Akebia Therapeutics, Inc.
Form S-1/A
March 17, 2014
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As filed with the Securities and Exchange Commission on March 17, 2014

Registration No. 333-193969

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 4

to

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

AKEBIA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	2834	20-8756903
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

245 First Street, Suite 1100

Cambridge, MA 02142

(617) 871-2098

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

John P. Butler

President and Chief Executive Officer

Akebia Therapeutics, Inc.

245 First Street, Suite 1100

Cambridge, MA 02142

(617) 871-2098

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to public: As soon as practicable after this Registration Statement is declared effective.

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, 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 x (Do not check if a smaller reporting company)	Smaller reporting company ¨

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 which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 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.

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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 it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated March 17, 2014

4,900,000 Shares

Akebia Therapeutics, Inc.

Common Stock

This is the initial public offering of shares of common stock of Akebia Therapeutics, Inc.

We are offering 4,900,000 shares of our common stock. Prior to this offering, there has been no public market for our common stock. It is currently estimated that the initial public offering price per share will be between $14.00 and $17.00. We have applied to have our common stock listed on the NASDAQ Global Market under the trading symbol AKBA.

We are an emerging growth company under the federal securities laws and are subject to reduced public company reporting requirements.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 11.

	Per share	Total
Initial public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds, before expenses, to Akebia	$	$

(1) See Underwriting for additional disclosure regarding underwriting discounts, commissions and expenses.

To the extent that the underwriters sell more than 4,900,000 shares of common stock, the underwriters have an option to purchase up to an additional 735,000 shares from us at the initial public offering price, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The underwriters expect to deliver the shares against payment in New York, New York on , 2014.

Certain of our existing stockholders and their affiliated entities, including holders of more than 5% of our common stock, have indicated an interest in purchasing an aggregate of approximately $22 million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares to any of these existing stockholders and any of these existing stockholders could determine to purchase more, less or no shares in this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Morgan Stanley **Credit Suisse**

UBS Investment Bank

Nomura

, 2014

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We are responsible for the information contained in this prospectus and in any free-writing prospectus we prepare or authorize. We have not, and the underwriters 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 this prospectus is accurate as of any date other than the date on the cover page of this prospectus.

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Summary

This summary highlights information contained in other parts of this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes and the information set forth under the sections titled Risk Factors, Cautionary Note Regarding Forward-Looking Statements and Management s Discussion and Analysis of Financial Condition and Results of Operations. Unless the context requires otherwise, references in this prospectus to Akebia, we, us, our, the Company and similar designations refer to Akebia Therapeutics, Inc.

Overview

We are a biopharmaceutical company focused on the development of novel proprietary therapeutics based on hypoxia inducible factor, or HIF, biology and the commercialization of these products for patients with kidney disease. HIF is the primary regulator of the production of red blood cells, or RBCs, in the body and a potentially novel mechanism of treating anemia. Our lead product candidate, AKB-6548, is being developed as a once-daily oral therapy that has successfully completed a Phase 2a proof of concept study demonstrating that AKB-6548 safely and predictably raised hemoglobin levels in patients with anemia secondary to chronic kidney disease, or CKD, not requiring dialysis.

We are conducting a Phase 2b trial for AKB-6548 in patients with anemia secondary to CKD who are not dependent on dialysis and expect data to be available in the fourth quarter of 2014. We have also initiated a development program for patients dependent on dialysis. If the results of our Phase 2b trial are positive, we would expect to initiate Phase 3 trials for anemia secondary to CKD in 2015, and would anticipate submitting a New Drug Application, or NDA, for AKB-6548 in the United States by 2018 if the Phase 3 data are favorable.

We own worldwide rights to our HIF-based product candidates, including AKB-6548. If approved by regulatory authorities, we plan to commercialize AKB-6548 in the United States ourselves and intend to seek one or more collaborators to commercialize the product candidate in additional markets.

Anemia is a serious medical condition in which blood is deficient in RBCs and hemoglobin, both of which are critical in delivering oxygen to tissue. Anemia generally exists when hemoglobin, a protein in RBCs that carries oxygen, is less than 13 g/dL in men or 12 g/dL in women. Untreated anemia is associated with chronic fatigue, increased risk of progression of multiple diseases and death. Anemia is common in patients with CKD, cancer, heart failure, inflammatory diseases and other critical illnesses, as well as in the elderly.

