AGILE THERAPEUTICS INC
Form S-1/A
May 05, 2014

Use these links to rapidly review the document
TABLE OF CONTENTS
FINANCIAL STATEMENTS

Table of Contents

As filed with the Securities and Exchange Commission on May 5, 2014

Registration Statement No. 333-194621

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

AGILE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**23-2936302**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(IRS Employer Identification Number)*

101 Poor Farm Road
Princeton, New Jersey 08540
(609) 683-1880

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

Alfred Altomari
Chief Executive Officer
Agile Therapeutics, Inc.
101 Poor Farm Road
Princeton, New Jersey 08540
(609) 683-1880

(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 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, check the following box. o

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

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. o

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. o

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. (Check one):

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

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 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 declared 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 May 5, 2014

Shares

COMMON STOCK

We are offering shares of our common stock. This is our initial public offering and no public market currently exists for our common stock. We expect that the initial public offering price will be between $ and $ per share.

We have applied to list our common stock on the NASDAQ Global Market under the symbol "AGRX."

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, and will be subject to reduced public company reporting requirements.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 13.

	Per Share	Total
Initial public offering price	$	$
Underwriting discount and commissions(1)	$	$
Proceeds, before expenses, to us	$	$

(1) See "Underwriting" in this prospectus for a description of compensation payable to the underwriters.

We have granted the underwriters an option to purchase up to additional common shares to cover over-allotments, if any, exercisable at any time until 30 days after the date of this prospectus. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $ and the total proceeds to us, before expenses, will be $.

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

The underwriters expect to deliver the shares on or about , 2014.

RBC CAPITAL MARKETS **WILLIAM BLAIR**

CANTOR FITZGERALD & CO. **JANNEY MONTGOMERY SCOTT**

Prospectus dated , 2014

Table of Contents

TABLE OF CONTENTS

You should rely only on the information contained in this prospectus and any free writing prospectus prepared by or on behalf of us or to which we have referred you. We have not authorized anyone to provide you with information that is different from that contained in such prospectuses. We are offering to sell shares of our common stock, and seeking offers to buy shares of our common stock, only in jurisdictions where such offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.

Until and including , 2014, 25 days after the date of this prospectus, all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to unsold allotments or subscriptions.

For investors outside of the United States: neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

Table of Contents

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. Before you decide to invest in our common stock, you should read the entire prospectus carefully, including the "Risk Factors" section and the financial statements and related notes appearing at the end of this prospectus. In this prospectus, unless otherwise stated or the context otherwise indicates, references to "Agile," "we," "us" or "our" refer to Agile Therapeutics, Inc.

Overview

We are a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products. Our product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Our lead product candidate, Twirla™, also known as AG200-15, is a once-weekly prescription contraceptive patch currently in Phase 3 clinical development. We anticipate receiving data from our Phase 3 trial by the end of 2015, and, if approved, we plan to launch Twirla in the United States through a focused specialty sales force. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to provide advantages over currently available patches and is intended to optimize patch adherence and stability and patient comfort. Twirla is a combined hormonal contraceptive, or CHC, patch that contains the active ingredients ethinyl estradiol, or EE, which is a synthetic estrogen, and levonorgestrel, or LNG, which is a type of progestin, a synthetic steroid harmone, both of which have an established history of efficacy and safety in currently marketed combination low-dose, oral contraceptives. Twirla is designed to consistently deliver both hormones over a seven-day period at levels comparable to currently marketed low-dose oral contraceptives. By delivering these active ingredients over seven days, in a comfortable, convenient and easy-to-use weekly patch, Twirla is designed to promote enhanced patient compliance.

The U.S. hormonal contraceptive market, with total market sales of $5.6 billion in 2013, represents the greatest opportunity for Twirla. Over half of those sales were generated by branded products. Contraceptive methods, other than sterilization, can be divided into non-hormonal and hormonal alternatives. Non-hormonal contraceptive products available in the United States include the diaphragm, male condom and female condom. There are several methods of hormonal contraception available in the United States, including oral contraceptives, a vaginal ring, intrauterine contraceptive devices, or IUDs, subcutaneous implants, injectables and a transdermal patch which is available in branded and generic versions. Over the years, the doses of EE most commonly included in CHCs have steadily decreased to 35 micrograms per day or below, due to associated safety risks of higher EE doses. The currently approved transdermal patch products deliver EE at a level that is 60% higher than that delivered with low-dose oral contraceptives containing 35 micrograms of EE. As a result, the currently approved patch products carry a black box warning describing safety risks associated with this higher level of EE. Before these issues were identified with the first marketed patch, it achieved rapid market uptake and quickly captured approximately 10% of the CHC market. We believe there is an unmet market need for a low-dose transdermal patch as a contraceptive option that does not carry the additional safety risks associated with higher levels of EE.

