 weeks. The primary outcome measure will be the weekly mean of the average daily pain intensity score as assessed using an 11-point numerical rating scale. Secondary endpoints will include WOMAC, PGIC, CGIC, and responder status.

We initiated a Phase 2a clinical trial of synovial fluid pharmacokinetics in November 2013 to establish duration of exposure to TCA from FX006 in the joint. The clinical trial is a multi-center, open-label study in up to 50 patients with OA of the knee. Patients are being assigned sequentially to one of five groups to receive a single IA injection of either 10 or 40 mg of FX006 or 40 mg of TCA IR. Synovial fluid will be collected via aspiration on day 1 just prior to study treatment administration, and again at weeks 12, 16 or 20 depending on the group assignment. Data from this trial will inform us on the dosing regimen for our planned repeat dose safety clinical trial that will assess when repeat dosing of FX006 can be safely administered.

FX006 Regulatory Strategy

We expect to conduct an end of Phase 2 meeting with the FDA following completion of our planned confirmatory Phase 2b clinical trial to discuss and gain agreement on a Phase 3 development plan and the requirements to support a New Drug Application, or NDA, for FX006 under Section 505(b)(2) of the FDCA.

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FX007 For Post-Operative Pain

Overview

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 nerve growth factor, commonly known as 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 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.

Post-operative pain is usually most severe in the first few days following the completion of a surgical procedure and is a response to tissue damage during surgery which stimulates peripheral nerves that signal the brain to produce a sensory and physiological response. Numerous studies reveal that the incidence and severity of post-operative pain is primarily determined by the type of surgery, duration of surgery and the pain treatment choice following surgery.

Unrelieved acute pain causes patient suffering and can lead to other complications, which delays recovery from surgery and may result in higher healthcare costs. This is particularly true with respect to post-operative TJA pain, which can compromise rehabilitation and result in poor outcomes. According to the Agency for Healthcare Research and Quality, aggressive prevention of the onset of pain is better than treatment of pain because, once established, pain is more difficult to suppress. Current multimodal therapy for post-operative pain includes administration of local anesthetics to the wound combined with the systemic administration of opioid and NSAID analgesics. Opioids are associated with a variety of unwanted and potentially severe side effects, such as respiratory depression, hypotension and constipation, and many physicians seek alternatives to opioids for their patients. These side effects may require additional medications or treatments and prolong a patient s stay in the post-anesthesia care unit and the hospital or ambulatory surgery center, thereby increasing costs significantly. The use of injectable NSAIDs, such as ketorolac and ibuprofen, is severely limited in the post-operative period because they increase the risk of bleeding and gastrointestinal and renal complications.

There are approximately 51 million surgeries performed in the United States each year, and the global post-operative pain market was estimated to be $5.9 billion in 2010. 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. Given the limitations of current post-operative therapies, we are developing FX007 as a superior alternative to manage post-operative pain. The blockade of the NGF-TrkA pathway results in highly effective analgesia. Additionally, acute local administration has the potential to avoid the side-effects associated with systemic and persistent blockade of NGF.

FX007 Development Program

FX007 is being developed to treat post-operative pain. 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, unlike FX005 and FX006, we do not believe it will be necessary to formulate FX007 with PLGA, which should expedite development of this compound.

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We have conducted preclinical PoC studies for FX007 using models of OA and post-operative pain and demonstrated efficacy in both. We plan to initiate a proof of concept clinical trial for FX007 in the second half of 2014.

FX005 For End-Stage OA Pain

Overview

FX005 is intended as therapy for patients with end-stage OA pain, particularly those patients awaiting TJA, as an alternative to opioids. FX005 is a p38 MAP kinase inhibitor formulated for sustained-release delivered via IA injection, which is designed to have both analgesic and anti-inflammatory benefits without the systemic side effects of oral p38 MAP kinase inhibitors. p38 MAP kinase is an enzyme in an inflammatory cascade that upregulates in response to stress and culminates in the elaboration of multiple proinflammatory cytokines, including interleukin 1 and tumor necrosis factor, as well as enzymes like matrix metalloproteinases that have 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. For example, a recent clinical study of an oral p38 MAP kinase inhibitor in OA demonstrated pain relief comparable to oxycodone but was associated with concerning side effects, including QTc prolongation which could increase the risk of arrhythmias. Because FX005 leverages the same PLGA technology used in FX006 in order to achieve persistent therapeutic concentrations of drug in the joint while maintaining very low plasma concentrations, it may have the potential to provide durable pain relief while avoiding p38 MAP kinase inhibitor systemic side effects. We believe the preclinical and clinical data we have generated to date support this potential.

We have a composition of matter patent in the United States that covers the p38 MAP kinase inhibitor and has an expiration date in 2028. We have also filed a composition of matter patent application on a novel formulation for FX005, which, if issued as a patent, is expected to expire in 2029. Like FX006, we have manufacturing know-how and trade secrets that we believe will provide us with additional proprietary advantages for FX005.

FX005 Development Program

In May 2012, FX005 completed a Phase 2a clinical trial in which 70 patients were randomized to FX005 and 70 patients were randomized to placebo. The Phase 2a clinical trial demonstrated positive effects of FX005 on both pain and function. These effects increased substantially in a sub-population of patients with higher baseline pain scores.

Study FX005-2010-001. A Phase 2a clinical trial in 140 patients with knee OA was conducted as a multi-center, randomized, double-blind, placebo-controlled trial and consisted of a single ascending dose phase, or SAD Phase, followed by a single dose PoC Phase. In the SAD Phase of the study, escalating doses of 1, 10, and 45 mg of FX005 were compared to blank PLGA microspheres and diluent in three cohorts of twelve patients, with six patients receiving FX005, three patients receiving blank PLGA microspheres and three patients receiving diluent in each cohort. Diluent is a placebo containing all components of the FX005 formulation except the active drug and the PLGA microspheres. Each patient in the SAD Phase was followed for safety and pharmacokinetics for six weeks after a single IA injection. FX005 was well-tolerated at each dose level and, as a result, the highest dose of 45 mg was advanced to the next phase.

In the PoC Phase, 52 patients were randomized to receive 45 mg of FX005, 26 patients were randomized to receive blank PLGA microspheres as a placebo control, and 26 patients were randomized to receive diluent as a placebo control, each as a single IA injection. Each patient was followed for 12 weeks

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after the injection for safety, pharmacokinetics, and efficacy. The primary endpoint was the change from baseline in the WOMAC pain subscale at four weeks. Secondary efficacy assessments included the WOMAC function subscale and responder status. FX005 demonstrated pain relief and functional improvement at four weeks, and the absolute magnitude of effect in both subscales was persistent through 12 weeks. These effects were substantially enhanced in a prespecified exploratory subset analysis of patients with high baseline pain. FX005 also demonstrated efficacy in responder analysis. Overall, FX005 was well-tolerated systemically and local tolerability was similar to that documented for marketed HA preparations.

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

These additional toxicology studies showed that at the human equivalent dose of 3 and 1 mg, there was no evidence of the damage to cartilage that had been associated with doses greater than or equal to 10 mg. Based on this, we expect that any further development of FX005, if any, would involve a dose substantially lower than the doses studied in the previously-conducted Phase 2a clinical trial. We will continue to evaluate further development of FX005 taking into consideration, among other factors, our available capital resources.

Manufacturing

We believe that the multifaceted nature of PLGA manufacturing and the limited number of capable contract manufacturing companies that offer PLGA manufacturing provides a competitive advantage. The technology is designed to enable novel formulations of pharmaceuticals by providing controlled, sustained release of drugs over time and the physical properties of the polymer-drug matrix can be varied to achieve specified drug loads and release rates.

We currently do not have manufacturing facilities and thus utilize contract manufacturers to produce our drug substances and drug products used for preclinical and clinical supplies. Manufacture of PLGA microspheres is a complex process and there are a limited number of contract manufacturing sites with PLGA experience. Our injectable IA immediate-release technology allows us to incorporate pharmaceuticals in PLGA microspheres for administration of FX006 and FX005. Following extensive development programs, we have generated formulations of FX006 and FX005 designed to sustain local concentrations of drug in the joint for several months. The FX005 and FX006 microsphere PLGA formulations have gone through numerous iterations and have been optimized to provide a controlled diffusion of drug over an extended period of time. In developing this unique combination of manufacturing process and formulation, we have established numerous trade secrets that relate to precise pharmaceutical release profiles.

FX006 . The active pharmaceutical ingredient in FX006, TCA, is manufactured and supplied by Farmabios SpA in accordance with current good manufacturing practice standards, or cGMP. This supplier is subject to regular inspections by the FDA. The microspheres finished product and diluent are manufactured by Evonik Corporation, or Evonik. Evonik is a global, commercial-scale supplier of cGMP-compliant bioabsorbable polymers for a wide variety of medical devices and implantable/injectable sustained-release products. Their materials are components of marketed pharmaceutical and medical device products in the United States, Europe, India and Asia.

FX007 . The active ingredient for FX007 is manufactured by AstraZeneca. Existing inventory of drug substance is from AstraZeneca and is suitable for preclinical and early clinical development. We are in the process of identifying a

new supplier to manufacture drug substance for use in later-phase manufacture of clinical supplies and commercial product.

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FX005 . The drug substance in FX005 is currently manufactured by Cambridge Major Laboratories. The microsphere-based finished drug product and associated diluent are manufactured by Evonik.

Commercial Strategy

We intend to build a commercial infrastructure in the United States to effectively support the commercialization of FX006, FX007 and FX005, in advance of anticipated drug approval of FX006. We believe that we can cost effectively penetrate the universe of prescribing orthopedic surgeons and rheumatologists in the United States with a targeted, 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. Additional requisite capabilities will include focused management of key accounts such as managed care organizations, group purchasing organizations, and government accounts.

Of patients who are treated for OA, it is estimated that 69.0% of OA patients receive IA injections from orthopedic surgeons and 31.0% receive IA injections from rheumatologists. Out of the approximate 27,300 orthopedic specialists in the United States, of whom approximately 17,800 are active orthopedic surgeons, and 5,700 rheumatologists, approximately the top 40% are considered to be the most relevant from an OA patient treatment perspective. We believe we can effectively cover both specialties and successfully execute our future commercial plans using a cost-efficient strategy, particularly given that orthopedists and rheumatologists are familiar with IA injections utilizing the same steroid in the same dose.

FX006 demonstrates clinically meaningful and significantly better pain relief and functional status compared to a commercially available immediate-release TCA. We believe FX006 s prolonged analgesia may delay the need for TJA, a costly, highly-invasive procedure with a protracted recovery time. Our own market research has indicated that healthcare payors would be willing to reimburse any additional OA therapies that have the potential for pharmacoeconomic benefits reflecting differential efficacy and durability and the potential to delay costly and invasive TJAs. As a result of both increased patient satisfaction and the potential to delay TJA, we believe FX006 will be priced competitively with existing HA therapies.

Outside of the United States, we are exploring selective partnerships with third parties for the development and commercialization of our products.

Competition

Overview

Our industry is highly competitive and subject to rapid and significant technological change. The large size and expanding scope of the pain market makes it an attractive therapeutic area for biopharmaceutical businesses. Our potential competitors include pharmaceutical, biotechnology and specialty pharmaceutical companies. Several of these companies have robust drug pipelines, readily available capital, and established research and development organizations. We believe our success will be driven by the ability to actively manage a portfolio of assets that remains highly focused on OA patients and their needs.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, durability, safety, price and the availability of reimbursement from government and other third party payors. We believe we will compete favorably by having:

best-in-class product candidates that have validated mechanisms of action for pain relief;

sustained-release technology that enable our therapies to maintain persistent therapeutic concentrations in the joint and provide durable efficacy; and

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product candidates with attractive safety profiles with limited systemic exposures and the potential for fewer side effects.

FX006 Competition

Immediate-release steroids and HA are currently the two marketed classes of IA products that would compete with FX006. Immediate-release steroids are generic and widely used as a 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 immediate-release TCA in the joint by that time. FX006 also provides prolonged analgesia significantly better than that seen with immediate-release TCA. In addition to immediate-release steroids, FX006 will compete with HA in patients considering something beyond an immediate-release steroid injection. HA therapy, which has demonstrated only marginal pain relief over placebo in knee OA patients, generated U.S. sales of over $690 million in 2012. 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.

In addition to marketed IA medications for OA, other companies have OA product candidates in advanced stages of clinical development. These IA products include Fidia Farmaceutici S.p.A s Hymovis, a physical hydrogel based on HA with properties that appear to be similar to most approved HA products, and Ampio Pharmaceuticals, Inc. s Ampion. Ampion is a derivative of human serum albumin, is described as having anti-inflammatory properties, and is formulated for immediate release. It is currently in Phase 2/3 clinical trials and the 3 month data suggest it has an HA-like efficacy profile. Other programs, such as Orthotrophix s TPX-100, Carbylan BioSurgery, Inc. s Hydros-TA, Merck Serono s FGF-18 and Allergan, Inc. s botulinum toxin, we believe, have not yet entered Phase 3 clinical trials. Autologous cartilage transplantation products, like Carticel, are appropriate for focal defects in cartilage, not the kind of diffuse disease that is seen with OA. Stem cell approaches to OA are being explored, but these are earlier in development, bear significant technical risks and it remains to be seen how applicable they will be to the treatment of OA. Early clinical data from Eupraxia s EP-104 is a pre-clinical/Phase I therapy that combines an unapproved carrier technology (Plexis) with a steroid (fluticasone) that is not commonly used for the treatment of knee OA.

Finally, there are many new oral therapies in development for OA pain, but we believe these therapies are likely to expose patients to systemic safety risks greater than that of FX006.

FX007 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. However, these all have limitations in terms of inadequate magnitude and duration of pain relief, serious side effects or functional impairment. Pacira Pharmaceuticals has more recently 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.

FX005 Competition

FX005 would compete mainly against oral opioids, as patients require very strong analgesic therapy prior to receiving a TJA. Opioids have numerous systemic side effects, including addiction and

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constipation, and also cause a higher incidence of falls and fractures in an older OA patient population. Competitors for FX005 include new formulations of existing opioids, including Janssen Pharmaceuticals, Inc. s Nucynta ER and Johnson & Johnson s OROS. For patients with end-stage disease, monoclonal anti-NGF antibodies have the potential to offer powerful pain relief, but in controlled clinical trials these agents were associated with accelerated progression to joint replacement and were placed on clinical hold for the treatment of OA by the FDA in 2010. At the present time, we are not aware of any ongoing trials of monoclonal anti-NGF antibodies in OA.

Intellectual Property/Patents and Proprietary Rights

Intellectual Property and Exclusivity

We seek to protect our product candidates and our technology through a combination of patents, trade secrets, proprietary know-how, FDA exclusivity and contractual restrictions on disclosure.

Patents and Patent Applications

Our policy is to seek to protect the proprietary position of our product candidates by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. U.S. patents generally have a term of 20 years from the earliest effective date of the application.

As of December 31, 2013, we exclusively license one U.S. patent, one U.S. patent application and their foreign counterparts directed to FX007 and one U.S. patent, one U.S. patent application and their foreign counterparts directed to FX005. In addition, we own two pending U.S. non-provisional patent applications and counterpart foreign patent applications, along with two pending U.S. provisional patent applications, all directed to our FX006 product candidate.

There is one issued U.S. patent covering the TrkA antagonist compound, FX007, which is owned by AstraZeneca and to which we have an exclusive license. This patent is scheduled to expire in 2028. We have also licensed counterpart foreign patents that have granted in 49 countries, which include Australia, Canada, and other countries. These patents in Australia, Canada and multiple European countries are scheduled to expire in 2026. We have licensed counterpart patent applications that are pending in Brazil, Ecuador, Egypt, India, Malaysia, Norway, Pakistan, Uruguay, Venezuela, Argentina, Indonesia, and Thailand.

There is one issued U.S. patent covering the p38 compound, FX005, which is owned by AstraZeneca and to which we have an exclusive license. This patent is scheduled to expire in 2028. We have also licensed counterpart foreign patents that have granted in over 50 countries, which include Australia, Canada, and other countries. The patents in Australia, Canada and multiple European countries are scheduled to expire in 2024. We have also licensed counterpart patent applications that are pending in Argentina, Brazil, Egypt, Indonesia, Norway, Uruguay, Thailand, and Venezuela.

We have rights to four pending U.S. patent applications directed to:

- Sustained-Release Formulations, Populations of Microparticles, Method of Manufacture and Method of Use: Corticosteroids for the Treatment of Joint Pain (FX006) a patent, if issued based on this application, would be expected to expire in 2031.

Formulation patent application for FX007 a patent, if issued based on this application, would be expected to expire in 2031.

Two sustained-release formulation patent applications for FX005 patents, if issued based on these applications, would be expected to expire in 2029.

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In addition to our pending U.S. patent applications to formulations containing FX005 or FX007, we have rights in an issued European patent directed to formulations containing FX005 and rights in a pending European patent application directed to formulations containing FX007. The issued European patent directed to formulations containing FX005 is scheduled to expire in 2029. A patent, if granted, based on the pending European patent application directed to formulations containing FX007 is estimated to expire in 2031. In addition, we also have rights in patents or pending patent applications to formulations containing FX005 in over 20 foreign countries and we have rights in pending patent applications to formulations containing FX007 in over 25 countries.

Further, for our FX006 product candidate, we have rights in foreign patent applications pending in Australia, Canada, Europe and other foreign countries. Our three related pending U.S. provisional patent applications directed to our FX006 product candidate which, if pursued as a non-provisional patent application, could result in a patent expiring in 2034.

We have other patent applications, including an international application, on formulations or uses of compounds that are not relevant to our current programs in development.

Trade Secrets and Proprietary Information

The FX005 and FX006 microsphere PLGA formulations have gone through numerous iterations and have been optimized to deliver the drug substance with a controlled diffusion of drug over an extended period of time. In developing this unique combination of manufacturing process and formulation, we have established numerous trade secrets, including those that relate to a precise pharmaceutical release profile. In addition, due to the complexity of the sustained-release technology and the time, costs and technical risks involved in demonstrating bioequivalence through clinical trials, we believe that the ability of manufacturers to gain market approval for generic alternatives to our products upon expiration of our patents and FDA exclusivity will be challenging.

We seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring our employees to execute Proprietary Information, Inventions, Non-Solicitation, and Non-Competition Agreements upon the commencement of their employment. Consultants and other advisors are required to sign consulting agreements. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not be disclosed to third parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment shall be our exclusive property to the extent permitted by law. Further, we require confidentiality agreements from entities that receive our confidential data or materials.

License Agreements

We have entered into license agreements with AstraZeneca for the license of FX007 and FX005.

AstraZeneca FX007. On September 3, 2010, we entered into an exclusive license agreement with AstraZeneca for FX007. The agreement grants us an exclusive, royalty-bearing, world-wide right and license (with a right to sublicense, subject to certain conditions described below) under AstraZeneca s patent rights and certain know-how covering FX007. We paid AstraZeneca a non-refundable fee following execution of the agreement and will owe up to an aggregate of $21 million upon the achievement of certain regulatory and development milestones for a first licensed product for OA indications or up to an aggregate of $15 million 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, we will owe AstraZeneca tiered royalty payments on

net sales based on a percentage ranging from low single digits to low double digits, depending on the volume of

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sales of the applicable product, as well as up to $75 million in additional payments based on the achievement of certain sales milestones. Our obligation to pay royalties to AstraZeneca will continue on a country-by-country basis until the later to occur of 12 years following the first commercial sale of the applicable product in the applicable country, or the date that the product is no longer covered by AstraZeneca s patent rights or any applicable data or marketing exclusivity periods in such country.

Under the terms of the agreement, we may not grant sublicenses except in the territory of Japan prior to the achievement of a specified development milestone. In addition, the agreement provides that in the event we desire to offer rights to FX007 to a third party prior to the achievement of a specified development milestone, we must make certain diligence materials available to AstraZeneca, and AstraZeneca will have the right to make an offer to re-acquire rights to FX007. In such circumstances, we are not required to accept AstraZeneca s offer, but we may not enter into an agreement with a third party containing financial terms and conditions that on the whole are more favorable to the third party than the terms and conditions last offered by AstraZeneca.

Unless earlier terminated, the agreement will continue in effect for as long as we are obligated to pay royalties to AstraZeneca, after which the licenses granted to us will survive and become royalty-free, perpetual and irrevocable. AstraZeneca has the right to terminate the agreement if we fail to use commercially reasonable efforts to develop, commercialize and sell licensed products in major markets (subject to a good-faith negotiation and cure period) or if we or any of our affiliates or sublicensees institute, prosecute or otherwise participate in any proceeding challenging the AstraZeneca patent rights that are licensed under the agreement. AstraZeneca also has a right to terminate the agreement in the event of a change of control of us prior to the achievement of a specified development milestone, unless we pay a fee to AstraZeneca (which can be offset against future milestone payments), in which case this termination right will be forfeited. We have the right to terminate the agreement in its entirety, or on a country-by-country basis, for any reason upon three months prior written notice to AstraZeneca. In addition, either party may terminate the agreement in the event of the other party s uncured material breach of the agreement, or in the event of the other party s bankruptcy or insolvency.

AstraZeneca FX005. On June 12, 2009, we entered into an exclusive license agreement with AstraZeneca for FX005. The agreement grants us an exclusive, royalty-bearing, world-wide right and license (with a right to sublicense) under AstraZeneca s patent rights and certain know-how covering FX005. We paid AstraZeneca a non-refundable fee upon execution of the agreement and will owe up to an aggregate of $17 million upon the achievement of certain regulatory and development milestones for a first licensed product for OA indications or up to an aggregate of $11 million 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, we will owe AstraZeneca tiered royalty payments on net sales based on a percentage ranging from low to high single digits, depending on the volume of sales of the applicable product, as well as up to $45 million in additional payments based on the achievement of certain sales milestones. Our obligation to pay royalties to AstraZeneca will continue on a country-by-country basis until the later to occur of 12 years following the first commercial sale of the applicable product in the applicable country, or the date that the product is no longer covered by AstraZeneca s patent rights or any applicable data or marketing exclusivity periods in such country.

The agreement provides that in the event we desire to offer rights to FX005 to a third party prior to the achievement of a specified development milestone, we must make certain diligence materials available to AstraZeneca and AstraZeneca will have the right to make an offer to re-acquire rights to FX005. However, pursuant to a separate letter agreement entered into between the parties on December 3, 2012, AstraZeneca agreed to waive this right for a specified period.

Unless earlier terminated, the agreement will continue in effect for as long as we are obligated to pay royalties to AstraZeneca, after which the licenses granted to us will survive and become royalty-free,

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perpetual and irrevocable. AstraZeneca has the right to terminate the agreement if we fail to use commercially reasonable efforts to develop, commercialize and sell licensed products in major markets (subject to a good-faith negotiation and cure period) or if we or any of our affiliates or sublicensees institute, prosecute or otherwise participate in any proceeding challenging the AstraZeneca patent rights that are licensed under the agreement. We have the right to terminate the agreement in its entirety, or on a country-by-country basis, for any reason upon three months prior written notice to AstraZeneca. In addition, either party may terminate the agreement in the event of the other party s uncured material breach of the agreement, or in the event of the other party s bankruptcy or insolvency. AstraZeneca initially had a right to terminate the agreement in the event of a change of control of us prior to the achievement of a specified development milestone for FX005. However, AstraZeneca agreed to waive this right pursuant to the separate letter agreement described above. Pursuant to the same letter agreement, we are now free to assign our rights under the agreement to our affiliates or to a third party in connection with a change of control.

Government Regulation and Product Approval

Government authorities in the United States at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. FX006 and any other drug candidate that we develop must be approved by the FDA before they may be legally marketed in the United States and by the corresponding foreign regulatory agencies before they may be legally marketed in foreign countries.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the FDCA and implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA s refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices, or GLP, or other applicable regulations;

- submission to the FDA of an investigational new drug, or IND, application, which must become effective before human clinical trials may begin;

- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;

performance of adequate and well-controlled human clinical trials according to the FDA s laws and regulations pertaining to the conduct of human clinical studies, collectively referred to as Good Clinical Practices, or GCP, and according to the International Conference of Harmonization, or ICH, GCP guidelines, to establish the safety and efficacy of the proposed drug for its intended use;

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submission to the FDA of an NDA for a proposed new drug;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA s cGMP requirements, to assure that the facilities, methods and controls are adequate to preserve the drug s identity, strength, quality and purity;

potential FDA audit of the non-clinical and clinical trial sites that generated the data in support of the NDA; and

FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and approvals are inherently uncertain.

Before testing any compounds with potential therapeutic value in humans, the drug candidate enters the non-clinical testing stage, also referred to as preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the drug candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLP. The IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, among other things, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trial.

Clinical trials involve the administration of the drug candidate to healthy subjects or patients with the target disease under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor s control. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with the FDA s regulations which reflect the ICH GCP requirements. Further, each clinical trial must be reviewed and approved by an IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until it is completed.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the end of Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

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Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

Phase 1. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted only in patients having the specific disease.

Phase 2. The drug is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule for patients having the specific disease.

Phase 3. The drug is administered to an expanded patient population in adequate and well-controlled clinical trials to generate sufficient data to statistically confirm the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product. Generally, at least two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA. In some cases, the FDA has approved a drug based on the results of a single adequate and well-controlled Phase 3 study of excellent design and which provided highly reliable and statistically strong evidence of important clinical benefit, such as an effect on survival, and a confirmatory study would have been difficult to conduct on ethical grounds.

Post-approval studies, also referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the FDA as part of the approval process.

Progress reports detailing the status of drug development and results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects or patients. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB s requirements or if the drug has been associated with unexpected serious harm to study subjects.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

FDA Review and Approval Processes

The results of product development, preclinical studies and clinical trials for the claimed indications in all relevant pediatric subpopulations and the support for dosing and administration for each pediatric subpopulation for which the product is safe and effective, are contained in an NDA. The FDA may grant

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deferrals for submission of pediatric data or full or partial waivers after the initial submission of a pediatric study plan following an end of Phase 2 meeting unless otherwise agreed upon by the FDA and the sponsor. In addition, descriptions of the manufacturing process and controls, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are also submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has 12 months after submission of an NDA in which to complete its initial review of a standard NDA and respond to the applicant, and eight months for a priority review NDA. The FDA does not always meet its PDUFA goal dates for review of standard and priority review NDAs. The review process and the PDUFA goal date may be extended by additional three month review periods whenever the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission at any time during the review cycle.

The FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product s identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the drug approval process, the FDA also will determine whether a risk evaluation and mitigation strategy, or REMS, is necessary to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required.

Before approving an NDA, the FDA will inspect the facilities at which the product is to be manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with FDA regulations regarding conduct of clinical trials for the product s trials. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information.

The NDA review and approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data, which could delay, limit or prevent regulatory approval. The FDA will issue a complete response letter if the agency decides not to approve the NDA. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

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If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post approval studies, referred to as Phase 4 testing, which involves clinical trials designed to further assess a product s safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Post-Approval Requirements

Any drug products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. These promotion and advertising requirements include, among other things, standards for direct-to-consumer advertising, prohibitions against promoting drugs for uses or in patient populations that are not described in the drug s approved labeling (known as off-label use), rules for conducting industry-sponsored scientific and educational activities, and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Manufacturers of our products are required to comply with applicable FDA manufacturing requirements contained in the FDA s cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are also required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA. These restrictions may include suspension of a product until the FDA is assured that quality standards can be met, continuing oversight of manufacturing by the FDA under a consent decree of permanent injunction, which frequently includes the imposition of costs and continuing inspections over a period of many years, as well as possible withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and adequate reimbursement from third party payors. Third party payors include government payor programs at the federal and state levels, including Medicare and Medicaid, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third party payors may limit coverage to

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specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our drug candidates may not be considered medically necessary or cost-effective. A payor s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

The cost of pharmaceuticals continues to generate substantial governmental and third party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Third party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as the drug candidates that we are developing and could adversely affect our net revenue and results.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular drug candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

Healthcare Reform

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The Medicare Modernization Act expanded Medicare coverage for drug purchases by the elderly by establishing Medicare Part D and introduced a new reimbursement methodology based on average sales

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prices for physician administered drugs under Medicare Part B. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class under the new Medicare Part D program. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement rate that we receive for any of our approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, PPACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among other things, PPACA revises the definition of average manufacturer price for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. Although it is too early to determine the effect of PPACA, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. For example, on August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

We expect that PPACA, as well as other healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenue. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. For example, various activities, including but not

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limited to sales, marketing and scientific/educational grant programs, must comply with the anti-fraud and abuse provisions of the Social Security Act, the federal Anti-Kickback Statute, the federal False Claims Act and similar state laws, each as amended. Failure to comply with such requirements could potentially result in substantial penalties to us. Even if we structure our programs with the intent of compliance with such laws, there can be no certainty that we would not need to defend against enforcement or litigation, in light of the fact that there is significant enforcement interest in pharmaceutical companies in the United States, and some of the applicable laws are quite broad in scope.