More than 30 million people in the United States have CKD, with estimates that over 1.8 million of these patients suffer from anemia. Anemia from these indications is currently treated by injectable recombinant protein erythropoiesis stimulating agents, or rESAs including Epogen, Aranesp and Procrit with iron supplementation or an RBC transfusion. Based on the reported revenues of companies that market and sell rESAs, we estimate that global sales of injectable rESAs were $6.3 billion in 2012, the vast majority of which were for renal indications.

rESAs are designed to stimulate production of RBCs by binding directly to and saturating erythropoietin, or EPO, receptors. While injectable rESAs and transfusions may be effective in raising hemoglobin levels, they carry significant potential side effects and also need to be delivered subcutaneously or intravenously. In particular, injectable rESAs may lead to thrombosis, stroke, myocardial infarction and death, and these risks are described in black box warnings on the prescribing information of all products marketed in this class. These safety concerns, which became

evident starting in 2006, have led to a significant reduction in the use of

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injectable rESAs. Today anemia is either not treated or inadequately treated in the majority of CKD patients, and we believe that a safe, effective, oral therapeutic option will take significant market share and meaningfully grow the market in patients not requiring dialysis.

AKB-6548 works by a differentiated mechanism of action that we believe has the potential to be safer than that of injectable rESAs. This novel mechanism of action is referred to as HIF prolyl-hydroxylase, or HIF-PH, inhibition. Instead of binding directly to the EPO receptors on cells in the bone marrow, AKB-6548 leads to activation of critical pathways for hemoglobin and RBC production. This approach mimics the physiological adjustment made by the body when exposed to reduced oxygen levels at higher altitudes.

To date, AKB-6548 has been studied in eight clinical trials across four separate patient populations: healthy volunteers and patients with CKD stages 3, 4 and 5 (non-dialysis). Our largest study was a Phase 2a trial in 91 patients with anemia secondary to CKD, which showed significantly increased hemoglobin levels among subjects taking AKB-6548 compared to baseline in a dose-dependent manner across all treatment arms ($p < 0.0001$). No drug-related serious adverse events were reported, and dosing was well-tolerated. In addition, AKB-6548 was also shown to stabilize the iron supply to the bone marrow while improving hemoglobin production.

Our ongoing Phase 2b trial explores a dosing approach for AKB-6548 to enable subjects with anemia secondary to CKD to appropriately and safely raise hemoglobin levels. As of February 28, 2014, we had enrolled over 80% of our targeted 200 patients in this study at investigational sites in the United States, with data expected in the fourth quarter of 2014. With positive data, we plan to progress to Phase 3 global registration studies for AKB-6548 in patients with anemia secondary to CKD. We anticipate the design of the Phase 3 studies will mirror the Phase 2b study, except that they will be longer and larger in size, positioning us to file for approval in the United States by 2018.

Given the burdens of the current standard of care and costs associated with administering an injectable rESA, we believe AKB-6548 is a promising alternative for the overall cost-effective treatment of anemia. We intend to commercialize AKB-6548 ourselves in the United States for the treatment of anemia in patients with CKD. These patients are primarily treated by approximately 7,000 nephrologists, and we believe we can reach most of this market with a specialty sales force of approximately 125 people. We intend to seek one or more commercial collaborators for the development and commercialization of AKB-6548 outside of the United States. We may also explore opportunities to expand AKB-6548 into additional markets not adequately addressed by injectable rESAs because of safety or dosing delivery issues, including idiopathic anemia of aging, or IAA, and anemia of congestive heart failure.

We are led by a team of experienced biopharmaceutical executives with a background in developing and commercializing drugs for the treatment of renal and metabolic disorders. John P. Butler, our CEO, was former President of Genzyme Corp. s renal division which grew to over $1 billion in annual revenue under his leadership, and is current Chairman of the Board of the American Kidney Fund, the leading patient advocacy organization for kidney disease patients. Earlier in his career, Mr. Butler held sales and marketing positions at Amgen, working on the early commercial launch of injectable rESAs in the renal anemia market. Our executive team also includes Robert Shalwitz, M.D., CMO and co-founder of Akebia. Dr. Shalwitz is an academic pediatric endocrinologist and has extensive industry experience developing novel pharmaceuticals at Abbott Laboratories and Reliant Pharmaceuticals. He has developed extensive knowledge of HIF biology over his career, particularly over the past seven years in leading development at Akebia.

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Our Strategy

Our strategy is to develop novel therapeutics for patients based on HIF biology and to commercialize products for patients with kidney disease, beginning with AKB-6548 for patients with anemia secondary to CKD. The key elements of our strategy are to:

Complete the development of AKB-6548 for anemia secondary to CKD. We plan to complete the Phase 2b trial that is currently enrolling in the United States. We intend to initiate a Phase 3 development program in 2015 following our end of Phase 2 meeting with the United States Food and Drug Administration, or FDA.

