Flexion Therapeutics Inc
Form S-1/A
December 11, 2014
Table of Contents

As filed with the Securities and Exchange Commission on December 11, 2014

Registration No. 333-200668

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 2

TO

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

Flexion Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**2834**	**26-1388364**
(State or Other Jurisdiction of Incorporation or Organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

10 Mall Road, Suite 301

Burlington, MA 01803

(781) 305-7777

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant s Principal Executive Offices)

Michael D. Clayman, M.D.

Chief Executive Officer

Flexion Therapeutics, Inc.

10 Mall Road, Suite 301

Burlington, MA 01803

(781) 305-7777

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

Copies to:

Thomas A. Coll, Esq.

Sean M. Clayton, Esq.

Cooley LLP

500 Boylston Street, 14th Floor

Boston, Massachusetts 02116

(617) 937-2300

Mitchell Bloom, Esq.

Edward King, Esq.

Ryan Sansom, Esq.

Goodwin Procter LLP

53 State Street

Boston, Massachusetts 02109

(617) 570-1000

Approximate date of commencement of proposed sale to the public:

As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the Securities Act), check the following box. ¨

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨ Accelerated filer ¨

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	**Proposed maximum aggregate offering price(1)**	**Amount of registration fee(2)**
Common Stock, $0.001 par value per share	$87,229,800	$10,137

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act. Includes the offering price of shares that the underwriters have the option to purchase to cover over-allotments, if any.

(2) $8,082 was previously paid.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject To Completion, Dated December 11, 2014

Preliminary Prospectus

4,200,000 Shares

Common Stock

Flexion Therapeutics, Inc.

We are offering 4,200,000 shares of our common stock.

Our common stock is listed on the Nasdaq Global Market under the symbol FLXN . The closing price of our common stock on the Nasdaq Global Market on December 10, 2014, was $18.06 per share.

We have granted the underwriters an option to purchase up to 630,000 additional shares of our common stock.

Investing in our common stock involves risks. See Risk Factors beginning on page 10.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012, and, as such, we have elected to take advantage of certain reduced reporting requirements for this prospectus and may elect to comply with certain reduced public company reporting requirements for future filings.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public Offering Price	$	$
Underwriting Discount(1)	$	$
Proceeds to Flexion (before expenses)	$	$

(1) We refer you to Underwriting beginning on page 109 for additional information regarding underwriting compensation.

The underwriters expect to deliver the shares to purchasers on or about December , 2014 through the book-entry facilities of The Depository Trust Company.

BMO Capital Markets RBC Capital Markets

Needham & Company

Janney Montgomery Scott Summer Street Research Partners

Table of Contents

We are responsible for the information contained in or incorporated by reference into this prospectus and in any free-writing prospectus we prepare or authorize. We have not authorized anyone to provide you with different information, and we take no responsibility for any other information others may give you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in or incorporated by reference into this prospectus is accurate as of any date other than the date of this prospectus or the date of the document incorporated by reference, as applicable.

TABLE OF CONTENTS

Table of Contents

SUMMARY

This summary highlights information contained in other parts of or incorporated by reference into this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere or incorporated by reference into this prospectus. You should read the entire prospectus and the information incorporated herein carefully, especially Risk Factors and our consolidated financial statements and the related notes incorporated by reference into this prospectus, before deciding to buy shares of our common stock. Unless the context requires otherwise, references in this prospectus to Flexion Therapeutics, we, us and our refer to Flexion Therapeutics, Inc.

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, or OA, a type of degenerative arthritis. 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, targeted pain therapies.

Our lead product candidate, FX006, is a first-in-class injectable, sustained-release, intra-articular, or IA, meaning in the joint, steroid treatment for patients with moderate to severe OA pain. FX006 combines a commonly administered steroid, triamcinolone acetonide, or TCA, with poly lactic-co-glycolic acid, referred to as PLGA, to provide sustained therapeutic concentrations in the joint and persistent analgesic effect. We specifically designed FX006 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.