The federal Anti-Kickback Statute prohibits any person, including a prescription drug manufacturer (or a party acting on its behalf), from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. The term remuneration is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain business arrangements from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability. The reach of the Anti-Kickback Statute was broadened by PPACA, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Additionally, many states have adopted laws similar to the federal Anti-Kickback Statute, and some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any third-party payor, not only the Medicare and Medicaid programs in at least some cases, and do not contain safe harbors.

The federal False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third party payor and not merely a federal healthcare program. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare numbers when detailing the provider of services, improper promotion of off-label uses (i.e., uses not expressly approved by FDA in a drug s label), and allegations as to misrepresentations with respect to the services rendered. Our future activities relating to the reporting of discount and rebate information and other information affecting federal, state and third party

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reimbursement of our future products, and the sale and marketing of our future products and our service arrangements or data purchases, among other activities, may be subject to scrutiny under these laws. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the cost of defending such claims, as well as any sanctions imposed, could adversely affect our financial performance. Also, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several new federal crimes, including healthcare fraud, and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, we may be subject to, or our marketing activities may be limited by, data privacy and security regulation by both the federal government and the states in which we conduct our business. For example, HIPAA and its implementing regulations established uniform federal standards for certain covered entities (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included expansion of HIPAA s privacy and security standards called the Health Information Technology for Economic and Clinical Health Act, referred to as HITECH, which became effective on February 17, 2010. Among other things, HITECH makes HIPAA s privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that create, receive, maintain, or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney s fees and costs associated with pursuing federal civil actions. We may also be subject to various federal and state marketing expenditure tracking and reporting laws, which generally require certain types of expenditures in the United States to be tracked and reported. Compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships. Several states have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, or register their sales representatives, as well as prohibiting pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and prohibiting certain other sales and marketing practices. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. If we fail to track and report as required by these laws or otherwise comply with these laws, we could be subject to the penalty provisions of the pertinent state and federal authorities.

Where our activities involve foreign government officials, they may also potentially be subject to the Foreign Corrupt Practices Act. If we seek to have a product covered in the United States by the Medicaid programs, various obligations, including government price reporting, are required under the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended, which generally require products to be offered at substantial rebates/discounts to such programs and certain purchasers. In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to

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adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Many of our current as well as possible future activities are potentially subject to federal and state consumer protection and unfair competition laws. We must also comply with laws that require clinical trial registration and reporting of clinical trial results on the publicly available clinical trial databank maintained by the National Institutes of Health at www.ClinicalTrials.gov. We are subject to various environmental, health and safety regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous substances. From time to time, and in the future, our operations may involve the use of hazardous materials.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

U.S. Marketing Exclusivity

Hatch-Waxman Exclusivity. Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications of other companies seeking to reference another company s NDA. If the new drug is a new chemical entity subject to an NDA, the FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, such an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric Exclusivity. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to any existing exclusivity period or patent term. This six-month exclusivity may be granted by the FDA based on the completion of a pediatric clinical trial in accordance with provisions of the FDCA.

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Europe/Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our future products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a clinical trial application, or CTA, must be submitted to each country s national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country s requirements, the clinical trial described in that CTA may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with the ICH GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. In the European Economic Area, or EEA (which is comprised of the 27 Member States of the European Union plus Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations: the Community MA, which is issued by the European Commission through the Centralized Procedure based on the opinion of the Committee for Medicinal Products for Human Use, a body of the European Medicines Agency, or the EMA, and which is valid throughout the entire territory of the EEA; and the National MA, which is issued by the competent authorities of the Member States of the EEA and only authorized marketing in that Member State s national territory and not the EEA as a whole.

The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. The National MA is for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member state, or RMS. If the RMS proposes to authorize the product, and the other Member States do not raise objections, the product is granted a national MA in all the Member States where the authorization was sought. Before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

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Employees

As of December 31, 2013, we had 16 full-time employees. None of our employees is represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good

Research and Development

We invested $11.1 million, $11.1 million, and $8.2 million in research and development in the years ended December 31, 2013, 2012 and 2011, respectively.

Corporate and Other Information

We were incorporated in Delaware in November 2007. Our principal executive offices are located at 10 Mall Road, Suite 301, Burlington, Massachusetts 01803, and our telephone number is (781) 305-7777. Our corporate website address is www.flexiontherapeutics.com. Information contained on or accessible through our website is not a part of this Annual Report, and the inclusion of our website address in this Annual Report is an inactive textual reference only.

This Annual Report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Form 10-K, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

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Item 1A. Risk Factors

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report as well as our other public filings with the Securities and Exchange Commission.

Risks Related to Our Financial Condition and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a development stage company with limited operating history. To date, we have focused primarily on developing our lead product candidate, FX006. We have two additional product candidates, FX007 and FX005. All of our product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have incurred significant net losses in each year since our inception, including net losses of $18.2 million, $15.0 million and $11.4 million for fiscal years 2013, 2012 and 2011, respectively. As of December 31, 2013, we had an accumulated deficit of $66.2 million.

We have devoted most of our financial resources to product development, including our non-clinical development activities and clinical trials. To date, we have financed our operations exclusively through the sale of equity securities and debt. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue. To date, none of our product candidates have been commercialized, and if our product candidates are not successfully developed or commercialized, or if revenue is insufficient following marketing approval, we will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval to market our product candidates in the United States, our revenue is also dependent upon the size of the markets outside of the United States, as well as our ability to obtain market approval and achieve commercial success.

We expect to continue to incur substantial and increased expenses as we expand our development activities and advance our clinical programs, particularly with respect to our planned clinical development for FX006. We also expect an increase in our expenses associated with creating additional infrastructure to support operations as a public company. As a result of the foregoing, we expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future.

We have never generated any revenue and may never be profitable.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize our product candidates. We do not anticipate generating revenue from sales of our product candidates for the foreseeable future, if ever. Our ability to generate future revenue from product sales depends heavily on our success in:

- completing clinical development of FX006, as well as advancing clinical development of our other product candidates;

obtaining regulatory approval for FX006 as well as our other product candidates; and

launching and commercializing any product candidates for which we receive regulatory approval, either by building our own targeted sales force or by collaborating with third parties.

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Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of increased expenses, when, or if, we will begin to generate revenue from product sales, or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we are required by the FDA to perform studies in addition to those that we currently anticipate.

Even if one or more of our product candidates is approved for commercial sale, to the extent we do not engage a third party collaborator, we anticipate incurring significant costs associated with commercializing any approved product candidate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

If we fail to obtain additional financing, we would be forced to delay, reduce or eliminate our product development programs.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs, including our planned and future clinical trials for FX006.

As of December 31, 2013, we had cash, cash equivalents and marketable securities of $16.4 million and working capital of $11.6 million. On February 18, 2014 we completed the initial public offering of our common stock and received net proceeds of approximately $67.2 million, after deducting the underwriting discounts and commissions and offering expenses payable by us. Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital requirements at least into late 2015, including through the completion of our on-going FX006 synovial fluid pharmacokinetic clinical trial and our planned FX006 confirmatory Phase 2b clinical trial, which we expect to initiate in the second quarter of 2014, and our planned FX007 PoC clinical trial, which we expect to initiate in the second half of 2014, as well as the initiation of a planned repeat dose safety clinical trial for FX006 and potential Phase 3 clinical development. Regardless of our expectations as to how long our existing cash, cash equivalents and marketable securities will fund our operations, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our clinical trials may encounter technical, enrollment or other difficulties that could increase our development costs more than we expect. In any event, we will require additional capital prior to completing Phase 3 development of, filing for regulatory approval for, or commercializing, FX006 or any of our other product candidates.

Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of our product candidates;

- seek corporate partners for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;

relinquish or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or

significantly curtail, or cease, operations.

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If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects.

We may sell additional equity or debt securities to fund our operations, which may result in dilution to our stockholders and impose restrictions on our business.

In order to raise additional funds to support our operations, we may sell additional equity or debt securities, which could adversely impact our existing stockholders, as well as our business. The sale of additional equity or convertible debt securities would result in the issuance of additional shares of our capital stock and dilution to all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

Our credit and security agreement with MidCap Financial SBIC, LP, or MidCap, contains restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay the outstanding indebtedness earlier than we expect under our credit and security agreement if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a materially adverse effect on our business.

In January 2013, we entered into a credit and security agreement with MidCap and drew down the full $5.0 million under the facility. The agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- incur or assume certain debt;
- merge or consolidate or acquire all or substantially all of the capital stock or property of another entity;
- enter into any transaction or series of related transactions that would be deemed to result in a change in control of us under the terms of the agreement;
- change the nature of our business;
- change our organizational structure or type;
- amend, modify or waive any of our organizational documents;
- license, transfer or dispose of certain assets;

grant certain types of liens on our assets;

make certain investments;

pay cash dividends;

enter into material transactions with affiliates; and

amend or waive provisions of material agreements in certain manners.

The restrictive covenants of the agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial.

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A breach of any of these covenants could result in an event of default under the agreement. An event of default will also occur if, among other things, a material adverse change in our business, operations or condition occurs, which could potentially include negative results in our planned clinical trials, or a material impairment of the prospect of our repayment of any portion of the amounts we owe under the agreement occurs. In the case of a continuing event of default under the agreement, MidCap could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted MidCap a security interest under the agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the agreement are secured by all of our existing and future assets, excluding intellectual property, which is subject to a negative pledge arrangement.

We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to repay our indebtedness at the time any such repayment is required. In such an event, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our business, financial condition and results of operations could be materially adversely affected as a result.

Risks Related to Clinical Development and Regulatory Approval

We are heavily dependent on the success of our lead product candidate FX006, which is in a later stage of development than our other product candidates. We cannot give any assurance that FX006 will successfully complete clinical development or receive regulatory approval, which is necessary before it can be commercialized.

Our business and future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and successfully commercialize our lead product candidate FX006, for which we plan to initiate a confirmatory Phase 2b clinical trial in the second quarter of 2014 and a planned repeat dose safety clinical trial in the second half of 2014. Any delay or setback in the development of any of our product candidates, but particularly FX006, could adversely affect our business and cause our stock price to decline. Should our planned FX006 clinical development fail to be completed in a timely manner or at all, we may rely on our other product candidates, FX007 and FX005, which are at an earlier development stage and will require additional time and resources to obtain regulatory approval and proceed with commercialization. We cannot assure you that our planned clinical development for FX006 will be completed in a timely manner, or at all, or that we will be able to obtain approval for FX006 from the FDA or any foreign regulatory authority.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical failure can occur at any stage of clinical development. We have never conducted a pivotal clinical trial or submitted a NDA.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials. In particular, the positive results generated in the completed FX006 Phase 2b dose-ranging clinical trial do not ensure that our planned confirmatory Phase 2b clinical trial will demonstrate similar results.

In our completed Phase 2b dose-ranging clinical trial, the 60 mg dose of FX006 unexpectedly showed inferior efficacy compared to the 40 mg dose. While we have investigated potential causes of this clinical outcome and believe we understand the basis for the performance of the 60 mg dose, we may not be correct. Therefore, we cannot guarantee that the underlying cause is unique to the 60 mg dose and will not

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impact the doses we intend to study in our planned confirmatory Phase 2b clinical trial, or will not otherwise result in regulatory delays or the need for additional studies prior to seeking or obtaining regulatory approval.

Although we have successfully conducted non-clinical toxicology studies with repeat doses of FX006, all of our clinical trials to date have been with single doses of FX006. We intend to study FX006 in a separate repeat dose safety clinical trial, and it is possible that the FDA could impose restrictions on the initiation of the repeat dose study or that in the course of that study we could observe unexpected outcomes with the repeat doses of FX006 that would harm our ability to seek or obtain regulatory approval or would limit the commercial potential of FX006, if approved.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In addition to the safety and efficacy traits of any product candidate, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, placebo effect and patient enrollment criteria. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we or our collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Our future clinical trial results may not be successful.

If FX006 or any other product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business would be materially harmed. For example, if the results of our planned confirmatory Phase 2b or other clinical trials for FX006 demonstrate unexpected safety findings or do not achieve the primary efficacy endpoints, the prospects for approval of FX006 as well our stock price and our ability to create stockholder value would be materially and adversely affected.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If we are unable to bring any of our current or future product candidates to market, our ability to create long-term stockholder value will be limited.

If the FDA does not conclude that FX006 satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for FX006 under Section 505(b)(2) are not as we expect, the approval pathway for FX006 will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We intend to seek FDA approval through the Section 505(b)(2) regulatory pathway for FX006. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for FX006, and

complications and risks associated with FX006, would likely substantially increase. We may need to obtain additional funding, which could result in significant

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dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than FX006, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that FX006 will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, some pharmaceutical companies and others have objected to the FDA s interpretation of Section 505(b)(2). If the FDA s interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We may experience delays in clinical trials of our product candidates. We plan to initiate a confirmatory Phase 2b clinical trial of FX006 in the second quarter of 2014, and a PoC clinical trial of FX007 and a planned repeat dose safety clinical trial of FX006 in the second half of 2014. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required IRB approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;

clinical sites dropping out of a trial to the detriment of enrollment;

time required to add new clinical sites; or

delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

For example, our completed Phase 2b dose-ranging clinical trial for FX006 was subject to a clinical hold imposed by the FDA due to the observation of effects of PLGA microspheres on synovial tissue from FX006 injections. While we later resumed enrollment at non-U.S. sites and the clinical hold was eventually lifted without restriction by the FDA, the hold delayed our completion of the trial and resulted in additional expense.

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If initiation or completion of our planned clinical trials are delayed for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize and commence sales of our product candidates could be materially harmed, which could have a material adverse effect on our business.

Our product candidates may cause adverse events or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events, or AEs, caused by our product candidates or other potentially harmful characteristics of our product candidates could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. For example, in rat toxicology studies with repeat doses of FX005, an abnormal decrease of cartilage cells and components of cartilage matrix was observed. Based on these findings, we conducted additional non-clinical studies involving different doses and/or dose frequencies for FX005 to guide further clinical development. While we have identified a lower dose of FX005 that avoids these toxicology issues, we will need to demonstrate that doses lower than those used in the Phase 2a clinical trial will be effective, or we may need to pursue further development of FX005 as a single-dose treatment, which could limit its overall market potential.

While no serious adverse events, or SAEs, related to study drug were observed in our completed Phase 2b dose-ranging clinical trial of FX006, the clinical trials conducted by us with our product candidates to date have generated some AEs related to the study drug. For example, although 17.6% of patients treated with immediate-release TCA experienced AEs, 10.7% of FX006 patients were judged by their physicians to have an AE at least possibly related to study drug. The most commonly observed FX006 AEs were arthralgia (joint pain) and joint stiffness and were generally mild to moderate in severity. If drug-related SAEs are observed in any of our clinical trials, our ability to obtain regulatory approval for our product candidates may be adversely impacted.

Further, if any of our approved products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in the form of a modified Risk Evaluation and Mitigation Strategy;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies,

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regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate s clinical development and may vary among jurisdictions. For example, we cannot guarantee that our on-going synovial fluid pharmacokinetic trial or our planned confirmatory Phase 2b clinical trial for FX006 will be sufficient to allow subsequent Phase 3 development or that the FDA will not require additional or different clinical trials prior to initiating Phase 3 development of FX006. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate s clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market FX006 or our other product candidates, which would harm our business, results of operations and prospects significantly.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products,

may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates. For example, we believe that, to the extent our clinical development of FX006 continues to focus on knee OA, any initial indication of FX006 would be limited to the treatment of knee OA, as opposed to the treatment of OA generally. If an initial indication is limited to knee OA, we would likely need to conduct additional clinical trials in order to market FX006 for other indications and expand its market potential.

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We have not previously submitted an NDA or any similar drug approval filing to the FDA or any comparable foreign authority for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product s approved labeling. If we receive marketing approval for our product candidates as a therapy for knee OA, physicians may nevertheless use our product for their patients in a manner that is inconsistent with the approved label, potentially including as an injection in other joints. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Even if we obtain regulatory approval for FX006 or other product candidates, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties.

Even if we obtain regulatory approval in the United States, the FDA may still impose significant restrictions on the indicated uses or marketing of our product candidates, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. FX006 and our other product candidates, if approved, will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and adherence to commitments made in the NDA. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

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If we fail to comply with applicable regulatory requirements following approval of a product candidate, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

Any relationships with potential customers and third party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, marketing expenditure tracking and disclosure (or sunshine) laws, government price reporting, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Our operations may be directly, or indirectly, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance are also likely to increase. These laws may impact, among other things, our current activities with investigators and research subjects, as well as proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made

under a federal healthcare program, such as the Medicare and Medicaid programs;

federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

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HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform services involving the use or disclosure of individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;

the federal Open Payments program, created under Section 6002 of PPACA, and its implementing regulations requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children s Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to HHS ownership and investment interests held by physicians (as defined above) and their immediate family members;

state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third party payor, including commercial insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals); and

federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

In addition, the FDA approval and commercialization of any of our product candidates in the United States will also likely subject us to the following types of laws, among others:

state and federal government price reporting laws that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs (participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts); and

state and federal marketing expenditure tracking and reporting laws, which generally require certain types of expenditures in the United States to be tracked and reported (compliance with such requirements may require

investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities).

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Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil, criminal, and administrative penalties, damages, fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other government healthcare programs, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Even if we obtain FDA approval for FX006 or any other product candidate in the United States, we may never obtain approval for or commercialize our product candidates outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects will be limited.

Our long-term growth strategy is to develop, acquire or in-license and commercialize a portfolio of product candidates in addition to FX006 and our other existing product candidates. We do not have internal new drug discovery capabilities. As a result, our primary means of expanding our pipeline of product candidates is to develop improved formulations and delivery methods for existing FDA-approved products and/or select and acquire or in-license product candidates for the treatment of therapeutic indications that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Developing new formulations of existing products or identifying, selecting and acquiring or licensing promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual development, acquisition or license of a particular product candidate, potentially resulting in a diversion of our management s time and the expenditure of our resources with no resulting benefit. If we are unable to add additional product candidates to our pipeline, our long-term business and prospects will be limited.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

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We have relied upon and plan to continue to rely upon third party CROs to monitor and manage data for our preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with FDA laws and regulations regarding GCP which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of ICH guidelines for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our product candidates are expected to be conducted outside of the United States, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of our CROs have an ability to terminate their respective agreements with us if, among other reasons, it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely completely on third parties to manufacture our preclinical and clinical drug supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate.

If we were to experience an unexpected loss of supply of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, clinical trials. We do not

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currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers or other third party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA to the FDA. While we work closely with our third party manufacturers on the manufacturing process for our product candidates, including quality audits, we generally do not control the implementation of the manufacturing process of, and are completely dependent on, our contract manufacturers or other third party manufacturers for compliance with cGMP regulatory requirements and for manufacture of both active drug substances and finished drug products. If our contract manufacturers or other third party manufacturers cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers or other third party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We rely on our manufacturers to purchase from third party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial, unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a contract manufacturer or other third party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates.

As part of our planned development program for FX006, we will need to provide appropriate regulatory agencies with a chemistry, manufacturing and control manufacturing site change filing. Specifically, after drug product was manufactured and used in our completed Phase 2b dose-ranging clinical trial of FX006, new equipment, including a new spray chamber, was put in place, and a new contract manufacturer, Evonik, was engaged to produce the finished microspheres product. FX006 drug product produced by this new manufacturer using the new equipment has not yet been used in a clinical trial. An IND amendment for a manufacturing site change from Southwest Research Institute to Evonik where we provide data to demonstrate suitability of Evonik to manufacture FX006 finished product must be filed prior to initiating the planned confirmatory Phase 2b clinical trial of FX006 and other planned and future clinical trials for FX006. The absence of a timely approval could adversely affect the availability of suitable FX006 drug product and thus adversely impact both our ability to commence, as well as the timing of, the planned confirmatory Phase 2b clinical trial of FX006. Even if we demonstrate adequate comparability of drug product produced with the new equipment to the drug product used in our completed Phase 2b dose-ranging clinical trial, the drug product used in our planned confirmatory Phase 2b clinical trial may still cause unexpected results or otherwise adversely affect the confirmatory Phase 2b clinical trial.

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We expect to continue to depend on contract manufacturers or other third party manufacturers for the foreseeable future. We have not entered into long-term commercial supply agreements with our current contract manufacturers or with any alternate fill/finish suppliers. Although we intend to do so prior to any commercial launch in order to ensure that we maintain adequate supplies of finished drug product, we may be unable to enter into such an agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business.

We rely on limited sources of supply for our product candidates and any disruption in the chain of supply may cause delay in developing and commercializing our product candidates.

Currently, for FX006, we use Farmabios SpA as our sole source of TCA, and for both FX006 and FX005, Evonik as our sole source of finished microspheres drug product. Because of the unique equipment and process for loading TCA onto PLGA microspheres, transferring manufacturing activities for FX006 to an alternate supplier would be a time-consuming and costly endeavor, and there are only a limited number of manufacturers that we believe are capable of performing this function for us. Switching FX006 finished drug suppliers may involve substantial cost and could result in a delay in our desired clinical and commercial timelines. For FX006, we expect that initially only one supplier will be qualified as a vendor with the FDA. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply. Any alternative vendor would need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new FX006 supplier is relied upon for commercial production.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.

As we scale up manufacturing of our product candidates and conduct required stability testing, we may encounter product, packaging, equipment and process-related issues that may require refinement or resolution in order to proceed with our planned clinical trials and obtain regulatory approval for commercial marketing. In the future, we may identify impurities, which could result in increased scrutiny by the regulatory agencies, delays in our clinical program and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our product candidates.

We may not be successful in establishing development and commercialization collaborations which could adversely affect, and potentially prohibit, our ability to develop our product candidates.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we are exploring collaborations with third parties outside of the United States that have more resources and experience. For example, we are exploring selective partnerships with third parties for FX006 development and commercialization outside of the United States. If we are unable to obtain a partner for FX006, we may be unable to advance the development of FX006 in territories outside of the United States, which may limit the market potential for this product candidate. In situations where we enter into a development and commercial collaboration arrangement for a product candidate, we may also seek to establish additional collaborations for development and commercialization in territories outside of those addressed by the first

collaboration arrangement for such product candidate. If any of our product

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candidates receives marketing approval, we may enter into sales and marketing arrangements with third parties with respect to otherwise unlicensed or unaddressed territories outside of the United States. There are a limited number of potential partners, and we expect to face competition in seeking appropriate partners. If we are unable to enter into any development and commercial collaborations and/or sales and marketing arrangements on acceptable terms, if at all, we may be unable to successfully develop and seek regulatory approval for our product candidates and/or effectively market and sell future approved products, if any, in all of the territories outside of the United States where it may otherwise be valuable to do so.

In addition, under the terms of our license agreement with AstraZeneca AB, or AstraZeneca, for FX007, we may not, without the consent of AstraZeneca, grant sublicenses to FX007 except in the territory of Japan prior to the achievement of a specified development milestone. Further, the agreement provides that in the event we desire to offer rights to FX007 to a third party prior to the achievement of a specified development milestone, we must make certain diligence materials available to AstraZeneca, and AstraZeneca will have the right to make an offer to re-acquire rights to FX007. In such circumstances, we are not required to accept AstraZeneca s offer, but we may not enter into an agreement with a third party containing financial terms and conditions that on the whole are more favorable to the third party than the terms and conditions last offered by AstraZeneca. These provisions may limit our ability to partner with a third party during the early development stages of FX007.

We may not be successful in maintaining development and commercialization collaborations, and any partner may not devote sufficient resources to the development or commercialization of our product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop certain of our product candidates and our financial condition and operating results.

Even if we are able to establish collaboration arrangements, any such collaboration may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and growth prospects. If we partner with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. It is possible that a partner may not devote sufficient resources to the development or commercialization of our product candidate or may otherwise fail in development or commercialization efforts, in which event the development and commercialization of such product candidate could be delayed or terminated and our business could be substantially harmed. In addition, the terms of any collaboration or other arrangement that we establish may not prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of our common stock. In some cases, we may be responsible for continuing development of a product candidate or research program under a collaboration, and the payment we receive from our partner may be insufficient to cover the cost of this development. Moreover, collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain.

We are subject to a number of additional risks associated with our dependence on collaborations with third parties, the occurrence of which could cause our collaboration arrangements to fail. Conflicts may arise between us and partners, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a partner could act in its own self-interest, which may be adverse to our best interests. Any such disagreement between us and a partner could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating sufficient revenue to achieve or maintain profitability:

reductions in the payment of royalties or other payments we believe are due pursuant to the applicable collaboration arrangement;

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actions taken by a partner inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration; or

unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities.

Risks Related to Commercialization of Our Product Candidates

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, healthcare payors, patients and the medical community.

Even if we obtain regulatory approval for FX006 or any of our other product candidates, the product may not gain market acceptance among physicians, healthcare payors, patients and the medical community, which is critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

the efficacy and safety as demonstrated in clinical trials;

the timing of market introduction of the product candidate as well as competitive products;

the clinical indications for which the product candidate is approved;

acceptance by physicians, the medical community and patients of the product candidate as a safe and effective treatment;

the convenience of prescribing and initiating patients on the product candidate;

the potential and perceived advantages of such product candidate over alternative treatments;

the cost of treatment in relation to alternative treatments, including any similar generic treatments;

the availability of coverage and adequate reimbursement and pricing by third party payors and government authorities;

relative convenience and ease of administration;

the prevalence and severity of adverse side effects; and

the effectiveness of sales and marketing efforts.

If our product candidates, including FX006, are approved but fail to achieve an adequate level of acceptance by physicians, healthcare payors, patients and the medical community, we will not be able to generate significant revenue, and we may not become or remain profitable.

Guidelines and recommendations published by various organizations can reduce the use of our product candidates.

Government agencies promulgate regulations and guidelines directly applicable to us and to our product candidates. In addition, professional societies, such as the American Academy of Orthopedic Surgeons, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare

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and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our product candidates or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our product candidates.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

Although we intend to establish a targeted sales and marketing organization to promote any approved products in the United States, we currently have no such organization or capabilities, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved, we must build sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We may enter into strategic partnerships with third parties to commercialize our product candidates outside of the United States.

To date, we have not entered into any strategic partnerships for any of our product candidates. We face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be intricate and time consuming to negotiate and document. We may not be able to negotiate strategic partnerships for territories outside of the United States on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic partnerships outside of the United States because of the numerous risks and uncertainties associated with establishing strategic partnerships. To the extent that we enter into collaboration arrangements, our future collaboration partners may not dedicate sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective collaborations to enable the sale of our product candidates in territories outside of the United States, or if our potential future collaboration partners do not successfully commercialize our product candidates in these territories, our ability to generate revenue from product sales will be adversely affected.

If we are unable to negotiate a strategic partnership or obtain additional financial resources for a product candidate, we may be forced to curtail the development of such product candidate, delay potential commercialization, reduce the scope of our sales or marketing activities or undertake development or commercialization activities at our own expense. In addition, without a partnership, we will bear all the risk related to the development of the product candidate, including in territories outside of the United States. If we elect to increase our expenditures to fund development or commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring FX006 or any other product candidates to market or generate product revenue.