Obtain regulatory approval of AKB-6548 for anemia secondary to CKD in the United States, Europe and other markets. We plan to complete an end of Phase 2 meeting with the FDA and seek scientific advice from the European Medicines Agency, or EMA, to define the Phase 3 development program necessary to secure regulatory approval to market AKB-6548. We would expect to initiate Phase 3 trials for anemia secondary to CKD in 2015, and would anticipate submitting an NDA for AKB-6548 in the United States by 2018 if the Phase 3 data are favorable.

Commercialize AKB-6548 in the United States and other territories. We will establish a specialty sales and marketing organization to commercialize AKB-6548 in the United States. Outside of the United States, we intend to seek one or more commercial collaborators.

Continue to develop AKB-6548 for further indications. We plan to initiate, in the first half of 2014, a Phase 2 study for AKB-6548 in dialysis patients with anemia, the second indication we intend to pursue. Additionally, we plan to evaluate the product candidate in IAA and other indications.

Advance our earlier stage pipeline asset. We plan to advance AKB-6899, a second HIF-PH inhibitor product candidate, which we believe, based on preclinical testing, has the ability to increase EPO levels while reducing vascular endothelial growth factor, or VEGF, levels. We intend to file an Investigational New Drug, or IND, application and begin Phase 1 trials to determine its potential use in oncology and ophthalmology.

Acquire or in-license additional nephrology products. If we are able to successfully launch AKB-6548, we will look to leverage our commercial infrastructure with additional products that would be prescribed by nephrologists.

We may enter into strategic collaborations to fully realize all of the elements of our strategy.

AKB-6548 as a Potential Solution

We are developing our lead product candidate, AKB-6548, to be a best in class HIF-PH inhibitor for the treatment of anemia secondary to CKD. We expect AKB-6548 to offer:

Predictable, meaningful and sustained improvements in hemoglobin levels;

Once a day therapy delivered orally;

A dosing regimen that restores the normal diurnal EPO pattern;

Robust pharmacodynamics and substantially lower peak EPO levels than with injectable rESAs; and

Reduced administration of IV or oral iron supplementation to patients treated for anemia secondary to CKD.

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Potential Best in Class Profile

We believe AKB-6548 has compelling clinical data demonstrating a best in class profile with several potential safety and efficacy advantages over current injectable rESA therapy in the treatment of anemia secondary to CKD.

AKB-6548 significantly increases hemoglobin in anemic CKD patients. We have successfully completed a Phase 2a trial, in which AKB-6548 significantly increased hemoglobin levels compared to baseline in a dose-dependent manner across all treatment arms ($p < 0.0001$). Further, AKB-6548 provides a physiologic reticulocyte, or newly formed RBC, response, which leads to a more gradual and consistent increase in hemoglobin levels than what is seen with injectable rESA therapies, meaning that these improvements occur without causing patients hemoglobin to rise to levels that cause concern.

AKB-6548 may have the potential to restore the normal diurnal variation of EPO for a patient with anemia in a way that an injectable rESA cannot. Instead of binding directly to and saturating the EPO receptor for prolonged periods of time as is the case with current injectable rESA treatments, AKB-6548 acts by simulating the body s natural response to hypoxia that is carried out by stabilization of HIFa.

Oral, once-daily dosing. Once-daily, oral dosing of AKB-6548 offers improved convenience for patients as compared to injectable rESAs. This convenience may increase access to anemia therapy for the largely underserved population of patients with anemia secondary to CKD who are not yet on dialysis and for patients with other forms of anemia, such as idiopathic anemia of aging. AKB-6548 offers the potential of flexible oral dosing that provides a more gradual and reliable means of titration than that of injectable rESAs.

Ability to stabilize the iron supply to the bone marrow while improving hemoglobin production. In clinical trials, AKB-6548 has demonstrated a dose-related increase in total iron binding capacity. These results indicate that AKB-6548 will stabilize the iron supply to the bone marrow while improving hemoglobin production and should improve EPO responsiveness. As a result, unlike injectable rESAs, which have no effect on iron mobilization, AKB-6548 offers the added potential benefit of reducing the amount of supplemental iron required by anemia patients.

Differentiated safety profile. AKB-6548 s novel mechanism of action and dosing profile offer the opportunity to potentially avoid the black box label ascribed to injectable rESAs. In our recently completed Phase 2a study, no drug-related serious adverse events were reported. Dosing was well-tolerated and there was no evidence of undesirable vascular response.