Table of Contents

Twirla is designed to be highly appealing to patients and healthcare professionals as a method of contraception. Twirla delivers approximately 30 micrograms of EE per day, a dose of EE consistent with low-dose oral contraceptives. The daily delivery of EE from Twirla is much lower than the levels of EE delivered by the currently approved patch products, as reported in that patch's label. Twirla is round and made of a soft, flexible, silky fabric, designed to flex with the movement of a woman's body. Twirla is a matrix patch consisting of several layers of material which contain the active ingredients EE and LNG, inactive ingredients to assist in transport of EE and LNG across the skin, and adhesives that allow adherence to the skin. There is a barrier formed between the inner portion of the patch, which contains the active ingredients, and the outer portion of the patch, which only contains the adhesive. This barrier is intended to prevent the active and inactive ingredients from migrating to the peripheral portion of the patch, and from breaking down the adhesive in that portion of the patch. Twirla is also designed to help prevent seepage of the adhesives from around the edges of the patch where it could collect dirt and leave a sticky black ring on the skin. The six layers of the patch are integrated to create a patch which has a slim profile, less than one half millimeter, and is unobtrusive when applied. The results of multiple clinical trials suggest that Twirla delivers the active ingredients needed for contraception over a seven-day period, and that it remains adhered to the skin of most subjects for the full seven-day period, even under conditions of heat, humidity, showering, exposure to water and vigorous exercise.

We have conducted a comprehensive clinical program enrolling over 2,100 women in Phase 1, Phase 2 and Phase 3 trials, over 1,500 of whom received Twirla. In the larger of our two completed Phase 3 trials, 485 women received Twirla for 12 months. In Phase 1 and Phase 2 clinical trials, we demonstrated that Twirla delivers levels of both EE and LNG to the blood stream that are consistent with current low-dose oral contraceptives. In our two completed Phase 3 clinical trials that enrolled over 1,900 women in the aggregate for up to 12 months, we demonstrated that Twirla generally had comparable efficacy and tolerability to an approved low-dose oral contraceptive. Across all clinical trials, Twirla was generally well tolerated and had a favorable safety profile.

In our Phase 3 trials, the primary measure of efficacy is the Pearl Index, or PI, which is a measure of the rate of unintended pregnancies experienced by women in the study. Specifically, the PI is expressed as the number of pregnancies per 100 woman-years of use. The PI values in the pooled completed Phase 3 trials for both the Twirla patch, 5.76, and the combined oral contraceptive control, 6.72, were higher than the PI range of 1.34 to 3.19 for products approved by the U.S. Food & Drug Administration, or FDA, within the past ten years. We believe that the results for both the patch and oral contraceptive control arms in our completed Phase 3 trials were affected primarily by issues with study conduct at several study sites, including rapid enrollment which led to an inability to manage the study population, poor subject compliance and high rates of loss to follow-up. The results were also likely affected in part by the study population, which differed in composition from the populations enrolled in trials of previously approved CHCs. Our Phase 3 trials had a high number of new users and minorities as compared to other CHC clinical trials. In particular, many contraceptive trials have enrolled a high proportion of subjects who immediately switched from other hormonal contraceptives, referred to as current users. For example, the subject population for the primary contraceptive efficacy clinical trial for the product Yaz® consisted of 60% current users and for the North American clinical trial

Table of Contents

for the product Natazia® consisted of 59% current users. However, only 17.8% of subjects in our larger Phase 3 trial randomized to receive Twirla were current users, and therefore, we had a higher than usual proportion of new users of contraception. Notably, there was a higher incidence of noncompliance in new users as compared to experienced users. In our Phase 3 studies, noncompliance, as verified by nondetectable serum levels of LNG and EE in a subject, was approximately three times as high in new users as compared to experienced users in both the Twirla and oral contraceptive arms of the study. Higher rates of noncompliance in contraceptive studies often correlate with a higher contraceptive failure rate.