We and any collaboration partners that we may engage will be competing with many companies that currently have extensive and well-funded marketing and sales operations. If we, alone or with commercialization partners, are unable to compete successfully against these established companies, the commercial success of any approved products will be limited.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If FX006 or other product candidates are approved for commercialization, we may enter into agreements with third parties to market these products outside of the United States. We expect that we will be subject to additional risks related to entering into international business relationships, including:

different regulatory requirements for drug approvals in foreign countries;

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reduced protection for intellectual property rights;

unexpected changes in tariffs, trade barriers and regulatory requirements;

economic weakness, including inflation, or political instability in particular foreign economies and markets;

compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

foreign taxes, including withholding of payroll taxes;

foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;

workforce uncertainty in countries where labor unrest is more common than in the United States;

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;

business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires; and

unfavorable pricing approved in countries, which could result in reduced revenue.

If we are unable to differentiate our lead product candidate, FX006, from existing generic therapies for the treatment of OA, or if the FDA or other applicable regulatory authorities approve generic products that compete with any of our product candidates, the ability to successfully commercialize those product candidates would be adversely affected.

Immediate-release TCA and other injectable immediate-release steroids, which are the current standard of care, are available in generic form and are therefore relatively inexpensive compared to the price we would expect to receive for FX006. These generic steroids also have well-established market positions and familiarity with physicians, healthcare payors and patients. Although we believe FX006 has the potential for clinically meaningful differentiation in sustained pain relief as compared to immediate-release TCA, as clinical development of FX006 advances and we receive data from additional clinical trials, it is possible that the data will not support such differentiation. If we are unable to achieve significant differentiation for FX006 from immediate-release TCA and other injectable immediate-release steroids, our opportunity for FX006 to achieve premium pricing and be commercialized successfully, if approved, would be adversely affected.

In addition to existing generic steroids, such as immediate-release TCA, the FDA or other applicable regulatory authorities may approve generic products that could compete with our product candidates. Once an NDA, including a

Section 505(b)(2) application, is approved, the product covered thereby becomes a listed drug which can, in turn, be cited by potential competitors in support of approval of an ANDA. The FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling, as our product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our product candidate. These generic equivalents, which must meet the same quality

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standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents to our product candidates would materially adversely impact our ability to successfully commercialize our product candidates.

We face significant competition from other biopharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industries are intensely competitive and subject to rapid and significant technological change. In addition, the competition in the pain and OA market is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, the injectable OA treatment market today includes many injectable immediate-release steroids, including TCA, the active ingredient in FX006, as well as HA injections. In addition, we expect that injectable therapies such as FX006 will continue to be used primarily after oral medications no longer provide adequate pain relief. To the extent that new or improved oral pain medications are introduced that demonstrate better long-term efficacy and safety, patients and physicians may further delay the introduction of injectable therapies such as FX006 in the OA treatment continuum. FX006 could also face competition from other formulations or devices that deliver pain medication on a sustained basis, such as transdermal delivery systems or implantable devices.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than FX006 or any other drug candidate that we are currently developing or that we may develop.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety of our product candidates, including as relative to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to maintain a good relationship with regulatory authorities;
- the ability to commercialize and market any of our product candidates that receive regulatory approval;

the price of our products, including in comparison to branded or generic competitors;

whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;

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- the ability to protect intellectual property rights related to our product candidates;

- the ability to manufacture on a cost-effective basis and sell commercial quantities of any of our product candidates that receive regulatory approval; and

- acceptance of any of our product candidates that receive regulatory approval by physicians and other healthcare providers.

If our competitors market products that are more effective, safer or less expensive than our future products, if any, or that reach the market sooner than our future products, if any, we may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because we have limited research and development capabilities, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

If we are unable to achieve and maintain adequate levels of third party payor coverage and reimbursement for FX006 or any other product candidates, if approved, on reasonable pricing terms, their commercial success may be severely hindered.

Successful sales of any approved product candidates depend on the availability of adequate coverage and reimbursement from third party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for FX006 and any of our other product candidates will depend significantly on access to third party payors drug formularies, or lists of medications for which third party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third party coverage and reimbursement for FX006 or any of our other

product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

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Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain.

The United States and some foreign jurisdictions are considering, or have enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidates profitably, once they are approved for sale. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, PPACA was enacted, which includes measures that have or will significantly change the way healthcare is financed by both governmental and private insurers. Among the PPACA provisions of importance to the pharmaceutical industry are the following:

an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, that began in 2011;

an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;

a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50.0% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D;

extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133.0% of the Federal Poverty Level, thereby potentially increasing manufacturers Medicaid rebate liability;

expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

new requirements under the federal Open Payments program, created under Section 6002 of PPACA and its implementing regulations that manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children s Health Insurance Program (with certain

exceptions) report annually to HHS information related to payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals and that applicable manufacturers and applicable group purchasing organizations report annually to HHS ownership and investment interests held by physicians (as defined above) and their immediate family members, with data collection currently required and reporting to the Centers for Medicare & Medicaid Services required by March 31, 2014 and by the 90th day of each subsequent calendar year;

a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;

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expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for non-compliance;

a licensure framework for follow-on biologic products;

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

creation of the Independent Payment Advisory Board, which has authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and

establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation s automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Risks Related to Our Business Operations and Industry

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team listed under Management located elsewhere in this Annual Report, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment agreements or offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are at will employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit or the loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2013, we had 16 full-time employees. As our company matures, we expect to expand our employee base to increase our managerial, scientific and engineering, operational, sales,

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marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize FX006 and our other product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

impairment of our business reputation;

withdrawal of clinical trial participants;

costs due to related litigation;

distraction of management s attention from our primary business;

substantial monetary awards to patients or other claimants;

the inability to commercialize our product candidates; and

decreased demand for our product candidates, if approved for commercial sale.

We currently carry product liability insurance with limits of $10 million in the aggregate and $10 million per occurrence. Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to

liability. If and when we obtain marketing approval for our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

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We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

Business interruptions could delay us in the process of developing our product candidates and could disrupt our sales.

Our headquarters are located in Burlington, Massachusetts. We are vulnerable to natural disasters such as hurricanes, tornadoes and severe storms, as well as other events that could disrupt our operations. We do not carry insurance for natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection, confidentiality agreements and proprietary know how, and intend to seek marketing exclusivity for any approved product, in order to protect the intellectual property related to product candidates, but to date we do not have any issued patents covering FX006. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. If this were to occur, early generic competition could be expected against FX006 and potentially our other product candidates in development. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Also, a third party may challenge our ownership of patents and patent applications assigned to us, or may challenge our exclusive rights to patents and patent applications that we license from third parties. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold with respect to FX006 or our other product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them, and threaten our ability to commercialize any resulting products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable or will go unthreatened by third parties. Further, if we encounter delays in regulatory approvals, the period of time during which we could market FX006 or any other product candidate under patent protection could be reduced. Furthermore, patent applications by third parties can result in an interference proceeding in the United States being provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. See Business Patents and Patent Applications for additional information regarding our material patents and patent applications.

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In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development process that involve proprietary know-how, information or technology that is not covered by patents. For example, we maintain trade secrets with respect to certain of the formulation and manufacturing techniques related to the TCA-formulated PLGA microspheres in FX006, including those that relate to precise pharmaceutical release. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the U.S. Patent and Trademark Office, or U.S. PTO. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of FX006 and/or our other product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any drug substance formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire. Similarly, if any third party patent were held by a court of competent jurisdiction to cover aspects of our formulations or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may request and/or obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense

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and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products or manufacturing processes, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research, manufacture clinical trial supplies or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business.

We are a party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. For example, our rights to FX007 and FX005 are the subject of separate exclusive license agreements with AstraZeneca. If we fail to comply with our obligations under our agreements with AstraZeneca (including, among other things, if we fail to use commercially reasonable efforts to develop, commercialize and sell products based on FX007 and FX005 in major markets) or our other license agreements, or we are subject to a bankruptcy or insolvency, the licensor may have the right to terminate the license. In addition, under our agreement with AstraZeneca for FX007, AstraZeneca has a right to terminate the agreement in the event of a change of control of us prior to the achievement of a specified development milestone, unless we pay a fee to AstraZeneca. In the event that any of our important technology licenses were to be terminated by the licensor, we would likely cease further development of the related program or be required to spend significant time and resources to modify the program to not use the rights under the terminated license.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, you may not be able to resell your shares at a desired market price and you could lose all or part of your investment.

Prior to our recently completed initial public offering, there was no public market for our common stock. We cannot assure you that an active, liquid trading market for our shares will develop or persist. You may not be able to sell your shares quickly or at a recently reported market price if trading in our common stock is not active.

The trading price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

adverse results or delays in clinical trials;

inability to obtain additional funding;

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any delay in filing an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA s review of that NDA;

failure to successfully develop and commercialize our product candidates;

changes in laws or regulations applicable to our product candidates;

inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices;

adverse regulatory decisions;

introduction of new products or technologies by our competitors;

failure to meet or exceed product development or financial projections we provide to the public;

failure to meet or exceed the estimates and projections of the investment community;

the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;

announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

additions or departures of key scientific or management personnel;

significant lawsuits, including patent or stockholder litigation;

changes in the market valuations of similar companies;

sales of our common stock by us or our stockholders in the future; and

trading volume of our common stock.

In addition, the stock market in general, and the Nasdaq Global Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of the closing of our initial public offering on February 18, 2014, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially owned approximately 68.6% of our outstanding voting stock. These stockholders will have the ability to influence us through this ownership position and may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

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We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our other periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

We completed our initial public offering on February 18, 2014. As a newly public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. For

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example, as a public company, we are now subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. We have incurred and will continue to incur costs associated with the preparation in filing of these reports. In addition, the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC, and the Nasdaq Global Market have imposed various other requirements on public companies, and we have incurred and will continue to incur costs associated with compliance with such requirements. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as say on pay and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Substantially all of our existing stockholders are currently subject to lock-up agreements with the underwriters of our initial public offering that restrict the stockholders ability to transfer shares of our common stock for at least 180 days from February 11, 2014, the date of the final prospectus for our initial public offering. These lock-up agreements limit the number of shares of common stock that may be sold during the lock-up period. Subject to certain limitations, including sales volume limitations with respect to shares held by our affiliates, substantially all of our outstanding shares prior to our initial public offering will become eligible for sale upon expiration of the lock-up period. In addition, shares issued or issuable upon exercise of options vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act, subject to the 180-day lock-up arrangement described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution.

We may sell common stock, convertible securities or other equity

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securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2013 Equity Incentive Plan, or the 2013 plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2013 plan will automatically increase each year by 4% of all shares of our capital stock outstanding as of December 31 of the prior calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2013 plan each year. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management s attention and resources, which could harm our business.

We have broad discretion in the use of the net proceeds from our recently completed initial public offering and may not use them effectively.

Our management has broad discretion in the application of the net proceeds from our recently completed initial public offering. Because of the number and variability of factors that will determine our use of the net proceeds from our initial public offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from our initial public offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change, generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. As of December 31, 2013, we had $35.1 million and $32.8 million of federal and state net operating loss carryforwards, respectively, and $1.6 million and$1.1 million of federal and state research and development tax credit carryforwards, respectively, available to offset our future taxable income, if any. These federal net operating loss carryforwards and research and development tax credit carryforwards expire at various dates beginning in 2028 and 2029, respectively, if not utilized and are subject to review and possible adjustment by the Internal Revenue Service. The state net operating loss carryforwards and research and development tax credit carryforwards expire at various dates beginning in 2014 and 2024, respectively, if not utilized and are subject to review and possible adjustment by the state tax authorities. We believe that, with our initial public offering, our most recent private placement and other transactions that have occurred over the past three years, we may have triggered an ownership change limitation. We may also experience ownership changes in the future as a result of subsequent shifts in our stock

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ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Additionally, our credit and security agreement with MidCap contains covenants that restrict our ability to pay dividends. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is

desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Item 1B. Unresolved Staff Comments

Not applicable.

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Item 2. Properties

Our offices are located at one leased facility, an 11,754 square foot leased facility in Burlington, MA used primarily for corporate functions. The lease expires in October 2016. We believe that our existing facility is sufficient for our needs for the foreseeable future.

Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock began trading on the Nasdaq Global Market on February 12, 2014 and trades under the symbol FLXN . Prior to February 12, 2014, there was no public market for our common stock. As a result we have not set forth quarterly information with respect to the high and low prices for our common stock for the two most recent fiscal years or provided a performance graph. On March 25, 2014, the last reported sale price of our common stock was $16.73.

Holders of Record

As of March 25, 2014, there were approximately 32 stockholders of record of our common stock. Certain shares are held in street name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. In addition, pursuant to our credit and security agreement with MidCap, we are prohibited from paying cash dividends without the prior consent of MidCap. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities

During the year ended December 31, 2013, we issued and sold the following unregistered securities:

From January 1, 2013 to December 31, 2013, we granted stock options under our 2009 Equity Incentive Plan, or the 2009 plan, to purchase an aggregate of 177,121 shares of common stock (net of cancellations) to our employees, directors and consultants, having exercise prices ranging from $6.59 to $7.89 per share.

In November 2013, we issued 4,868 shares of our common stock to a consultant pursuant to the exercise of options granted prior to January 1, 2013, for aggregate consideration of approximately $12,300.

The offers, sales and issuances of the securities described above were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were our employees, directors

or bona fide consultants and received the

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securities under the 2009 plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

Use of Proceeds

On February 11, 2014, we commenced our initial public offering pursuant to a registration statement on Form S-1 (File No. 333-193233) that was declared effective by the SEC on February 11, 2014 and that registered an aggregate of 5,000,000 shares of our common stock for sale to the public at a price of $13.00 per share. In addition, at the closing of the initial public offering on February 18, 2014, the underwriters exercised their over-allotment option to purchase 750,000 additional shares of our common stock in the initial public offering at the public offering price of $13.00 per share, for an aggregate offering price of $74.8 million. BMO Capital Markets Corp. and Wells Fargo Securities, LLC acted as joint book-running managers of our initial public offering, which has now terminated. After deducting underwriting discounts, commissions and offering costs paid by us of $7.5 million, the net proceeds from the offering were approximately $67.2 million. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities, or to any of our affiliates.

The net proceeds from the offering have been invested primarily in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, and direct or guaranteed obligations of the U.S. government pending their use. There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b).

Item 6. Selected Financial Data

The following selected financial data should be read together with Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes included elsewhere in this Annual Report. The selected financial data in this section are not intended to replace our consolidated financial statements and the related notes. Our historical results are not necessarily indicative of the results that may be expected in the future and results of interim periods are not necessarily indicative of the results for the entire year.

The selected statement of operations data for the years ended December 31, 2013, 2012 and 2011 and the selected balance sheet data as of December 31, 2013 and 2012 are derived from our audited consolidated financial statements appearing elsewhere in this Annual Report. The selected financial data for all periods presented reflects the 1-for-8.13 reverse stock split effected by the Company on January 27, 2014.

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	2013	Year Ended December 31, 2012 (in thousands)	2011
Statement of Operations Data:			
Revenue	$	$	$
Operating expenses:			
Research and development	11,061	11,065	8,241
General and administrative	6,704	3,947	3,047
Total operating expenses	17,765	15,012	11,288
Loss from operations	(17,765)	(15,012)	(11,288)
Other income (expense):			
Interest income	234	194	173
Interest expense	(449)		
Other income (expense), net	(207)	(164)	(332)
Total other income (expense)	(422)	30	(159)
Net loss	(18,187)	$ (14,982)	$ (11,447)
Net loss attributable to common stockholders	(18,187)	$ (14,982)	$ (11,447)
Net loss per share attributable to common stockholders, basic and diluted[(1)]	$ (23.02)	$ (27.58)	$ (23.26)
Weighted average common shares outstanding, basic and diluted[(1)]	790	543	492

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	2013	2012
	(in thousands)	
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 16,438	$ 29,383
Working capital[2]	11,583	27,147
Total assets	18,776	30,008
Total debt[3]	5,047	
Convertible preferred stock	74,806	74,806
Total stockholders equity (deficit)	(64,704)	(47,523)

(1) See Note 3 to our consolidated financial statements appearing elsewhere in this Annual Report for further details on the calculation of basic and diluted net loss per share attributable to common stockholders.

(2) We define working capital as current assets less current liabilities.

(3) Total debt includes the current and long-term portion of our debt.

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of financial condition and results of operations should be read in conjunction with Item 6. Selected Financial Data and our consolidated financial statements and related notes appearing elsewhere in this Annual Report. This discussion and analysis and other parts of this Annual Report contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under Item 1A. Risk Factors . You should carefully read the Risk Factors section of this Annual Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled Special Note Regarding Forward-Looking Statements.

Overview

We are a specialty pharmaceutical company focused on the development and commercialization of novel, injectable pain therapies. We are targeting anti-inflammatory and analgesic therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis, a type of degenerative arthritis, referred to as OA. Our broad and diversified portfolio of product candidates addresses the OA pain treatment spectrum, from moderate to severe pain, and provides us with multiple unique opportunities to achieve our goal of commercializing novel, patient-focused pain therapies. Our pipeline consists of three proprietary product candidates: FX006, a sustained-release, intra-articular steroid; FX007, a TrkA receptor antagonist for post-operative pain; and FX005, a sustained-release intra-articular p38 MAP kinase inhibitor. We retain the exclusive worldwide rights to our product candidates.

We were incorporated in Delaware in November 2007, and to date we have devoted substantially all of our resources to our development efforts relating to our product candidates, including conducting clinical trials with our product candidates, providing general and administrative support for these operations and protecting our intellectual property. We are a development stage company and do not have

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any products approved for sale and have not generated any revenue from product sales. From our inception through December 31, 2013, we have funded our operations primarily through the sale of our convertible preferred stock and, to a lesser extent, debt financing. From our inception through December 31, 2013, we have raised $80.0 million from such transactions. On February 18, 2014, we completed the initial public offering of our common stock, which resulted in net proceeds to us of approximately $67.2 million, after deducting underwriting discounts, commissions and offering costs.

We have incurred net losses in each year since our inception in 2007. Our net losses were $18.2 million, $15.0 million and $11.4 million for the years ended December 31, 2013, 2012 and 2011, respectively. As of December 31, 2013, we had an accumulated deficit of $66.2 million. Substantially all of our net losses resulted from costs incurred in connection with our development programs and from general and administrative expenses associated with our operations.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially in connection with our ongoing activities, as we:

- continue the development of our lead product candidate, FX006, including the planned and future clinical trials;
- seek to obtain regulatory approvals for FX006;
- prepare for the potential launch and commercialization of FX006, if approved;
- establish a sales and marketing infrastructure for the commercialization of FX006, if approved;
- expand our development activities and advance additional product candidates;
- maintain, expand and protect our intellectual property portfolio; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts and operations as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital prior to completing clinical development of FX006 or any of our other product candidates. Until such time that we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding and collaborations, and licensing arrangements. However, we may be unable to raise additional funds or enter into such arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our development programs or commercialization efforts or grant to others rights to

develop or market product candidates that we would otherwise prefer to develop and market ourselves. Failure to receive additional funding could cause us to cease operations, in part or in full.

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Financial Overview

Revenue

We have not generated any revenue since our inception. We do not have any products approved for sale, and we do not expect to generate any revenue from the sale of products in the near future. In the future, if our research and development efforts result in clinical success and regulatory approval, we may generate revenue from the sales of our product candidates, or we may generate revenue from grant income or from licensing rights to our product candidates to third parties. If we fail to complete the development of FX006 or our other product candidates, our ability to generate future revenue, and our results of operations and financial position will be adversely affected.

Operating Expenses

The majority of our operating expenses to date have been related to in-licensing certain of our product candidates and the development activities of FX006 and FX005.

Research and Development Expenses. Since our inception, we have focused our resources on our development activities, including: preclinical studies and clinical trials and chemistry manufacturing and controls, or CMC. Our development expenses consist primarily of:

- expenses incurred under agreements with consultants, contract research organizations, or CROs, and investigative sites that conduct our preclinical studies and clinical trials;
- costs of acquiring, developing and manufacturing clinical trial materials;
- personnel costs, including salaries, benefits, stock-based compensation and travel expenses for employees engaged in scientific research and development functions;
- costs related to compliance with regulatory requirements;
- expenses related to the in-license of certain technologies from pharmaceutical companies; and
- allocated expenses for rent and maintenance of facilities, insurance and other general overhead.

We expense research and development costs as incurred. Our direct research and development expenses consist primarily of external-based costs, such as fees paid to investigators, consultants, investigative sites, CROs and companies that manufacture our clinical trial materials, and are tracked on a program-by-program basis. We do not allocate personnel costs, facilities or other indirect expenses to specific research and development programs. These indirect expenses are included within the amounts designated as Personnel and other costs in the table below.

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The following table summarizes our research and development expenses for the periods presented:

	Year Ended December 31,		
	2013	2012	2011
	(in thousands)		
Direct research and development expenses by program:			
FX006	$ 5,593	$ 6,365	$ 2,611
FX007	370	52	89
FX005	1,659	2,074	3,195
Terminated programs			
Total direct research and development expenses	7,622	8,491	5,895
Personnel and other costs	3,439	2,574	2,346
Total research and development expenses	$ 11,061	$ 11,065	$ 8,241

Our research and development expenses are expected to increase in the foreseeable future. Specifically, our costs associated with FX006 will increase as we initiate our planned confirmatory Phase 2b and repeat dose safety clinical trials and otherwise advance our FX006 development program. We cannot determine with certainty the duration of and completion costs associated with future clinical trials of FX006. The duration, costs and timing associated with the development and commercialization of FX006 and our other product candidates will depend on a variety of factors, including uncertainties associated with the results of our clinical trials and our ability to obtain regulatory approval. We anticipate that we will make determinations as to which development programs to pursue and how much funding to direct to each program on an ongoing basis in response to preclinical and clinical success of each product candidate, as well as ongoing assessments of the commercial potential of each product candidate. As a result of these uncertainties, we are currently unable to estimate with any precision our future research and development expenses for any product candidate, when or if we will achieve regulatory approval, generate revenue from sales of any product candidate or achieve a positive cash flow position.

General and Administrative Expenses. General and administrative expenses consist primarily of personnel costs, including salaries, related benefits, travel expenses and stock-based compensation of our executive, finance, business development, information technology, legal and human resources functions. Other general and administrative expenses include an allocation of facility-related costs, patent filing expenses, and professional fees for legal, consulting, auditing and tax services.

We anticipate that our general and administrative expenses will increase in the future as we continue to build our corporate infrastructure to support the continued development of FX006. Additionally, we anticipate increased expenses related to the audit, legal, regulatory, investor relations and tax-related services associated with maintaining compliance with the Securities and Exchange Commission and Nasdaq requirements, director and officer insurance premiums and other costs associated with operating as a public company.

Other Income (Expense)

Interest income. Interest income consists of interest earned on our cash and cash equivalents balances and our marketable securities. The primary objective of our investment policy is capital preservation.

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Interest expense. Prior to 2013, we had only incurred interest expense on our related-party debt which had been outstanding during 2008 and 2009. In January 2013, we borrowed $5.0 million under a credit facility with MidCap Financial SBIC, LP, or MidCap, and began to incur interest related to this borrowing at a fixed rate of 8.0% per annum. We expect to incur future interest expense related to this borrowing until September 1, 2016. See Liquidity and Capital Resources for a more detailed description of our credit facility.

Other expense. Other expense consists of the net amortization of premiums related to our marketable securities, our realized gains (losses) on redemptions of our marketable securities, and a Swiss business tax we paid in 2011. We will continue to incur expenses related to net amortization of premiums on marketable securities for as long as we hold these investments.

Income Taxes

As of December 31, 2013, we had $35.1 million and $32.8 million of federal and state net operating loss carryforwards, respectively, and $1.6 million and $1.1 million of federal and state research and development tax credit carryforwards, respectively, available to offset our future taxable income, if any. These federal net operating loss carryforwards and research and development tax credit carryforwards expire at various dates beginning in 2028 and 2029, respectively, if not utilized and are subject to review and possible adjustment by the Internal Revenue Service. The state net operating loss carryforwards and research and development tax credit carryforwards expire at various dates beginning in 2014 and 2024, respectively, if not utilized and are subject to review and possible adjustment by the state tax authorities. At December 31, 2013, a full valuation allowance was recorded against our net operating loss carryforwards and our research and development tax credit carryforwards.

If we experience a greater than 50 percent aggregate change in ownership of certain stockholders over a three-year period, utilization of our then-existing net operating loss carryforwards and research and development tax credit carryforwards will be subject to an annual limitation.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, and the reported revenue and expenses during the reported periods. We evaluate these estimates and judgments, including those described below, on an ongoing basis. We base our estimates on historical experience, known trends and events, contractual milestones and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 3 to our financial statements appearing elsewhere in this Form 10-K, we believe that the estimates and assumptions involved in the following accounting policies may have the greatest potential impact on our financial statements and, therefore, consider these to be critical for fully understanding and evaluating our financial condition and results of operations.

Research and Development Costs

As part of the process of preparing our financial statements, we are required to estimate our accrued and prepaid research and development expenses. We base our accrued expenses related to clinical trials

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on estimates of patient enrollment and related expenses at clinical investigator sites, as well as estimates for services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. We review new and open contracts and communicate with applicable internal and vendor personnel to identify services that have been performed on our behalf and estimate the level of service performed and the associated costs incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost for accrued expenses. The majority of our service providers invoice us monthly in arrears for services performed; however, some require advanced payments. For any services that require such advanced payments, we perform a review, with applicable internal and vendor personnel, to estimate the level of services that have been performed and the associated costs that have been incurred at each reporting period. We accrue expenses related to clinical trials based on contractual amounts applied to the level of patient enrollment and activity according to the protocol. We make estimates of our accrued and prepaid expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis. If we do not identify costs that we have begun to incur, or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. To date, we have not adjusted our estimates at any particular balance sheet date in any material amount.

Stock-Based Compensation

We measure stock-based awards granted to employees and directors at fair value on the date of the grant and recognize the corresponding compensation expense for those awards, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award, using the straight-line method. We measure stock-based awards granted to non-employees for services received based on the fair value of the equity instrument issued. The measurement date of the fair value of the equity instrument issued to non-employees is the earlier of the date on which the counterparty s performance is complete or the date on which there is a commitment to perform.

The fair value of each stock-based award granted is estimated using the Black-Scholes option-pricing model. Until February 11, 2014, we were a private company and we lacked company-specific historical and implied volatility information. Therefore, we estimated our expected stock volatility based on the historical volatility of our publicly traded peer companies for periods that are commensurate with the expected term (in years) of our stock-based awards, and we expect to continue to do so until such time as we have adequate historical data regarding the volatility of our traded stock price. The expected term of our stock options has been determined utilizing the simplified method for awards that qualify as plain vanilla options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future. The assumptions used to determine the fair value of stock-based awards using the Black-Scholes option-pricing model were as follows, presented on a weighted-average basis:

	Year Ended December 31,		
	2013	**2012**	**2011**
Risk-free interest rate	1.00%	0.93%	2.20%
Expected term (in years)	6.0	6.1	6.1
Expected volatility	71%	71%	75%

Dividend yield	0%	0%	0%

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We recognize compensation expense only for the portion of awards that are expected to vest. In developing a forfeiture rate estimate, we have considered our historical experience to estimate pre-vesting forfeitures for service-based awards. The impact of a forfeiture rate adjustment will be recognized in full in the period of adjustment, and if the actual forfeiture rate is materially different from our estimate, we may be required to record adjustments to stock-based compensation expense in future periods. These assumptions represent our best estimates, but involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

RESULTS OF OPERATIONS

Year Ended December 31, 2013 Compared to Year Ended December 31, 2012

The following table summarizes our results of operations for the years ended December 31, 2013 and 2012 (certain items may not foot due to rounding):

	Year Ended December 31,		
	2013	2012	Change
		(in thousands)	
Revenue	$	$	$
Operating expenses:			
Research and development	11,061	11,065	(4)
General and administrative	6,704	3,947	2,757
Total operating expenses	17,765	15,012	2,753
Loss from operations	(17,765)	(15,012)	(2,753)
Other income (expense):			
Interest income	234	194	40
Interest expense	(449)	0	(449)
Other expense	(207)	(164)	(43)
Total other income (expense)	(422)	30	(452)
Net loss	$ (18,187)	$ (14,982)	$ (3,205)

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Research and Development Expenses

	Year Ended December 31, 2013	2012	Change
		(in thousands)	
Direct research and development expenses by program:			
FX006	$ 5,593	$ 6,365	$ (772)
FX007	370	52	318
FX005	1,659	2,074	(415)
Total direct research and development expenses	7,622	8,491	(869)
Personnel and other costs	3,439	2,574	865
Total research and development expenses	$ 11,061	$ 11,065	$ (4)

Research and development expenses were $11.1 million and $11.1 million for the years ended December 31, 2013 and 2012, respectively. The lack of any significant change in research and development expenses year over year was primarily due to an increase of $0.3 million in development expense related to our FX007 program and an increase of $0.9 million in personnel and other costs, both offset by a decrease in development expenses related to our FX006 and FX005 programs. The increase of $0.3 million in FX007 program expenses related to expenses for our non-clinical toxicology study and material costs related to this study. The increase of $0.9 million in personnel and other costs primarily related to employee related costs due to an increase in headcount, stock compensation expense and consulting costs. The decrease of $0.8 million in FX006 program expenses was due to the completion of the Phase 2b clinical trial and toxicology studies partially offset by an increase in manufacturing expenses. The decrease of $0.4 million in FX005 program expenses was due to the completion of the Phase 2a clinical trial partially offset by an increase in toxicology studies.