In April 2014, we initiated a pivotal Phase 2b clinical trial of FX006 to further identify a safe and well-tolerated dose of FX006 that demonstrates superior pain relief to placebo. On September 16, 2014, the U.S. Food and Drug Administration, or FDA, notified us that it had placed a clinical hold on the FX006 investigational new drug application IND due to a single occurrence of what was then reported as septic arthritis, an infection of the injected knee joint, in a patient in the clinical trial. We subsequently performed testing and investigation requested by the FDA, which demonstrated that the FX006 drug product was not contaminated. This is consistent with the fact that no production batch of FX006 has ever failed sterility testing. On October 28, 2014, we received notification that based on the highly atypical nature of the patient s clinical presentation as it relates to knee joint infection and the patient s subsequent clinical course which was most consistent with rheumatoid arthritis, the principal investigator had changed the initial serious adverse event diagnosis from septic arthritis, possibly related to study drug treatment, to inflammatory arthritis, unrelated to study drug treatment. This information was promptly shared with the FDA. It is assumed that the original, and only, positive synovial fluid culture obtained from this patient was a false positive, which occurs in approximately 5% of such cases. Thus there have been no confirmed diagnoses of septic arthritis and no serious adverse events related to drug treatment among the more than 300 patients treated with FX006 in all clinical trials to date. After reviewing the information we provided in response to the FDA s requests, on December 1, 2014, the FDA notified us that it had lifted the clinical hold on FX006. As a result we immediately resumed recruitment and dosing in the pivotal Phase 2b trial of FX006, and we expect to report top-line data from the trial in the second half of 2015.

Table of Contents

In 2014, the FDA informed us that it will consider our on-going pivotal Phase 2b trial as one of two pivotal efficacy trials required for registration of a single-dose administration of FX006. In addition, the FDA informed us that a second placebo-controlled pivotal trial would be sufficient to support the filing of a new drug application, or NDA, for single-dose administration of FX006 and that data from a repeat-dose safety trial would not be required. As a result, we plan to initiate a placebo-controlled Phase 3 trial of FX006 in early 2015 and expect to develop and file repeat-dose safety data in a supplemental NDA after an approval and launch of FX006 for single-dose administration.

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 compared to the current injectable standard of care,
- persistent therapeutic concentrations of drug in the joint and durable efficacy, and
- an attractive safety profile with limited systemic exposures and the potential for fewer side effects.

Among 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 Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, regulatory pathway seeking approval for a novel formulation of the same dose of the already approved immediate-release steroid used by orthopedists and rheumatologists.

Familiarity of orthopedists and rheumatologists with IA injections utilizing the same steroid in the same dose.

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 are conducting preclinical local toxicology experiments and plan to initiate a proof of concept, or PoC, clinical trial for FX007 following the generation of the preclinical data. 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 product candidates. We also have an exclusive worldwide license agreement with Southwest Research Institute, or SwRI, with respect to the use of SwRI s proprietary microsphere manufacturing technologies for certain steroids formulated with PLGA, including FX006. 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 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.

Table of Contents

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 often culminates 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 he or she will require repeat surgery in their lifetime.

Our projections indicate that by 2030 approximately 23.5 million of the 45 million OA patients will have knee OA. According to IMS Health, each year over four million OA patients in the United States receive IA steroid injection treatments in the knee, hip, shoulder, hand and foot, with over three million of these being knee injections. In 2012, the number of patients that received knee injections of IA steroids increased approximately 12%. We estimate that an additional 1.3 million patients received knee injections of IA HA, which the FDA has approved for use only in the knee. Sales of HA in the United States were approximately $700 million in 2013, the vast majority of which we believe were related to knee therapy. Our clinical trials to date have treated patients with knee OA, which represents the most common joint treated with IA therapies.

While worldwide sales of HA injections are approaching $2 billion, 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. For example, Sanofi Biosurgery, which sells the market leading HA treatment, Synvisc, reported a 7% drop in U.S. net sales during the first-nine months of 2014 when compared to the first nine months of 2013. This could be in part due to the fact that select payer groups have limited reimbursement for the entire class of HA products.

Given the limitations of current therapies, we believe FX006, if successfully commercialized, would provide an attractive therapeutic alternative. Clinical trials to date for FX006 have demonstrated clinically meaningful and significantly better pain relief compared to the current injectable standard of care, persistent therapeutic concentrations of drug in the joint and durable efficacy, and an attractive safety profile with limited systemic exposures and the potential for fewer side effects.

Table of Contents

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. Currently available IA steroids, none of which are formulated for sustained release, leave the joint rapidly and confer pain relief that typically wanes after two to four weeks. Since, by medical practice, steroids are not typically injected more frequently than every three months, patients can experience months of pain during that time. 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 and is being formulated 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 the Section 505(b)(2) NDA pathway under the 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 with the potential to replace IA steroids and HA, FX005 is targeted for patients who progress to end-stage disease as an alternative to opioids 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.