Risk Associated with Our Business

An investment in our common stock involves a high degree of risk. Any of the factors set forth under Risk Factors may limit our ability to successfully execute our business strategy. You should carefully consider all of the information set forth in this prospectus and, in particular, should evaluate the specific factors set forth under Risk Factors in deciding whether to invest in our common stock. These risk factors include, among others:

We depend heavily on the success of one product candidate, AKB-6548, which is in a Phase 2b clinical trial. Even if we obtain favorable clinical results, we may not be able to obtain regulatory approval for, or successfully commercialize, AKB-6548.

We have incurred significant losses since inception and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We will require substantial additional financing. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

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We have not obtained agreement with the FDA, the EMA or other regulatory authorities on the design of our Phase 3 development program.

Clinical drug development is a lengthy and expensive process with an uncertain outcome, and positive results from Phase 1 and Phase 2a clinical trials of AKB-6548 are not necessarily predictive of the results of our current Phase 2b and any future clinical trials of AKB-6548. If we cannot replicate the positive results from our Phase 1 and Phase 2a clinical trials of AKB-6548 in our Phase 2b and subsequent clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize AKB-6548.

Even if we receive regulatory approval for our product candidates, such drug products will be subject to ongoing regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

If our efforts to protect our proprietary technologies are not adequate, we may not be able to compete effectively in our market. We are currently involved in an opposition proceeding involving one of our European patents, and the outcome of that proceeding may affect our ability to establish a competitive advantage in the market or successfully commercialize our lead product candidate in the European Union.

Third-party claims of intellectual property infringement may be costly and time consuming, and may delay or harm our drug discovery and development efforts. We are currently involved in an opposition proceeding involving the granted European patent of one of our potential competitors.

Implications of Being an Emerging Growth Company

As a company with less than $1 billion in revenue during our most recently completed fiscal year, we qualify as an emerging growth company as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, as modified by 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, in general, to public companies that are not emerging growth companies. These provisions include:

Reduced disclosure about our executive compensation arrangements;

Exemption from the non-binding shareholder advisory votes on executive compensation or golden parachute arrangements;

Exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting; and

Reduced disclosure of financial information in this prospectus, such as being permitted to include only two years of audited financial information and two years of selected financial information 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.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1 billion in annual revenues as of the end of a fiscal year, have more than $700 million in market value of our capital stock held by non-affiliates as of any June 30 or if we issue more than $1 billion of non-convertible

debt over a three-year-period. We may choose to take advantage of some, but not all, of the available exemptions. We have

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taken advantage of some reduced reporting burdens in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

The JOBS Act permits an emerging growth company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public 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 non-emerging growth companies.

Corporate Information

We were incorporated under the laws of the state of Delaware in February 2007. In December 2011, we spun out our programs focused on the treatment of diabetic eye disease and inflammatory bowel disease into Aerpio Therapeutics, Inc., or Aerpio, which has since operated as a stand-alone company. Our principal executive office is located at 245 First Street, Suite 1100, Cambridge MA 02142, and our telephone number is 617-871-2098. Our website address is *www.akebia.com*. We have included our website address in this prospectus solely as an inactive textual reference. The information on, or that can be accessed through, our website is not part of this prospectus, and you should not rely on any such information in making the decision whether to purchase our common stock.

This prospectus contains trademarks and tradenames of other businesses that are the property of their respective owners. We have omitted the ® and ™ designations, as applicable, for the trademarks named in this prospectus.

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The Offering

Common stock offered by us	4,900,000 shares
Common stock to be outstanding immediately following this offering	18,285,674 shares
Underwriters over-allotment option	The underwriters have an option to purchase up to 735,000 additional shares of common stock to cover over-allotments as described in Underwriting.
Use of proceeds	We estimate that the net proceeds from the issuance of our common stock in this offering will be approximately $67.8 million, or approximately $78.4 million if the underwriters exercise their over-allotment option in full, assuming an initial public offering price of $15.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to continue clinical development of AKB-6548 in patients with anemia secondary to CKD, including the preparation for and initiation of the Phase 3 trials; to conduct a Phase 2 clinical trial of AKB-6548 in idiopathic anemia of aging; to advance our preclinical candidate, AKB-6899, through Phase 1 development in oncology; and for working capital and other general corporate purposes. See Use of Proceeds for additional information.
Risk factors	See Risk Factors and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Proposed NASDAQ Global Market symbol	We have applied for listing of our common stock on the NASDAQ Global Market under the symbol AKBA.