General and Administrative Expenses

General and administrative expenses were $6.7 million and $3.9 million for the years ended December 31, 2013 and 2012, respectively. The increase in general and administrative expenses year over year of $2.8 million, or 70%, was primarily due to an increase of $1.6 million in salary and related costs due to an increase in headcount and an increase in stock compensation expense as compared to the prior year, $0.6 million in legal fees related to corporate legal activity and patents for our intellectual property and $0.6 million in professional fees.

Other Income (Expense)

Interest income was $0.2 million and $0.2 million for the years ended December 31, 2013 and 2012, respectively. Interest income was consistent year over year.

Interest expense was $0.4 million and $0.0 million for the years ended December 31, 2013 and 2012, respectively. The increase of $0.4 million was due to the interest incurred on $5.0 million of borrowings under our credit facility, which we obtained in January 2013.

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Other expense was $0.2 million and $0.2 million for the years ended December 31, 2013 and 2012, respectively. Other expense was consistent year over year.

Year Ended December 31, 2012 Compared to Year Ended December 31, 2011

The following table summarizes our results of operations for the years ended December 31, 2012 and 2011 (certain items may not foot due to rounding):

	Year Ended December 31,		
	2012	2011	Change
		(in thousands)	
Revenue	$	$	$
Operating expenses:			
Research and development	11,065	8,241	2,824
General and administrative	3,947	3,047	900
Total operating expenses	15,012	11,288	3,724
Loss from operations	(15,012)	(11,288)	(3,724)
Other income (expense):			
Interest income	194	173	21
Other expense	(164)	(332)	168
Total other income (expense)	30	(159)	189
Net loss	$ (14,982)	$ (11,447)	$ (3,535)

Research and Development Expenses

	Year Ended December 31,		
	2012	2011	Change
		(in thousands)	
Direct research and development expenses by program:			
FX006	$ 6,365	$ 2,611	$ 3,754
FX007	52	89	(37)
FX005	2,074	3,195	(1,121)
Total direct research and development expenses	8,491	5,895	2,596

Personnel and other costs	2,574	2,346	228
Total research and development expenses	$ 11,065	$ 8,241	$ 2,824

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Research and development expenses were $11.1 million and $8.2 million for the years ended December 31, 2012 and 2011, respectively. The increase in research and development expenses year over year of $2.8 million, or 34%, was primarily due to an increase of $3.8 million in development expense related to our FX006 program and an increase of $0.2 million in personnel and other costs, both offset by a decrease in development expenses related to our FX005 program. The increase of $3.8 million in FX006 program expenses related to expenses for our Phase 2a clinical trial, which commenced in July 2012, and our Phase 2b dose-ranging clinical trial, which commenced in June 2012; additional toxicology studies conducted during the year ended 2012; and increased material costs related to our clinical trials. The increase of $0.2 million in personnel and other costs primarily related to increased consulting costs and sponsored research costs. The decrease of $1.1 million in FX005 program expenses was due to the completion of the Phase 2a proof of concept clinical trial in April 2012.

General and Administrative Expenses

General and administrative expenses were $3.9 million and $3.0 million for the years ended December 31, 2012 and 2011, respectively. The increase in general and administrative expenses year over year of $0.9 million, or 30%, was primarily due to an increase of $0.6 million in salary and related costs from an increase in headcount, and $0.3 million in legal fees related to patents for our intellectual property and corporate matters.

Other Income (Expense)

Interest income was $0.2 million and $0.2 million for the years ended December 31, 2012 and 2011, respectively. Interest income was consistent year over year.

Other expense was $0.2 million and $0.3 million for the years ended December 31, 2012 and 2011, respectively. The decrease of $0.1 million, or 51%, related to $0.2 million of Swiss business tax we paid in 2011, offset by an increase of $0.1 million in net amortization of premiums on our marketable securities.

Liquidity and Capital Resources

To date, we have not generated any revenue and have incurred losses since our inception in 2007. As of December 31, 2013, we had an accumulated deficit of $66.2 million. We anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may seek to obtain through one or more equity offerings, debt financings, government or other third-party funding, and licensing or collaboration arrangements.

Since our inception through December 31, 2013, we have funded our operations principally through the receipt of funds from the private placement of $80.0 million of equity and debt securities. As of December 31, 2013, we had cash and cash equivalents of $16.2 million and marketable securities of $0.3 million. On February 18, 2014, we completed the initial public offering of our common stock, which resulted in net proceeds to us of approximately $67.2 million, after deducting underwriting discounts, commissions and offering costs. We anticipate that our existing cash, cash equivalents and marketable securities, including the proceeds we received from our initial public offering, will fund our operations into late 2015. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to capital preservation.

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The following table shows a summary of our cash flows for each of the years ended December 31, 2013, 2012 and 2011:

	Year Ended December 31,		
	2013	2012	2011
	(in thousands)		
Cash flows used in operating activities	$ (16,187)	$ (13,980)	$ (10,350)
Cash flows provided by (used in) investing activities	15,641	(9,534)	(4,102)
Cash flows provided by financing activities	3,899	32,992	13,000
Net increase (decrease) in cash and cash equivalents	$ 3,353	$ 9,478	$ (1,452)

Net Cash Used in Operating Activities

Operating activities used $16.2 million of cash in 2013. The cash flow used in operating activities resulted primarily from our net loss of $18.2 million for the period, offset by net non-cash charges of $1.3 million and cash provided by changes in our operating assets and liabilities of $0.7 million. Our non-cash charges consisted of $0.2 million related to depreciation expense and amortization of premiums on marketable securities and $1.0 million of stock-based compensation expense. Net cash provided by changes in our operating assets and liabilities consisted primarily of a $0.5 million increase in our accounts payable and a $0.3 million decrease in our prepaid expenses and other current assets partially offset by a $0.1 million decrease in accrued expenses and other current liabilities. The increase in accounts payable was primarily due to the timing of our payments to manufacturers, CROs and legal counsel. The decrease in prepaid expenses and other current assets was primarily due to a $0.1 million decrease in prepaid patent application fees for FX006, which were expensed in 2013 when the applications were filed, a $0.1 million reduction in interest receivable on our marketable securities, which decreased during the period, a decrease in prepaid expenses related to the conclusion of the Phase 2b dose-ranging clinical trial of FX006 and the refund of a security deposit resulting from our office move. The $0.1 million decrease in accrued expenses and other current liabilities was primarily attributable to a decrease of expenses related to clinical research and contract manufacturing expenses.

Operating activities used $14.0 million of cash in 2012. The cash flow used in operating activities resulted primarily from our net loss of $15.0 million for the year, offset by net non-cash charges of $0.3 million and net cash provided by changes in our operating assets and liabilities of $0.7 million. Our non-cash charges consisted of $0.2 million related to depreciation expense and amortization of premiums on marketable securities and $0.1 million of stock-based compensation expense. Net cash provided by changes in our operating assets and liabilities consisted primarily of a $1.1 million increase in our accrued expenses and other current liabilities, partially offset by a $0.2 million increase in prepaid expenses and other current assets and a $0.2 million decrease in our accounts payable. The increase in accrued expenses and other current liabilities was primarily attributable to the increase in expenses related to clinical research and contract manufacturing services. The increase in our prepaid expenses and other current assets was primarily due to prepayments we made for legal services related to our patent filings. The decrease in our accounts payable was primarily due to the timing of our payments to manufacturers and CROs.

Operating activities used $10.3 million of cash in 2011. The cash flow used in operating activities resulted primarily from our net loss of $11.4 million for the year, offset by net non-cash charges of $0.5 million and net cash provided by changes in our operating assets and liabilities of $0.6 million. Our non-cash charges primarily consisted of $0.2 million related to depreciation expense and amortization of premiums on marketable securities, $0.2 million related to

a loss on disposal of property and equipment

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and $0.1 million of stock-based compensation expense. Net cash provided by changes in our operating assets and liabilities consisted primarily of a $0.5 million increase in our accounts payable and a $0.2 million decrease in prepaid expenses and other current assets, all partially offset by a $0.1 million decrease in accrued expenses and other current liabilities. The increase in our accounts payable was primarily due to the timing of our payments to manufacturers and CROs. The decrease in our prepaid expenses and other current assets was primarily due to the collection in 2011 of our research and development tax credit receivable, which we initially recorded in 2010.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $15.6 million in the year ended December 31, 2013. Net cash provided by investing activities in the year ended December 31, 2013 consisted primarily of cash received from the redemption of marketable securities of $31.2 million, partially offset by cash used for the purchase of marketable securities of $15.0 million and to purchase property and equipment of $0.4 million.

Net cash used in investing activities was $9.5 million and $4.1 million in the years ended December 31, 2012 and 2011, respectively. Net cash used in investing activities consisted primarily of cash paid to purchase marketable securities of $28.5 million and $16.8 million in 2012 and 2011, respectively, partially offset by cash received from the redemption of marketable securities of $19.0 million and $12.8 million in 2012 and 2011, respectively.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $3.9 million, $33.0 million and $13.0 million in the years ended December 31, 2013, 2012 and 2011, respectively. Net cash provided by financing activities in the year ended December 31, 2013 consisted of $5.0 million in proceeds from borrowings under our term loan, partially offset by the payment of fees incurred in connection with our initial public offering of $1.1 million. Net cash provided by financing activities in the year ended December 31, 2012 primarily consisted of $13.1 million received from the sale of Series A preferred stock net of issuance costs and $19.9 million received from the sale of Series B preferred stock net of issuance costs. Net cash provided by financing activities in the year ended December 31, 2011 primarily consisted of $13.0 million from the sale of Series A preferred stock.

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Contractual Obligations

The following table discloses aggregate information about our contractual obligations and the periods in which payments are due as of December 31, 2013:

	Payments Due By Period				
	Total	Less Than 1 Year	1 3 Years	3 5 Years	More Than 5 Years
			(in thousands)		
Long-term debt (including interest)[1]	$ 5,800	$ 1,865	$ 3,935	$	$
Operating lease obligations[2]	801	267	534		
Total[3]	$ 6,601	$ 2,132	$ 4,469	$	$

(1) Represents the contractually required principal and interest payments on our credit facility in accordance with the required payment schedule and the $175,000 final payment to the lender on September 1, 2016. Amounts associated with future interest payments to be made were calculated using the fixed interest rate of 8.0% per annum.

(2) Represents the contractually required payments under our operating lease obligations in existence as of December 31, 2013 in accordance with the required payment schedule. No assumptions were made with respect to renewing the lease terms at the expiration date of their initial terms.

(3) Milestone payments of up to $184.0 million will become due under our agreements with AstraZeneca as we achieve regulatory and commercial milestones. In addition, we will pay tiered royalties on product sales. We have not included these amounts in this table as we cannot estimate or predict when, or if, those amounts will become due.

The table above reflects only payment obligations that are fixed or determinable. We enter into contracts in the normal course of business with CROs for clinical trials and clinical supply manufacturing, and with vendors for preclinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements.

Recent Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board, or FASB, issued guidance to provide information about the amounts reclassified out of accumulated other comprehensive income, or AOCI, by component. An entity is required to present, either on the face of the financial statements or in the notes,

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significant amounts reclassified out of AOCI by the respective line items of net income, but only if the amount reclassified is required to be reclassified in its entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional details about those amounts. On January 1, 2013, we adopted this standard, which had no impact on our financial position, results of operations or cash flows.

In July 2012, the FASB issued Accounting Standards Update (ASU) 2012-02, *Testing Indefinite-Lived Intangible Assets for Impairment*. The guidance allows companies, at their option, to perform a qualitative assessment of indefinite-lived assets to determine if it is more likely than not that the fair value of the assets exceeds its carrying value. If analysis of the qualitative factors results in the fair value of the indefinite-lived asset exceeding the carrying value, then performing the quantitative assessment is not required. This guidance is effective for interim and annual periods beginning after December 15, 2012. We adopted this standard on January 1, 2013, and it had no impact on our financial position, results of operations or cash flows.

JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We are relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an emerging growth company, we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10.0% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates on our investment portfolio.

We have borrowed $5.0 million under our credit facility. Amounts outstanding under the credit facility bear interest at a fixed rate equal to 8.0% per annum.

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We do not believe that our cash, cash equivalents and marketable securities have significant risk of default or illiquidity. While we believe our cash and cash equivalents and certificates of deposit do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

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Item 8. Financial Statements and Supplementary Data

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders

of Flexion Therapeutics, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, of changes in convertible preferred stock and stockholders deficit and of cash flows present fairly, in all material respects, the financial position of Flexion Therapeutics, Inc. and its subsidiaries (a development stage company) at December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the three years then ended and, cumulatively, for the period from November 5, 2007 (date of inception) to December 31, 2013 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

March 28, 2014

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Flexion Therapeutics, Inc.

(A Development Stage Enterprise)

Consolidated Balance Sheets

	December 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 16,188,254	$ 12,835,330
Marketable securities	250,047	16,548,000
Prepaid expenses and other current assets	181,962	488,340
Total current assets	16,620,263	29,871,670
Property and equipment, net	375,239	63,843
Deferred offering costs	1,623,540	
Other assets	28,875	42,178
Restricted cash	128,000	30,000
Total assets	$ 18,775,917	$ 30,007,691
Liabilities, Convertible Preferred Stock and Stockholders Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,279,874	$ 483,984
Accrued expenses and other current liabilities	2,256,680	2,240,620
Current portion of long-term debt	1,500,000	
Total current liabilities	5,036,554	2,724,604
Long-term debt	3,546,667	
Other long-term liabilities	90,373	
Total liabilities	8,673,594	2,724,604
Commitments and contingencies		
Convertible preferred stock (Series A and B), $0.001 par value; 73,780,250 shares authorized, 72,780,250 shares issued and outstanding as of December 31, 2013 and 2012; aggregate liquidation preference of $75,043,464 at December 31, 2013 and 2012	74,806,213	74,806,213
Stockholders equity (deficit):		
Common stock, $0.001 par value; 94,000,000 shares authorized; 794,090 and 789,222 shares issued and outstanding at December 31,	794	789

2013 and 2012, respectively		
Additional paid-in capital	1,458,503	450,070
Accumulated other comprehensive income	(28)	2,450
Deficit accumulated during the development stage	(66,163,159)	(47,976,435)
Total stockholders equity (deficit)	(64,703,890)	(47,523,126)
Total liabilities, convertible preferred stock and stockholders equity (deficit)	$ 18,775,917	$ 30,007,691

The accompanying notes are an integral part of these consolidated financial statements.

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Flexion Therapeutics, Inc.

(A Development Stage Enterprise)

Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,			Cumulative Period From Inception (November 5, 2007) to December 31, 2013
	2013	2012	2011	
Revenue	$	$	$	$
Operating expenses:				
Research and development	11,060,912	11,065,137	8,241,102	42,294,364
General and administrative	6,704,297	3,946,505	3,046,432	23,625,519
Total operating expenses	17,765,209	15,011,642	11,287,534	65,919,883
Loss from operations	(17,765,209)	(15,011,642)	(11,287,534)	(65,919,883)
Other income (expense):				
Interest income	233,999	193,900	173,289	776,121
Interest expense	(448,889)			(660,154)
Other income (expense), net	(206,625)	(163,877)	(332,664)	(359,243)
Total other income (expense)	(421,515)	30,023	(159,375)	(243,276)
Net loss	$ (18,186,724)	$ (14,981,619)	$ (11,446,909)	$ (66,163,159)
Net loss attributable to common stockholders	$ (18,186,724)	$ (14,981,619)	$ (11,446,909)	$ (66,163,159)
Net loss per share attributable to common stockholders, basic and diluted	$ (23.02)	$ (27.58)	$ (23.26)	

Weighted average common shares outstanding, basic and diluted	790,038	543,301	492,100	
Other comprehensive (loss)income:				
Unrealized (losses)gains from available-for-sale securities, net of tax of $0	(2,478)	1,647	1,858	(28)
Total other comprehensive (loss)income	(2,478)	1,647	1,858	(28)
Comprehensive loss	$ (18,189,202)	$ (14,979,972)	$ (11,445,051)	$ (66,163,187)

The accompanying notes are an integral part of these consolidated financial statements.

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Flexion Therapeutics, Inc.

(A Development Stage Enterprise)

Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders Deficit

	Series A and B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Tot Stockho Defi
	Shares	Amount	Shares	Par Value				
e at Inception ber 5, 2007)		$		$	$	$	$	$
e of common stock to s			109		900			
							(183,819)	(183
e at December 31, 2007			109		900		(183,819)	(182
e of common stock to lders			301,350	301	20,449			2
							(3,247,767)	(3,247
e at December 31, 2008			301,459	301	21,349		(3,431,586)	(3,409
e of Series A Convertible d Stock and common et of issuance costs of 3	28,950,000	28,835,747	44,280	44	(44)			
e of common stock in ion with a licensing ent			184,501	185	29,815			3
ased compensation					9,608			
							(8,952,123)	(8,952
omprehensive income						581		
e at December 31, 2009	28,950,000	28,835,747	530,240	530	60,728	581	(12,383,709)	(12,321
ased compensation					168,023			16
							(9,164,198)	(9,164
omprehensive loss						(1,636)		(1
e at December 31, 2010	28,950,000	28,835,747	530,240	530	228,751	(1,055)	(21,547,907)	(21,319
e of Series A ible Preferred Stock	13,000,000	13,000,000						

ased compensation								
					83,190			8
							(11,446,909)	(11,446
omprehensive income						1,858		
e at December 31, 2011	41,950,000	41,835,747	530,240	530	311,941	803	(32,994,816)	(32,681
e of Series A ible d Stock, net of issuance $11,476	13,093,464	13,081,988						
e of Series B Convertible d Stock, net of issuance $111,522	17,736,786	19,888,478						
e of stock options			258,982	259	41,851			4
ased compensation								
					96,278			9
							(14,981,619)	(14,981
omprehensive income						1,647		
e at December 31, 2012	72,780,250	74,806,213	789,222	789	450,070	2,450	(47,976,435)	(47,523
e of stock options			4,868	5	12,266			1
ased compensation								
					996,167			99
							(18,186,724)	(18,186
omprehensive loss						(2,478)		(2
e at December 31, 2013	72,780,250	$ 74,806,213	794,090	$ 794	$ 1,458,503	$ (28)	$ (66,163,159)	$ (64,703

The accompanying notes are an integral part of these consolidated financial statements.

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Flexion Therapeutics, Inc.

(A Development Stage Enterprise)

Consolidated Statements of Cash Flows

	Year Ended December 31,			Cumulative Peri From Inceptio (November 5, 20 to
	2013	2012	2011	December 31, 20
n flows from operating activities				
oss	$ (18,186,724)	$ (14,981,619)	$ (11,446,909)	$ (66,163,159
stments to reconcile net loss to cash used in operating ities:				
reciation	79,808	43,233	105,574	434,935
k-based compensation expense	996,167	96,278	83,190	1,353,266
ortization of premium (discount) on marketable securities	151,138	137,163	135,523	561,875
on disposal of property and equipment	14,111		153,996	168,107
r non-cash charges	63,167			103,243
nges in operating assets and liabilities:				
aid expenses and other current and long-term assets	343,896	(178,571)	188,553	(129,144
ounts payable	475,821	(176,272)	507,248	959,805
rued expenses and other current and long-term liabilities	(124,328)	1,079,925	(77,387)	2,079,974
cash used in operating activities	(16,186,944)	(13,979,863)	(10,350,212)	(60,631,097
n flows from investing activities				
hases of property and equipment	(405,315)	(34,914)	(39,538)	(978,280
nge in restricted cash	(98,000)			(128,000
hases of marketable securities	(15,015,663)	(28,465,790)	(16,815,322)	(81,484,671
emption of marketable securities	31,160,000	18,967,000	12,752,644	80,662,644
cash provided by (used in) investing activities	15,641,022	(9,533,704)	(4,102,216)	(1,928,307
n flows from financing activities				
eeds from issuance of related-party notes				4,100,000
ment of related-party notes				(4,100,000
eeds from borrowings under term loan	5,000,000			5,000,000

ments of debt issuance costs	(40,715)	(21,161)		(61,876
ment of initial public offering costs	(1,072,710)			(1,072,710
eeds from issuance of Series A Convertible Preferred k, net of issuance costs		13,081,988	13,000,000	54,917,735
eeds from issuance of Series B Convertible Preferred k, net of issuance costs		19,888,478		19,888,478
eeds from the issuance of common stock				21,650
eeds from the exercise of stock options	12,271	42,110		54,381
cash provided by financing activities	3,898,846	32,991,415	13,000,000	78,747,658
increase (decrease) in cash and cash equivalents	3,352,924	9,477,848	(1,452,428)	16,188,254
and cash equivalents at beginning of period	12,835,330	3,357,482	4,809,910	
and cash equivalents at end of period	$ 16,188,254	$ 12,835,330	$ 3,357,482	$ 16,188,254
plemental disclosures of cash flow information:				
paid for interest	$ 367,778	$	$	$ 579,043
plemental disclosures of non-cash financing activities:				
issuance costs included in accounts payable and accrued nses	$	$ 36,318	$	$
erred initial public offering costs included in accounts ble or accrued expenses	$ 550,830	$	$	$ 550,830

The accompanying notes are an integral part of these consolidated financial statements.

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Flexion Therapeutics, Inc.

(A Development Stage Enterprise)

Notes to Consolidated Financial Statements

1. Nature of the Business

Flexion Therapeutics, Inc. (Flexion or the Company) was incorporated under the laws of the state of Delaware on November 5, 2007. Flexion is a specialty pharmaceutical company focused on the development and commercialization of novel, injectable pain therapies. The Company is targeting anti-inflammatory and analgesic therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis, a type of degenerative arthritis (OA) and post-operative pain. Flexion s broad and diversified portfolio of product candidates addresses the OA pain treatment spectrum, from moderate to severe pain, and provides the Company with multiple opportunities to achieve its goal of commercializing novel, patient-focused pain therapies.

The accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company is in the development stage and has incurred recurring losses and negative cash flows from operations. As of December 31, 2013 and December 31, 2012, the Company had cash and cash equivalents and marketable securities of $16,438,301 and $29,383,330, respectively. Management believes that current cash, cash equivalents and marketable securities on hand at December 31, 2013, together with the cash proceeds from the Company s initial public offering completed on February 18, 2014 should be sufficient to fund operations at least through December 31, 2014 . The future viability of the Company is dependent on its ability to raise additional capital to finance its operations and to fund increased research and development costs in order to seek approval for commercialization of its product candidates. The Company s failure to raise capital as and when needed would have a negative impact on its financial condition and its ability to pursue its business strategies as this capital is necessary for the Company to perform the research and development activities required to develop the Company s product candidates in order to generate future revenue streams.

On January 27, 2014, the Company effected a 1-for-8.13 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of Convertible Preferred Stock (Note 10). Accordingly, all share and per share amounts for all periods presented in these consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance reporting capabilities. The Company s product candidates are all in the development stage. There can be no assurance that development efforts, including clinical trials, will be successful or that the Company will have the ability to continue into later stages of clinical trials. Even if the Company s product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

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At December 31, 2013, the Company is considered a development stage enterprise. Until planned principal operations have commenced and significant revenue is generated, financial statements prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) are required to report cumulative statements of operations and comprehensive loss, stockholders equity (deficit) and cash flows.

2. Initial Public Offering

On February 18, 2014, the Company completed its initial public offering of 5,000,000 shares of common stock at a price of $13.00 per share. In addition, at the closing of the initial public offering, the underwriters exercised their over-allotment option to purchase 750,000 additional shares of our common stock in the initial public offering at the public offering price of $13.00 per share, for an aggregate offering of $74.8 million. After deducting underwriting discounts, commissions and offering costs of $7.5 million, the net proceeds from the offering were approximately $67.2 million.

3. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in conformity with GAAP and, in periods prior to 2013, are consolidated, including the accounts of the Company and its wholly owned subsidiary after elimination of all significant intercompany accounts and transactions.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the valuation of common stock and stock-based awards and the accrual of research and development expenses. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less at the date of purchase to be cash equivalents. The Company currently invests available cash in money market funds of a major financial institution, corporate bonds and commercial paper.

Marketable Securities

Marketable securities consist of investments with original maturities greater than ninety days and less than one year from the balance sheet date. Long-term investments consist of investments with maturities of greater than one year. The Company classifies all of its investments as available-for-sale securities. Accordingly, these investments are recorded at fair value, which is based on quoted market prices. Realized gains and losses are determined on a specific identification basis and are included in other income (loss).

Restricted Cash

The Company purchased a $30,000 certificate of deposit to collateralize a credit card account with a commercial bank that was classified as long-term restricted cash as of December 31, 2013 and 2012. In

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addition, the Company posted a letter of credit to the lessor of the Company s Burlington facility in the amount of $98,000 as a security deposit pursuant to the lease agreement in the year ended December 31, 2013. That amount was classified as long-term restricted cash at December 31, 2013.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation and amortization expense is recognized using the straight-line method over the following estimated useful lives:

	Estimated Useful Life (Years)
Computer and office equipment	3
Manufacturing equipment	7
Furniture and fixtures	5

Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the related asset. Costs of major additions and betterments are capitalized and depreciated on a straight-line basis over their useful lives. Repairs and maintenance costs are expensed as incurred. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to income.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows.

Debt Issuance Costs, net

Debt issuance costs, net represent legal costs related to the Company s Credit and Security Agreement (Note 9). These costs are recorded as debt issuance costs on the balance sheets at the time they are incurred and are being amortized to interest expense through the scheduled final principal payment date. As of December 31, 2013 and 2012, the carrying value of debt issuance costs was $16,500 and $15,300, respectively, reported in prepaid expenses and other current assets and $28,875 and $42,178, respectively, reported in other assets. In addition, $16,500 was recognized as interest expense in the statement of operations for the year ended December 31, 2013 and from inception through

December 31, 2013 related to the amortization of debt issuance costs. The Company did not recognize any interest expense related to debt issuance costs during the years ended December 31, 2012 and 2011.

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as other assets until such financings are consummated. After

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consummation of the equity financing, these costs are recorded in stockholders deficit as a reduction of additional paid-in capital generated as a result of the offering. Had the equity financing no longer been considered probable of being consummated, the deferred offering costs would be expensed immediately as a charge to operating expenses in the consolidated statement of operations. As of December 31, 2013, the Company recorded deferred offering costs of $1,623,540 in the accompanying balance sheet in contemplation of a 2014 equity financing. The Company did not record any deferred offering costs as of December 31, 2012. The company completed its initial public offering in February 2014.

Research and Development

Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries and benefits, facilities costs, overhead costs, depreciation, clinical trial and related clinical manufacturing costs, contract services and other related costs. Research and development costs are expensed to operations as the related obligation is incurred.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are recorded as general and administrative expenses as incurred, as recoverability of such expenditures is uncertain.