We have filed a Section 505(b)(2) New Drug Application, or NDA, for approval of Twirla by the FDA, which is required before marketing a new drug in the United States. Our 505(b)(2) NDA relies in part on clinical trials that we conducted and in part on the FDA's findings of safety and efficacy from investigations for approved products containing the active ingredients and published scientific literature for which we have not obtained a right of reference. The FDA has indicated in a Complete Response Letter, or CRL, that our NDA was not sufficient for approval as originally submitted, due in part to the higher than desired PI. The FDA recommended that we conduct an additional Phase 3 trial with a simplified clinical trial design and improved study conduct, including site monitoring and data collection procedures. The FDA also required additional information relating to the laser etching of label information on each patch and required that the patch used in the new trial utilize the same etching as will be used for the commercial product, in order to demonstrate that it does not adversely affect the performance of the patch. Furthermore, the FDA also requested in the CRL additional information on controls and release specifications related to the patch, and manufacturing and control information related to the Drug Master File of one of the raw materials in Twirla. After multiple communications with the FDA, we have received significant guidance as to what additional clinical development and other activities need to be completed prior to approval. In accordance with the FDA's advice and comments, we are preparing to conduct an additional Phase 3 clinical trial and we expect to enroll our first subject in the third quarter of 2014. Based on the guidance that we received from the FDA, we believe that this additional trial will address all of the clinical issues raised in the CRL.

We have designed our additional Phase 3 trial as a single-arm study in which approximately 2,000 female subjects will receive Twirla for up to one year. We plan on enrolling subjects at 50 to 70 U.S. sites that have experience in conducting contraceptive studies. To manage the study, we recently hired a new Chief Medical Officer, and we intend to retain a new clinical research organization, or CRO, that is experienced in contraceptive clinical studies. We believe that by utilizing a more experienced CRO and more experienced clinical sites, we will be able to enroll subjects who will be more compliant with our protocol. Various technologies will be employed throughout the study to collect information on a real-time basis to ensure compliance with recruitment and protocol procedures. For example, subjects will use an electronic diary to record the data that are critical to the calculation of the PI, such as sexual activity, back-up contraception use and patch usage. In addition, we will employ an independent Pregnancy Review Committee to ensure accurate and timely pregnancy adjudication. Assuming successful completion of this additional study by the end of 2015, we plan to submit a complete response that includes the additional clinical trial results to the FDA in the first half of 2016.

Obstetricians and gynecologists, or ObGyns, contribute nearly 50% of the U.S. contraception prescription volume, and Nurse Practitioners and Physician Assistants, or NP/PAs, who are often

Table of Contents

affiliated with an ObGyn practice, contribute an additional 23% of the U.S. prescriptions. We believe that we can address this market with a specialty sales force of approximately 70 to 100 representatives. We also intend to augment our sales force through digital marketing and other techniques to market directly to patients.

Our Skinfusion technology makes Twirla the first patch capable of delivering a contraceptive dose of LNG across the skin, allowing weekly application using a patch that is soft and flexible and is designed to adhere well with low levels of skin irritation. We, along with Corium International, Inc., or Corium, our manufacturing partner, have made a significant investment in a proprietary process to manufacture Twirla. We believe we have developed a robust process to reliably manufacture Twirla on a commercial scale. The materials produced for our clinical trials were manufactured using the same process that will be used for our commercial-scale manufacturing, and we have made a significant investment in equipment for commercial-scale manufacturing if Twirla is approved. We believe that the technical challenges and know-how involved in manufacturing, including proprietary chemistry, production to scale and use of custom equipment and reproducibility, present significant barriers to entry for other pharmaceutical companies who might potentially want to replicate our Skinfusion technology.

Our intellectual property represents an additional barrier to potential competitors. We have five issued U.S. patents which cover Twirla that we intend to list in the Orange Book, the last of which expires in 2028. The Orange Book lists drug products, including related patent and exclusivity information, approved by the FDA under the Federal Food, Drug, and Cosmetic Act. If a patent is listed in the Orange Book, potential competitors seeking approval of drug products under an Abbreviated New Drug Application, which provides for the marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, of a previously approved product, or a 505(b)(2) application, for which the listed drug is a reference product, must provide a patent certification in their application stating either that (1) no patent information on the drug product has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. In addition, we continue to prosecute additional patent applications relating to Twirla, as well as our other product candidates, both in the United States and internationally. The intellectual property behind all of our product candidates in the pipeline and our Skinfusion technology consists of patent families developed and wholly-owned by us. There are no royalties or payments owed to third parties on our Skinfusion technology or any of our product candidates.