Table of Contents

Risk Factors

Our business is subject to many risks and uncertainties of which you should be aware before you decide to invest in our common stock. These risks are discussed more fully under Risk Factors in this prospectus and in the documents incorporated herein by reference. Some of these risks include:

- we have incurred significant losses since our inception resulting in an accumulated deficit of $85.7 million as of September 30, 2014, 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 may require additional capital beyond this offering, including prior to approval and commercialization of FX006 or any of our other product candidates;
- we have not completed 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; and
- we may be unable to adequately maintain and protect our proprietary intellectual property assets, which could impair our commercial opportunities.

Implications of Being an Emerging Growth Company

We qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced Management s Discussion and Analysis of Financial Condition and Results of Operations disclosure;
- reduced disclosure about our executive compensation arrangements;
- no requirement that we solicit non-binding advisory votes on executive compensation or golden parachute arrangements; and

an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We will cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.0 billion or more; (ii) December 31, 2019; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. Also, we have irrevocably elected to opt out of the exemption for the delayed adoption of certain accounting standards and, therefore, are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Table of Contents

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 prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ 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.

Table of Contents

The Offering

Common stock offered by us	4,200,000 shares
Common stock to be outstanding after this offering	19,827,288 shares
Option to purchase additional common stock	630,000 shares
Use of proceeds	We intend to use the net proceeds from this offering to complete our planned Phase 3 clinical trial and the submission of an NDA for FX006, for preparatory activities for commercial launch of FX006, for development of FX007 and for general development expenses, working capital and other general corporate purposes. See Use of Proceeds for more information.
Risk factors	You should read the Risk Factors section of this prospectus for a discussion of certain of the factors to consider carefully before deciding to purchase any shares of our common stock.
Nasdaq Global Market symbol	FLXN

The number of shares of our common stock to be outstanding after this offering is based on 15,627,288 shares of common stock outstanding as of September 30, 2014 and excludes:

- 420,974 shares of common stock issuable upon the exercise of outstanding stock options as of September 30, 2014, at a weighted average exercise price of $3.20 per share;
- 967,502 shares of common stock reserved for future issuance under our 2013 equity incentive plan, or the 2013 plan, as of September 30, 2014; and
- 209,102 shares of common stock reserved for future issuance under our 2013 employee stock purchase plan, or the 2013 purchase plan, as of September 30, 2014.

Unless otherwise indicated, all information contained in this prospectus assumes:

- no exercise of the outstanding options described above; and

no exercise by the underwriters of their option to purchase up to an additional 630,000 shares of our common stock.

Table of Contents

Summary Financial Data

The following table summarizes certain of our financial data. We derived the summary statement of operations data for the years ended December 31, 2012 and 2013 from our audited consolidated financial statements incorporated by reference into this prospectus from our Annual Report on Form 10-K for the year ended December 31, 2013. The summary statement of operations data for the nine months ended September 30, 2013 and 2014, and the summary balance sheet data as of September 30, 2014 were derived from our unaudited financial statements incorporated by reference into this prospectus from our Quarterly Report on Form 10-Q for the quarter ended September 30, 2014. The unaudited financial statements, in management s opinion, have been prepared on the same basis as the audited consolidated financial statements and related notes incorporated herein by reference, and include all adjustments, consisting only of normal recurring adjustments, that management considers necessary for a fair presentation of the financial information as of and for the periods presented. 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 summary financial data should be read together with our consolidated financial statements and related notes, Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this prospectus or incorporated by reference herein.

	Year Ended December 31,		Nine Months Ended September 30,	
	2013	2012	2014	2013
			(unaudited)	
	(in thousands, except per share data)			
Statement of Operations Data:				
Revenue	$	$	$	$
Operating expenses:				
Research and development	11,061	11,065	12,424	8,825
General and administrative	6,704	3,947	6,822	5,363
Total operating expenses	17,765	15,012	19,246	14,188
Loss from operations	(17,765)	(15,012)	(19,246)	(14,188)
Other income (expense):				
Interest income	234	194	319	219
Interest expense	(449)		(315)	(335)
Other income (expense), net	(207)	(164)	(266)	(192)
Total other income (expense)	(422)	30	(262)	(308)
Net loss	$ (18,187)	$ (14,982)	$ (19,508)	$ (14,496)
Net loss attributable to common stockholders	$ (18,187)	$ (14,982)	$ (19,508)	$ (14,496)
Net loss per share attributable to common stockholders, basic and diluted[(1)]	$ (23.02)	$ (27.58)	$ (1.50)	$ (18.37)
Weighted average common shares outstanding, basic and diluted[(1)]	790	543	13,008	789

Table of Contents

	As of September 30, 2014	
	Actual	Pro Forma[2]