Accounting for Stock-Based Compensation

The Company measures all stock options and other stock based-awards granted to employees at the fair value at the date of grant using the Black-Scholes option-pricing model. The fair value of the awards is recognized as expense, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. The straight-line method of expense recognition is applied to all awards with service-only conditions.

For stock-based awards granted to non-employees, compensation expense is recognized over the period during which services are rendered by such non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is re-measured using the then current fair value of the Company s common stock and updated assumption inputs in the Black-Scholes option-pricing model.

The Company classifies stock-based compensation expense in the consolidated statements of operations in the same manner in which the award recipient s payroll costs are classified, or in the case of a non-employee, in the same manner as the award recipient s service costs are classified.

The Company recognizes compensation expense only for the portion of awards that are expected to vest. In developing a forfeiture rate estimate, the Company has considered its historical experience to estimate pre-vesting forfeitures for service-based awards. The impact of a forfeiture rate adjustment will be recognized in full in the period of adjustment, and if the actual forfeiture rate is materially different from the Company s estimate, the Company may be required to record adjustments to stock-based compensation expense in future periods.

Concentration of Credit Risk and Significant Suppliers

Financial instruments that potentially expose the Company to concentration of credit risk consist primarily of commercial paper and bonds. The Company generally invests its cash in money market funds, government and corporate bonds, and commercial paper at one financial institution. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

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The Company is completely dependent on third-party manufacturers and product suppliers for preclinical research activities. In particular, the Company relies and expects to continue to rely exclusively on one manufacturer and relies on the manufacturer to purchase from third-party suppliers the materials necessary to produce its product candidates for its clinical trials. These research programs would be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients.

Comprehensive Loss

Comprehensive income (loss) includes net loss as well as other changes in stockholders deficit that result from transactions and economic events other than those with stockholders. The Company s only element of other comprehensive income (loss) in all periods presented was unrealized gains (losses) on available-for-sale securities.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences of events that have been recognized in the financial statements or in the Company s tax returns. Deferred taxes are determined based on the differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted rates in effect for the year in which these temporary differences are expected to be recovered or settled. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Fair Value Measurements

Fair value is defined as the exchange price that would be received to sell an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1 Quoted market prices in active markets for identical assets or liabilities. Level 1 consists primarily of financial instruments whose value is based on quoted market prices, such as exchange-traded

instruments and listed equities.

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Level 2 Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company s financial instruments consist of cash equivalents, marketable securities, restricted cash, accounts payable and accrued expenses, and its term loan (Note 9). The estimated fair value of the Company s financial instruments approximates their carrying values.

Net Loss Per Share

The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based on their respective rights to receive dividends as if all income for the period had been distributed.

The Company s convertible preferred shares contractually entitle the holders of such shares to participate in dividends, but do not contractually require the holders of such shares to participate in the losses of the Company. Accordingly, in periods in which the Company reports a net loss or a net loss attributable to common stockholders resulting from preferred stock dividends, net losses are not allocated to participating securities. In periods of net loss, the Company does not increase its net loss attributable to common stockholders by accreting dividends on preferred stock, as the dividends are not cumulative under the terms of the preferred stock. The Company reported a net loss attributable to common stockholders for the year ended December 31, 2013, 2012 and 2011.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities, including outstanding stock options and unvested restricted common stock. Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock options and unvested restricted common stock. For periods in which the Company has reported net losses, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. Potential common shares will always be anti-dilutive for periods in which the Company has reported a net loss. Diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders for the years ended December 31, 2013, 2012 and 2011.

Segment Data

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. The Company is a specialty pharmaceutical company focused on the development and commercialization of novel, injectable pain therapies. No revenue has been generated since inception, and all assets

are held in the United States.

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Reclassifications

Certain intra-period amounts have been reclassified. Specifically, deferred offering costs have been reclassified from current assets to long term assets.

Recently Issued and Adopted Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board (FASB) issued guidance to provide information about the amounts reclassified out of accumulated other comprehensive income (AOCI) by component. An entity is required to present, either on the face of the financial statements or in the notes, significant amounts reclassified out of AOCI by the respective line items of net income, but only if the amount reclassified is required to be reclassified in its entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional details about those amounts. On January 1, 2013, the Company adopted this standard, which had no impact on its financial position, results of operations or cash flows.

In July 2012, the FASB issued Accounting Standards Update (ASU) 2012-02, *Testing Indefinite-Lived Intangible Assets for Impairment*. The guidance allows companies, at their option, to perform a qualitative assessment of indefinite-lived assets to determine if it is more likely than not that the fair value of the assets exceeds its carrying value. If analysis of the qualitative factors results in the fair value of the indefinite-lived asset exceeding the carrying value, then performing the quantitative assessment is not required. This guidance is effective for interim and annual periods beginning after December 15, 2012. On January 1, 2013, the Company adopted this standard, which had no impact on its financial position, results of operations or cash flows.

4. Fair Value of Financial Assets

The following tables present information about the Company s assets and liabilities that are measured at fair value on a recurring basis as December 31, 2013 and 2012 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of December 31, 2013 Using:			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents	$	$ 14,957,788	$	$ 14,957,788
Marketable securities		250,047		250,047
	$	$ 15,207,835	$	$ 15,207,835

	Fair Value Measurements as of December 31, 2012 Using:			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents	$ 6,234,758	$ 5,299,213	$	$ 11,533,971
Marketable securities		16,548,000		16,548,000
	$ 6,234,758	$ 21,847,213	$	$ 28,081,971

As of December 31, 2013 and 2012, the Company s cash equivalents that are invested in money market funds are valued based on Level 2 inputs and Level 1 inputs, respectively. The Company measures

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the fair value of marketable securities using Level 2 inputs and primarily relies on quoted prices in active markets for similar marketable securities. During the years ended December 31, 2013 and 2012, there were no transfers between Level 1, Level 2 and Level 3.

The term loan outstanding under the Company s credit and security agreement (Note 9) is reported at its carrying value in the accompanying balance sheet. The Company determined the fair value of the term loan using an income approach, utilizing a discounted cash flow analysis based on current market interest rates for debt issuances with similar remaining years to maturity, adjusted for credit risk. The term loan was valued using Level 2 inputs as of December 31, 2013. The result of the calculation yielded a fair value that approximates carrying value.

5. Marketable Securities

As of December 31, 2013 and 2012, the fair value of available-for-sale marketable securities by type of security was as follows:

	December 31, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	250,075		(28)	250,047
	$ 250,075	$	$ (28)	$ 250,047

	December 31, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 9,491,006	$ 5,922	$	$ 9,496,928
Corporate bonds	7,054,544		(3,472)	7,051,072
	$ 16,545,550	$ 5,922	$ (3,472)	$ 16,548,000

At December 31, 2013 and 2012, marketable securities consisted of investments that mature within one year.

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6. Prepaid Expenses and Other Current Assets and Other Assets

Prepaid expenses and other current assets and other assets consisted of the following as of December 31, 2013 and 2012:

	December 31, 2013	December 31, 2012
Prepaid expenses	$ 132,266	$ 305,602
Security deposits		28,300
Debt issuance costs	16,500	15,300
Interest receivable on marketable securities	33,196	139,138
Total prepaid expenses and other current assets	$ 181,962	$ 488,340

	December 31, 2013	December 31, 2012
Debt issuance costs	$ 28,875	$ 42,178
Total other assets	$ 28,875	$ 42,178

In connection with entering into a credit and security agreement (Note 9), the Company incurred debt acquisition costs in the amount of $61,876. The Company capitalized these costs and is amortizing them as interest expense over the term of the term loan using the effective interest rate method. Total amortization expense for the debt issuance costs was $16,500 for the year ended December 31, 2013 and from November 5, 2007 (date of inception) to December 31, 2013.

7. Property and Equipment, Net

Property and equipment, net, as of December 31, 2013 and 2012 consisted of the following:

	December 31, 2013	December 31, 2012
Computer and office equipment	$ 257,346	$ 126,928
Manufacturing equipment	99,684	16,695
Furniture and fixtures	149,183	60,722
Leasehold improvements	130,626	43,873
	636,839	248,218
Less: Accumulated depreciation	(261,600)	(184,375)

Total property and equipment, net	$ 375,239	$ 63,843

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Depreciation expense for the years ended December 31, 2013, 2012 and 2011, and from November 5, 2007 (date of inception) through December 31, 2013 was $79,808, $43,233, $105,574, $435,013, respectively. During the year ended December 31, 2013 and 2011, $16,695 and $324,748 of property and equipment was disposed of, resulting in a loss of $14,111 and $153,996, respectively.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities at December 31, 2013 and 2012 consisted of the following:

	December 31, 2013	December 31, 2012
Clinical research	$ 163,521	$ 1,221,042
Contract manufacturing services	529,287	168,607
Payroll and other employee-related expenses	792,165	546,571
Preclinical services	5,685	44,499
Consultant fees and expenses	21,718	28,750
Professional services fees	642,052	164,696
Interest expense	34,445	
Other	67,807	66,455
Total accrued expenses and other current liabilities	$ 2,256,680	$ 2,240,620

9. Long-term Debt

On January 3, 2013, the Company entered into a credit and security agreement with MidCap under which it immediately borrowed $5,000,000 as a term loan. The term loan accrues interest monthly at an interest rate of 8.0% per annum and has a term of 45 months. As the term loan has a 15-month interest-only period, the term loan principal balance, along with any accrued interest, is to be paid in 30 equal monthly installments beginning April 1, 2014 and ending September 1, 2016. In addition to these principal payments, the Company is required to make a payment of $175,000 to the lender on September 1, 2016, which is being accreted to the carrying value of the debt using the effective interest rate method. As of December 31, 2013, the carrying value of the term loan was $5,046,667, of which $1,500,000 was classified as the current portion of long-term debt on the balance sheet as of December 31, 2013. In connection with the credit and security agreement, the Company granted MidCap a security interest in all of the Company s personal property now owned or hereafter acquired, excluding intellectual property but including the proceeds from the sale, if any, of intellectual property, and a negative pledge on intellectual property. The credit and security agreement also contains certain representations, warranties and non-financial covenants of the Company. As of December 31, 2013, the Company was compliant with all covenants.

10. Convertible Preferred Stock

As of December 31 2013, the Company s Certificate of Incorporation, as amended, authorizes the Company to issue 73,780,250 shares of preferred stock with a par value of $0.001 per share. The Company has issued Series A and

Series B Convertible Preferred Stock (collectively, the Convertible Preferred Stock). Of the 73,780,250 authorized shares, 72,780,250 shares are issued; 55,043,464 of the issued shares are designated as Series A Convertible Preferred Stock (Series A Preferred Stock) and 18,736,786 are designated as Series B Convertible Preferred Stock (Series B Preferred Stock).

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In 2009, the Company issued 28,950,000 shares of Series A Preferred Stock at a purchase price of $1.00 per share (Series A Original Issue Price). In conjunction with the preferred stock financing, 360,000 shares of common stock were issued to Series A Preferred Stock investors. The Series A Preferred Stock issuance resulted in net proceeds of $28,835,747.

In March 2011, the Company issued 13,000,000 additional shares of Series A Preferred Stock at a purchase price of $1.00 per share. The Series A Preferred Stock issuance resulted in proceeds of $13,000,000.

In February 2012, the Company issued 13,093,464 additional shares of Series A Preferred Stock at a purchase price of $1.00 per share. The Series A Preferred Stock issuance resulted in net proceeds of $13,081,988.

In December 2012, the Company issued 17,736,786 shares of Series B Preferred Stock at a purchase price of $1.1276 per share (Series B Original Issue Price). The Series B Preferred Stock issuance resulted in net proceeds of $19,888,478. Included in the Series B Preferred Stock issuance are contingently issuable warrants for the purchase of 218,160 shares of common stock at $0.01 per share. These warrants are contingently issuable if the Company does not initiate and enroll the first patient in a multi-dose Phase 2b clinical trial with planned enrollment of at least 100 patients for the Company s product candidate identified as FX005 by February 15, 2014. Additionally, the obligation to issue the warrants will terminate on the earlier to occur of (i) the consummation of a registered initial public offering, which is defined as a firmly underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, covering the offer and sale of common stock for the account of the Company and (ii) the occurrence of a liquidation event or the consummation of a deemed liquidation event. The Company determined that the contingently issuable common stock warrants were equity in nature. As such, the Company allocated the Series B Preferred Stock proceeds to both the Series B Preferred Stock and the contingently issuable common stock warrants based on relative fair values at the issuance date. Given the low probability assessed by the Company of not satisfying the contingency and having to issue the warrants, the amount ascribed to the warrants was immaterial and the full amount of the proceeds was allocated to the Series B Preferred Stock.

On January 27, 2014, the Company and holders of a majority of the Company s Series A Convertible Preferred Stock and Series B Convertible Preferred Stock entered into a Conversion, Amendment and Waiver Agreement. This agreement amended the milestone date associated with the contingently issuable common stock warrants from February 15, 2014 to February 21, 2014. As the Company s IPO was completed prior to February 21, 2014 these warrants expired.

The following is a summary of the Company s Convertible Preferred Stock as of December 31, 2013 and 2012, respectively:

	December 31, 2013			
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion

Series A Preferred Stock	55,043,464	55,043,464	$ 54,917,735	$ 55,043,464	6,770,411
Series B Preferred Stock	18,736,786	17,736,786	19,888,478	20,000,000	2,181,646
	73,780,250	72,780,250	$ 74,806,213	$ 75,043,464	8,952,057

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	December 31, 2012				
	Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Preferred Stock	55,043,464	55,043,464	$ 54,917,735	$ 55,043,464	6,770,411
Series B Preferred Stock	18,736,786	17,736,786	19,888,478	20,000,000	2,181,646
	73,780,250	72,780,250	$ 74,806,213	$ 75,043,464	8,952,057

The holders of the preferred stock have the following rights and preferences:

Voting Rights

The holders of preferred stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote. Each preferred stockholder is entitled to the number of votes equal to the number of shares of common stock into which each preferred share is convertible at the time of such vote.

Dividends

The holders of both Series A and B Preferred Stock are entitled to receive, out of funds legally available, non-cumulative dividends at an annual rate of 8.0%, when and if declared by the board of directors. Holders of Series B Preferred Stock receive such dividends in preference to any dividend on Series A Preferred Stock or common stock. After payment of any amounts payable to holders of Series B Preferred Stock, the holders of Series A Preferred Stock are entitled to receive such dividends in preference to any dividend on common stock. No dividends have been declared or paid from the cumulative period from inception (November 5, 2007) to December 31, 2013.

Liquidation

Upon any liquidation, dissolution, or winding up of the Company, whether voluntary or involuntary (each, a Liquidation Event), before any distribution or payment shall be made to the holders of any common stock, the Company shall make payment to the holders of preferred stock as follows: The holders of the Series B Preferred Stock, in preference to the holders of the Series A Preferred Stock and common stock, shall each be entitled to be paid out of the assets of the Company legally available for distribution for each share of Series B Preferred Stock held by them, an amount per share equal to the applicable Series B Original Issue Price plus all declared and unpaid dividends on such shares of Series B Preferred Stock, if any (the Series B Liquidation Preference).

After the payment of the full liquidation preference of the Series B Preferred Stock, the holders of Series A Preferred Stock, in preference to holders of common stock, shall be entitled to be paid out of the assets of the Company legally available for distribution for each share of Series A Preferred Stock held by them, an amount per share of Series A Preferred Stock equal to the Series A Original Issue Price plus all declared and unpaid dividends on the Series A

Preferred Stock, if any (the Series A Liquidation Preference).

After payment in full of the Series B Liquidation Preference and the Series A Liquidation Preference as set forth above, the remaining assets of the Company legally available for distribution, if any, shall be distributed ratably to the holders of the common stock.

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Shares of Series A and B Preferred Stock shall not be entitled to be converted into shares of common stock in order to participate in any distribution, or series of distributions, as shares of common stock, without first foregoing participation in the distribution, or series of distributions, as shares of Series A and B Preferred Stock.

Conversion

Each share of Series A and B Preferred Stock is convertible at any time at the option of the stockholder into fully paid and non-assessable shares of common stock. The number of shares of common stock to which a holder of any series of Series A and B Preferred Stock shall be entitled upon conversion shall be the product obtained by multiplying the Conversion Rate then in effect for such series of preferred stock by the number of shares of such series of preferred stock being converted.

The conversion rate in effect at any time for conversion of the preferred stock (the Conversion Rate) shall be (i) for the Series A Preferred Stock, the quotient obtained by dividing the Series A Original Issue Price by the Conversion Price of the Series A Preferred Stock and (ii) for the Series B Preferred Stock, the quotient obtained by dividing the Series B Original Issue Price by the Conversion Price of the Series B Preferred Stock.

The Conversion Price of Series A Preferred Stock was $8.13 as of December 31, 2013 and 2012, and the Conversion Price of Series B Preferred Stock was $9.166575 as of December 31, 2013 and 2012. As a result, as of December 31, 2013 and 2012, all outstanding shares of Series A Preferred Stock and Series B Preferred Stock were convertible into common stock on a 0.123001-for-1 basis. The Conversion Price of each series of preferred stock is subject to adjustment for stock splits, stock dividends and other recapitalizations in accordance with the Company s Certificate of Incorporation, as amended.

In addition to the above optional conversion feature, the Series A and B Preferred Stock include a mandatory conversion feature whereby upon a qualifying initial public offering, all outstanding shares of Series A and B Preferred Stock shall automatically be converted into shares of common stock at the then effective conversion rate. A qualifying initial public offering is an initial public offering in which (i) the per share price is at least $27.48 (as adjusted for any stock splits, dividends, combinations, recapitalizations and the like after the filing date), and (ii) the gross cash proceeds to the Company (before underwriting discounts, commissions and fees) are at least $40,000,000. All shares that are required to be surrendered per the provisions above will be deemed to have been retired and canceled and may not be reissued as shares of preferred stock.

11. Common Stock

Upon inception of the Company on November 5, 2007, the Company authorized 10,000,000 shares of common stock and issued 109 shares to the founders. In 2009, the Company amended its Certificate of Incorporation and authorized an additional 69,000,000 shares of common stock, $0.001 par value, bringing the total number of shares of common stock authorized to 79,000,000. In 2012, the Company amended its Certificate of Incorporation and authorized an additional 15,000,000 shares of common stock, $0.001 par value, bringing the total number of shares of common stock authorized to 94,000,000.

In December 2008, the Company issued 301,350 shares of common stock for proceeds of $20,750.Additionally 110,701 shares were issued to the founders of the Company, 73,800 shares were issued to a prospective preferred stock investor, and 116,849 shares were issued to non-employee consultants. The 110,701 shares issued to the founders and 116,849 of the shares issued to non-employee consultants were subject to restrictions that were satisfied over a four-year vesting period. In 2009, the Company issued 184,501 shares of common stock in connection with a

licensing agreement.

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Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company s stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of the holders of the Series A and B Preferred Stock. As of December 31, 2013, no dividends have been declared.

On January 27, 2014, the Company and the holders of a majority of the Company s Series A Convertible Preferred Stock and Series B Convertible Preferred Stock entered into a Conversion, Amendment and Waiver Agreement. This agreement provides for the automatic conversion of all outstanding shares of the Company s Convertible Preferred Stock into shares of common stock effective immediately prior to the closing of an initial public offering by the Company, provided that the price per share of the common stock sold to the public in the initial public offering is approved by the board of directors.

12. Commitments and Contingencies

Operating Leases

In September 2008, the Company entered into a lease for office space in Woburn, Massachusetts. The lease was for a 60-month term with minimum monthly lease payments of $11,043 per month. The lease payments were subject to an annual increase of the CPI adjustment percentage. The Company paid the lessor $35,100 as a security deposit pursuant to the lease agreement.

In April 2011, the Company renegotiated its lease for office space in Woburn, Massachusetts. The lease extension agreement extended the lease for an additional 12-month term with minimum monthly lease payments of $9,102 per month. The lease payments were subject to an annual increase of the CPI adjustment percentage. The lease was planned to expire on August 30, 2014. The Company reduced the security deposit to the lessor to $28,300 as part of the lease extension agreement. The Company opted to terminate this lease using an early-out clause; the lease in Woburn, Massachusetts was terminated on June 30, 2013 and the security deposit was refunded.

In May 2013, the Company entered into a lease for office space in Burlington, Massachusetts. The lease is for a 42-month term with minimum monthly lease payments beginning at $17,588 per month and escalating over the lease term. The Company provided a letter of credit to the lessor in the amount of $98,000 as a security deposit pursuant to the lease agreement to secure its obligations under the lease.

The Company incurred rent expense of $227,381, $123,023, $127,998 for the years ended December 31, 2013, 2012 and 2011, respectively, and $800,406 from November 5, 2007 (date of inception) December 31, 2013.

Future minimum lease payments under operating leases as of December 31, 2013, together with the new Burlington lease, were as follows:

Year Ending December 31,	
2014	$ 267,317
2015	289,972
2016	243,532

Total	$ 800,821

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AstraZeneca License Agreements

On September 3, 2010, the Company entered into an exclusive license agreement with AstraZeneca for FX007. The agreement grants the Company an exclusive, royalty-bearing right and license to the patent rights detailed in the agreement. Per the terms of the license agreement, the Company was required to pay a nonrefundable fee of $1,000,000: $500,000 within thirty days of the execution of the agreement and $500,000 six months after the execution of the agreement. The Company recorded $1,000,000 as research and development expense during 2010. The agreement includes terms for potential future milestone payments including up to an aggregate of $21 million upon the achievement of certain regulatory and development milestones for a first licensed product for OA indications, or up to an aggregate of $15 million 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, the Company will owe AstraZeneca tiered royalty payments on net sales based on a percentage ranging from low single digits to low double digits, depending on the volume of sales of the applicable product, as well as up to $75 million in additional payments based on the achievement of certain sales milestones. There were no payments made or expenses recorded under this agreement in 2013, 2012 or 2011.

On June 12, 2009, the Company entered into an exclusive license agreement with AstraZeneca for FX005. The agreement grants the Company an exclusive, royalty-bearing right and license to the patent rights detailed in the agreement. Per the terms of the license agreement, the Company paid a nonrefundable fee of $1,000,000 upon execution of the agreement. The Company recorded the $1,000,000 payment as research and development expense during 2009. The agreement includes terms for potential future milestone payments including up to an aggregate of $17 million upon the achievement of certain regulatory and development milestones for a first licensed product for OA indications, or up to an aggregate of $11 million 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, the Company will owe AstraZeneca tiered royalty payments on net sales based on a percentage ranging from low to high single digits, depending on the volume of sales of the applicable product, as well as up to $45 million in additional payments based on the achievement of certain sales milestones. There were no payments made or expenses recorded under this agreement in 2013, 2012 or 2011.

13. Stock-Based Compensation
Stock Incentive Plan

The Company currently grants stock-based awards pursuant to its Stock Incentive Plan (the 2009 Plan), adopted for founders, employees, officers, directors and consultants in 2009.

The 2009 Plan, which is administered by the board of directors, permits the Company to sell or award restricted common stock or to grant incentive and nonqualified stock options for the purchase of common stock, up to a maximum of 756,457 shares. In February 2012, the Company increased the number of shares of common stock available for issuance under the 2009 Plan by 615,006, bringing the total number of shares to 1,371,463. As of December 31, 2013, 272,621 shares were available for future issuance under the 2009 Plan. Stock option vesting typically occurs over four years for employees and directors and is at the discretion of the board of directors. Options granted have a maximum term of up to 10 years.

Stock Options

During the years ended December 31, 2013, 2012 and 2011, the Company granted stock options for the purchase of 201,721, 403,382, and 76,260 shares of common stock, respectively, to certain employees,

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non-employee consultants and directors. The vesting conditions for most of these awards are time-based, and the awards typically vest 25% after one year and monthly thereafter for the next 36 months. Awards typically expire after 10 years.

Of the stock options granted in 2012 for the purchase of 403,382 shares of common stock, options for the purchase of 264,944 shares were granted with performance-based vesting conditions to certain executives. The options vest in the event of a corporate transaction with the amount to vest contingent upon the transaction. The grant date fair value of these options was $236,940. In September 2012, performance-based options for the purchase of 18,450 shares of common stock were forfeited. No expense was recognized related to these options for the year ended December 31, 2012 as the performance conditions were not considered probable of achievement at December 31, 2012. On July 16, 2013, in connection with the Company s proposed initial public offering, the board of directors exercised its election to change the vesting conditions of these stock options from performance-based vesting to time-based vesting. As a result, these stock options now vest over a four-year period commencing effective August 29, 2012. The change in the vesting conditions was accounted for as a modification of these stock options. The modification resulted in an aggregate increase in the fair value of the options of $2,185,729, of which $481,729 was recorded as stock-based compensation expense on the modification date, July 16, 2013, and $1,704,000 was unrecognized stock-based compensation expense, which is expected to be recognized over the remaining vesting terms of the options through August 2016.

Stock Option Valuation

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of its publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company s stock options has been determined utilizing the simplified method for awards that qualify as plain vanilla options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. The relevant data used to determine the value of the stock option grants for the years ended December 31, 2013, 2012 and 2011 is as follows:

	December 31,		
	2013	**2012**	**2011**
Risk-free interest rates	1.00%	0.93%	2.20%
Expected dividend yield	0.00%	0.00%	0.00%
Expected term (in years)	6.0	6.1	6.1
Expected volatility	71%	71%	75%

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The following table summarizes stock option activity for the years ended December 31, 2013, 2012 and 2011:

	Shares Issuable Under Options	Weighted Average Exercise Price
Outstanding as of December 31, 2010	469,897	$ 0.16
Granted	76,260	2.20
Exercised		
Canceled	(922)	0.16
Outstanding as of December 31, 2011	545,235	$ 0.49
Granted	403,382	2.52
Exercised	(258,981)	0.16
Canceled or forfeited	(26,906)	1.79
Outstanding as of December 31, 2012	662,730	$ 1.87
Granted	201,721	7.48
Exercised	(4,868)	2.52
Canceled	(24,600)	6.59
Outstanding as of December 31, 2013	834,983	$ 2.99
Options vested and expected to vest at December 31, 2013	834,983	
Options exercisable at December 31, 2013	386,334	

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the Company s common stock for those options that had exercise prices lower than the fair value of the Company s common stock. A total of 4,868 options were exercised during the year ended December 31, 2013. The aggregate intrinsic value of stock options exercised was $45,125 and $610,600 for the year ended December 31, 2013 and 2012, respectively. No options were exercised during the year ended December 31, 2011.

At December 31, 2013, 2012 and 2011, the Company had options for the purchase of 834,983, 662,730, and 545,235 shares of common stock outstanding, with a weighted average remaining contractual term of 8.0, 8.5, and 7.95 years, respectively, and with a weighted average exercise price of $2.99, $1.87, and $0.49 per share, respectively. At December 31, 2013, 2012 and 2011 there were options for the purchase of 386,334, 198,439, and 310,603 shares of common stock exercisable under these stock option awards, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2013, 2012 and 2011 was $6.99, $1.63, and $1.46, respectively.

Restricted Common Stock

The Company s 2009 Plan provides for the award of restricted stock. The Company has granted restricted common stock with time-based vesting conditions. Unvested shares of restricted common stock may not be sold or transferred by the holder. These restrictions lapse according to the time-based vesting.

During the years ended December 31, 2013 and 2012, the Company did not issue any shares of restricted common stock.

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In December 2008, the Company issued 110,701 shares of restricted common stock to the founders and 116,849 shares of restricted common stock to non-employee consultants, which shares were subject to restrictions that were satisfied over a four-year vesting period. Unvested shares are subject to repurchase by the Company, at the issuance price, at the Company s sole discretion. The Company does not have a past practice of exercising its right to repurchase these shares and does not intend to repurchase these shares prior to the employees bearing the risk and rewards of ownership. As such, these restricted stock awards are classified as equity awards, and compensation expense related to them is equal to the excess, if any, of the fair value of the Company s common stock on date of grant over the original purchase price per share, multiplied by the number of shares of restricted common stock issued.