In addition to Twirla, we are developing a pipeline of other new transdermal contraceptive products, including AG200-ER, which is a regimen designed to allow a woman to extend the length of her cycle, AG200-SP, which is a regimen designed to provide a shortened hormone-free interval, and AG890, which is a progestin-only contraceptive patch intended for use by women who are unable or unwilling to take estrogen. AG200-ER utilizes the same drug product as Twirla, and therefore requires no further patch development. We believe that a regimen for AG200-ER could be presented to the FDA and a Phase 3 study started once a protocol is developed. AG200-SP requires additional patch development work prior to conducting Phase 1 studies. Initial Phase 1/2 work has been conducted on AG890, but this product candidate requires additional patch development work for dose selection prior to conducting further Phase 1 and 2 studies. We

Table of Contents

do not expect to be required to conduct preclinical studies for any of these product candidates. Based upon a number of factors, including, but not limited to, our available capital resources and feedback from the FDA, we intend to review the clinical path for each of these three product candidates in 2015.

Our Corporate Strategy

Key elements of our strategy include:

- Further developing Twirla to obtain regulatory approval in major commercial markets;
- Commercializing Twirla in the United States through a focused sales force;
- Contracting with commercial partners to develop and commercialize Twirla outside of the United States;
- Leveraging our strong scientific team and extensive in-house expertise in drug development to pursue the development of additional women's health products; and
- Opportunistically seeking to in-license or acquire complementary women's health products.

Risks Associated with Our Business

Our business and our ability to implement our business strategy are subject to numerous risks, as more fully described in the section entitled "Risk Factors" immediately following this prospectus summary. You should read these risks before you invest in our common stock. We may be unable to implement our business strategy for many reasons, including those that are beyond our control. In particular, risks associated with our business include:

- We are highly dependent on the success of Twirla, which is still in clinical development, and we may not be able to successfully obtain regulatory or marketing approval for, or successfully commercialize, this product candidate.
- Clinical development is a lengthy and expensive process with an uncertain outcome, as evidenced by our receipt of a CRL to our NDA submission for Twirla. Our planned Phase 3 clinical trial for Twirla may not have favorable results, or Twirla may not receive regulatory approval.
- Our development and commercialization strategy for Twirla depends, in part, upon the FDA's prior findings of safety and efficacy of EE and LNG based on data not developed by us, but upon which the FDA may rely in reviewing our NDA.
- We may experience delays in the commencement or completion of our clinical trials, which could result in increased costs to us and delay our ability to pursue regulatory approval and generate product revenues.
- If we are unable to establish sales and marketing capabilities, we may not be able to effectively market and sell Twirla, if approved, and generate product revenue.
- We have incurred significant operating losses since our inception and had an accumulated deficit of approximately $117.5 million as of March 31, 2014.

Table of Contents

We anticipate that we will continue to incur losses for the foreseeable future and, we may never be profitable. Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern, and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2013 with respect to this uncertainty.

Physicians, patients and payors may not adopt a new contraceptive patch due to concerns based upon the prior experience with the first contraceptive patch.

Assuming approval of Twirla, we will require additional capital to commence commercialization. Raising additional funds through debt or equity financing may be dilutive or restrict our operations and raising funds through collaborations or licenses may require us to relinquish rights to our product candidates.

We have no manufacturing capacity and anticipate continued reliance on third party manufacturers, such as Corium, for the development and commercialization of our product candidates in accordance with manufacturing regulations.

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.

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 decline.

Corporate Information

We were incorporated under the laws of the State of Delaware in December 1997. Our principal executive offices are located at 101 Poor Farm Road, Princeton, New Jersey 08540, and our telephone number is (609) 683-1880. Our website address is www.agiletherapeutics.com. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

We have proprietary rights to a number of trademarks used in this prospectus which are important to our business, including Agile Therapeutics®, Twirla™ and Skinfusion®. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

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. An emerging growth company may take advantage of

Table of Contents

relief from certain reporting requirements and other burdens 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;
- exemption from the auditor attestation requirement on the effectiveness of our internal controls over financial reporting;
- reduced disclosure about our executive compensation arrangements; and
- no requirements for non-binding advisory votes on executive compensation or golden parachute arrangements.

We may take advantage of these provisions for up to five years or such earlier time that we no longer qualify as an emerging growth company. We would cease to be an emerging growth company if we have more than $1.0 billion in annual revenue, have more than $700 million in market value of our capital stock held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens. For example, we have taken advantage of the reduced reporting requirements with respect to disclosure regarding our executive compensation arrangements, have presented only two years of audited financial statements, have presented reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure and have taken the exemption from auditor attestation on the effectiveness of our internal controls over financial reporting. To the extent that we take advantage of these reduced burdens, the information that we provide stockholders may be different than you might obtain from other public companies in which you hold equity interests.