Certain of our existing stockholders and their affiliated entities, including holders of more than 5% of our common stock, have indicated an interest in purchasing an aggregate of approximately $22 million in shares of our common stock in this offering at the initial public offering price. Assuming an initial public offering price of $15.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, these entities would purchase an aggregate of up to approximately 1,435,483 of the 4,900,000 shares in this offering based on these indications of interest. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares to any of these existing stockholders and any of these existing stockholders could determine to purchase, more, less or no shares in this offering.

The number of shares of common stock to be outstanding after this offering is based on 13,385,674 shares of common stock outstanding as of December 31, 2013, including 957,189 shares of restricted stock and

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12,002,329 shares of our common stock issuable upon the automatic conversion of all outstanding shares of our preferred stock, and excludes the following:

- 1,251,398 shares of common stock issuable upon exercise of stock options outstanding as of December 31, 2013 at a weighted-average exercise price of $1.01 per share;
- 155,108 shares of common stock reserved for future issuance under our Amended and Restated 2008 Equity Incentive Plan as of December 31, 2013; and
- 1,785,000 shares of common stock reserved for future issuance under our 2014 Incentive Plan.

Unless otherwise indicated, all information in this prospectus reflects or assumes the following:

- a 1.75-for-1 forward stock split of our common stock that we effected on March 6, 2014;
- the amendment and restatement of our certificate of incorporation and bylaws, which will occur immediately prior to the closing of this offering;
- the conversion of all of our outstanding shares of our preferred stock into 12,002,329 shares of common stock, which will occur automatically upon the closing of this offering;
- no exercise of stock options on or after December 31, 2013; and
- no exercise by the underwriters of their option to purchase up to an additional 735,000 shares of common stock in this offering.

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Summary Financial Data

The following summary financial data for the years ended December 31, 2012 and 2013, and the period from February 27, 2007 (inception) to December 31, 2013 are derived from our audited financial statements included elsewhere in this prospectus. You should read this data together with our financial statements and related notes included elsewhere in this prospectus and the information under the captions Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our interim period results are not necessarily indicative of results to be expected for a full year or any other interim period.

	Year Ended December 31,		Period from February 27, 2007 (Date of Inception) to December 31, 2013
	2012	2013	
	(dollars in thousands, except per share data)		
Consolidated statements of operations data:			
Revenue		$	$
Expenses:			
Research and development	5,632	10,781	51,748
General and administrative	2,891	5,152	15,269
Total expenses	8,523	15,933	67,017
Loss from operations	(8,523)	(15,933)	(67,017)
Other income, net	327	2,766	3,975
Net loss	$ (8,196)	$ (13,167)	$ (63,042)
Net loss per share applicable to common stockholders basic and diluted[1]	$ (27.82)	$ (126.94)	$ (481.04)
Weighted-average number of common shares used in net loss per share applicable to common stockholders basic and diluted		544,002	
Pro forma net loss per share applicable to common stockholders basic and diluted (unaudited)[1]		$ (1.31)	
Pro forma weighted-average number of common shares used in net loss per share applicable to common stockholders basic and diluted (unaudited)		10,132,528	

(1) See Note 2 within the notes to our financial statements appearing elsewhere in this prospectus for a description of the method used to calculate basic and diluted net loss per share of common stock. Pro forma basic and diluted net loss per share of common stock is calculated by dividing net loss attributable to common stockholders, excluding the impact of gains (losses) on the extinguishment of preferred stock, accretion of preferred stock and including the impact of compensation expense associated with awards of restricted stock that contain a performance condition wherein vesting is contingent upon our consumption of a Liquidity Event, as defined in the Restricted Stock Agreement from the December 23, 2013 grants, by the pro forma weighted-average number of common shares outstanding.

The pro forma balance sheet data set forth below give effect to the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 12,002,329 shares of our common stock upon the closing of this offering.

The pro forma as adjusted balance sheet data set forth below give further effect to our issuance and sale of 4,900,000 shares of our common stock in this offering at an assumed initial public offering price of $15.50 per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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The pro forma as adjusted information presented in the summary balance sheet data are illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase or decrease in the assumed initial public offering price of $15.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease each of cash and cash equivalents, total assets and total stockholders deficit on a pro forma as adjusted basis by approximately $4.6 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1,000,000 shares offered by us at the assumed initial public offering price would increase or decrease each of cash and cash equivalents, total assets and total stockholders deficit on a pro forma as adjusted basis by approximately $14.4 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.