The table below summarizes activity relating to restricted common stock for the years ended December 31, 2012 and 2011:

	Shares	Weighted Average Grant Date Fair Value
Unvested restricted common stock as of December 31, 2010	74,538	$ 0.16
Issued		
Vested	(73,800)	0.16
Forfeited		
Unvested restricted common stock as of December 31, 2011	738	$ 0.16
Issued		
Vested	(738)	0.16
Forfeited		
Unvested restricted common stock as of December 31, 2012		$

As of December 31, 2013 and 2012, there were no shares related to restricted stock awards that were unvested and subject to repurchase.

The aggregate intrinsic value of restricted stock awards is calculated as the difference between the grant date fair value of the restricted stock awards and the fair value of the Company s common stock. For the years ended December 31, 2012 and 2011, the aggregate intrinsic value of vested restricted stock awards was $1,422,711 and $520,520, respectively, and for restricted stock awards expected to vest was $0 and $1,741, respectively. The weighted average remaining contractual term for restricted stock awards as of December 31, 2012 and 2011 was 0 years. The fair value of restricted stock awards that vested during the years ended December 31, 2012 and 2011 was $2.52 and $2.52, respectively, per share.

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options and restricted stock for the years ended December 31, 2013, 2012 and 2011 as follows:

	Year Ended December 31,		
	2013	**2012**	**2011**
Research and development	$ 347,470	$ 36,258	$ 20,854
General and administrative	648,697	60,020	62,336
	$ 996,167	$ 96,278	$ 83,190

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As of December 31, 2013, unrecognized stock-based compensation expense for stock options outstanding was $2,463,319, which is expected to be recognized over a weighted average period of 2.8 years. As of December 31, 2012, unrecognized stock-based compensation expense for stock options outstanding was $491,022, which is expected to be recognized over a weighted average period of 1.69 years.

Employee Stock Purchase Plan

On January 27, 2014, the Company s stockholders approved the Employee Stock Purchase Plan. A total of 209,102 shares of common stock were reserved for issuance under this plan. The Employee Stock Purchase Plan became effective on February 11, 2014, the date of execution of the underwriting agreement pursuant to which the Company s common stock is priced for its initial public offering.

2013 Equity Incentive Plan

On January 27, 2014, the Company s stockholders approved the 2013 Equity Incentive Plan (the 2013 Plan), which became effective on February 11, 2014, the date of execution of the underwriting agreement pursuant to which the Company s common stock is priced for its initial public offering. The 2013 Plan provides for the grant of incentive stock options (ISOs), non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, and other forms of equity compensation. Initially, the aggregate number of shares of the Company s common stock that may be issued pursuant to stock awards under the 2013 Plan after the 2013 Plan becomes effective is the sum of (i) 1,230,012 shares, plus (ii) the number of shares remaining available for grant under the 2009 Plan, plus (iii) any shares subject to outstanding stock options or other stock awards that would have otherwise returned to the 2009 Plan (such as upon the expiration or termination of a stock award prior to vesting). Additionally, the number of shares of common stock reserved for issuance under the 2013 Plan will automatically increase on January 1 of each year, beginning on January 1, 2015 (assuming the 2013 Plan becomes effective in 2014), and continuing through and including January 1, 2023, by 4% of the total number of shares of the Company s capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under the 2013 Plan is 4,684,989 shares.

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14. Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows for the years ended December 31, 2013, 2012 and 2011:

	Year Ended December 31,		
	2013	**2012**	**2011**
Numerator:			
Net loss	$ (18,186,724)	$ (14,981,619)	$ (11,446,909)
Accretion of dividends on convertible preferred stock			
Net income attributable to participating securities			
Net loss attributable to common stockholders:	$ (18,186,724)	$ (14,981,619)	$ (11,446,909)
Denominator:			
Weighted average common shares outstanding, basic and diluted	790,038	543,301	492,100
Net loss per share attributable to common stockholders, basic and diluted	$ (23.02)	$ (27.58)	$ (23.26)

Stock options for the purchase of 648,591, 580,419 and 525,037 weighted average shares of common stock were excluded from the computation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2013, 2012 and 2011, respectively, because those options had an anti-dilutive impact due to the net loss attributable to common stockholders incurred for those periods. In addition, 0, 36 and 37,407 weighted average shares of unvested restricted common stock were excluded from the computation of basic and diluted net loss per share attributable to common stockholders for the years ended December 31, 2013, 2012 and 2011, respectively.

15. Income Taxes

The Company has generated losses since inception. The Company has recorded no income tax benefits for those losses during the years ended December 31, 2013 and 2012, respectively, due to its uncertainty of realizing a benefit from those losses.

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A reconciliation of the U.S. federal statutory income tax rate to the Company s effective income tax rate is as follows:

	Year Ended December 31,	
	2013	2012
Federal statutory income tax rate	34.0%	34.0%
State taxes, net of federal benefit	4.8	5.0
Federal and state research and development tax credits	3.7	1.3
Decrease in foreign net operating loss carryforwards		(16.5)
Change in deferred tax asset valuation allowance	(38.1)	(21.7)
Other	(4.4)	(2.1)
Effective income tax rate	%	%

The Company s net deferred tax assets consisted of the following:

	December 31,	
	2013	2012
Net operating loss carryforwards	$ 13,677,136	$ 6,364,962
Research and development tax credit carryforwards	2,333,715	1,189,035
Capitalized research and development expenses, net	7,397,849	8,166,574
Accruals and other temporary differences	84,716	192,470
Intangible assets, net		635,958
Total deferred tax assets	23,493,416	16,548,999
Valuation allowance	(23,493,416)	(16,548,999)
Net deferred tax asset	$	$

As of December 31, 2013, the Company had federal and state net operating loss carryforwards of approximately $35,130,837 and $32,815,374, respectively, which begin to expire in 2028 for federal purposes and in 2014 for state purposes. In addition, the Company had federal and state research and development tax credit carryforwards of approximately $1,600,000 and $1,111,000, respectively, available to reduce future tax liabilities, which begin to expire in 2029 for federal purposes and 2024 for state purposes. Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss carryforwards and capitalized research and development expenses. Management has considered the Company s history of cumulative net losses incurred since inception, as well as its lack of commercialization of any products or generation of any revenue from product sales since inception, and determined that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. As a result, a full valuation allowance has been established at December 31, 2013 and 2012.

Pursuant to Section 382 of the Internal Revenue Code, certain substantial changes in the Company s ownership may result in a limitation on the amount of net operating loss carryforwards and research and development tax credit carryforwards that may be used in future years to reduce taxable income. During 2009 and 2012, there were changes in ownership that may limit the amount of net operating loss carryforwards and research and development tax credit carryforwards that the Company may be allowed to utilize in future years.

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Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2013 and 2012 were as follows:

	Year Ended December 31, 2013	2012
Valuation allowance as of beginning of year	$ (16,548,999)	$ (13,291,748)
Decreases recorded as benefit to income tax provision	1,726,638	2,717,147
Increases recorded to income tax provision	(8,671,055)	(5,974,398)
Valuation allowance as of end of year	$ (23,493,416)	$ (16,548,999)

In each reporting period, the Company considers whether a tax position of the Company is more likely than not to be sustained upon examination, including resolution of any related appeals of litigation processes, based on the technical merits of the position. For tax positions meeting the more likely than not threshold, the tax amount recognized in the financial statements is reduced by the largest benefit that has a greater than fifty percent likelihood of being realized upon the ultimate settlement with the relevant taxing authority. No liabilities for unrecognized tax benefits were recorded as of December 31, 2013 and 2012.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company s tax years are still open under statute from 2009 to the present. Earlier years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods. The resolution of tax matters is not expected to have a material effect on the Company s consolidated financial statements.

16. Related Party Transactions

The Company entered into a consulting agreement, which was terminated in 2011, for business management activities with an entity affiliated with several of the Company s stockholders. Consulting fees recorded as expense and paid in the year ended December 31, 2011 were $158,057. Consulting fees recorded as expense and paid from the date of inception (November 5, 2007) through December 31, 2013 and 2012 were $2,359,849. No amounts were payable to this entity as of or subsequent to December 31, 2011.

The Company has retained as external legal counsel one firm that is a stockholder of the Company and another firm whose partner is a stockholder of the Company. Legal fees of these firms incurred by the Company for the years ended December 31, 2013, 2012 and 2011 were $1,520,342, $314,256 and $50,142, respectively, and from the date of inception (November 5, 2007) through December 31, 2013 were $2,926,621. Legal fees of these firms paid by the Company during the years ended December 31, 2013, 2012 and 2011 were $1,281,612, $179,163 and $43,082, respectively. Amounts payable to these firms as of December 31, 2013, 2012 and 2011 were $379,237, $140,619 and $8,586, respectively.

During 2008 and 2007, the Company received proceeds of $2,600,000 and $500,000, respectively, by issuing convertible promissory notes to a stockholder of the Company. Per the terms of the convertible promissory notes, the loans accrued interest at a rate of 8.0% per annum. The outstanding balance, including accrued interest, was paid in

full in 2009.

In 2009, the Company entered into a bridge loan agreement with a stockholder of the Company in the amount of $1,000,000 (the 2009 Bridge Loan). Per the terms of the 2009 Bridge Loan, the loan accrued

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interest based on the prime rate. The interest in the note was noncompounding and computed on the basis of a year of 365 days for the actual number of days elapsed. The outstanding balance, including accrued interest, was paid in full in 2009.

17. Quarterly Financial Data (unaudited)

The following information has been derived from unaudited consolidated financial statements that, in the opinion of management, include all recurring adjustments necessary for a fair statement of such information.

	Three Months Ended			
	March 31, 2013	**June 30, 2013**	**September 30, 2013**	**December 31, 2013**
Operating expenses	$ 4,707,639	$ 4,490,078	$ 4,990,196	$ 3,577,296
Net loss	(4,798,087)	(4,597,774)	(5,100,378)	(3,690,485)
Net loss per common share basic and diluted	$ (6.08)	$ (5.83)	$ (6.46)	$ (4.66)
Weighted average common shares basic and diluted	789,222	789,222	789,222	792,432

	Three Months Ended			
	March 31, 2012	**June 30, 2012**	**September 30, 2012**	**December 31, 2012**
Operating expenses	$ 3,006,785	$ 3,339,582	$ 4,559,413	$ 4,105,862
Net loss	(2,992,839)	(3,341,615)	(4,550,366)	(4,096,799)
Net loss per common share basic and diluted	$ (5.65)	$ (6.30)	$ (8.58)	$ (7.04)
Weighted average common shares basic and diluted	530,098	530,246	530,246	582,184

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Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management s evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of December 31, 2013, the end of the period covered by this report.

Management s Report on Internal Control Over Financial Reporting

This annual report does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of the Company s registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors and Executive Officers

The following table sets forth certain information regarding our executive officers and directors as of the date of this Annual Report:

Name	Age	Position(s)
Executive Officers and Key Employees		
Michael D. Clayman, M.D.	61	President, Chief Executive Officer, Director and Co-Founder
Neil Bodick, M.D., Ph.D.	67	Chief Medical Officer and Co-Founder
Frederick W. Driscoll	63	Chief Financial Officer
Non-Employee Directors		
Patrick J. Mahaffy[2][3]	51	Chairman of the Board of Directors
Bradley J. Bolzon, Ph.D.[2]	54	Director
Samuel D. Colella[1][3]	74	Director
Elaine V. Jones, Ph.D.	59	Director
Heath Lukatch, Ph.D.[2][3]	46	Director
Alan Milinazzo[1]	54	Director
Andrew J. Schwab[1]	43	Director
Rafaèle Tordjman, M.D., Ph.D.[2]	44	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

Executive Officers

Michael D. Clayman, M.D. Dr. Clayman was a co-founder and has served as our President, Chief Executive Officer,

and as one of our directors since our inception in 2007. Previously, Dr. Clayman had a lengthy career at Eli Lilly and Company, a global pharmaceutical company, where he was most recently Vice President, Lilly Research Laboratories, and General Manager of Chorus, Lilly s early-phase development accelerator. During his career at Lilly, Dr. Clayman also led its Global Regulatory Affairs division, the Cardiovascular Discovery Research and Clinical Investigation, Research and Development at Advanced Cardiovascular Systems, a medical device subsidiary of Lilly, the Internal Medicine Division, the Lilly Clinic, Lilly s dedicated Phase 1 unit, and served as Chair of Lilly s Bioethics Committee. Prior to his tenure at Lilly, Dr. Clayman was an Assistant Professor in the School of Medicine at the University of Pennsylvania, where his research centered on the immunopathogenesis of renal disease. Dr. Clayman is

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the recipient of the Physician Scientist Award from the National Institutes of Health. Dr. Clayman earned a B.A., cum laude, from Yale University and an M.D. from the University of California, San Diego School of Medicine. Following an internship and residency in Internal Medicine at the University of California, San Francisco Moffitt Hospitals, Dr. Clayman completed clinical and research fellowships in Nephrology at the University of Pennsylvania. Our board of directors believes that Dr. Clayman s clinical and research experience, along with his more than 20 years of experience in pharmaceutical development, qualifies him to serve on our board of directors.

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

Frederick W. Driscoll. Mr. Driscoll has served as our Chief Financial Officer since May 2013. Prior to joining us, 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.

Non-Employee Directors

Patrick J. Mahaffy. Mr. Mahaffy has served as one of our directors and as Chairman of our board of directors since 2009. Mr. Mahaffy has served as the President, Chief Executive Officer, and a director of Clovis Oncology, Inc., a biopharmaceutical company, since 2009, and also serves on the board of directors of Orexigen Therapeutics, Inc., a biopharmaceutical company. Previously, Mr. Mahaffy served as President and Chief Executive Officer and as a member of the board of directors at Pharmion Corporation, a pharmaceutical company that he founded in 2000 and sold to Celgene Corporation in 2008. From 1992 through 1998, Mr. Mahaffy was President and Chief Executive Officer of NeXagen, Inc. and its successor, NeXstar Pharmaceuticals, Inc., a biopharmaceutical company. Prior to that, Mr. Mahaffy was a Vice President at the private equity firm E.M. Warburg Pincus and Co. He is also a trustee of Lewis and Clark College. Mr. Mahaffy earned a B.A. in international affairs from Lewis and Clark College and an M.A. in international affairs from Columbia University. Our board of directors believes that Mr. Mahaffy s experience and expertise in the pharmaceutical industry qualifies him to serve on our board of directors.

Bradley J. Bolzon, Ph.D. Dr. Bolzon has served as one of our directors since 2007. Since 2004, Dr. Bolzon has served as a Managing Director of Versant Ventures, a healthcare venture capital firm. Previously, Dr. Bolzon served as Executive Vice President, Global Head of Business Development, Licensing & Alliances with F. Hoffmann-La Roche Ltd., a global healthcare company. Dr. Bolzon has also held various executive positions at Eli Lilly and Company, a global pharmaceutical company. Dr. Bolzon conducted his post-doctoral research training at the Ottawa Heart Institute in Ottawa, Canada. He holds a Ph.D. and an M.S. degree in Pharmacology from the University of Toronto. Our board of directors believes that Dr. Bolzon s experience and expertise in the healthcare and pharmaceutical industries qualifies him to serve on our board of directors.

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Samuel D. Colella. Mr. Colella has served as one of our directors since 2008. Mr. Colella is a Managing Director of Versant Ventures, a healthcare venture capital firm he co-founded in 1999, and has been a general partner of Institutional Venture Partners since 1984. Mr. Colella currently serves as Chairman of the Board of Fluidigm Corporation, a biotechnology tools company, and is a member of the board of directors of Genomic Health, Inc., a molecular diagnostics company, and the boards of several private companies. Mr. Colella served on the board of directors of Alexza Pharmaceuticals, Inc., a pharmaceutical company, from 2002 to 2012 and Jazz Pharmaceuticals, Inc., a biopharmaceutical company, from 2003 to 2012. Mr. Colella earned a B.S. in business and engineering from the University of Pittsburgh and an M.B.A. from Stanford University. Our board of directors believes that Mr. Colella s broad understanding of the life science industry and his extensive experience in working with emerging private and public companies qualifies him to serve on our board of directors.

Elaine V. Jones, Ph.D. Dr. Jones has served as one of our directors since 2010. Since 2008, Dr. Jones has served as Executive Director, Venture Capital, of Pfizer Venture Investments, the venture capital arm of Pfizer, Inc., a global pharmaceutical company. Dr. Jones was a General Partner at EuclidSR Partners, a venture capital fund, from 2000 to 2008, and worked at S.R. One, a venture capital arm of GlaxoSmithKline, a global healthcare company, from 1999 to 2003. Dr. Jones has also served as Director of Scientific Licensing at SmithKline Beecham. Dr. Jones is a graduate of Juniata College and earned a Ph.D. in microbiology from the University of Pittsburgh. Our board of directors believes that Dr. Jones s strong background in research and product assessment, built on her significant experience in pharmaceutical drug discovery and business development, qualifies her to serve on our board of directors.

Heath Lukatch, Ph.D. Dr. Lukatch has served as one of our directors since 2012. Dr. Lukatch joined Novo Ventures (US) Inc., a life sciences venture capital firm, in 2006 and is currently a partner there. Dr. Lukatch is Chairman of the board of directors at Inogen, Inc. and also serves on the boards of directors at AnaptysBio, Inc., Cianna Medical, Inc., FLAPCo LLC and Panmira Pharmaceuticals LLC. Dr. Lukatch previously served on the boards of directors at Amira Pharmaceuticals, Elevation Pharmaceuticals, Inc., FoldRx Pharmaceuticals, Inc., InSound Medical, Inc. NeuroTherapeutics Pharma, Inc. and Synosia Therapeutics. Prior to joining Novo Ventures (US) Inc., Dr. Lukatch was a Managing Director responsible for biotechnology venture investments at Piper Jaffray Ventures and SightLine Partners. Dr. Lukatch also previously was a founder and Chief Executive Officer of AutoMate Scientific, Inc., a biotechnology instrumentation company. Dr. Lukatch earned a B.A. in biochemistry from the University of California, Berkeley, and a Ph.D. in neuroscience from Stanford University. Our board of directors believes that Dr. Lukatch s research experience and his experience serving on other boards of directors in the biotechnology and pharmaceutical industries qualifies him to serve on our board of directors.

Alan Milinazzo. Mr. Milinazzo has served as one of our directors since 2011. Since January 2013, Mr. Milinazzo has served as President, Chief Executive Officer and a director of InspireMD, a medical device company. Previously, Mr. Milinazzo served as President and Chief Executive Officer of Orthofix International N.V., a Nasdaq-listed medical device company, until August 2011, a position he was promoted to in 2006 after being hired a year earlier as Chief Operating Officer. He also served as a director of Orthofix International N.V. from December 2006 until June 2012. From 2002 to 2005, Mr. Milinazzo was the General Manager of Medtronic, Inc. s coronary and peripheral vascular businesses. Mr. Milinazzo also spent 12 years as an executive with Boston Scientific Corporation in numerous roles, including Vice President of Marketing for SCIMED Europe. Mr. Milinazzo has over 20 years of experience in management and marketing, including positions with Aspect Medical Systems and American Hospital Supply. Our board of directors believes that Mr. Milinazzo s more than two and a half decades of experience in the life sciences sector qualifies him to serve on our board of directors.

Andrew J. Schwab. Mr. Schwab has served as one of our directors since 2009. Mr. Schwab is a founder and Managing Partner of 5AM Ventures, a life sciences venture capital firm, and has served on the boards of directors at several private life sciences companies. Prior to founding 5AM Ventures in 2002,

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Mr. Schwab was a Principal at Bay City Capital, a life sciences venture capital firm. Previously, Mr. Schwab was Vice President of Business Development at Digital Gene Technologies, Inc. and a Vice President in the life science investment banking group of Montgomery Securities. Mr. Schwab earned a B.S. with honors in genetics and ethics from Davidson College. Our board of directors believes that Mr. Schwab s venture capital and financial services background and prior service on other boards of directors qualifies him to serve on our board of directors.

Rafaèle Tordjman, M.D., Ph.D. Dr. Tordjman has served as one of our directors since 2009. Dr. Tordjman joined the French venture capital firm Sofinnova Partners in 2001 and is a Managing Partner specializing in life sciences investments. Dr. Tordjman has also served on the boards of directors at several life sciences companies including DBV Technologies, a French public company specializing in allergy therapies, and Ascendis Pharma, which developed a novel prodrug technology, or Preglem, specializing in reproductive female medicine. Previously, Dr. Tordjman was a research scientist at the Institut National de la Santé et de la Recherche Médicale (INSERM) in Cochin Hospital, Paris, France. Dr. Tordjman has also practiced as a medical doctor, specializing in clinical hematology and internal medicine. Dr. Tordjman earned an M.D. and fellowship in hematology and internal medicine from the Paris University Hospitals and a Ph.D. with high honors in hematopoiesis and angiogenesis, and a post-doctoral fellowship in immunology, from the University of Paris VII. Our board of directors believes that Dr. Tordjman s medical knowledge, clinical and research experience, and industry perspective qualifies her to serve on our board of directors.

Board Composition

Our business and affairs are organized under the direction of our board of directors, which currently consists of nine members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Our board of directors has determined that all of our directors other than Dr. Clayman are independent directors, as defined by Rule 5605(a)(2) of the Nasdaq Listing Rules.

Our board of directors is divided into three classes, as follows:

- Class I, which will consist of Dr. Bolzon, Dr. Clayman and Dr. Jones, whose terms will expire at our annual meeting of stockholders to be held in 2015;
- Class II, which will consist of Mr. Colella, Mr. Schwab and Dr. Tordjman, and whose terms will expire at our annual meeting of stockholders to be held in 2016; and
- Class III, which will consist of Dr. Lukatch, Mr. Mahaffy and Mr. Milinazzo, and whose terms will expire at our annual meeting of stockholders to be held in 2017.

At each annual meeting of stockholders, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of our board of directors is currently nine members. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the

directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 66 2/3% of our voting stock.

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Board Leadership Structure

Our board of directors is currently chaired by Mr. Mahaffy. As a general policy, our board of directors believes that separation of the positions of Chairman and Chief Executive Officer reinforces the independence of the board of directors from management, creates an environment that encourages objective oversight of management s performance and enhances the effectiveness of the board of directors as a whole. As such, Dr. Clayman serves as our President and Chief Executive Officer while Mr. Mahaffy serves as our Chairman of the board of directors but is not an officer. We expect and intend the positions of Chairman of the board of directors and Chief Executive Officer to continue to be held by two individuals in the future.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. The board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee.

Audit Committee

Our audit committee consists of Mr. Colella, Mr. Milinazzo and Mr. Schwab. Our board of directors has determined that each of the members of our audit committee satisfies the Nasdaq Stock Market and SEC independence requirements. Mr. Schwab serves as the chair of our audit committee. The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our engagement team as required by law;

prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;

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reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption Management s Discussion and Analysis of Financial Condition and Results of Operations, and discussing the statements and reports with our independent auditors and management;

reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;

reviewing with management and our auditors any earnings announcements and other public announcements regarding material developments;

establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;

preparing the report that the SEC requires in our annual proxy statement;

reviewing and providing oversight of any related-person transactions in accordance with our related person transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;

reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented;

reviewing on a periodic basis our investment policy; and

reviewing and evaluating on an annual basis the performance of the audit committee, including compliance of the audit committee with its charter.

Our board of directors has determined that Mr. Schwab qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Listing Rules. In making this determination, our board has considered Mr. Schwab s previous and current experience in investment banking and financial oversight roles. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

Compensation Committee

Our compensation committee consists of Dr. Bolzon, Dr. Lukatch, Mr. Mahaffy and Dr. Tordjman. Mr. Mahaffy serves as the chair of our compensation committee. Our board of directors has determined that each of the members of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act, is an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code, and satisfies the Nasdaq Stock Market independence requirements. The functions of this committee

include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;

- reviewing and approving the compensation and other terms of employment of our executive officers;

- reviewing and approving performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;

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reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;

evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;

reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the type and amount of compensation to be paid or awarded to our non-employee board members;

establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation;

reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;

administering our equity incentive plans;

establishing policies with respect to equity compensation arrangements;

reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;

reviewing and approving the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;

reviewing the adequacy of its charter on a periodic basis;

reviewing with management and approving our disclosures under the caption Compensation Discussion and Analysis in our periodic reports or proxy statements to be filed with the SEC;

preparing the report that the SEC requires in our annual proxy statement; and

reviewing and assessing on an annual basis the performance of the compensation committee.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Mr. Colella, Dr. Lukatch and Mr. Mahaffy. Our board of directors has determined that each of the members of this committee satisfies the Nasdaq Stock Market independence requirements. Mr. Colella serves as the chair of our nominating and corporate governance committee. The functions of this committee include, among other things:

identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;

determining the minimum qualifications for service on our board of directors;

evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;

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evaluating, nominating and recommending individuals for membership on our board of directors;

evaluating nominations by stockholders of candidates for election to our board of directors;

considering and assessing the independence of members of our board of directors;

developing a set of corporate governance policies and principles, including a code of business conduct and ethics, periodically reviewing and assessing these policies and principles and their application and recommending to our board of directors any changes to such policies and principles;

considering questions of possible conflicts of interest of directors as such questions arise;

reviewing the adequacy of its charter on an annual basis; and

annually evaluating the performance of the nominating and corporate governance committee.

Procedures for Stockholders to Recommend Director Nominees

The Nominating and Corporate Governance Committee will consider director candidates recommended by stockholders. The Nominating and Corporate Governance Committee does not intend to alter the manner in which it evaluates candidates based on whether or not the candidate was recommended by a stockholder. Stockholders who wish to recommend individuals for consideration by the Nominating and Corporate Governance Committee to become nominees for election to the Board may do so by delivering a written recommendation to the Nominating and Corporate Governance Committee at the following address: 10 Mall Road, Suite 301, Burlington, MA 01803, Attn: Secretary, no later than the 90th day and no earlier than the 120th day prior to the one year anniversary of the preceding year s annual meeting. Submissions must include (1) the name and address of the Company stockholder on whose behalf the submission is made; (2) number of Company shares that are owned beneficially by such stockholder as of the date of the submission; (3) the full name of the proposed candidate; (4) description of the proposed candidate s business experience for at least the previous five years; (5) complete biographical information for the proposed candidate; (6) a description of the proposed candidate s qualifications as a director and (7) any other information required by the Company Bylaws. The Company may require any proposed nominee to furnish such other information as it may reasonably require to determine the eligibility of such proposed nominee to serve as an independent director of the Company or that could be material to a reasonable stockholder s understanding of the independence, or lack thereof, of such proposed nominee.

Section 16(a) Beneficial Ownership Reporting Compliance

We did not have any class of equity securities registered pursuant to Section 12 of the Exchange Act during our most recent fiscal year. As a result, none of our directors, officers or other affiliated persons were subject to Section 16 of the Exchange Act during such year.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the code is available on the Corporate Governance section of our website, www.flexiontherapeutics.com. We intend to disclose on our website any amendments to, or waivers from, our code of business conduct and ethics that are required to be disclosed pursuant to SEC rules.

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Limitation of Liability and Indemnification

We have entered into, and intend to continue to enter into, separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated bylaws. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder s investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Item 11. Executive Compensation

Our named executive officers for the year ended December 31, 2013, which consist of our principal executive officer and the two other most highly compensated executive officers who were serving as executive officers as of December 31, 2013, are:

- Michael D. Clayman, M.D., our President and Chief Executive Officer;
- Neil Bodick, M.D., Ph.D., our Chief Medical Officer; and
- Frederick W. Driscoll, our Chief Financial Officer.

Summary Compensation Table

The following table provides information regarding the compensation provided to our named executive officers during the last two completed fiscal years:

Name and Principal Position	Year	Salary ($)	Option Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)[2]	All Other Compensation ($)	Total ($)
Michael D. Clayman, M.D.	2013	$ 437,091	$ 1,210,659	$ 137,684	$ 31,688[3]	$ 1,817,122
President, Chief Executive Officer, Director and	2012	437,091	0	137,684	31,152	605,927

Co-Founder						
Neil Bodick, M.D., Ph.D.	2013	327,818	516,984	83,593	30,315[4]	958,710
Chief Medical Officer and Co-Founder	2012	327,818	0	88,511	290,195	706,524
Frederick W. Driscoll[5]	2013	186,538	709,786	55,479	13,153[6]	964,956
Chief Financial Officer	2012					

(1) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during the respective fiscal year computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation

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transactions, or ASC 718. Assumptions used in the calculation of these amounts are included in Note 13 to our consolidated financial statements. For Dr. Clayman and Dr. Bodick, the amount in this column for 2013 represents the incremental fair value resulting from the modifications of Dr. Clayman s and Dr. Bodick s August 2012 stock options, computed as of the July 16, 2013 modification date in accordance with ASC 718. The September 2013 increase to the exercise price of Mr. Driscoll s stock option did not result in any incremental fair value under ASC 718.