Table of Contents

THE OFFERING

Common stock offered by us	shares
Common stock to be outstanding immediately after this offering	shares
Option to purchase additional shares	We have granted the underwriters an option for 30 days from the date of this prospectus to purchase up to additional shares of common stock.
Use of proceeds	We estimate that the net proceeds to us from this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately $ million, assuming the shares are offered at $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus. We anticipate that the majority of the net proceeds from this offering will be used for costs associated with the commencement and completion of an additional Phase 3 trial for Twirla. The remaining proceeds will be used for completion of the Corium equipment validation, development of our product pipeline, and for working capital and general corporate purposes which may include scheduled payments of principal and interest on our outstanding loan. See "Use of Proceeds" for additional information.
Risk factors	You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Proposed NASDAQ Market symbol	AGRX

The number of shares of our common stock that will be outstanding immediately after this offering includes 81,085 shares of common stock outstanding as of March 31, 2014, shares of common stock issuable upon conversion of all currently outstanding shares of our convertible preferred stock upon the completion of this offering and shares of common stock issuable upon conversion of all currently outstanding convertible subordinated promissory notes upon the completion of this offering. This calculation excludes:

- any shares of common stock issuable upon exercise of the over-allotment option granted to the underwriters;
- 990,922 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2014 at a weighted average exercise price of $5.86 per share;

Table of Contents

25,002 shares of common stock issuable upon the exercise of outstanding warrants as of March 31, 2014, at an exercise price of $15.00 per share; and

shares of common stock available for future grant under our 2014 Incentive Compensation Plan as of March 31, 2014.

Unless otherwise indicated, all information in this prospectus assumes that the underwriters will not exercise the over-allotment option granted to them by us, and has been adjusted to reflect:

an amendment and restatement of our charter and bylaws immediately prior to the effectiveness of this offering;

the net exercise of all outstanding warrants to purchase shares of Series A-1 and Series A-2 convertible preferred stock assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover of this prospectus and the automatic conversion of such preferred shares into shares of common stock;

the conversion, on a one-for-one basis, of all outstanding shares of convertible preferred stock into shares of common stock upon the closing of this offering;

the conversion of all outstanding warrants to purchase shares of Series C convertible preferred stock into warrants to purchase 25,002 shares of common stock upon the closing of this offering;

the conversion of the aggregate principal amount of $3.0 million and interest accrued as of the date of this prospectus under our outstanding convertible subordinated promissory notes into shares of common stock upon the closing of the offering assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover of this prospectus. For a description of the convertible subordinated promissory notes, see "Management's Discussion and Analysis of Financial Condition and Results of Operations April 2014 Convertible Subordinated Note Financing;" and

a one-for- stock split of our common stock to be effected prior to the completion of this offering.

Table of Contents

SUMMARY FINANCIAL DATA

The following table summarizes our financial data. We have derived the following statement of operations data for the years ended December 31, 2012 and 2013 and the period from inception to December 31, 2013 and the balance sheet data as of December 31, 2013 from our audited financial statements, included elsewhere in this prospectus. We have derived the statements of operations data for the three months ended March 31, 2013 and 2014 and the balance sheet data as of March 31, 2014 from our unaudited financial statements included in this prospectus. The unaudited financial data include, in the opinion of management, all adjustments, consisting of normal recurring adjustments, that are necessary for a fair statement of our financial position and results of operations for these periods. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of the results to be expected for a full fiscal year. The following summary financial data should be read in conjunction with "Management's Discussion

Table of Contents

and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

	Years ended December 31,		Three Months Ended March 31,		Period from Inception (December 22, 1997) to March 31, 2014
	2012	2013	2013	2014	
	(In thousands, except share and per share data)				
Statement of operations data:					
Operating expenses:					
Research and development	$ 17,387	$ 9,154	$ 3,072	$ 1,394	$ 87,612
General and administrative	5,930	3,574	1,156	1,053	27,397
Total operating expenses	23,317	12,728	4,228	2,447	115,009
Loss from operations	(23,317)	(12,728)	(4,228)	(2,447)	(115,009)
Total other income (expense)	57	(1,592)	(377)	(366)	(631)
Loss before benefit for income taxes	(23,260)	(14,320)	(4,605)	(2,813)	(115,640)
Benefit from income taxes				3,652	4,325
Net loss	(23,260)	(14,320)	(4,605)	839	(111,315)
Beneficial conversion charge	(600)				(6,160)