(2) Amount represents annual performance-based cash bonuses earned for the respective fiscal year. For more information, see below under Annual Performance-Based Bonus Opportunity.

(3) Amount consists of (i) $2,568 for life insurance premiums, (ii) $26,688 for health and dental insurance premiums and (iii) $1,616 for long-term disability premiums and a $816 related tax gross up. For more information regarding these benefits, see below under Perquisites, Health, Welfare and Retirement Benefits.

(4) Amount consists of (i) $4,196 for life insurance premiums and a $288 related tax gross up, (ii) $24,407 for health and dental insurance premiums and (iii) $1,344 for long-term disability premiums and a $80 related tax gross up. For more information regarding these benefits, see below under Perquisites, Health, Welfare and Retirement Benefits.

(5) Mr. Driscoll joined us as our Chief Financial Officer in May 2013 at an annual salary of $300,000. Amounts shown represent the compensation earned by Mr. Driscoll during 2013 from and after his May 20, 2013 start date.

(6) Amount consists of (i) $198 for life insurance premiums, (ii) $11,275 for health and dental insurance premiums and (iii) $996 for long-term disability premiums and a $684 related tax gross up. For more information regarding these benefits, see below under Perquisites, Health, Welfare and Retirement Benefits.

Annual Base Salary

The compensation of our named executive officers is generally determined and approved by our board of directors, based on the recommendation of the compensation committee of our board of directors, or the Committee. Our board of directors approved the following 2013 base salaries for our named executive officers, which became effective on January 1, 2013, with the exception of Mr. Driscoll, whose base salary became effective upon his commencement of employment with us on May 20, 2013.

Name	2013 Base Salary
Michael D. Clayman, M.D.	$ 437,091
Neil Bodick, M.D., Ph.D.	$ 327,818
Frederick W. Driscoll	$ 300,000

Annual Performance-Based Bonus Opportunity

In addition to base salaries, our named executive officers are eligible to receive annual performance-based cash bonuses, which are designed to provide appropriate incentives to our executives to achieve defined annual corporate goals and to reward our executives for individual achievement towards these goals. The annual performance-based bonus that each named executive officer is eligible to receive is based on the individual s target bonus, as a percentage of base salary, or target bonus percentage, and the extent to which we achieve the corporate goals and the executive achieves his personal goals, if any, established for each year.

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The actual performance-based bonus paid to each executive, if any, is calculated by multiplying the executive s annual base salary, target bonus percentage, the percentage attainment of the corporate goals and personal goals, if any, established for such year with respect to the executive and is prorated for the duration of employment for that year. There is no minimum bonus percentage or amount established for the named executive officers and, as a result, the bonus amounts vary from year to year based on corporate and individual performance.

The corporate and personal goals are determined by the board of directors after recommendation by the Committee and generally communicated to the named executive officers each year, prior to or shortly following the beginning of the year to which they relate or if later, in connection with the commencement of employment of the named executive officer. The corporate goals are comprised of a subset of our most important annual corporate goals and various business accomplishments, which vary from time to time depending on our overall strategic objectives. The individual goals are composed of factors that relate to each named executive officer s ability to guide his or her own performance, and the performance of his or her direct employee reports towards reaching our corporate goals. The proportional emphasis placed on each goal within the corporate and individual goals may vary from time to time depending on our overall strategic objectives and the Committee s subjective determination of which goals have more impact on our performance.

At the end of the year, the board of directors reviews our performance against predetermined goal weightings assigned to each corporate goal and personal goal, and approves the extent to which we achieved each of such goals. The board of directors may award a bonus in an amount above or below the amount resulting from the calculation described above, based on other factors that the board of directors determines, in its sole discretion following recommendation by the Committee, are material to our corporate performance and provide appropriate incentives to our executives, for example based on events or circumstances that arise after the original corporate goals are set.

The board of directors sets the target bonus for each of the named executive officers at the beginning of each year for which the bonus will apply, or if later, in connection with the hiring of a new named executive officer. For 2013, the target annual bonuses for Dr. Clayman, Dr. Bodick and Mr. Driscoll, as a percentage of base salary, were 35%, 30% and 30%, respectively. Dr. Clayman and Dr. Bodick s bonuses were entirely dependent upon our achievement of corporate goals and Mr. Driscoll s bonus was weighted 50% based on our achievement of corporate goals and 50% based on Mr. Driscoll s achievement of his personal goals.

The corporate goals established by our board of directors for purposes of determining bonuses for 2013 included:

- Complete and report top line clinical data for a Phase 3 enabling study for FX006, our sustained-release intra-articular steroid for the treatment of osteoarthritis;
- Hold an end of Phase 2 FX006 meeting with the FDA to reach agreement on clinical pathway to Phase 3 and NDA;
- Advance development of one of our non-lead assets;
- Establish new vendor with GMP manufacturing capabilities;

Explore various business development strategic alternatives; and

Complete a financing transaction.

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On February 25, 2014, the board of directors, upon the recommendation of the Committee, determined that we had achieved 90% of the 2013 corporate goals for purposes of 2013 annual performance-based bonuses. In determining that we had achieved 90% of our 2013 corporate goals, the board of directors and Committee considered, among other factors, that we had:

- completed and reported top line clinical data for our Phase 2b dose-ranging clinical trial for FX006 in June 2013;
- held an end of Phase 2 FX006 meeting with the FDA in September 2013;
- advanced FX007, one of our non-lead assets, through pre-clinical PoC studies in 2013;
- engaged Evonik, a manufacturer with GMP capabilities, to manufacture microspheres finished product and diluent for FX006;
- held various business development discussions with potential strategic partners in 2013; and
- completed significant preparations for our initial public offering, although the initial public offering was not completed in 2013.

Based on the determination of 90% corporate goal achievement, Dr. Clayman was awarded a 2013 annual performance-based cash bonus in the amount of $137,684. Additionally, based on the Committee s and Dr. Clayman s assessment, Dr. Bodick and Mr. Driscoll were awarded 2013 annual performance-based cash bonuses in the amounts of $83,593 and $55,479, respectively. Mr. Driscoll s annual bonus for 2013 took into consideration his personal achievements of assisting us with filing the registration statement for our initial public offering with the SEC and successfully organizing all functions required to launch our initial public offering, and was prorated for the period during which Mr. Driscoll was employed by the Company during 2013 following his May 20, 2013 start date.

Also on February 25, 2014 the Committee approved revised target bonus percentages for the executive officers that will be effective for consideration of annual cash bonuses for 2014 and future years. Each named executive officer s target bonus percentage is set forth below:

Name	Target bonus (% of base salary)
Michael D. Clayman, M.D.	50%
Neil Bodick, M.D., Ph.D.	40%

Frederick W. Driscoll	35%

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our interests with those of our employees and consultants, including our named executive officers. The board of directors or the Committee is responsible for approving equity grants. We have generally granted stock options to our executive officers and employees as incentive compensation, however we entered into restricted stock purchase agreements with each of Dr. Clayman and Dr. Bodick in connection with their commencement of services with us in 2007. Vesting of equity awards is generally tied to continuous service with us and serves as an additional retention measure. Although we may grant equity awards to our employees and consultants from time to time, we do not have a current practice of making annual equity grants to our executives. In addition, our executives generally are awarded an initial grant upon commencement of employment. Additional grants may occur periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

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Prior to February 11, 2014, which was the date the 2013 plan became effective, we granted all stock options pursuant to the 2009 Equity Incentive Plan, or the 2009 plan, the terms of which are described below under Equity Benefit Plans. All options are granted with a per share exercise price equal to no less than the fair market value of a share of our common stock on the date of grant of each award. Generally our stock option awards to employees vest over a four-year period and accelerate vesting and exercisability upon the occurrence of a change in control and the optionholder s termination of service under certain circumstances, as further described below under Potential Payments Upon Termination or Change of Control.

On May 20, 2013, the board of directors granted an option to purchase 135,301 shares of common stock to Mr. Driscoll in connection with his commencement of employment with a four-year vesting schedule subject to his continued service. This option was originally granted with an exercise price of $6.59 per share. In September 2013, we and Mr. Driscoll agreed to increase the exercise price of the option from $6.59 to $7.89 per share. We did not grant any equity awards to Dr. Clayman or Dr. Bodick in 2013. However, in connection with our initial public offering, on July 16, 2013 the board of directors exercised its election to provide that the options granted in August 2012 to each of Dr. Clayman and Dr. Bodick would vest over a four-year period from August 29, 2012. The exercise prices and detailed vesting terms of these option grants are described in the footnotes to the Outstanding Equity Awards at Fiscal Year End table below.

Agreements with our Named Executive Officers

Below are written descriptions of our employment or consulting agreements or offer letters with our named executive officers.

Agreement with Dr. Clayman. We entered into a letter agreement with Dr. Clayman in November 2007 setting forth the terms of his employment, subsequently amended and restated the agreement in September 2013 and further amended the agreement in March 2014. Pursuant to his agreement, Dr. Clayman is entitled to a 2013 annual base salary of $437,091, subject to increase by the board of directors, and is eligible to receive an annual cash performance bonus based on a percentage of his base salary as described above under Annual Performance-Based Bonus Opportunity. Dr. Clayman is additionally entitled to certain severance and change of control benefits, the terms of which are described below under Potential Payments Upon Termination or Change of Control.

Agreement with Dr. Bodick. We entered into a letter agreement with Dr. Bodick in November 2007 setting forth the terms of his employment, subsequently amended and restated the agreement in September 2013 and further amended the agreement in March 2014. Pursuant to his agreement, Dr. Bodick is entitled to a 2013 annual base salary of $327,818, subject to increase by the board of directors, and is eligible to receive an annual cash performance bonus based on a percentage of his base salary as described above under Annual Performance-Based Bonus Opportunity. Dr. Bodick is additionally entitled to certain severance and change of control benefits, the terms of which are described below under Potential Payments Upon Termination or Change of Control.

Agreement with Mr. Driscoll. Mr. Driscoll commenced employment as our Chief Financial Officer in May 2013, and his letter agreement was amended and restated in September 2013 and further amended in March 2014. Pursuant to his agreement, Mr. Driscoll is entitled to a 2013 annual base salary of $300,000 and is eligible to receive an annual cash performance bonus based on a percentage of his base salary as described above under Annual Performance-Based Bonus Opportunity. Pursuant to the agreement, Mr. Driscoll was granted an option to purchase 135,301 shares of our common stock on May 20, 2013, which vests over a four year period. Mr. Driscoll is additionally entitled to certain severance and change of control benefits, the terms of which are described below under Potential Payments Upon Termination or Change of Control.

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Potential Payments Upon Termination or Change of Control

Regardless of the manner in which a named executive officer s service terminates, the named executive officer is entitled to receive amounts earned during his term of service, including salary and unused vacation pay.

Pursuant to their amended and restated letter agreements entered into in September 2013, as amended in February 2014, each of our named executive officers is entitled to certain severance and change of control payments and benefits. In the event that the executive is terminated without cause or upon the executive s resignation for good reason, upon his execution of a release and waiver in favor of us, each executive is entitled to receive (1) payments at the rate of his then current salary for 18 months (with respect to Dr. Clayman), 15 months (with respect to Dr. Bodick) or 12 months (with respect to Mr. Driscoll); (2) reimbursement of COBRA health and dental premiums for up to 18 months (with respect to Dr. Clayman), 15 months (with respect to Dr. Bodick) and 12 months (with respect to Mr. Driscoll); (3) with respect to Dr. Clayman and Dr. Bodick, accelerated vesting of their outstanding equity awards granted prior to February 25, 2014, to the extent they would have vested during the following 12 months or, if Dr. Clayman s or Dr. Bodick s termination without cause or resignation for good reason occurs within 12 months following a change of control, accelerated vesting of all outstanding equity awards in full and (4) with respect to Mr. Driscoll, accelerated vesting of all outstanding equity awards in full in the event of a termination without cause or resignation for good reason within 12 months following a change of control. In addition, each of our named executive officers holds stock options under our 2009 plan that provide that the options will vest in full upon the executive s termination without cause or resignation for good reason within 12 months of a change of control. A description of the termination and change of control provisions in such equity incentive plans and stock option agreements is provided below under Equity Benefit Plans.

For purposes of the letter agreements:

cause for purposes of Dr. Clayman s and Dr. Bodick s letter agreements generally means the executive s termination by us due to his (i) repeated and willful failure to satisfactorily perform his duties after written notice and an opportunity to cure; (ii) misconduct or dishonesty that materially injures our business, business reputation or business relationships; (iii) conviction of, or pleading guilty or nolo contendere to, a felony; (iv) any act of fraud against us; (v) personal dishonesty taken in connection with his responsibilities that is intended to result in substantial personal enrichment; (vi) repeated refusal or failure to follow lawful directions of the board of directors, which remain uncured after written notice; or (vii) engagement or participation in any activity directly competitive with or injurious to us or, which violates any material provisions of his proprietary information and inventions agreement with us or permitted activities described in his letter agreement after written notice.

cause for purposes of Mr. Driscoll s letter agreement generally means his termination by us due to his (i) commission of a felony or crime involving fraud, dishonesty or moral turpitude; (ii) attempted commission of, or participation in, a fraud or act of dishonesty against us; (iii) intentional, material violation of any contract or agreement with us or of any statutory duty owed to us; (iv) unauthorized use or disclosure of our confidential information or trade secrets; (v) gross misconduct; or (vi) failure or refusal to perform the material duties and responsibilities of his position.

change of control for purposes of each of the named executive officer s letter agreements generally means (i) any person or entity becomes the owner of more than 50% of our combined voting power; (ii) a consummated merger, consolidation or similar transaction to which we are a party and our stockholders do not own more than 50% of the combined voting power of the surviving entity or its parent company; (iii) a consummated sale, lease or other disposition of all

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or substantially all of our consolidated assets; or (iv) with respect to Mr. Driscoll, our stockholders or board of directors approves a plan of complete dissolution or liquidation or such dissolution or liquidation otherwise occurs.

good reason for purposes of each of the named executive officer s letter agreements generally means the executive s resignation within 90 days after the occurrence of any of the following events, provided the executive first gives written notice to us and an opportunity to cure for 30 days after such notice: (i) a material reduction in his duties, authority or responsibilities; (ii) a material reduction in his annual base salary; (iii) a relocation of his principal place of employment that increases his one-way commute by more than 50 miles; or (iv) with respect to Dr. Clayman and Dr. Bodick, a material breach of his employment letter agreement.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information regarding outstanding equity awards granted to our named executive officers that remain outstanding as of December 31, 2013.

		Option awards[1]			
Name	**Grant Date**	**Number of Securities Underlying Unexercised Options (#) Exercisable**	**Number of Securities Underlying Unexercised Options (#) Unexercisable**	**Option Exercise Price Per Share[2]**	**Option Expiration Date**
Michael D. Clayman, M.D.	9/24/2009	15,369		$ 0.16	9/23/2019
	8/29/2012	45,510	91,020(3)	2.52	8/28/2022
Neil Bodick, M.D., Ph.D.	9/24/2009	87,702		0.16	9/23/2019
	8/29/2012	19,434	38,868(4)	2.52	8/28/2022
Frederick W. Driscoll	5/20/2013		135,301(5)	7.89	5/19/2023

(1) All of the option awards listed in the table above were granted under the 2009 plan, the terms of which are described below under Equity Benefit Plans. Except as otherwise indicated, each option award becomes exercisable as it becomes vested and all vesting is subject to the executive s continuous service with us through the vesting dates.

(2) All of the option awards listed in the table above were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, as determined in good faith by our board of directors with the assistance of a third party valuation expert.

(3) The option vests at the rate of 1/4th of the total number of shares subject to the option one year after August 29, 2012, with 1/48th of the shares vesting monthly thereafter over the next three years. In the event Dr. Clayman s employment is terminated by us without cause or by Dr. Clayman for good reason, the option shall accelerate and vest to the extent it would have vested in the 12-month period following the date of termination and, if such termination occurs within 12 months following a change of control transaction, the option shall accelerate and vest in full.

(4) The option vests at the rate of 1/4th of the total number of shares subject to the option one year after August 29, 2012, with 1/48th of the shares vesting monthly thereafter over the next three years. In the event Dr. Bodick s employment is terminated by us without cause or by Dr. Bodick for good reason, the option shall accelerate and vest to the extent it would have vested in the 12-month period following the date of termination and, if such termination occurs within 12 months following a change of control transaction, the option shall accelerate and vest in full.

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(5) The option vests at the rate of 1/4th of the total number of shares subject to the option one year after May 20, 2013, with 1/48th of the shares vesting monthly thereafter over the next three years, subject to acceleration in the event Mr. Driscoll s employment is terminated by us without cause or by Mr. Driscoll for good reason, in each case within 12 months following a change of control transaction. The option was originally granted with an exercise price of $6.59 per share and was subsequently amended to increase the exercise price to $7.89 per share.

Option Modifications

On July 16, 2013, the board of directors exercised its election to provide that the options granted in August 2012 to each of Dr. Clayman and Dr. Bodick would vest over a four-year period from August 29, 2012. These options were originally granted with a vesting schedule based on the aggregate consideration we receive in the event of certain types of corporate transactions or, at the board of directors election in connection with an equity financing or our initial public offering, over a four-year period. In addition, in September 2013, we and Mr. Driscoll agreed to increase the exercise price of his option granted on May 20, 2013 from $6.59 to $7.89 per share.

Perquisites, Health, Welfare and Retirement Benefits

Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, group life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees. We provide a 401(k) plan to our employees, including our named executive officers, as discussed in the section below entitled 401(k) Plan.

We generally do not provide perquisites or personal benefits to our named executive officers, except in certain limited circumstances. We do, however, pay the premiums for group term life insurance and long-term disability benefits (and, with respect to long-term disability benefits, we provide a tax gross up relating to such payment) for all of our employees, including our named executive officers and we pay or reimburse our named executive officers for their health and dental premiums. In addition, we made tax gross up payments relating to life insurance benefits for Dr. Bodick in 2013. None of our named executive officers participate in qualified or non-qualified defined benefit plans sponsored by us. Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

401(k) Plan

We maintain a defined contribution employee retirement plan, or 401(k) plan, for our employees. Our executive officers are also eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Code. The plan provides that each participant may contribute up to the lesser of 100% of his or her compensation or the statutory limit, which was $17,500 for calendar year 2013. Participants that are 50 years or older can also make catch-up contributions, which in calendar year 2013 was up to an additional $5,500 above the statutory limit. We currently do not make matching contributions into the 401(k) plan on behalf of participants. Participant contributions are held and invested, pursuant to the participant s instructions, by the plan s trustee.

Non-qualified Deferred Compensation

None of our named executive officers participate in or have account balances in non-qualified defined contribution plans or other non-qualified deferred compensation plans maintained by us. Our board of directors may elect to provide our officers and other employees with non-qualified defined contribution or other non-qualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

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2013 Equity Incentive Plan

Our board of directors adopted the 2013 plan in August 2013, and our stockholders approved the plan in January 2014. The 2013 plan became effective on February 11, 2014, the date of execution of the underwriting agreement pursuant to which our common stock was priced for our initial public offering.

Stock Awards. The 2013 plan provides for the grant of incentive stock options, or ISOs, non-statutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, and other forms of equity compensation, collectively, stock awards, all of which may be granted to employees, including officers, non-employee directors and consultants of us and our affiliates. Additionally, the 2013 plan provides for the grant of performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants.

Share Reserve. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2013 plan is the sum of (i) 1,230,012 shares, plus (ii) the 272,621 shares remaining available for grant under our 2009 plan at the time our 2013 plan became effective, plus (iii) any shares subject to outstanding stock options or other stock awards that would have otherwise returned to our 2009 plan (such as upon the expiration or termination of a stock award prior to vesting). Additionally, the number of shares of our common stock reserved for issuance under our 2013 plan will automatically increase on January 1 of each year, beginning on January 1, 2015, and continuing through and including January 1, 2023, by 4% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under our 2013 plan is 4,684,989 shares.

No person may be granted stock awards covering more than 3,000,000 shares of our common stock under our 2013 plan during any calendar year pursuant to stock options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the fair market value on the date the stock award is granted. Additionally, no person may be granted in a calendar year a performance stock award covering more than 3,000,000 shares or a performance cash award having a maximum value in excess of $3,000,000. Such limitations are designed to help assure that any deductions to which we would otherwise be entitled with respect to such awards will not be subject to the $1,000,000 limitation on the income tax deductibility of compensation paid to any covered executive officer imposed by Section 162(m) of the Code.

If a stock award granted under the 2013 plan expires or otherwise terminates without being exercised in full, or is settled in cash, the shares of our common stock not acquired pursuant to the stock award again will become available for subsequent issuance under the 2013 plan. In addition, the following types of shares under the 2013 plan may become available for the grant of new stock awards under the 2013 plan: (1) shares that are forfeited to or repurchased by us prior to becoming fully vested; (2) shares withheld to satisfy income or employment withholding taxes; or (3) shares used to pay the exercise or purchase price of a stock award. Shares issued under the 2013 plan may be previously unissued shares or reacquired shares bought by us on the open market. As of the date hereof, stock awards covering a total of 27,675 share of common stock have been issued under the 2013 plan.

Administration. Our board of directors, or a duly authorized committee thereof, has the authority to administer the 2013 plan. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees (other than other officers) to be recipients of certain stock awards, and (2) determine the number of shares of common stock to be subject to such stock awards. Subject to the terms of the 2013 plan, our board of directors or the authorized committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted

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and the terms and conditions of the stock awards, including the period of their exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under our 2013 plan. Subject to the terms of our 2013 plan, the plan administrator has the authority to reduce the exercise, purchase or strike price of any outstanding stock award, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Stock Options. Incentive and non-statutory stock options are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2013 plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2013 plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2013 plan, up to a maximum of 10 years. Unless the terms of an option holder s stock option agreement provide otherwise, if an option holder s service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder s service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, and (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder s death.

Tax Limitations On Incentive Stock Options. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Awards. Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the plan administrator. Restricted stock awards may be granted in consideration for (1) cash, check, bank draft or money order, (2) services rendered to us or our affiliates, or (3) any other

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form of legal consideration. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the plan administrator. Rights to acquire shares under a restricted stock award may be transferred only upon such terms and conditions as set by the plan administrator. Except as otherwise provided in the applicable award agreement, restricted stock awards that have not vested will be forfeited upon the participant s cessation of continuous service for any reason.

Restricted Stock Unit Awards. Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock awards that have not vested will be forfeited upon the participant s cessation of continuous service for any reason.

Stock Appreciation Rights. Stock appreciation rights are granted pursuant to stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (1) the excess of the per share fair market value of our common stock on the date of exercise over the strike price, multiplied by (2) the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2013 plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

The plan administrator determines the term of stock appreciation rights granted under the 2013 plan, up to a maximum of ten years. Unless the terms of a participant s stock appreciation right agreement provides otherwise, if a participant s service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. The stock appreciation right term may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant s service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. The 2013 plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the $1,000,000 limitation on the income tax deductibility of compensation paid to a covered executive officer imposed by Section 162(m) of the Code. To help assure that the compensation attributable to performance-based awards will so qualify, our compensation committee can structure such awards so that stock or cash will be issued or paid pursuant to such award only after the achievement of certain pre-established performance goals during a designated performance period.

The performance goals that may be selected include one or more of the following: (1) earnings (including earnings per share and net earnings); (2) earnings before interest, taxes and depreciation; (3) earnings before interest, taxes, depreciation and amortization; (4) earnings before interest, taxes, depreciation, amortization and legal settlements; (5) earnings before interest, taxes, depreciation,

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amortization, legal settlements and other income (expense); (6) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense) and stock-based compensation; (7) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation and changes in deferred revenue; (8) total stockholder return; (9) return on equity or average stockholder s equity; (10) return on assets, investment or capital employed; (11) stock price; (12) margin (including gross margin); (13) income (before or after taxes); (14) operating income; (15) operating income after taxes; (16) pre-tax profit; (17) operating cash flow; (18) sales or revenue targets; (19) increases in revenue or product revenue; (20) expenses and cost reduction goals; (21) improvement in or attainment of working capital levels; (22) economic value added (or an equivalent metric); (23) market share; (24) cash flow; (25) cash flow per share; (26) share price performance; (27) debt reduction; (28) implementation or completion of projects or processes (including, without limitation, clinical trial initiation, clinical trial enrollment, clinical trial results, new and supplemental indications for existing products, regulatory filing submissions, regulatory filing acceptances, regulatory or advisory committee interactions, regulatory approvals and product supply); (29) user satisfaction; (30) stockholders equity; (31) capital expenditures; (32) debt levels; (33) operating profit or net operating profit; (34) workforce diversity; (35) growth of net income or operating income; (36) billings; (37) bookings; (38) the number of users, including but not limited to unique users; (39) employee retention; (40) initiation of phases of clinical trials and/or studies by specific dates; (41) patient enrollment rates; (42) budget management; (43) submission to, or approval by, a regulatory body (including, but not limited to the U.S. Food and Drug Administration) of an applicable filing or a product candidate; (44) regulatory milestones; (45) progress of internal research or clinical programs; (46) progress of partnered programs; (47) partner satisfaction; (48) timely completion of clinical trials; (49) submission of INDs and NDAs and other regulatory achievements; (50) research progress, including the development of programs; (51) strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property; and (52) to the extent that an award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by our board of directors.

The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the goals are established, we will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of any extraordinary items as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; (12) to exclude the effect of any other unusual, non-recurring gain or loss or other extraordinary item; and (13) to exclude the effects of the timing of acceptance for review and/or approval of submissions to the U.S. Food and Drug Administration or any other regulatory body. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the goals. The performance goals may differ from participant to participant and from award to award.

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Other Stock Awards. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

Changes to Capital Structure. In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (a) the class and maximum number of shares reserved for issuance under the 2013 plan, (b) the class and maximum number of shares by which the share reserve may increase automatically each year, (c) the class and maximum number of shares that may be issued upon the exercise of ISOs, (d) the class and maximum number of shares subject to stock awards that can be granted in a calendar year (as established under the 2013 plan pursuant to Section 162(m) of the Code) and (e) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. In the event of certain specified significant corporate transactions, the plan administrator has the discretion to take any of the following actions with respect to stock awards:

- arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;
- accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- arrange for the lapse of any reacquisition or repurchase right held by us;
- cancel or arrange for the cancellation of the stock award in exchange for such cash consideration, if any, as our board of directors may deem appropriate; or
- make a payment equal to the excess of (a) the value of the property the participant would have received upon exercise of the stock award over (b) the exercise price otherwise payable in connection with the stock award.

Our plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

Under the 2013 plan, a corporate transaction is generally the consummation of (i) a sale or other disposition of all or substantially all of our consolidated assets, (ii) a sale or other disposition of at least 90% of our outstanding securities, (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Change of Control. The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change of control. Under the 2013 plan, a change of control is generally (i) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction; (ii) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined voting power of the surviving entity; (iii) a consummated sale, lease or exclusive license or other disposition of all or substantially of our consolidated assets; or (iv) our complete liquidation or dissolution (or the approval by our stockholders or our board of directors of our complete liquidation or dissolution).

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Amendment and Termination. Our board of directors has the authority to amend, suspend, or terminate our 2013 plan, provided that such action does not materially impair the existing rights of any participant without such participant s written consent. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2013 plan.

2009 Equity Incentive Plan

Our board of directors and our stockholders approved our 2009 plan, which became effective in September 2009. As of March 14, 2014, there were outstanding stock awards covering a total of 722,091 shares that were granted under our 2009 plan. No additional awards will be granted under the 2009 plan, and all awards granted under the 2009 plan that are repurchased, forfeited, expire, are cancelled or otherwise not issued will become available for grant under the 2013 plan in accordance with its terms.

Stock awards. The 2009 plan provides for the grant of stock awards, all of which may be granted to employees, including officers, non-employee directors, and consultants of us and our affiliates. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants.

Share Reserve. The aggregate number of shares of our common stock originally reserved for issuance pursuant to stock awards under the 2009 plan was 1,371,463 shares. The maximum number of shares that may be issued upon the exercise of ISOs under our 2009 plan was 2,742,927 shares.

If a stock award granted under the 2009 plan expires or otherwise terminates without being exercised in full, or is settled in cash, the shares of our common stock not acquired pursuant to the stock award again will become available for subsequent issuance under the 2009 plan. In addition, the following types of shares under the 2009 plan may become available for the grant of new stock awards under the 2009 plan: (1) shares that are forfeited to or repurchased by us prior to becoming fully vested; (2) shares withheld to satisfy income or employment withholding taxes; or (3) shares used to pay the exercise or purchase price of a stock award. Shares issued under the 2009 plan may be previously unissued shares or reacquired shares bought by us on the open market.

Administration. Our board of directors, or a duly authorized committee thereof, has the authority to administer the 2009 plan. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees (other than other officers) to be recipients of certain stock awards, and (2) determine the number of shares of common stock to be subject to such stock awards. Subject to the terms of the 2009 plan, our board of directors or the authorized committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted, and the terms and conditions of the stock awards, including the period of their exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted, and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under our 2009 plan. Subject to the terms of our 2009 plan, the plan administrator has the authority to reduce the exercise, purchase or strike price of any outstanding stock award, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Stock Options. ISOs and NSOs are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2009

plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2009 plan vest at the rate specified by the plan administrator.

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The plan administrator determines the term of stock options granted under the 2009 plan, up to a maximum of 10 years. Unless the terms of an option holder s stock option agreement provide otherwise, if an option holder s service relationship with us or any of our affiliates ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder s service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, and (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder s death.

Tax Limitations On Incentive Stock Options. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed $100,000. Options, or portions thereof, that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (2) the option is not exercisable after the expiration of five years from the date of grant.

Changes to Capital Structure. In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (a) the class and maximum number of shares reserved for issuance under the 2009 plan, (b) the class and maximum number of shares that may be issued upon the exercise of ISOs, and (c) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. Unless otherwise provided in the terms of an individual stock award or another written agreement between us and the holder of a stock award, in the event of certain specified significant corporate transactions, outstanding stock awards may be assumed, continued or substituted for similar stock awards by the surviving or acquiring corporation. If any surviving or acquiring corporation fails to assume, continue or substitute such stock awards, stock awards held by participants whose continuous service has terminated will accelerate vesting in full prior to the corporate transaction and all stock awards will terminate at or prior to the corporate transaction.

Under the 2009 plan, a corporate transaction is generally the consummation of (i) a sale or other disposition of all or substantially all of our consolidated assets, (ii) a sale or other disposition of at least 90% of our outstanding securities, (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

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Change of Control. The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us, that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change of control. All of our outstanding option agreements with our employees provide for acceleration in full of the stock option if within 12 months after a change of control a participant is terminated without cause or resigns for good reason (which includes a resignation due to assignment of duties or responsibilities that result in a material diminution of function, material reduction in base salary, a relocation of employment by more than 50 miles or a material breach by us of the terms of the 2009 plan, option agreement or other material agreement with the company concerning employment). Under the 2009 plan, a change of control is generally (i) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction; (ii) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined voting power of the surviving entity; (iii) our complete liquidation or dissolution or approval by the stockholders or our board of directors of a plan of complete dissolution or liquidation of us; or (iv) a consummated sale, lease or exclusive license or other disposition of all or substantially of our consolidated assets.

Amendment and Termination. The 2009 plan will terminate on September 23, 2019. However, our board of directors has the authority to amend, suspend, or terminate our 2009 plan, provided that such action does not materially impair the existing rights of any participant without such participant s written consent.

2013 Employee Stock Purchase Plan

Our board of directors adopted the 2013 Employee Stock Purchase Plan, or the ESPP, in August 2013 and our stockholders approved the ESPP in January 2014. The ESPP became effective on February 11, 2014, the date of execution of the underwriting agreement pursuant to which our common stock was priced for our initial public offering. The purpose of the ESPP is to retain the services of new employees and secure the services of new and existing employees while providing incentives for such individuals to exert maximum efforts toward our success and that of our affiliates.

Share Reserve. The ESPP authorizes the issuance of 209,102 shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2015 through January 1, 2023 by the least of (a) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, (b) 375,768 shares, or (c) a number determined by our board of directors that is less than (a) and (b). The ESPP is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Code. As of the date hereof, no shares of our common stock have been purchased under the ESPP.

Administration. Our board of directors has delegated its authority to administer the ESPP to our compensation committee. The ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for accounts of employees participating in the ESPP at a price per share equal to the lower of (a) 85% of the fair market value of a share of our common stock on the first date of an offering or (b) 85% of the fair market value of a share of our common stock on the date of purchase.

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Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors: (a) customarily employed for more than 20 hours per week, (b) customarily employed for more than five months per calendar year or (c) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of $25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value pursuant to Section 424(d) of the Code.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large non-recurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to (a) the number of shares reserved under the ESPP, (b) the maximum number of shares by which the share reserve may increase automatically each year and (c) the number of shares and purchase price of all outstanding purchase rights.

Corporate Transactions. In the event of certain significant corporate transactions, including: (i) a sale of all our assets, (ii) the sale or disposition of 90% of our outstanding securities, (iii) the consummation of a merger or consolidation where we do not survive the transaction, and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants accumulated payroll contributions will be used to purchase shares of our common stock within 10 business days prior to such corporate transaction, and such purchase rights will terminate immediately.

Plan Amendments, Termination. Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances any such amendment or termination may not materially impair any outstanding purchase rights without the holder s consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

Director Compensation

Historically, we have not paid cash or equity compensation to directors who are also our employees for service on our board of directors, nor have we paid cash or equity compensation to our non-employee directors who are associated with our principal stockholders for service on our board of directors. We have reimbursed and will continue to reimburse all of our non-employee directors for their travel, lodging and other reasonable expenses incurred in attending meetings of our board of directors and committees of our board of directors.

We provide compensation to Mr. Mahaffy for his services as the chairman of the board of directors pursuant to a letter agreement we entered into with Mr. Mahaffy in October 2009. Under the letter agreement, we provide Mr. Mahaffy an annual cash retainer of $62,500 payable quarterly in arrears as well as reimbursement for his reasonable expenses incurred in attending meetings. In addition, in connection with his letter agreement with us, Mr. Mahaffy was granted an option under our 2009 plan to purchase 30,824 shares, which vests over a four-year period measured from September 24, 2009, subject to his continued service to us, and becomes fully vested upon a change of control (as

defined in the 2009 plan).

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We provide compensation to Mr. Milinazzo for his services as a member of our board of directors pursuant to a letter agreement we entered into with Mr. Milinazzo in May 2011. Under the letter agreement, we provide Mr. Milinazzo an annual cash retainer of $25,000 payable quarterly in arrears as well as reimbursement for his reasonable expenses incurred in attending meetings. In addition, in connection with his letter agreement with us, Mr. Milinazzo was granted an option under our 2009 plan to purchase 18,450 shares, which vests over a four-year period measured from May 20, 2011, subject to his continued service to us, and becomes fully vested upon a change of control (as defined in the 2009 plan).

The following table sets forth in summary form information concerning the compensation that we paid or awarded during the year ended December 31, 2013 to each of our non-employee directors:

Name[1]	Fees Earned or Paid in Cash	Option Awards[2]	All Other Compensation	Total
Patrick J. Mahaffy.	$ 62,500	$	$	$ 62,500
Bradley J. Bolzon, Ph.D.				
Samuel D. Colella				
Elaine V. Jones, Ph.D.				
Heath Lukatch, Ph.D.				
Alan Milinazzo	25,000			25,000
Andrew J. Schwab				
Rafaèle Tordjman, M.D., Ph.D.				

(1) Dr. Clayman was an employee director during 2013 and his compensation is fully reflected in the Summary Compensation Table above. Dr. Clayman did not receive any compensation in 2013 for services provided as a member of our board of directors.

(2) We did not grant any stock options to our non-employee directors in 2013. The aggregate number of shares subject to each non-employee director s outstanding option awards as of December 31, 2013 was as follows: Patrick J. Mahaffy, 30,824 outstanding and unexercised; Alan Milinazzo, 18,450 outstanding and unexercised.

Effective upon the date of the underwriting agreement related to our initial public offering, our board of directors adopted a new compensation policy that is applicable to all of our non-employee directors. The policy was subsequently revised by the board of directors, upon the recommendation of the Committee, on February 25, 2014. The compensation policy, as revised, provides that each such non-employee director, other than any non-employee director who disclaims such compensation, will receive the following compensation for service on our board of directors:

an annual cash retainer of $35,000;

an additional annual cash retainer of $27,500 for service as chairman of the board of directors;

an additional annual cash retainer of $7,500 for service as a member of the audit committee or $15,000 for service as chair of the audit committee;

an additional annual cash retainer of $5,000 for service as a member of the compensation committee or $10,000 for service as chair of the compensation committee;

an additional annual cash retainer of $3,750 for service as a member of the nominating and corporate governance committee or $7,500 for service as chair of the nominating and corporate governance committee;

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upon first joining our board of directors, an automatic initial grant of an option to purchase 18,000 shares of our common stock vesting over three years following the grant date; and

for each non-employee director whose term continues on the date of our annual meeting each year, an automatic annual grant of an option to purchase 9,000 shares of our common stock (with respect to all non-employee directors other than the Chairman of the Board) or 18,000 shares of our common stock (with respect to the Chairman of the Board), in each case vesting over one year following the grant date.

Each of the option grants described above will vest in full upon a change in control (as defined under our 2013 plan). The term of each option will be 10 years. The options will be granted under our 2013 plan, the terms of which are described in more detail above under Equity Benefit Plans 2013 Equity Incentive Plan.

Because we will not hold an annual meeting until 2015, our board of directors, upon recommendation of the Committee, approved one-time grants of stock options for 2014 to our non-employee directors (other than Dr. Jones and Mr. Lukatch, who disclaimed receipt of such options) in the amounts that would otherwise have been granted to our non-employee directors under the compensation policy described above. Such options were granted effective as of March 3, 2014.

Compensation Committee Interlocks and Insider Participation

We have established a compensation committee which has and will make decisions relating to compensation of our executive officers. Our board of directors has appointed Dr. Bolzon, Dr. Lukatch, Mr. Mahaffy and Dr. Tordjman to serve on the compensation committee. None of these individuals has ever been an executive officer or employee of ours. None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth information regarding beneficial ownership of our common stock as of March 14, 2014 by:

each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;

each of our directors;

each of our named executive officers; and

all of our current executive officers and directors as a group.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting

power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before May 13, 2014, which is 60 days after March 14, 2014. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that

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person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Percentage of beneficial ownership is based on 15,609,039 shares of common stock outstanding as of March 14, 2014. Except as otherwise noted below, the address for each person or entity listed in the table is c/o Flexion Therapeutics, Inc., 10 Mall Road, Suite 301, Burlington, Massachusetts 01803.

Name and address of beneficial owner	Number of shares beneficially owned	Percentage of shares beneficially owned
5% or greater stockholders		
Versant Venture Capital III, L.P. and its affiliates[1] 3000 Sand Hill Road, Bldg 4, Suite 210 Menlo Park, CA 94025	3,206,807	20.54%
Sofinnova Capital VI FCPR[2] 16-18 rue de 4 Septembre 75002 Paris, France	2,105,491	13.49%
Pfizer Inc. 235 E. 42nd Street New York, NY 10017	1,687,250	10.81%
5AM Ventures II, L.P. and its affiliates[3] 2200 Sand Hill Road, Suite 110 Menlo Park, CA 94025	1,512,076	9.69%
Novo A/S[4] Tuborg Havnevej 19 DK-2900 Hellerup Denmark	1,783,131	11.42%
Directors and named executive officers		
Michael D. Clayman, M.D.[5]	759,201	4.84%
Neil Bodick, M.D., Ph.D.[6]	537,613	3.43%
Frederick Driscoll Patrick J. Mahaffy[7]	33,824	*
Bradley J. Bolzon, Ph.D.[8]	3,208,307	20.55%

Samuel D. Colella [9]	3,208,307	20.55%
Elaine V. Jones, Ph.D. Heath Lukatch, Ph.D. Alan Milinazzo[10]	14,953	*
Andrew J. Schwab[11]	1,513,576	9.70%
Rafaèle Tordjman, M.D., Ph.D.[12]	2,106,991	13.50%
All current executive officers and directors as a group (11 persons)[13]	7,398,599	46.83%

* Represents beneficial ownership of less than one percent.

(1) Includes (a) 2,803,385 shares of common stock held by Versant Venture Capital III, L.P. and (b) 14,739 shares of common stock held by Versant Side Fund III, L.P. Also includes 388,683 shares of common

stock held by Versant Development Fund III, LLC. Brian G. Atwood, Ross A. Jaffe, M.D., Samuel D. Colella, Donald B. Milder, Rebecca B. Robertson, Bradley J. Bolzon, Ph.D., William J. Link, Ph.D., Charles M. Warden, and Barbara N. Lubash, as managing directors of Versant Ventures III, LLC, share voting and investment authority over the shares held by Versant Venture Capital III, L.P. and Versant Side Fund III, L.P. Versant Venture Capital III, L.P. is the majority member of Versant Development Fund III, LLC.

(2) Represents shares of common stock held by Sofinnova Capital VI FCPR. Sofinnova Partners SAS, a French corporation and the management company of Sofinnova Capital VI FCPR, may be deemed to have sole voting and investment power, and Dennis Lucquin, Antoine Papiernik, Dr. Tordjman and Monique Saulnier, the managing partners of Sofinnova Partners SAS, may be deemed to have shared voting and investment power with respect to such shares.

(3) Includes (a) 1,454,679 shares of common stock held by 5AM Ventures II, L.P. and (b) 57,397 shares of common stock held by 5AM Co-Investors II, L.P. John D. Diekman, Andrew J. Schwab and Scott M. Rocklage are managing members of 5AM Partners II LLC, the general partner of 5AM Ventures II L.P. and 5AM Co-Investors II L.P., and as such, share voting and investment authority over the shares held by 5AM Ventures II L.P. and 5AM Co-Investors II L.P.

(4) Represents shares of common stock held by Novo A/S. Novo A/S is a Danish limited liability company. The board of directors of Novo A/S, which consists of Sten Scheibye, Göran Ando, Jørgen Boe, Jeppe Christiansen, Steen Riisgaard and Per Wold-Olsen, has shared investment and voting control with respect to the shares held by Novo A/S and may exercise such control only with the support of a majority of the members of the Novo A/S board of directors. As such, no individual member of the Novo A/S board of directors is deemed to hold any beneficial ownership or reportable pecuniary interest in the shares held by Novo A/S. Dr. Lukatch, a member of our board of directors, is employed as a Partner of Novo Ventures (US) Inc. Dr. Lukatch is not deemed a beneficial owner of, and does not have a reportable pecuniary interest in, the shares held by Novo A/S.

(5) Includes 273,661 shares of common stock held by Dr. Clayman and 72,257 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 14, 2014. Also includes 24,600 shares of common stock held by the Michael D. Clayman Irrevocable Trust, of which Dr. Clayman s spouse is trustee. Also includes 388,683 shares of common stock held by Versant Development Fund III, LLC. Dr. Clayman is a manager and minority member of Versant Development Fund III, LLC. Dr. Clayman disclaims any beneficial ownership of the shares held by Versant Development Fund III, LLC except to the extent of his pecuniary interest in these shares.

(6) Includes 86,937 shares of common stock held by Dr. Bodick and 61,993 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 14, 2014. Also includes 388,683 shares of common stock held by Versant Development Fund III, LLC. Dr. Bodick is a manager and minority member of Versant Development Fund III, LLC. Dr. Bodick disclaims any beneficial ownership of the shares held by Versant Development Fund III, LLC except to the extent of his pecuniary interest in these shares.

(7)

Represents shares of common stock issuable upon the exercise of options exercisable within 60 days of March 14, 2014.

(8) Includes the shares of capital stock held by the Versant Ventures entities referred to in footnote (1) above. Dr. Bolzon disclaims any beneficial ownership of the shares held by these entities except to the extent of his pecuniary interest in these entities. Also includes 1,500 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 14, 2014.

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(9) Includes the shares of capital stock held by the Versant Ventures entities referred to in footnote (1) above. Mr. Colella disclaims any beneficial ownership of the shares held by these entities except to the extent of his pecuniary interest in these entities. Also includes 1,500 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 14, 2014.

(10) Represents shares of common stock issuable upon the exercise of options exercisable within 60 days of March 14, 2013.

(11) Includes the shares of capital stock held by the 5AM Ventures entities referred to in footnote (3) above. Mr. Schwab disclaims any beneficial ownership of the shares held by these entities except to the extent of his pecuniary interest in these entities. Also includes 1,500 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 14, 2014.

(12) Includes the shares of capital stock held by Sofinnova Capital VI FCPR as described in footnote (2) above. Dr. Tordjman disclaims any beneficial ownership of the shares held by Sofinnova Capital VI FCPR except to the extent of her pecuniary interest in these entities. Also includes 1,500 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 14, 2014.

(13) Includes 7,209,572 shares held by all current executive officers and directors as a group and 189,027 shares that all current executive officers and directors as a group have the right to acquire from us within 60 days of March 14, 2014 pursuant to the exercise of stock options. The shares held by Versant Venture Capital III, L.P. and Versant Side Fund III, L.P., which are deemed to be beneficially owned by both Mr. Colella and Dr. Bolzon, and the shares held by Versant Development Fund III, LLC, which are deemed to be beneficially owned by Drs. Bodick, Bolzon and Clayman and Mr. Colella, are counted only once in this total.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2013, with respect to shares of our common stock that may be issued under our existing equity compensation plans:

	(a)	(b)	(c)
Plan Category	**Number of securities to be issued upon exercise of outstanding options, warrants and rights**	**Weighted-average exercise price of outstanding options, warrants and rights**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))**

Equity compensation plans approved by stockholders[1]:				
2009 Equity Incentive Plan[2]	834,983[3]	$	2.99	272,621
2013 Equity Incentive Plan[4]		$		
2013 Employee Stock Purchase Plan[5]		$		
Equity compensation plans not approved by stockholders:				
None				

(1) For a description of our equity compensation plans, see *Item 11. Executive Compensation.*

(2) Effective as of February 11, 2014, no additional awards will be granted under the 2009 plan, and all awards granted under the 2009 plan that are repurchased, forfeited, expire, are cancelled or otherwise not issued will become available for grant under the 2013 plan in accordance with its terms.

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(3) All shares issuable upon exercise of options.

(4) The 2013 plan became effective on February 11, 2014. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2013 plan is the sum of (i) 1,230,012 shares, plus (ii) the 272,621 shares remaining available for grant under our 2009 plan at the time our 2013 plan became effective, plus (iii) any shares subject to outstanding stock options or other stock awards that would have otherwise returned to our 2009 plan (such as upon the expiration or termination of a stock award prior to vesting). Additionally, the number of shares of our common stock reserved for issuance under our 2013 plan will automatically increase on January 1 of each year, beginning on January 1, 2015, and continuing through and including January 1, 2023, by 4% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under our 2013 plan is 4,684,989 shares.

(5) The ESPP became effective on February 11, 2014. The ESPP authorizes the issuance of 209,102 shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2015 through January 1, 2023 by the least of (a) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, (b) 375,768 shares, or (c) a number determined by our board of directors that is less than (a) and (b).

Item 13. Certain Relationships and Related Transactions, and Director Independence

The following includes a summary of transactions since January 1, 2013 to which we have been a party, in which the amount involved in the transaction exceeded $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under *Item 11. Executive Compensation*.

Initial Public Offering

In February 2014, we completed our initial public offering pursuant to which we issued and sold an aggregate of 5,750,000 shares of our common stock, at a price to the public of $13.00 per share. The following table sets forth the number of shares of common stock purchased by holders of more than 5% of our common stock or entities affiliated with them, including entities affiliated with certain of our directors at the closing of the initial public offering:

Name[1]	Shares of Common Stock	Purchase Price
Versant Venture Capital III, L.P. and its affiliates	307,692	$ 3,999,996
Sofinnova Capital VI FCPR	230,769	$ 2,999,997
Novo A/S	692,308	$ 9,000,004

(1) Additional detail regarding these stockholders and their equity holdings is provided under *Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.*

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Certain of our directors have affiliations with the investors that participated in our initial public offering as described above, as indicated in the table below:

Director	Investor
Bradley J. Bolzon, Ph.D.	Versant Venture Capital III, L.P. and its affiliates
Samuel D. Colella	Versant Venture Capital III, L.P. and its affiliates
Heath Lukatch, Ph.D.	Novo A/S
Rafaèle Tordjman, M.D., Ph.D.	Sofinnova Capital VI FCPR

Indemnification of Officers and Directors

We have entered into, and intend to continue to enter into, separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated bylaws. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder s investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Policies and Procedures for Transactions with Related Persons

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of related-person transactions. For purposes of our policy only, a related-person transaction is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any related person are participants involving an amount that exceeds $120,000.

Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A related person is any executive officer, director or a holder of more than 5% of our common stock, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of directors) for review. The presentation must include a description of, among other things, the material facts, the direct and indirect interests of the related persons, the benefits of the transaction to us and whether any alternative transactions are available. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors

and certain significant stockholders. In considering related-person transactions, our audit committee or other independent body of our board of directors takes into account the relevant available facts and circumstances including, but not limited to:

the risks, costs and benefits to us;

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the impact on a director s independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;

the terms of the transaction;

the availability of other sources for comparable services or products; and

the terms available to or from, as the case may be, unrelated third parties or to or from our employees generally.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

Independence of the Board of Directors

As required under the Nasdaq Listing Rules, a majority of the members of a listed company s board of directors must qualify as independent, as affirmatively determined by its board of directors. Our board of directors consults with the Company s counsel to ensure that the the board of dircectors determinations are consistent with relevant securities and other laws and regulations regarding the definition of independent, including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and the Company, its senior management and its independent auditors, our board of directors has affirmatively determined that, with the exception of Dr. Clayman, all of our directors are independent directors within the meaning of the applicable Nasdaq Listing Rules. In making this determination, the board of directors found that none of these directors had a material or other disqualifying relationship with the Company.

Item 14. Principal Accounting Fees and Services

Audit and All Other Fees

The following table presents fees for services rendered by PricewaterhouseCoopers LLP, our independent registered public accounting firm, for 2013 and 2012 in the following categories:

	December 31, 2013	2012
Audit Fees[1]	$ 1,172,685	$ 46,500
Audit-Related Fees		
Tax Fees[2]	16,500	12,000
All Other Fees		
Total Fees	$ 1,189,185	$ 58,500

(1) Audit fees consist of fees billed for professional services by PricewaterhouseCoopers LLP for audit and quarterly review of our financial statements and review of our registration statement on Form S-1, and related services that are normally provided in connection with statutory and regulatory filings or engagements.

(2) Tax fees consist of fees for professional services performed by PricewaterhouseCoopers LLP with respect to tax compliance, tax advice and tax planning.

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Pre-Approval Policies and Procedures

The Audit Committee has not adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by the Company s independent registered public accounting firm, and consequently all audit and non-audit services are approved by the whole Audit Committee or the Audit Chair, as appropriate.

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PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of this report.

1. Financial Statements

The financial statements of Flexion Therapeutics, Inc. listed below are set for the in Item 8 of this report for the year ended December 31, 2013:

2. Financial Statement Schedules

These schedules have been omitted because the required information is included in the consolidated financial statements or notes thereto or because they are not applicable or not required.

3. Exhibits

For a list of exhibits filed with this Annual Report on Form 10-K, refer to the exhibit index.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

FLEXION THERAPEUTICS, INC.

By: /s/ Michael D. Clayman, M.D.

Michael D. Clayman, M.D.

President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Michael D. Clayman, M.D. and Frederick Driscoll, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Michael D. Clayman, M.D.	President, Chief Executive Officer and Member of the Board of Directors	
Michael D. Clayman, M.D.	*(Principal Executive Officer)*	March 28, 2014
/s/ Frederick W. Driscoll	Chief Financial Officer	March 28, 2014
Frederick W. Driscoll	*(Principal Financial and Accounting Officer)*	

/s/ Patrick J. Mahaffy

Patrick J. Mahaffy	Chairman of the Board of Directors	March 28, 2014

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Signature	Title	Date
/s/ Bradley J. Bolzon, Ph.D. Bradley J. Bolzon, Ph.D.	Member of the Board of Directors	March 28, 2014
/s/ Samuel D. Colella Samuel D. Colella	Member of the Board of Directors	March 28, 2014
/s/ Elaine V. Jones, Ph.D. Elaine V. Jones, Ph.D.	Member of the Board of Directors	March 28, 2014
/s/ Heath Lukatch, Ph.D. Heath Lukatch, Ph.D.	Member of the Board of Directors	March 28, 2014
/s/ Alan Milinazzo Alan Milinazzo	Member of the Board of Directors	March 28, 2014
/s/ Andrew J. Schwab Andrew J. Schwab	Member of the Board of Directors	March 28, 2014
/s/ Rafaèle Tordjman, M.D., Ph.D. Rafaèle Tordjman, M.D., Ph.D.	Member of the Board of Directors	March 28, 2014

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EXHIBIT INDEX

Exhibit number	Description of document
3.1(1)	Form of Amended and Restated Certificate of Incorporation of the Registrant.
3.2(1)	Amended and Restated Bylaws of the Registrant.
4.1(2)	Form of Common Stock Certificate of the Registrant.
4.2(2)	Amended and Restated Investor Rights Agreement, dated December 3, 2012, by and among the Registrant and certain of its stockholders.
4.3(2)	Conversion, Amendment and Waiver Agreement, dated January 27, 2014, by and among the Registrant and certain of its stockholders.
10.1+(2)	Form of Indemnity Agreement by and between the Registrant and its directors and officers.
10.2+(2)	Flexion Therapeutics, Inc. 2009 Equity Incentive Plan and Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder.
10.3+(2)	Flexion Therapeutics, Inc. 2013 Equity Incentive Plan and Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder.
10.4+(2)	Flexion Therapeutics, Inc. 2013 Employee Stock Purchase Plan.
10.5+	Flexion Therapeutics, Inc. Non-Employee Director Compensation Policy, as revised.
10.6+(2)	Amended and Restated Offer Letter by and between the Registrant and Michael D. Clayman, M.D.
10.7+	Amendment to Amended and Restated Offer Letter by and between the Registrant and Michael D. Clayman, M.D.
10.8+(2)	Amended and Restated Offer Letter by and between the Registrant and Neil Bodick, M.D., Ph.D.
10.9+	Amendment to Amended and Restated Offer Letter by and between the Registrant and Neil Bodick, M.D., Ph.D.

10.10+(2)	Amended and Restated Offer Letter by and between the Registrant and Fred Driscoll.

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Exhibit number	Description of document
10.11+	Amendment to Amended and Restated Offer Letter by and between the Registrant and Fred Driscoll.
10.12*(2)	Out-Licence Agreement, dated June 12, 2009, by and between the Registrant (as successor in interest to Flexion Therapeutics AG) and AstraZeneca AB.
10.13*(2)	Out-Licence Agreement, dated September 3, 2010, by and between the Registrant and AstraZeneca AB.
10.14*(2)	Letter Agreement, dated December 3, 2012, by and between the Registrant and AstraZeneca AB.
10.15(2)	Credit and Security Agreement, dated January 3, 2013, by and between the Registrant and MidCap Financial SBIC, LP.
10.16(2)	Lease, dated February 22, 2013, by and between the Registrant and The Trustees of Mall Road Trust.
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Reference is made to the signature page hereto.
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.

+ Indicates management contract or compensatory plan.

* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(1) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed with the SEC on February 19, 2014.

(2) Incorporated by reference to the Registrant s Registration Statement of Form S-1 (File No. 333-193233), as amended.